COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

Understanding the Inflation Reduction Act's Pill Penalty

A technical fix is needed to ensure all patients continue to benefit from oral treatments.

The Inflation Reduction Act requires Medicare officials to set drug prices over the coming years. However, the law does not treat all medicines equally. The legislation subjects traditional "small-molecule" drugs to price controls just nine years after FDA approval and subjects large-molecule "biologic" therapies to price controls after 13 years.

This provision is already leading biotech companies to shift their research and development efforts away from small-molecule drugs. That's unfortunate for patients, since small molecules are typically convenient and easy to take. In addition, many rare diseases are treated with small molecule drugs.

Fixing the IRA to put small-molecule and biologic drugs on the same, 13-year timeline would help prevent the law's unintended consequences and ensure continued research into new treatments and cures, regardless of whether they're small or large molecules.

What is the small-molecule penalty?

- "Large molecule" biologics may face price setting **13 years** after FDA approval.
- "Small molecule" drugs may face price setting **nine years** after FDA approval.
- This new paradigm creates incentives to shift research into large molecule products
- Patients who rely on small-molecule drugs may find them more difficult to find and access.

How will the small-molecule penalty impact costs?

- Large molecule drugs are generally injected or infused in a doctor's office or hospital. Most insurers' cost-sharing arrangements require patients to pay something for both the administration of the drug and the drug itself.
- As a result, a shift towards large-molecule drugs will drive up costs for patients and taxpayers, as large-molecule drugs require more resources to administer. Distributing medicines at a pharmacy costs much less.
- Overall costs may also rise because generic biologics – known as "biosimilars" – are more difficult and costly to make than small-molecule generics and take longer to hit the market.

How will the small molecule penalty impact patients?

- Small-molecule drugs often give patients the option of taking their medicine in the comfort of their own homes. By allowing patients to avoid the time and expense of traveling to a hospital or clinic, small-molecule drugs are especially important for rural, low-income, and minority patient communities. An influx of patients to hospitals and clinics instead of pharmacies would intensify the healthcare worker shortage.
- Small molecule drugs are able to enter cells and can cross the blood-brain barrier, making them important treatment options for many patient groups, including those living with certain cancers and neurological conditions.

What can Congress do?

- Lawmakers should ensure all medications have 13 years of protection from price setting.
- Fixing the IRA so that price-setting starts 13 years after FDA approval -- regardless of whether a treatment is a small- or large-molecule drug -- would accomplish Congress' goal of reducing spending on older medicines that lack generic competitors, without leading to shifts in research funding and higher costs for patients who rely on small molecule drugs.