

PREVIEW: The Impact of the Small Molecule “Pill Penalty” Two Years Into the IRA

Research firm Vital Transformation is preparing a new analysis about the impacts of the Inflation Reduction Act on biopharma investment, research and development in the two years since the law’s passage. Early returns show significant harms to innovation and patients’ treatment options, particularly because of the IRA’s small molecule “pill penalty.”

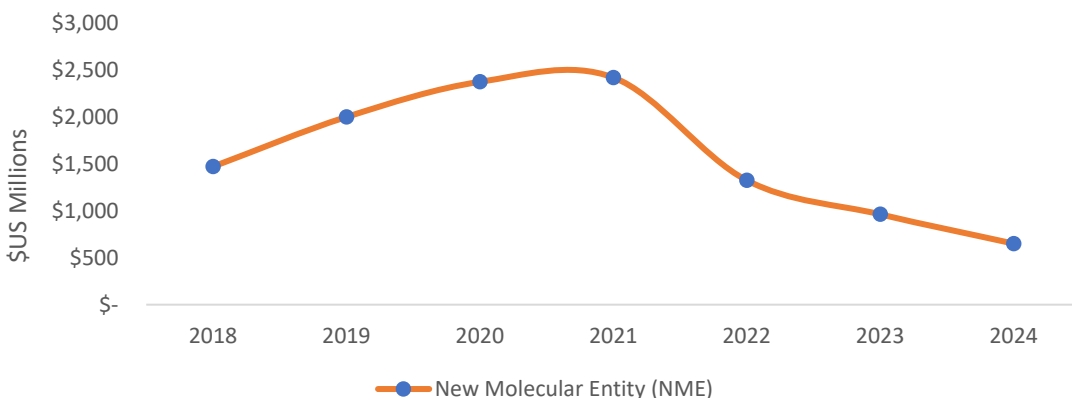
The IRA set small molecules on a shorter timeline than biologics (9 vs. 13 years) before they can be subjected to government price setting. Experts have warned this will have many negative consequences by disincentivizing the development of small molecules. This is a particular concern given the unique benefits of small molecules, including their ease of access and their ability to reach therapeutic targets inside cells and inside the brain. Small molecule medicines have long been the backbone of modern medicine, accounting for more than 90% of all prescriptions today.

Vital Transformation analyzed 161 early-stage lead assets under clinical development by emerging U.S. companies and uncovered a stark shift in investment. For the research assets studied:

- **Small molecule funding has dropped by 70% since September 2021** when the IRA was introduced.
- Through the first seven months of 2024, **biologics funding is now 10 times larger than small molecules**, despite small molecules being the most common and convenient treatment options for patients.

Total Investment in Small Molecule Lead Assets

1/2018 - 8/2024, Company valuation ≤ \$2 billion



Sources: Biomedtracker, Pitchbook, SEC Filings, ClinicalTrials.gov

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These numbers tell a clear story: the IRA has created a chilling effect on small molecule research, development, and clinical trials, while biologics — protected by a longer period before IRA price setting — continue to thrive. And this comes at a time of incredible promise in the small molecule space.

For millions of patients who rely on small molecule treatments for conditions like hypertension, diabetes and certain cancers, this decline in innovation could mean fewer options and longer waits for new therapies.

A previous [analysis](#) has shown that more than 75% of the medicines selected for price setting under the IRA over the next 10 years will be small molecules.

Potential Solution

There is a way for policymakers to address these unintended consequences. The Ensuring Pathways to Innovative Cures (EPIC) Act offers a promising solution: It would align small molecules with biologics under a 13-year timeline before negotiation eligibility, balancing the incentives needed to drive research and development for life-saving small molecule treatments.

By leveling the playing field, policymakers can reignite innovation and ensure patients have access to the treatments they need.

Check back on the We Work For Health [website](#) for a full report on Vital Transformation’s findings and more about the IRA’s impact over the last two years.

Source: The Inflation Reduction Act’s Impact upon Early-stage Venture Capital Investments (medRxiv)