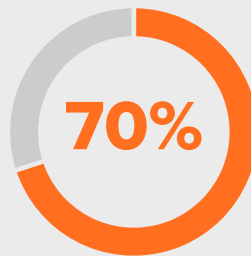


It's Time to Protect Patients and Fix the Pill Penalty

A penalty on treatment options isn't what seniors were promised.

The Pill Penalty: A provision in the Inflation Reduction Act (IRA) unfairly discriminates against small molecule medicines and will negatively impact patients, caregivers and providers. The pill penalty chills the development of medicines that typically come in pill form, like a capsule or tablet, by allowing them to be price set as early as nine years after they are first approved by the FDA. This is four years earlier than when selected biologic medicines are eligible for price setting. This misguided policy discourages research and development of innovative treatments that provide a significant benefit to patients.

While the IRA included some important policies that lower patient costs, such as capping out-of-pocket expenses for seniors and people with disabilities at \$2,000 and allowing seniors to spread their costs throughout the year, addressing the law's flawed policies, particularly the pill penalty, is crucial to ensuring patients have continued access to affordable, convenient and accessible treatment options.



We are already seeing the impact: Early-stage funding for small molecule development has fallen nearly **70%** since the IRA was introduced.¹

When we penalize the development of small molecule medicines, we risk losing the very tools that make health care more accessible, effective and affordable for millions of patients.

1. Lower cost: Pills are some of the lowest cost health care interventions available.

- ▶ Unlike more complex therapies that require hospital visits or specialized administration, pills do not incur the additional costs of health care providers and hospitals.
- ▶ Once generic versions of these medications are available, they can be purchased at a fraction of the original price, with an average copay of just \$6.16 and generic competition driving down prices by nearly 85%.^{2,3}

2. Essential in fighting disease: Pills are necessary in the treatment of diseases like cancer, mental health disorders and countless chronic conditions.

- ▶ Due to their smaller size, pills can reach therapeutic targets within cells, making them a critical tool in the fight against cancer.
- ▶ Pills are uniquely suited to treat a variety of mental health conditions due to their ability to cross from the blood-brain barrier and into the central nervous system.

3. More convenient, better outcomes: Pills offer unmatched convenience, helping patients better manage their condition and improve adherence.

- ▶ Pills can be taken in the comfort of a patient's home, reducing the need for frequent visits to the doctor's office or hospital. This is particularly important for rural patients who may have limited access to health care facilities.

Small Molecule Medicines: Convenient, Effective, Affordable

A small molecule medicine is what might first come to mind when you think of a medicine— in fact you probably have small molecule medicines in your medicine cabinet at home. These common medicines usually come in pill form but also include a wide variety of dosage forms like:



► Drops

► Powders

► Oral Suspensions

► Lozenges

► Nasal Sprays

► Ointments

The patient perspective: Countless patients count on small molecule medicines to manage their condition and live life to the fullest.

"Every breakthrough in medicine brings hope to veterans like me who are navigating mental health challenges. I wouldn't want any federal policy to steer research away from these efforts, and I want our lawmakers to ensure that we can access every available treatment."

— Jack J.
Michigan

"It's already hard enough for patients and families struggling with a mental health condition. Anything that makes taking their treatment easier is a huge relief."

— John H.
North Carolina

"I am concerned government price controls are going to get in the way of new cancer treatments coming to market... Policymakers need to prioritize the fight on cancer, not the fight on cures."

— Terry U.
Ohio

Congress should seize the opportunity to fix the pill penalty.

The EPIC Act – A Solution to the “Pill Penalty”

The Ensuring Pathways to Innovative Cures (EPIC) Act would fix the “pill penalty” by aligning the timeline for eligibility for price setting for small molecules with the timeline for biologics leveling the playing field for innovation.

Patients deserve policies that prioritize the fight against disease, not cures. The EPIC Act is a critical step toward fixing the pill penalty and ensuring that small molecule medicines remain a viable and accessible treatment option for millions of Americans.

The time to act is now.

Sources:

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3 U.S. Food and Drug Administration. Estimating Cost Savings from Generic Drugs. <https://www.fda.gov/media/182435/download?attachment>