Observational Research Reveals Unintended Consequences of the Inflation Reduction Act on Post-Approval Clinical Trials

NPC study supports that the IRA reduced evidence generation while raising concerns around the "pill penalty" — impacting innovation and patient access.

WASHINGTON, DC, UNITED STATES, April 22, 2025 /EINPresswire.com/ -- New evidence published in Therapeutic Innovation & Regulatory Science identifies the early signals of the impact of the Inflation Reduction Act (IRA) on pharmaceutical innovation, finding a strong correlation between the passage of the IRA and reduced industry investment in post-approval clinical trials. This research supports previous analyses that warned of unintended consequences of the IRA and is the first NPC peer-reviewed study that tests IRA observed impacts.

"The Inflation Reduction Act and Drug Development: Potential Early Signals of Impact on Post-Approval Clinical Trials" provides compelling evidence of the IRA's influence on the landscape of industry-sponsored, post-approval clinical trials, with a larger impact on small molecule drugs. The paper is authored by Hanke Zheng, MS, PhD, Julie A. Patterson, PharmD, PhD, and Jon D. Campbell, PhD.

The research found a large reduction in industry-funded, post-approval clinical trials following the passage of the IRA — particularly for small molecule drugs. Faced with a shorter "clock" to government price regulation than large molecule drugs, small molecule drugs are seeing reduced incentives for pharmaceutical manufacturers to invest in post-approval research — supporting "pill penalty" concerns. The study authors counted industry-sponsored, post-approval Phase I-III trials from July 2014 to August 2024 and found a 38.4% decrease in trials following the passage of the IRA, with small molecule drugs experiencing a 47.3% decline. Additional analyses, including no observed changes in government-sponsored trials, strengthened the relationship between industry-funded trial reductions and the IRA.

"The IRA introduces new challenges for drug development by shortening the timeline toward price erosion, discouraging investments in vital post-approval research," said Dr. Zheng. "Our study underscores the need for policymakers to consider the broader implications on innovation and patient access to new therapies, especially as a majority of post-approval drug trials and investment comes from industry rather than government."

In light of these findings, the authors advocate for several policy measures to mitigate adverse

impacts to innovation and access:
• Extending the small molecule Medicare Drug Price Negotiation Program (DPNP) eligibility to align with large molecule timelines;
• Delaying DPNP eligibility for new indications;
• Excluding orphan drugs treating rare conditions from DPNP eligibility; and
• Establishing a transparent framework for Maximum Fair Price (MFP) determination that appreciates the full value of medicines.

"The evidence tells us that manufacturers are likely already adjusting their investment strategies in response to the reduced incentives for post-approval research and development. It is crucial that future research continues to evaluate the long-term effects of the IRA, particularly on drug subgroups that may be disproportionately affected," stressed Dr. Campbell.

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