

Preserving Innovation for California Patients: Fixing the "IRA Pill Penalty"

Congress should prioritize fixing the IRA's "pill penalty" by passing the ***Ensuring Pathways to Innovative Cures (EPIC) Act (H.R. 7174)***.

Correcting the "Pill Penalty"

The *Inflation Reduction Act (IRA)* created a "pill penalty" that discourages the development of medicines known as small molecules. These medicines typically come in a pill or capsule form, and the IRA forces them into earlier price setting than other kinds of more treatments like biologics. The IRA allows the government to select pill and capsule medicines for price controls as early as seven years after they are first FDA approved.



Most medicines **average 13-14 years** on the market to recoup the costs of investment before competitive generics enter.

Unique Benefits of Small Molecules that Help Patients

Due to their small molecular size and simpler scientific structure small molecule medicines have significant therapeutic benefits that allow them to reach targets inside of cells, particularly important for cancer treatments, as well as cross the blood-brain barrier, particularly important for neurological treatments. Small molecules can also come in a variety of forms of administration and doses, which may improve adherence. **The difficult and risky research and development process requires sufficient time on the market to recoup investment, so that patients retain seeing the benefits of these medicines.**



176,000 Californians will be diagnosed with cancer this year.

Continued R&D is Disincentivized by the IRA Timeline

Many medicines today are developed as a result of continued research and development on an approved medicine. Researchers follow science to develop medicines for new diseases, new patient populations and in new forms of administration. Much of this post-approval R&D happens in the later stages of a medicine's lifecycle, the very part of the lifecycle that is cut off by IRA drug price negotiation.



More than 1.2 million adults in California have a serious mental illness.

The Negative and Early Impact of the "Pill Penalty"

Even before the law is fully implemented we are seeing how biopharmaceutical companies are being forced to make tough business-impacting decisions as a result of the "pill penalty".

In fact, estimates show that had IRA been in place over ten years ago, between 24-49 therapies currently available would most likely not have come to market. Looking ahead, **conservatively, as many as 139 drugs over the next 10 years are at risk of not being developed.**



Drug development takes on average **10-12 years**, costs about **\$2.6 billion**, and only around **10%** of medicines that begin clinical development, reach FDA approval.