



## **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 (IRA) mandates Medicare to set drug prices but treats small-molecule and biologic drugs differently. Small-molecule drugs face price controls nine years after FDA approval, while biologics are affected after 13 years.

Biotech companies are shifting research and development away from small-molecule drugs, which are typically more convenient for patients, leading to higher costs and fewer options, especially for those living with a rare disease. Aligning the timelines for both drug types would prevent these unintended consequences and support ongoing research and innovation.

### **What is the small-molecule penalty?**

- "Small molecule" drugs may face price setting **nine years** after FDA approval.
- "Large molecule" biologics may face price setting **13 years** after FDA approval.
- 70% drop in investments in small-molecule drugs since the IRA drug provisions were drafted in September 2021.
- 78% of companies reported they expect to cancel early-stage research projects.
- 12% expected overall reduction in research and development investments, resulting in 188 fewer small-molecule drugs over 20 years.
- 10x more funding was spent on biologics than small-molecule drugs in 2024.

### **How will the small-molecule penalty impact costs?**

- Shifting to large-molecule drugs raises costs for patients and taxpayers, as they require more resources to administer, while pharmacy distribution is much cheaper.
- Large-molecule drugs are typically injected or infused in a doctor's office or hospital, with insurers often requiring patients to pay for both the drug and its administration.
- Costs may rise as biosimilars are harder and more expensive to produce than small-molecule generics and take longer to reach the market.
- Plans are already adjusting for the pill penalty, resulting in tighter coverage and higher cost-sharing at the pharmacy counter, from 10.6% to 75.8%.

### **How will the small molecule penalty impact patients?**

- Small-molecule drugs can be taken at home, saving time and travel costs, especially for rural, low-income, and minority communities. Shifting patients to hospitals and clinics would worsen the healthcare worker shortage.
- Small-molecule drugs cross the blood-brain barrier and enter cells, making them vital for treating cancers and neurological conditions.
- Patients who rely on small-molecule drugs may find them more difficult to access.
- 116 million life years could be lost due to a reduction in research and development related to the IRA's policies.

### **What can Congress do?**

- Members of Congress must pass the EPIC Act – fixing the IRA pill penalty so that price-setting starts 13 years after FDA approval, regardless of whether a treatment is a small- or large-molecule drug.