FIXING THE 'PILL PENALTY'

PRESERVING INNOVATION FOR CALIFORNIA PATIENTS

CALIFORNIA LIFE SCIENCES

Congress should pass H.R.1492/S.832, the *Ensuring Pathways to Innovative Cures (EPIC) Act,* to fix the *Inflation Reduction Act's* (IRA) "pill penalty" and restore parity by giving small-molecule drugs the same 13-year protection period as biologics before price setting begins.

MYTH The "pill penalty" won't harm patients.

FACT Research shows significant long-term and downstream impacts on both the number of unique drugs, and the number of diseases and populations treated by these products.

- Had the IRA been in place ten years ago, estimates show that **at least 24, and up to 50, medicines we have today would not have come to market.**
- Had the IRA been in place during the last 20 years, **over one-third of expanded indications** achieved by novel small molecule drugs after nine years on the market may not have been realized.
- Investments will shrink, with conservative estimates showing **as many as 139 drugs over the next ten years are at risk of not being developed.**

HELP PATIENTS



Supporting the *EPIC Act* means ensuring the more than 176,000 Californians who will be diagnosed with cancer this year, and the more than 1.2 million adults in California with a serious mental illness, will have treatment options where there currently are none.

SUPPORT THE ECONOMY



Without the *EPIC Act* the life sciences sector in California is at risk. Passage of this law would restore investment interest in small-molecule drugs and the companies that research and develop them.

MYTH The "pill penalty" won't harm the life sciences sector.

FACT Production of small molecules in small companies account for 55% of all first in class drugs, so the "pill penalty" will result in significant damage to the viability of the entire business model.

- **Small molecule funding has dropped 70%** since September 2021 when the IRA was introduced.
- **The four-year difference** between small molecules and biologics accounts for such a significant proportion of the medicine's average revenue that any reduction to the revenue **makes investment in small molecule drug development unsustainable.**

MYTH There is little value in small molecule innovation, the future is entirely in biologics and gene therapies, most patients use those anyways.

FACT Neither category of medicines is more important, and both are necessary to improve patient health. Certain unique scientific characteristics of small molecules — such as their size and structure — allow them to reach targets inside cells and cross the blood-brain barrier, particularly important for cancer and mental health treatments. Small molecules can also come in a variety of forms or administration forms and doses, which can help with adherence and make it easier for patients to access the medicines they need. **The *EPIC Act* re-levels the playing field for this kind of innovation.**

VALUE SMALL MOLECULE MEDICINES



90% of all drugs on the market are small molecules, which are responsible for the more than a third of the gains in survival over the last 25 years.

FOSTER FOLLOW ON R&D



Over half of small molecules received at least one additional indication, and almost 50% of these subsequent approvals happen 7 years after initial approval.

MYTH Small molecule development stops at the time of initial FDA approval, therefore shorter time on the market makes sense.

FACT When drugs do achieve FDA approval, that is often just the beginning of research and development of the medicine. Building on the existing medicine is valuable because it is an efficient process to find new ways to address unmet needs. **The *EPIC Act* restores incentives for follow-on research and development that can lead to new medicines and new ways to take medicines for a variety of patient populations.**

MYTH Without negotiating small molecules at 9 years, patients' costs will not come down.

FACT The chances of patients facing lower costs **increases** if small molecules are negotiated at 13 years. The *EPIC Act* will restore the successful role generic medicines play in spurring competition and lowering costs. Price decreases after generic entry reach up to 95%, and collectively, generic drugs have saved patients and the U.S. health care system almost $3 trillion dollars. **Without the *EPIC Act*, we may see fewer new generics and reduced cost-containing competition.**

ENABLE COMPETITION



Currently small molecules experience competition at around 13 years after initial launch.