



PHARMA PR & COMMUNICATIONS

Summit

The Inflation Reduction Act

The Good, the Bad, & the Ugly



What is the Inflation Reduction Act (IRA)?



- » Signed on August 16th, 2022
- » Wide-ranging legislation: has tax reform, nearly ~\$400 billion in spending on energy and climate change
- » ***Big biopharma provisions-*** the most significant changes to Medicare since the prescription drug program (“Part D”) was enacted in 2003

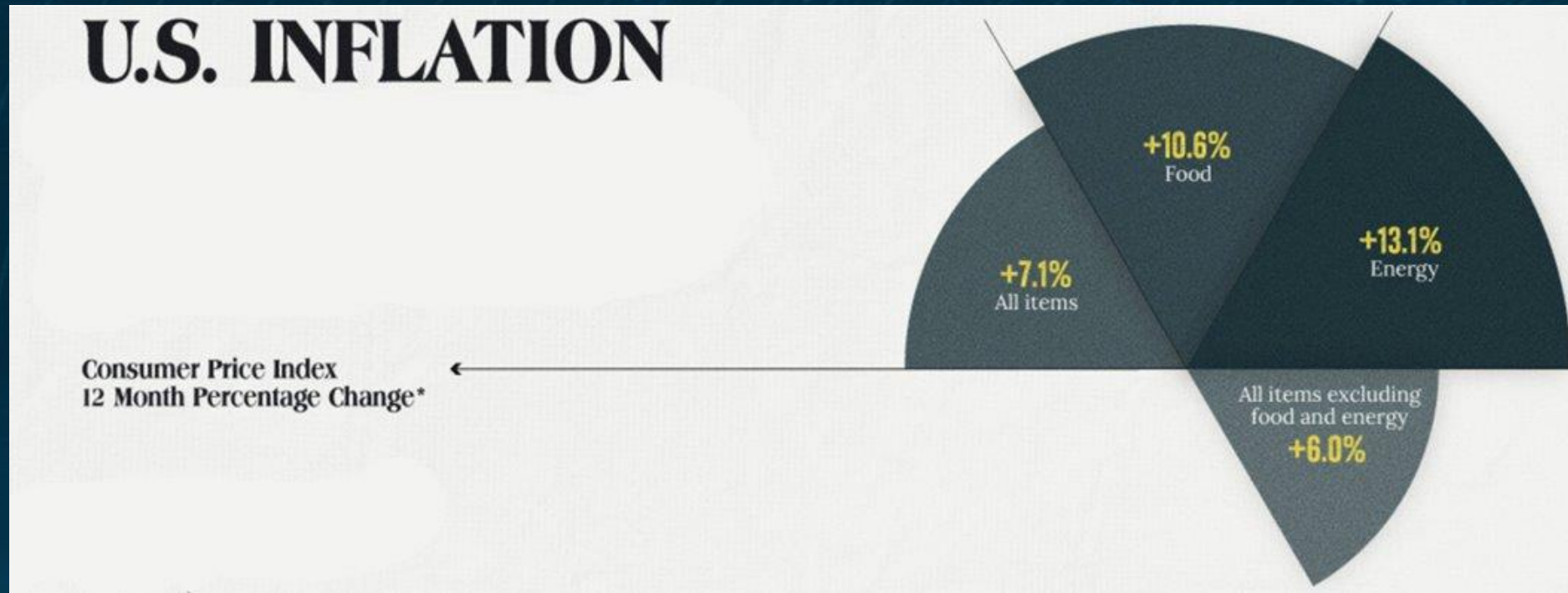


The Good: Out-of-pocket Relief for Patients

- » Out-of-pocket spending on prescription drugs for all Medicare beneficiaries is capped at \$2,000 beginning in 2025
- » “Smoothing” - spread their cost sharing over the course of the year
- » Insulin monthly costs are capped at \$35 for enrollees in Medicare Part D – 3.3 million beneficiaries used insulin in 2020.
- » No cost sharing for vaccines in Part D.

The Bad... Inflation Penalties

- » **Inflation Rebates:** Companies required to pay “inflation rebates” to Medicare if prices increase higher than the rate of inflation.
 - Prescription drug increase 2021-2022: 1.9% (unadjusted, year-over-year)



The Ugly...

- **Price Controls-** Requires CMS to “negotiate” prices for the drugs with the high spending in Medicare.
 - Top 10 (gross spending) Medicare Part D drugs will be selected in September 2023 (drugs added every year); the “negotiated” price takes effect in 2026
 - This is “negotiation” in name only – it is government price setting; the IRA includes outsized tax penalties if drug manufacturers do not participate.



Does This Only Affect Medicare?

- » Yes (but no!)
- » The IRA negotiation program doesn't directly impact private plans, but Medicare's price will be made public, so it's expected that private plans will seek a price similar to that in the Medicare program

Drugs Subject to Negotiation

Qualifying Single Source Drugs

- **Certain drugs/biologics approved/licensed by FDA:**
 - **Drugs at least 7 years post-approval** by the selection date
 - **Biologics at least 11 years post-licensure** by the selection date
- With **no generic/biosimilar on the market** (an “authorized generic drug” does not count)

Negotiation-Eligible Drugs

- The **50 qualifying single source drugs with highest total expenditures under Part D** and the **50 qualifying single source drugs with highest total expenditures under Part B** during a specified 12-month lookback period.

Selected Drugs

- A specified number of the **highest ranked negotiation-eligible drugs**, published by February 1 of the selection year, which is two years before the initial price applicability year:
- The selection of drugs for negotiation is **cumulative**: The Secretary must select **10 drugs for 2026**, another **15 for 2027**, another **15 for 2028**, and another **20 for 2029 and each year thereafter**
- **Only Part D drugs may be selected for 2026 and 2027**

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Some of This Could Get Very Ugly...

- » Avalere estimates that the IRA will cost biotech companies \$450 billion over the next decade
- » Vital Transformations estimates that the substantial reduction in revenue will result in as many as 139 drugs lost over the next 10 years
 - R&D cutbacks could result in roughly 600,000 lost biotech jobs in the United States by 2031
- » Small biotechs that drive innovation will be impacted by the law- venture capital investments will decrease, and (unlike large companies) they lack cash reserves and flexibility to pivot in response