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THE VOICE FOR HEALTH CARE CONSUMERS

2024 NFPRHA National Conference

Drug Pricing 101

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Conflict of Interest Disclosure:

I have no conflicts of interest to disclose.

- What is the problem?
- What is driving high drug costs?
- Inflation Reduction Act (IRA) drug pricing reforms: What are they and when do they go into effect?
- Expanding IRA reforms beyond Medicare
- Patent Reform

Sources

What is the Problem?

THE PROBLEM: RX DRUG PRICES ARE TOO HIGH

High prescription drug prices are forcing people to choose between filling their prescriptions and filling their fridge.

Almost 30% of adults skip or forgo their medications as prescribed due to cost.[1]

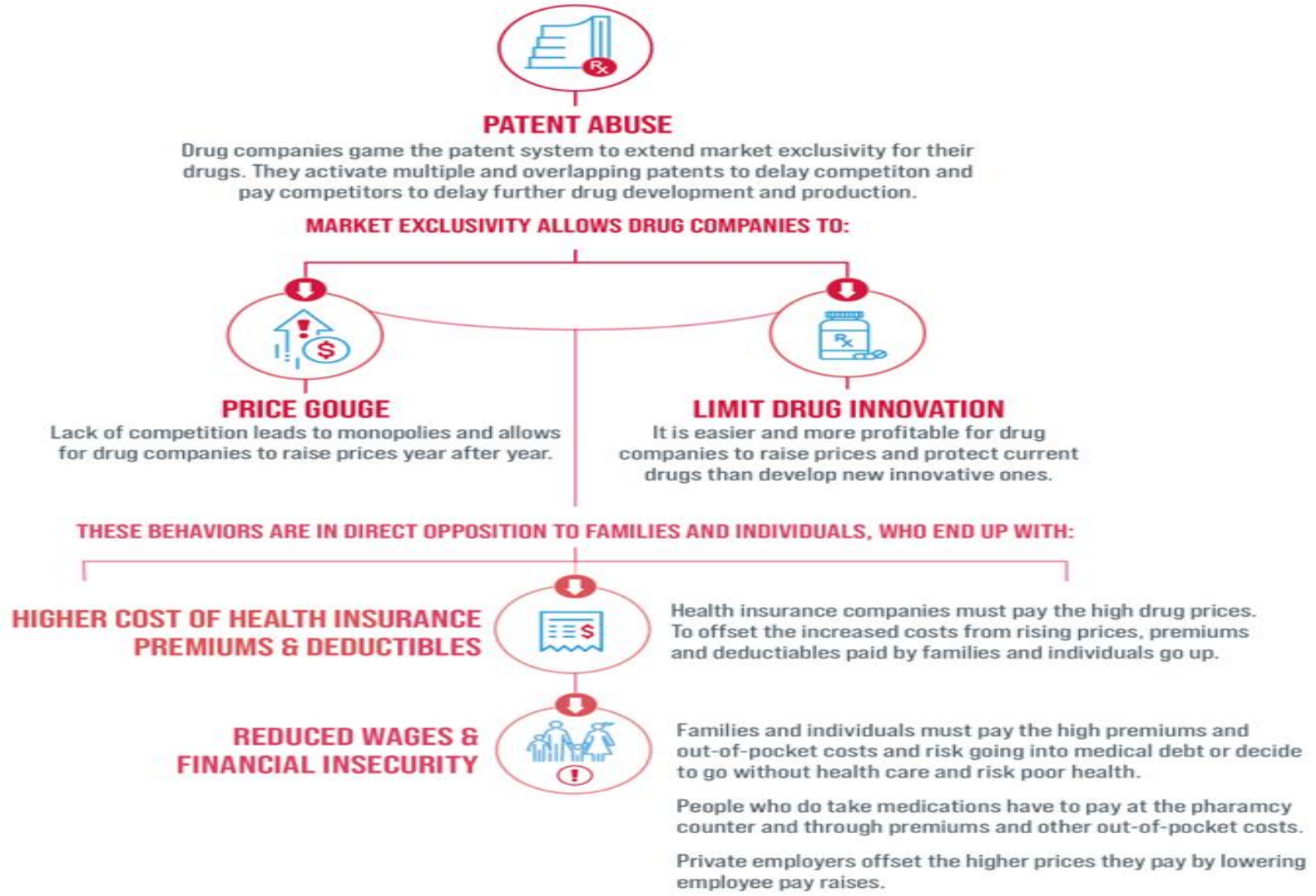
Almost 20% of high health insurance premiums are due to high prescription drug costs.[2,3]

And, as monthly premiums increase, wages rise more slowly.[4]

Taken altogether, it is clear that high and rising drugs prices are compounding families' financial insecurity.[5]

Source: https://www.familiesusa.org/wp-content/uploads/2024/04/Families-Need-Relief-from-Runaway-Prescription-Drug-Costs-w-Endnotes.pdf

What Drives High Drug Costs?



Source: https://familiesusa.org/wp-content/uploads/2023/11/Rx-Premium-paper_-for-publishing.pdf

IRA Drug Pricing Reforms: What Are They?

- Gives Medicare the ability to negotiate prices for a select group of drugs.
- Protects Medicare beneficiaries from excessive drug price increases by capping Medicare drug price increases at the rate of general inflation as of last year.
- Makes Medicare drug coverage more generous. It does so by capping monthly out-of-pocket costs for insulin at $35 starting in 2023. It also caps total out-of-pocket costs for prescription drugs at $2,000 by 2025. And as of 2024, the law removes cost-sharing during the "catastrophic phase" of Part D drug coverage, which is reached after a Medicare beneficiary spends a certain amount of money on prescription drugs during the year.
- Expands eligibility for "full benefit" Part D low-income subsidies (LIS) to Medicare beneficiaries with incomes up to 150 percent of the federal poverty level starting in 2024. These subsidies fully cover Part D premiums and deductibles and reduce copays. Previously, full LIS benefits were available only to beneficiaries with incomes up to 135 percent of poverty.
- Makes additional vaccines available at no cost to Medicare beneficiaries as of last year.

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Source: https://familiesusa.org/resources/advocacy-resource-ensuring-the-medicare-drug-negotiation-program-prioritizes-families-and-consumers/

IRA Drug Pricing Reforms: When Do They Go Into Effect?

2023

- Insulin $35 cap
- Make additional free vaccines available
- Inflationary Rebates go into effect
- Round 1 Negotiation Process
  - Sept 1 - first 10 drugs to be negotiated

2024

- Expanded low-income subsidy program goes into effect
- Round 1 Negotiation Process
  - February - initial price offering goes to manufacturers for first 10 drugs named in 2023
  - By September 1 - final negotiated price published
- Round 2 Negotiation Process
  - Announced annual timeline for second and all future negotiation processes

2025

- $2,000 Out-of-pocket goes into effect
- Round 2 Negotiation Process
  - By February 1 - announce next 15 drugs to be negotiated (totaling 25 drugs in negotiation)
  - By November 30 - final negotiated price published

2026

- Round 1 Negotiation Process
  - Prices for first 10 drugs goes into effect
- Round 3 Negotiation Process
  - By February 1 - announce next 15 drugs to be negotiated (totaling 40 drugs in negotiation)
  - By November 30 - final negotiated price published

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Expanding IRA Reforms Beyond Medicare

- **Expand the number of drugs eligible for negotiation in Medicare and allow commercial insurance to voluntarily adopt the negotiated rate:** HHS Secretary should be authorized — and required — to expand the list of drugs subject to negotiation and to extend all negotiated prices to private sector health insurance, should insurance plans want to adopt the Medicare negotiated price.

- **Extend the inflationary rebates into the commercial market:** Inflation rebates should be extended to include drugs covered in the commercial market to better protect individuals in employer-sponsored plans and other private plans from drug manufacturers' high prices and exorbitant yearly increases. This would also protect those in the commercial market from potential cost shifting by drug companies attempting to make more off all other payers when their prices drop in Medicare.

- **Encourage Prescription Drug Affordability Boards (PDABs) to use Medicare negotiated rates:** States with PDABs that also have an upper payment limit (UPL) that creates a maximum reimbursement rate for certain plans should utilize Medicare negotiated rates when applicable. Currently, only four states have a PDAB with authority to set a UPL including Maryland, Colorado, Minnesota, and Washington.

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Addressing Patent Reform

- **End patent abuses:** For decades, drug companies have systematically abused patent and market exclusivity rules to block competition. Policymakers should explore ways to address these decades of abuse and take action to eliminate harmful practices such as:
  - "Patent thickets" when a company blankets one drug with multiple or overlapping patents,
  - "Product hopping" when a company makes minor tweaks to existing drugs that typically confer no additional clinical benefit but allow for extended patent protections, and
  - "Pay-for-delay" schemes when drug companies pay potential competitions not to produce a generic drug.

- **Support bringing generic drugs to the market faster:** Generics, on average, cost 20% to 70% less than their brand-name counterparts, making them an affordable and effective solution for many consumers. Generics bring competition to the market and lower costs for specific drugs by as much as 85% when multiple competitors exist. The administration should simplify the generic approval process and help to bring affordable prescription drugs to consumers who are currently struggling to pay for their medications.
  - Stopping drug company abuse of citizen petitions before the Food and Drug Administration (FDA) that are often used to delay market entry.

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