Research Finds Post-Approval Cancer Trials Fell After IRA Passage, With Disproportionate Impact on Small Molecule Drugs

Findings highlight concerns of government price regulation and the IRA's "pill penalty."

WASHINGTON, DC, UNITED STATES, September 3, 2025 /EINPresswire.com/ -- New research published in Health Affairs Scholar finds that the passage of the government price-setting provisions of the Inflation Reduction Act (IRA) was associated with a broad decline in industry-funded oncology trials after first FDA approval, with disproportionally greater reductions for small molecule drugs. The IRA established the Medicare Drug Price Negotiation Program (DPNP), which allows small molecule drugs to be selected after seven years and biologics after 11 years. This shorter “clock” for small molecule drugs is often called the “pill penalty."

“Early Impact of the Inflation Reduction Act on Small Molecule vs Biologic Post-Approval Oncology Trials” sheds light on the influence of the IRA on industry-sponsored, post-approval clinical trials for oncology drugs — drugs that often have multiple indications that expand treatment options for patients with cancer. The study is authored by Hanke Zheng, PhD; Julie A. Patterson, PharmD, PhD; and Jon D. Campbell, PhD.

Using Citeline’s Trialtrove database, the authors analyzed the overall number of post-approval, industry-funded Phase I–III trials that were initiated for approved oncology drugs between July 2014 and August 2024 (excluding vaccine related trials). The authors found that after the IRA’s passage:

- Overall, monthly post-approval oncology trials fell by 40.0%, with sharper declines for small molecule drugs (45.3%) than for biologics (32.5%).

- The disproportionate decline for small molecule drugs translated into an additional reduction of 4.5 trials/month, when compared to biologics.

- The disproportionate decline for small molecule drugs was robust to a sensitivity analysis that limited the pre-IRA period to the post-COVID-19 era.

This evidence builds on previous National Pharmaceutical Council (NPC) research identifying a strong correlation between the passage of the IRA and reduced industry investment in post-approval clinical trials, with a larger impact on small molecule drugs.

“In addition to the therapeutic benefits, small molecule drugs often provide greater flexibility and convenience for patients, making cancer treatments possible through a pill taken at home," said Dr. Zheng, lead author and NPC Research Manager. "We sought to quantify the impact of their shorter ‘clock’ to government price regulation on post-approval clinical trials for oncology."

Study authors used a difference-in-difference analysis to control for other factors, like the COVID-19 pandemic, that could have impacted post-approval oncology clinical trials and isolate the true impact of the IRA’s differential DPNP eligibility timeline for small molecules.

"We used the trend of biologics as the control to estimate the impact of the shorter DPNP eligibility timeline on initiation of post-approval clinical trials among oncology small molecules," said Dr. Patterson, NPC Senior Director of Research. "The significant additional decline of nearly five fewer small molecule trials a month suggests that we're already observing the impact of the pill penalty in small molecule cancer research."

"This study quantifies just one of the IRA’s effects, spotlighting how government price-setting disincentivizes industry-funded post-approval oncology trials — with disproportionate impacts to trials investigating small molecule drugs," said Dr. Campbell, NPC Chief Science Officer. “Policymakers should consider how the discrepancies towards DPNP eligibility are obstructing innovation for new oncology medicines.”

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