United States House Committee on Ways & Means
CHAIRMAN JASON SMITH

ENERGY & COMMERCE
CHAIR RODGERS

UNITED STATES SENATE COMMITTEE ON FINANCE
RANKING MEMBER MIKE CRAPO

Impact of Democrats' Drug Price-Setting Scheme

The "Inflation Reduction Act" (IRA) will raise prescription drug prices – worsen patients' access to care, destroy new cures before they come to market, eliminate American jobs, threaten the United States' leading role in innovative research, and create potential constitutional concerns around government overreach.

Impact on Patients & Families

Government and third-party analyses show the Democrats' drug price-setting scheme will increase prescription drug prices and reduce access to more affordable, generic and biosimilar alternatives.

- "The [IRA's drug provisions] would **increase the launch prices for drugs that are not yet on the market** relative to what such prices would be otherwise." – Congressional Budget Office (August 2022)

> To blunt the impact of limits on future price increases, pharmaceutical companies are likely to l**aunch new drugs this year at higher prices than they would have before the legislation passed… [Manufacturers are] also likely to raise prices on existing drugs more than usual** while high inflation gives them cover.
>
> – Wall Street Journal (January 2023)

- The IRA will "replace competition – the only proven way to provide patients relief from high brand drug prices – with **a flawed framework for government price setting that will chill the development of, and reduce patient access to, lower-cost generic and biosimilar medicines**." – Association for Accessible Medicines (AAM)
- Generics account for 9 out of every 10 prescriptions filled in the U.S., and more than 92 percent of generic drug prescriptions have a final out-of-pocket cost lower than $20.

Impact on Drug Innovation

The IRA will derail and destroy current and future drug development, resulting in fewer cures and reduced innovation, according to research from the University of Chicago.

135 Fewer New Drugs

188 Fewer New Indications

$663B Drop in Innovative R&D

Real-World Example:

Alnylam has **stopped research** into a promising eye cancer treatment.
Novartis publicly stated they are **dropping early-stage cancer research.**
Genentech stated they will **slow research** for smaller disease populations.

The “small molecule penalty” contained in the IRA (price setting after 9 years for small molecule drugs compared with 13 years for biologics) and narrow orphan drug exemption will disincentivize research into consumer-friendly and rare disease drugs.

> “[The small molecule penalty] will shift R&D from low-copay, easy-to-genericize pills to higher-copay, harder-to-copy injectables, and saddle patients with even more costs: unlike pills, injectables often require a visit to the doctor or infusion center (and associated costs for administration).
>
> – Letter from more than 1,200 patient advocates, researchers, and drug developers (July 2022)”

- The law only exempts orphan drugs (drugs for rare diseases) with a *single* approved disease treatment from its price controls, meaning drugs that treat multiple diseases *will* be subject to the price controls, disincentivizing researchers from finding new disease treatments for existing drugs.
    - Since 2003, the Food and Drug Administration approved more than 150 follow-on disease treatments for orphan drugs.
    - **More than 60 percent of cancer medications receive at least one post-approval disease treatment**. 41 percent of post-approval disease treatments for cancer drugs occurred after seven years, which means the IRA’s narrowly crafted orphan drug policy will greatly discourage future rare cancer treatments.
- “The [IRA] may lead pharmaceutical manufacturers to develop more single-indication orphan drugs... rather than follow-on indications.” – Researchers in the Journal of the American Medical Association (August 2023)

Impact on America’s Economy

The IRA’s drug provisions will have devastating effects on the economy, eliminating jobs in important STEM fields and small businesses, according to research from Vital Transformation.

135,900 Fewer Direct Biopharmaceutical Jobs

676,000 Fewer Jobs Across the U.S.

70% of clinical trials are run by small businesses

Unworkable Bureaucratic Mess

The Biden Administration’s sub-regulatory guidance for the IRA’s price-setting scheme spends billions of taxpayer dollars to go beyond the language of the law while not soliciting public input.

- Funnels $3 billion into a new program with **no oversight or public recourse for citizen concerns**, creating opportunities for further waste, fraud, and abuse within the Medicare program.
- Uses an intentionally broad definition of qualifying drugs – **subjecting entirely different medications to price controls** and wrapping more drugs in red-tape that will discourage growth in treatments.
- Treats federal support for R&D as grounds for further price-controls that will **devalue innovation**.
- Restricts time for public input, **prioritizing the views of bureaucrats over the patients** affected.

Legally Dubious

Multiple lawsuits have been brought against the IRA’s constitutionality – noting violations of several articles of the Constitution, such as excessive fines, proving the IRA has been flawed from the start.

Up to a **1900%** Excise Tax

8 Lawsuits Filed

Potential violations of:

First Amendment	Due Process
Fifth Amendment	Orphan Drug Act
Eighth Amendment	Separation of Powers