PRESS RELEASE

New Research Reveals the Devastating Impact of the Inflation Reduction Act's "Pill Penalty" on Small Molecule Medicines

Small-molecule drug investment has fallen 68%—and 74% for diseases mainly affecting Medicare patients—since the IRA was introduced

FOR IMMEDIATE RELEASE

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WASHINGTON, D.C. – New research reveals the harmful impacts of the Inflation Reduction Act's drug pricing provisions on biopharmaceutical investment, research and development, and patients' treatment options. Vital Transformation's research found that aggregate small molecule investments by companies valued at less than $2 billion **dropped by 68% since the Inflation Reduction Act was introduced**. Further, the study also found a **74% drop in the median size of aggregate investments into indications specifically targeting the Medicare-aged population**, with a significant decrease in investments in small molecules compared to large molecules after the IRA was introduced. The peer-reviewed research was first published in the journal *Therapeutic Innovation and Regulatory Science*.

"This decline in innovation means fewer options at a higher cost and longer waits for millions of Americans—especially Medicare-aged patients—who rely on small molecule treatments like pills and tablets for conditions including hypertension, diabetes, some cancers and more," WWFH Executive Director Dan Leonard said. "For so long, small-molecule medications have been the backbone of affordable, convenient modern medicine, but the IRA's policies risk undermining this critical class."

The small molecule "pill penalty" has particularly exacerbated R&D funding of therapies with a high exposure to the Medicare-aged population. Experts have warned that by creating a shorter timeline before small-molecule drugs are subject to price setting, the IRA introduces negative consequences by disincentivizing the development of small molecule medicines, which account for more than 90% of all prescriptions.

Other key research findings include:

- The median size of investments into small molecule medicines with a high exposure to the

Medicare-aged population has declined, while investments with a low exposure to the Medicare-aged population have not.

- Removing the "pill penalty" by beginning IRA price setting for both small molecule drugs and biologics after **13 years would increase FDA approvals targeting the Medicare-aged population by 21%**.
- Between 2021-2023, in timing with the IRA's introduction, small and mid-size biotech companies endured a **35% reduction in early-stage phase I and II therapies** under development. With the average phase II and III clinical development time at roughly 40 months each, data indicates a **considerable reduction in FDA approvals targeting the Medicare-aged population in 5-6 years**.

These numbers tell an important story: The IRA has inflicted a chilling effect on small molecule drug research and development, even at a time of incredible advances in the scientific space.

"Our findings clearly lay out the current and future reality for early-stage biopharma innovators targeting patients in need," Vital Transformation CEO Duane Schulthess said. "The decline of small molecule investments targeting the Medicare-aged population over the last two years in highly innovative, young companies is undeniable and will not reverse without meaningful changes."

We Work For Health urges policymakers to address the unintended consequences of the "pill penalty" by passing the Ensuring Pathways to Innovative Cures (EPIC) Act. This promising solution would align small molecule drugs with biologics under a 13-year timeline and restore the incentives necessary to drive research and development on these treatments. By leveling the playing field, policymakers can take action to ensure that the Medicare-aged population continues to have access to needed new treatments.

The new study issued by We Work For Health and Vital Transformation modeled the impacts of IRA provisions by constructing a dataset of 161 early-stage therapies under clinical development by major U.S. companies. Vital Transformation's Consulting Economist Dr. Harry P. Bowen, Research Manager Dr. Daniel Gassull, Research Partner Gwen O'Loughlin, Research Intern Madeline Askeland, and CEO Duane Schulthess performed this analysis.

For the full study, please visit Vital Transformation or We Work For Health.

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About We Work For Health

We Work For Health brings together national and local business leaders, and labor, biopharma, patient advocacy and other healthcare-related stakeholders to support policies and initiatives that foster innovation and facilitate the delivery of lifesaving and life-enhancing medicines. As the

bedrock of innovative jobs in the U.S. today, the life sciences sector supports more than 4.9 million American employees. Advancing and protecting these jobs is critical for those employees, the economies they support and the patients they serve.

About Vital Transformation

Vital Transformation understands the implications of new medical procedures, technologies, and policies. We measure their impact on current clinical practices in close collaboration with health care professionals, researchers, and regulators. Through our web platform, client network and Vital Health Podcast series, we are able to communicate our findings with international decision makers and stakeholders.