

Unpacking the Prescription Drug Provisions of the Build Back Better Act

Wednesday, December 8, 2021

KFF

Filling the need for trusted information on national health issues.

Panelists



Juliette Cubanski
KFF

Deputy Director,
Program on
Medicare Policy



Mollyann Brodie
KFF

Executive Vice President
Executive Director,
Public Opinion and
Survey Research
Program



Jennifer Young
Tarplin, Downs & Young
Partner

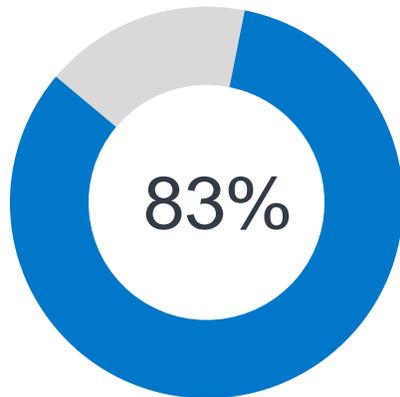


Chris Jennings
Jennings Policy
Strategies

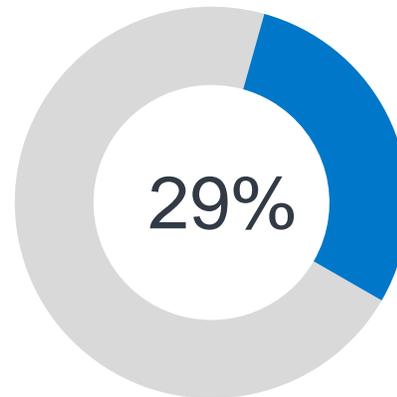
President

Americans Remain Concerned About the Cost of Prescription Drugs

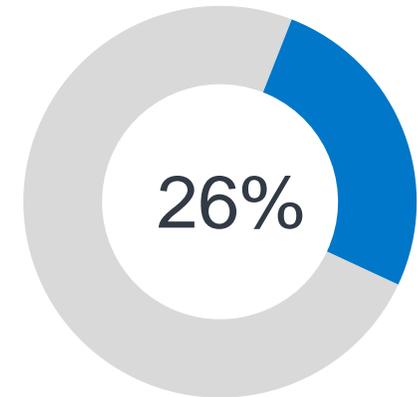
83% of adults think the cost of prescription drugs is **unreasonable**



29% say in the last year, they have **not taken prescription medicines** as directed **because of costs**



26% of adults say it is very **difficult for them to afford** to pay for their prescription drugs



Key Prescription Drug Provisions in the Build Back Better Act

- For the first time, **allows the federal government to negotiate prices** for some high-cost drugs covered under Medicare
- Requires drug companies to pay **rebates if drug prices rise faster than inflation** for Medicare and private insurance
- Adds a **\$2,000 cap on Medicare Part D out-of-pocket spending** & other benefit design changes
- Limits monthly **cost sharing for insulin products to \$35** for people with Medicare and private insurance
- **Eliminates cost sharing for adult vaccines** covered under Medicare Part D and improves access to adult vaccines under Medicaid and CHIP
- **Repeals** the Trump Administration's drug **rebate rule**

The BBBA Would Allow the Federal Government to Negotiate Prices for Some High-Cost Drugs Covered by Medicare

Which drugs qualify?

Top-spending **brands and biologics** without generic or biosimilar equivalents and **9+ years** (small-molecule drugs) or **13+ years** (biologics) from FDA approval, **plus all insulin products**

How many drugs qualify?

All insulin products, plus up to:

- **10** Part D drugs in **2025**
- **15** Part D drugs in **2026**; **15** Part D and Part B drugs in **2027**
- **20** Part D and Part B drugs in **2028 & later years**

What is the “maximum fair price”?

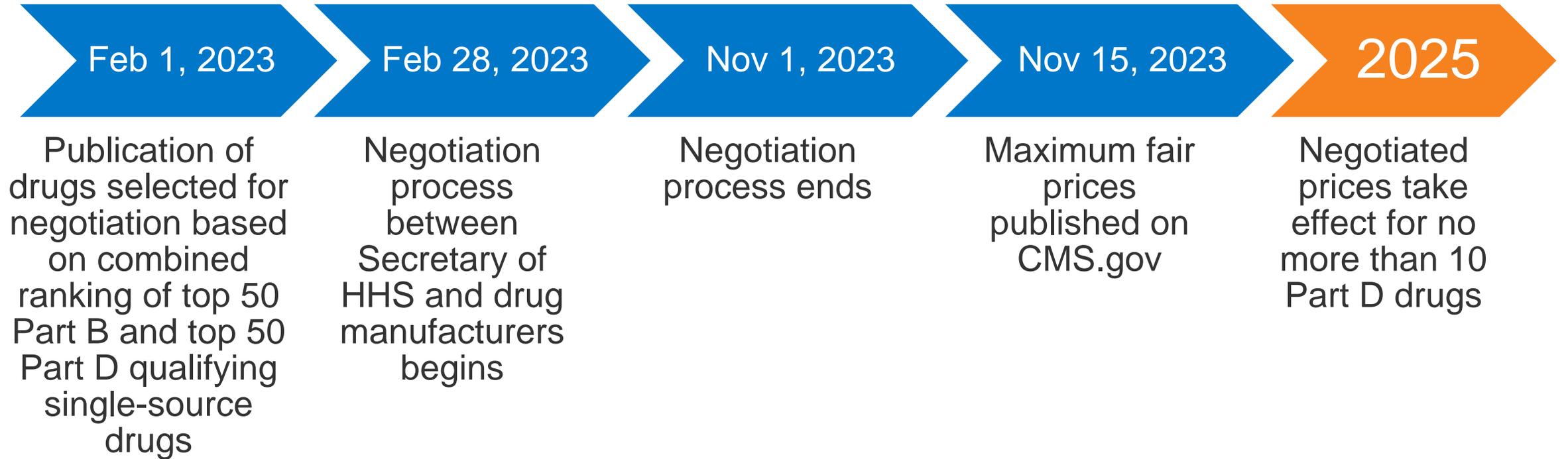
% of the non-federal average manufacturer price:

- **75%**: 9 years but <12 years beyond approval
- **65%**: 12 years but <16 years beyond approval
- **40%**: 16+ years beyond approval

Who is eligible?

Medicare beneficiaries in Part B or Part D, or providers who administer Part B drugs to beneficiaries

Timeline for Drug Price Negotiation, Based on the First Year of Negotiated Price Availability (2025)



Penalties for non-compliance

- **Excise tax** on total sales (up to 95%) for not negotiating
- **Civil monetary penalty** for not offering negotiated price

The BBBA Would Require Drug Manufacturers to Pay Rebates if Drug Price Increases Exceed Inflation

- Rebates paid by drug manufacturers if prices for single-source drugs and biologicals covered under Part B and nearly all Part D drugs increase faster than the rate of inflation (CPI-U)
- 2021 is the base year for measuring cumulative price changes relative to inflation
- Rebate calculation includes all units sold outside of Medicaid
- Rebate dollars deposited in the Medicare Supplementary Medical Insurance (SMI) trust fund
- Manufacturers that don't pay the required rebate would face a penalty of at least 125% of the rebate amount

The BBBA Includes Several Changes to the Part D Benefit Design, Including a Hard Cap on Out-of-Pocket Spending

Changes would lower beneficiary spending, reduce Medicare's liability for high drug costs, and increase Part D plan and manufacturer liability for high drug costs

Beneficiaries

- Caps out-of-pocket spending at \$2,000
- Lowers share of costs below the spending cap
- Lowers share of premium costs
- Allows spreading out costs over the year

Medicare

- Lowers share of costs above the spending cap ("reinsurance")
- Increases the premium subsidy

Plans

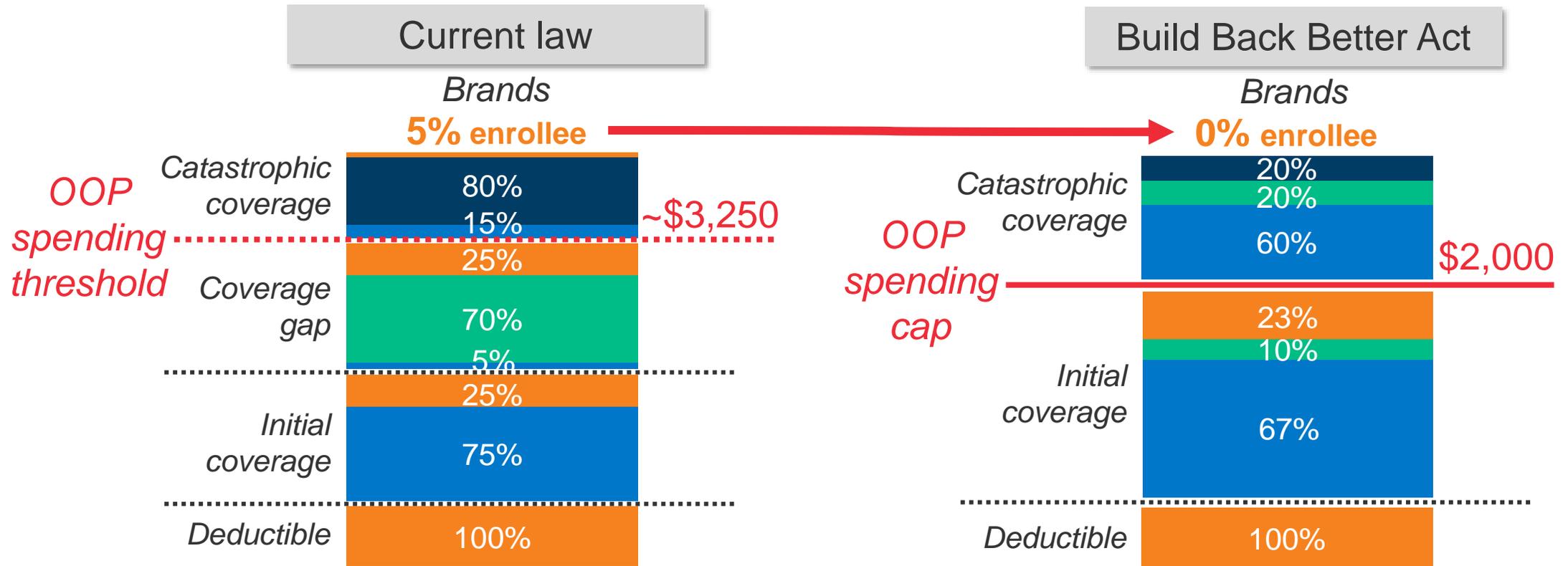
- Increases share of costs above the spending cap
- Modifies share of costs below the spending cap

Rx companies

- Requires a price discount on brand-name drugs above the spending cap
- Modifies the price discount on brands below the spending cap

The BBBA Caps Out-of-Pocket Drug Spending Under Medicare Part D at \$2,000

Share of costs paid by: ● Enrollees ● Part D Plans ● Drug manufacturers ● Medicare



NOTE: OOP is out-of-pocket. Out-of-pocket spending limits are for 2024. The out-of-pocket spending threshold will be \$7,800 in 2024, which translates to an out-of-pocket cap of approximately \$3,250 (based on brand-name drug use only).

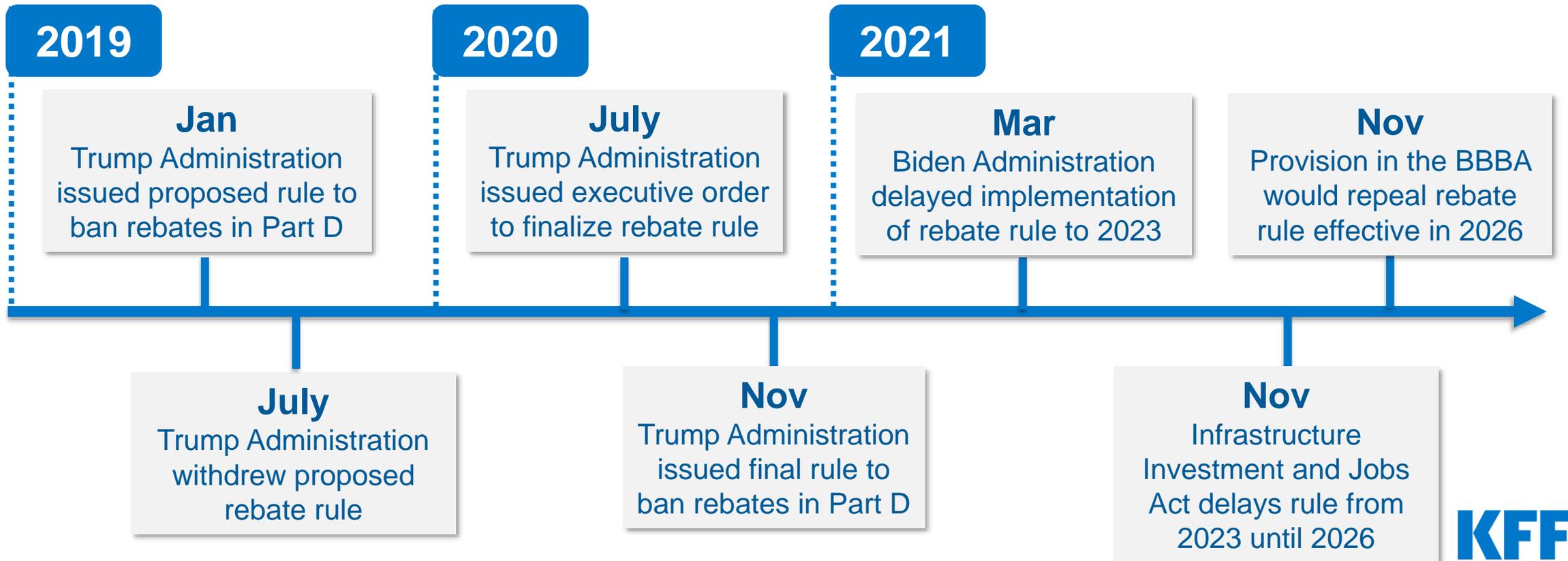
The BBBA Caps Monthly Copays for Insulin at \$35 and Makes Improvements to Coverage of Adult Vaccines

- **Limit monthly cost sharing for insulin products to \$35**
 - \$35 limit applies under Medicare Part D and private group or individual health plans
 - Requires private plans to offer \$35 copay on one insulin product of each dosage form (vial, pen) and type (rapid-acting, short-acting, intermediate-acting, and long-acting)
 - Requires Part D plans to charge no more than \$35 for covered insulin products in 2023 & 2024 and all insulin products beginning in 2025
- **Adult vaccines**
 - Eliminates cost sharing for adult vaccines recommended by ACIP covered under Medicare Part D
 - Requires coverage of adult vaccines in Medicaid and CHIP with no cost sharing

The BBBA Repeals the Trump Administration's Rebate Rule

What is the Rebate Rule?

It would remove the safe harbor protection under the anti-kickback statute covering rebate arrangements between drug manufacturers and PBMs/Part D plan sponsors. Estimated to result in higher Medicare spending and Part D premiums.

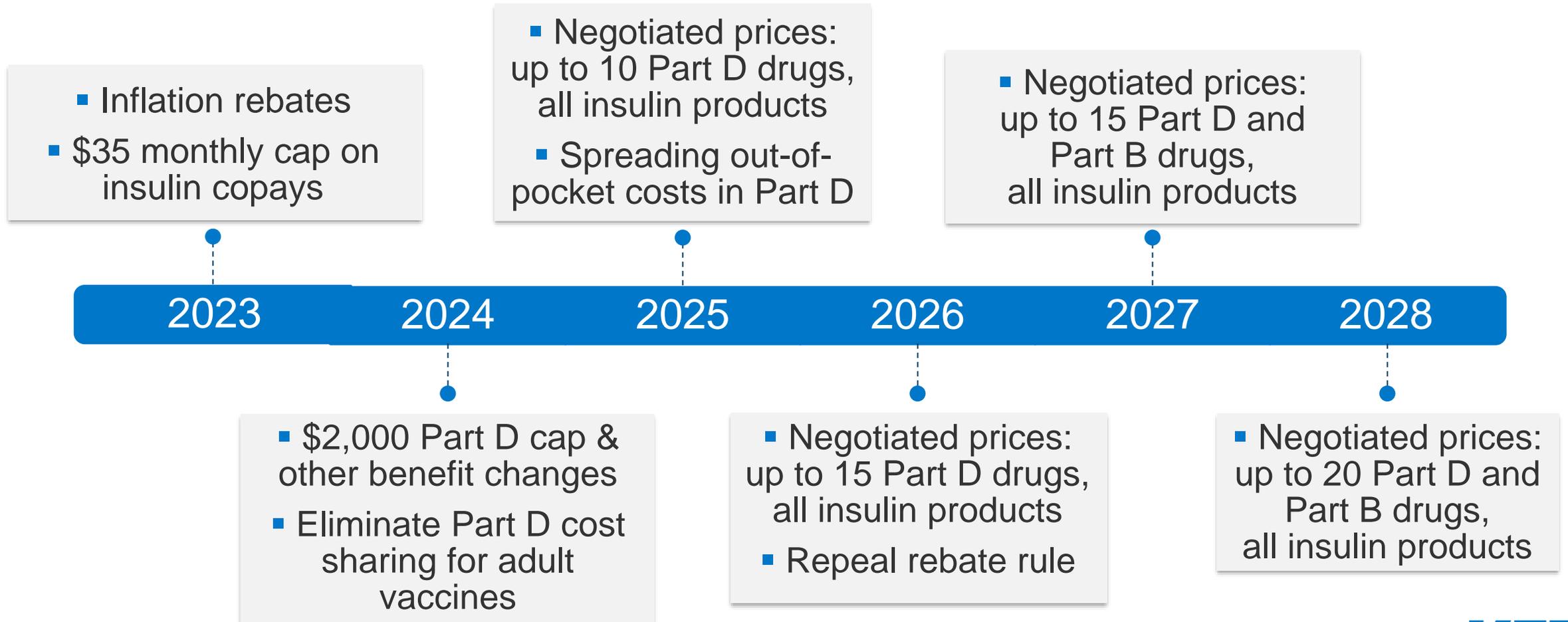


CBO Estimates Savings of ~\$300 Billion Over 10 Years from the Drug Pricing Provisions in the BBBA

Drug price negotiation	\$78.8 billion savings
Inflation rebates	\$83.6b net federal deficit reduction: \$49.4b in net savings ¹ + \$34.2b revenue increase
Part D benefit redesign	\$1.5b savings
Insulin cost-sharing limits - <i>Medicare Part D:</i>	\$0.9b spending
- <i>in private plans:</i>	\$5.1b spending & lower revenue
Adult vaccines coverage improvements	\$6.1b spending
Repeal Trump Administration's rebate rule	\$142.6b savings

¹Includes savings of \$61.8 billion in Medicare and \$7.7 billion in other federal programs, plus spending of \$20.1 billion in Medicaid.

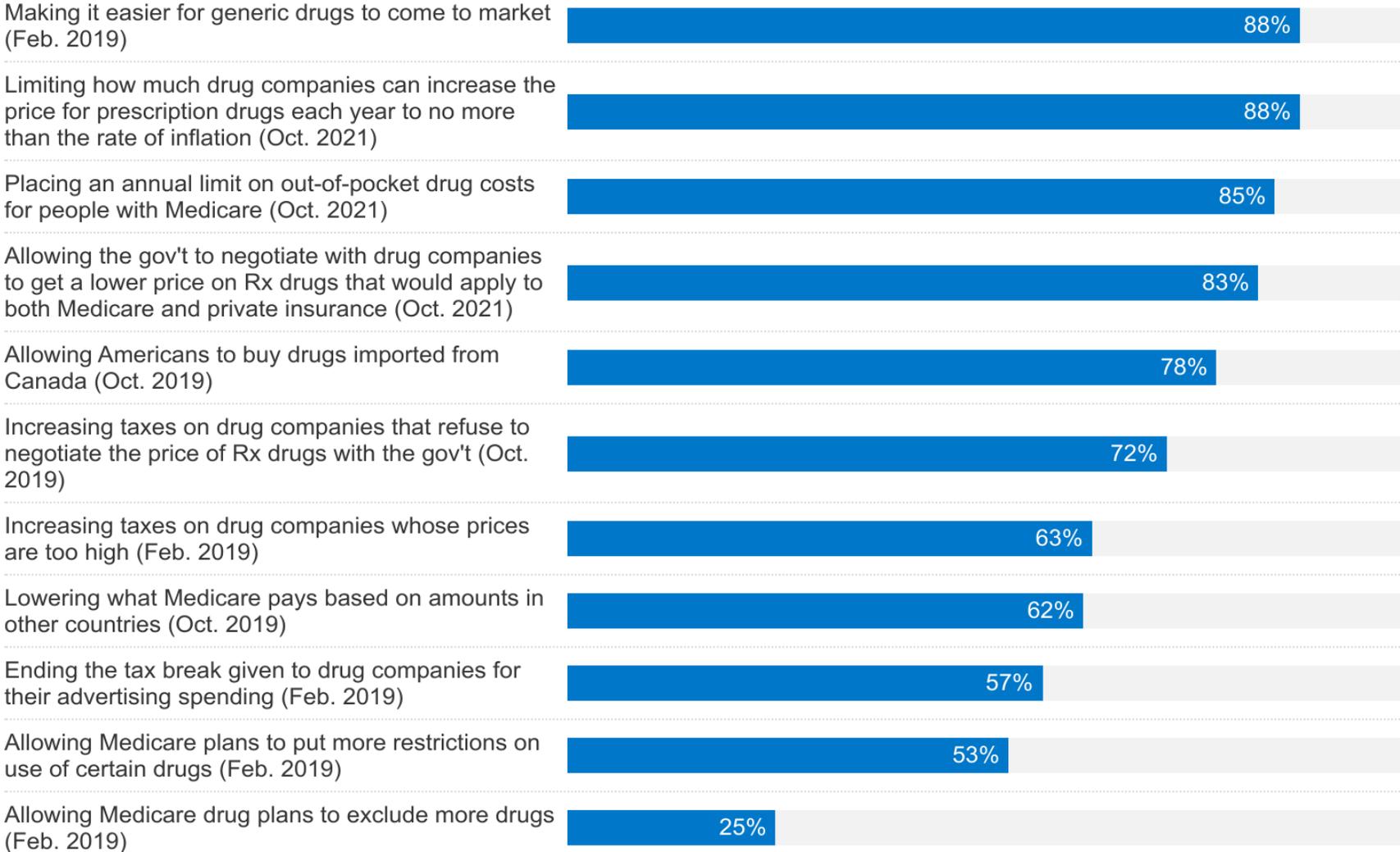
The Drug Pricing Provisions in the BBBA Would Be Implemented Over the Next Several Years, Beginning in 2023



25 yrs of Polling: The Public and Prescription Drugs

- Health care costs, including and especially the affordability of prescription drugs, are a “top priority”, “concern”, “worry”, “health care issue” for the public.
- Love/Hate relationship with pharmaceutical companies
 - Believe in the products – Rx drugs make our lives better
 - ALSO Believe profits are too high and are a major reason why prices of Rx drugs are high, and that Rx Cos. care more about making profits than what’s in the best interest of people
- **Bottom Line:** The public wants **THEIR costs** to be lower, and don’t care a lot about exactly how lawmakers plan to do it.

Most Adults Favor Many Potential Actions To Lower Drug Costs



NOTE: See topline for full question wording.

SOURCE: KFF Health Tracking Polls



Prescription Drug Price Negotiations Topped Public's Priorities For Congress Earlier This Year

Is each of the following a top priority for Congress, important but not a top priority, not too important, or should it not be done?

■ Top priority
 ■ Important but not a top priority
 ■ Not too important
 ■ Should not be done



Allowing the federal government to negotiate on Rx drugs



Expanding Medicare coverage



Allowing states to negotiate on Rx drugs



Limit out-of-pocket costs for seniors



COVID-19 vaccine distribution efforts



Expand health insurance coverage for lower-income people in non-expansion states



Creating a public option



Lowering the age of Medicare eligibility



Making permanent the help from the relief bill for people who buy their own insurance



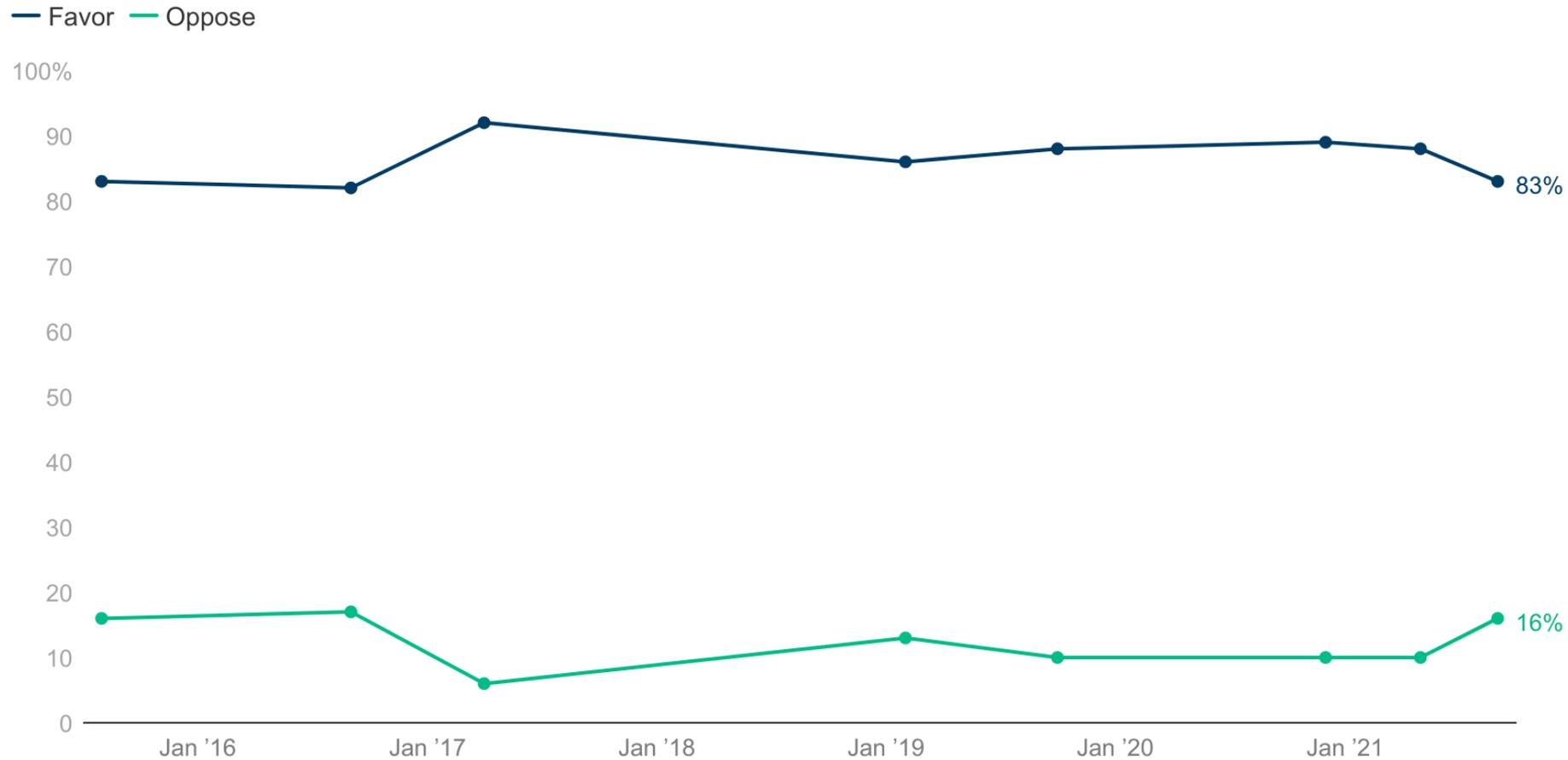
NOTE: See topline for full question wording.

SOURCE: KFF Health Tracking Poll (May 18-25, 2021)



Large Majorities Favor Government Negotiations On Prescription Drugs

Do you **FAVOR** or **OPPOSE** allowing the federal government to negotiate with drug companies to get a lower price on prescription drugs for people with Medicare and private insurance?



NOTE: See topline for full question wording.

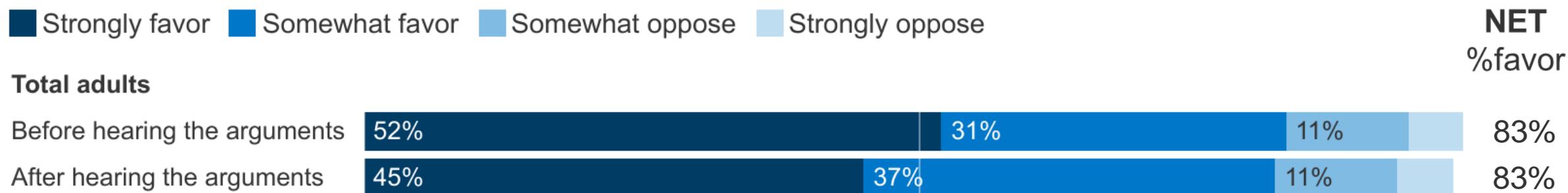
SOURCE: KFF Health Tracking Polls



Overall Favorability Remains Unchanged **After Public Hears Arguments On Both Sides** Of The Drug Negotiation Debate

Argument against: People opposed to allowing the federal government to negotiate prices with drug companies say this would have the government too involved and will lead to fewer new drugs being available in the future.

Argument in favor: People in favor of allowing the federal government to negotiate prices with drug companies say this is needed because Americans pay higher prices than people in other countries, many can't afford their prescriptions, and drug company profits are too high.



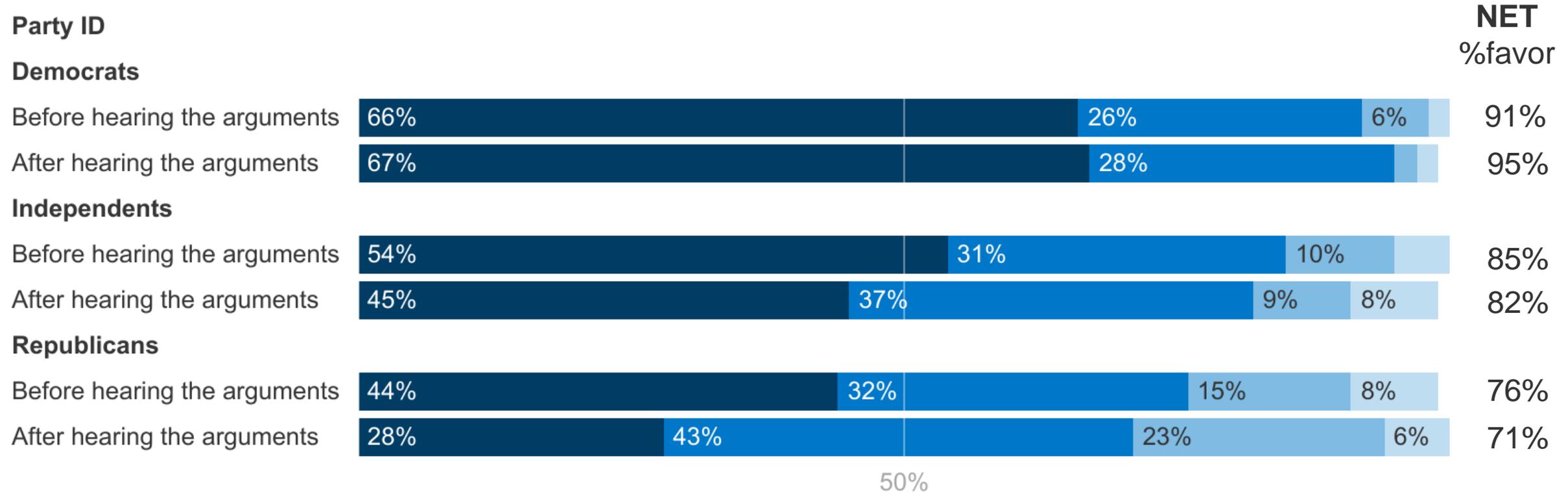
NOTE: See topline for full question wording.

SOURCE: KFF Health Tracking Poll (Sept. 23-Oct. 4, 2021)



After Hearing Arguments, Republican Support Softens

■ Strongly favor
 ■ Somewhat favor
 ■ Somewhat oppose
 ■ Strongly oppose



NOTE: Attitudes towards allowing the federal government to negotiate with drug companies to get a lower price on prescription drugs was measured before and after the common argument from each side of the debate was presented. See topline for full question wording.

SOURCE: KFF Health Tracking Poll (Sept. 23-Oct. 4, 2021)



Majorities Don't Buy Underlying Argument That Drug Companies Need To Charge Higher Prices In Order To Innovate

Which of the following comes closer to your view?

- Drug companies need to charge high prices in order to fund the innovative research necessary for developing new drugs
- Even if U.S. prices were lower, drug companies would still make enough money to invest in the research needed to develop new drugs



NOTE: See topline for full question wording.

SOURCE: KFF Health Tracking Poll (Sept. 23-Oct. 4, 2021)