Correcting the Inflation Reduction Act's "Pill Penalty"

The Inflation Reduction Act (IRA) created an unintended disparity between small molecule treatments—which often come in pill form—and biologics. This so-called "pill penalty" threatens future research and development into essential cures.

Background

The IRA gives the Centers for Medicare & Medicaid Services (CMS) the authority "to negotiate"—although this effectively means "to set"—prices for a select number of prescription drugs covered by Medicare. Under the law, two categories of pharmaceuticals are recognized: **small molecules** and **biologics.**

Small Molecules vs Biologics: What's the Difference?

Small molecules – drugs which are derived chemically and include pills, tablets, capsules and creams to treat a variety of diseases and conditions.

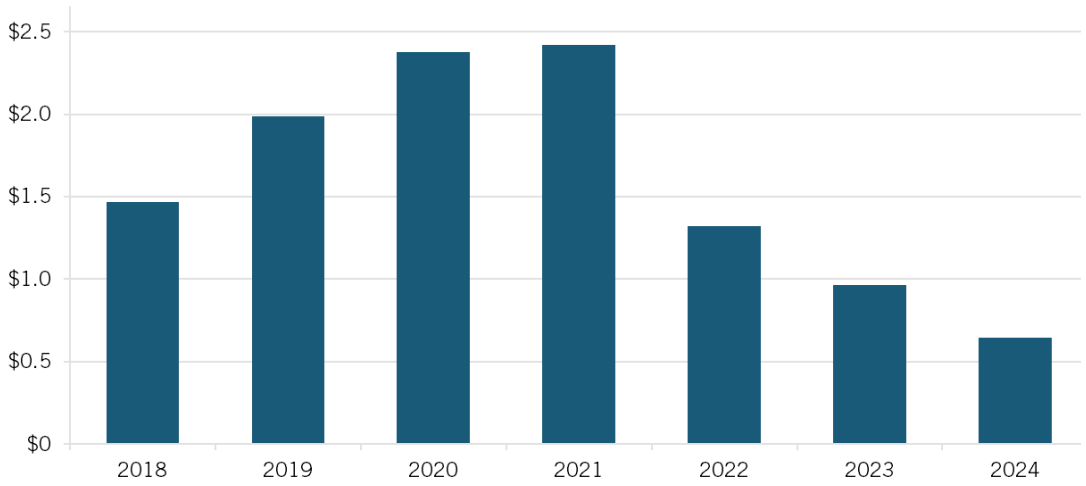
Biologics – large molecule drugs derived from living tissues. Common biologics include insulin and injectable medications to treat a variety of cancers and autoimmune conditions.

For selected drugs, the IRA requires that negotiated prices apply to small molecules after **nine years.** The new prices apply to large molecules after a **13-year period**.

This disparity is both harmful and arbitrary. By favoring large-molecule development with a longer period, the policy unintentionally shifts research and development incentives away from small molecule drugs. Consequently, this has **reduced funding opportunities for smaller biotech firms** that are pioneering effective small-molecule treatments for serious health conditions.

The Pill Penalty by the Numbers

86%	Percentage of all U.S. prescriptions that are small-molecule drugs.
70%	Drop in small-molecule drug investment since September 2021 when IRA provisions were initially drafted.
78%	Pharmaceutical companies reporting they expect to cancel early-stage small-molecule pipeline projects.
$5 vs $60	Average production cost per treatment for small-molecule drugs compared to biologics.
40%	Portion of a drug's total revenue typically generated between years 10-14, which small-molecule drugs would lose due to the pill penalty.



Investment in small-molecule drugs has dropped significantly since Sept. 2021, as shown in the chart.

Impact of the Pill Penalty

The drop in small-molecule drug investment coupled with surveys that show that pharmaceutical companies are expecting to cancel additional projects in their pipelines mean that many promising drugs may never even reach the later stages of research due to diminished economic viability.

Additionally, the IRA's pill penalty may discourage companies from investing in post-approval research, which is critical for developing additional indications for drugs—especially for cancer and rare disease patients who depend on these follow-up studies.

Post-pandemic data show that the development of infectious disease treatments has already declined by 34%, and any further disincentives could leave the United States more vulnerable to another pandemic. Moreover, the pill penalty risks undermining America's bioinnovation workforce, as smaller pharmaceutical companies struggle to secure necessary funding for small-molecule projects.

Patients Need Small-Molecule Drugs

Small-molecule drugs are a cornerstone of American healthcare. Breakthroughs in small-molecule research have driven significant advancements in areas such as cardiovascular treatments, antidepressants, blood pressure management, and even certain cancers.

Notably, small-molecule drugs can cross the blood-brain barrier and penetrate cellular walls, making them essential in treating a wide spectrum of diseases that disproportionately affect underserved and elderly populations.

For example, in 2023, the FDA approved 55 new drugs, 38 of which were small molecules, with many representing first-in-class approvals for oncology and rare disease treatments.

Further, since most treatments for infectious diseases rely on small molecules, supporting their development is vital for sustaining and improving public health.

Recommendation

Congress should pass the bipartisan **Ensuring Pathways to Innovative Cures (EPIC) Act,** which would fix the "pill penalty" by equalizing the amount of time before negotiated prices could be implemented for both small molecules and biologics at 13 years.

The **EPIC Act (H.R. 1492/S. 832)** was introduced in February 2025 by Reps. Greg Murphy (R-NC), Don Davis (D-NC), and Richard Hudson (R-NC) in the House and Senators Thom Tillis (R-NC), Ted Budd (R-NC), Marsha Blackburn (R-TN), James Lankford (R-OK), and Steve Daines (R-MT) in the Senate.

Read the full report, "The Inflation Reduction Act Is Negotiating the United States Out of Drug Innovation" at itif.org