

NEW ANALYSIS: The IRA Impact on Pharmaceutical R&D

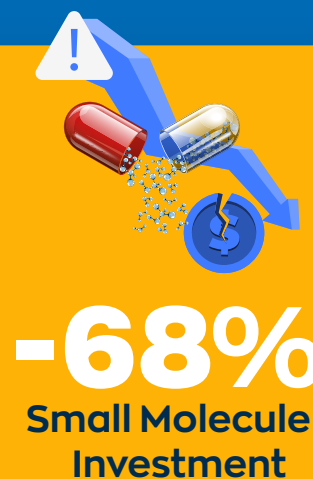


A new analysis by researchers at Vital Transformation examines the impact of the Inflation Reduction Act (IRA) on investment, research and development of prescription drugs since the IRA was introduced. The study analyzes data from 161 early-stage¹ therapies under clinical development by major U.S. companies, assessing changes in funding and R&D progress. Here are key highlights from the analysis:

1 A CHILLING EFFECT ON SMALL MOLECULE R&D INVESTMENT

The IRA sets a shorter timeline (9 years) for small molecules before government price setting begins, versus 13 years for biologics. This shorter timeline – known as the “pill penalty” – discourages investors from investing in small molecule development, risking future patient access to treatments that comprise 90% of prescriptions. Aggregate U.S. funding for early-stage small molecule R&D has **dropped by 68% since** the IRA was introduced.

Small molecules with a low exposure to the Medicare-aged population show no statistical decline in the size of their investments since the IRA was introduced, but small molecules with a high exposure to Medicare do. The study found a **74% drop in the median size of aggregate investments into indications specifically targeting the Medicare-aged population**, a statistically significant drop after the IRA was introduced in the median size of the investments made into small molecules versus those made into large molecules. IRA has created negative impacts on the very population the legislation is allegedly designed to aid. Namely, the Medicare-aged population requiring effective new therapies in areas of high unmet medical need, who are likely to have fewer new treatments available in the future.



¹Early stage companies are those with a total valuation less than or equal to \$2 billion USD.

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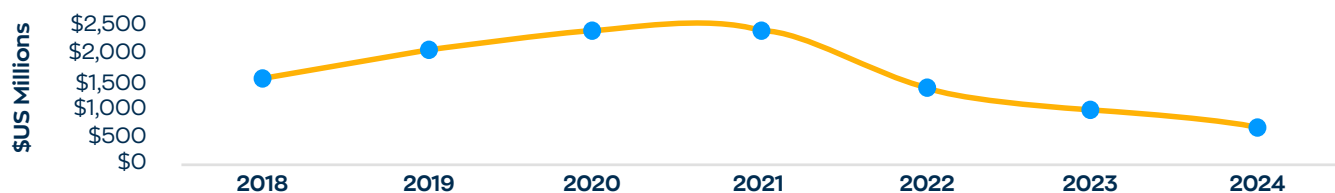
WE
WORK
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HEALTH

2 STEEP DECLINE IN EARLY-STAGE INVESTMENT

Since its introduction, the IRA has led to a 35% reduction in early-stage phase I and phase II therapies under development among small and mid-size biotech companies. As a result, we would expect to see a considerable **reduction in FDA approvals within 5-6 years**.

TOTAL INVESTMENT IN SMALL MOLECULE LEAD ASSETS

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



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

—●— New Molecular Entity (NME)

-35%
Early-Stage
Investment

Most Impacted Therapies

The hardest hit therapies are those that treat conditions that are common among the Medicare-aged population:



Dementia



Non-Small Cell
Lung Cancer



Prostate
Cancer



Multiple
Myeloma

3 GROWING DISPARITIES BETWEEN SMALL MOLECULES & BIOLOGICS

While investment in small molecule treatments has declined, investment in biologics, which are protected for a longer time frame, continues to deliver on important scientific advancements and life-changing medicines.



The EPIC Act - A Solution to the "Pill Penalty"



EPIC
ACT

The Ensuring Pathways to Innovative Cures (EPIC) Act would fix the "pill penalty" by aligning small molecules with biologics under a 13-year timeline, leveling the playing field. According to the study, fixing the "pill penalty" would **increase the number of therapies developed that target the Medicare-aged population by 21%**.

For the full study, please visit Vital Transformation www.vitaltransformation.com or We Work For Health www.weworkforhealth.org.