# The Inflation Reduction Act Discourages Vital R&D in Cancer Medicines

**The majority of cancer medicines approved by the U.S. Food and Drug Administration (FDA) are those which come in pill or tablet form, known as small molecules.** Under the Inflation Reduction Act's (IRA) drug price setting provisions, these medicines can be selected for government price setting just seven years after they've first been approved by the FDA, with the government set price effective two years later. Initiating government price setting so early in their lifespan ignores the real-life impact these medicines bring to patients and is already leading biopharmaceutical companies to reconsider investing in their development.

**Biopharmaceutical companies often continue to research new indications for medicines after FDA approval to see if medicines can improve patient care in other stages of disease or different diseases.** This is especially true for cancer. Medicines may receive additional FDA approvals in later years that provide important treatment options for patients with cancer or demonstrate the ability to extend overall survival. Because the IRA's price setting provisions begin so soon after a medicine is initially approved, it discourages researchers from following promising scientific leads. It will decimate incentives to invest in post-approval research if the government can set the price of a medicine long before companies even complete the additional research necessary to obtain approval for additional indications.

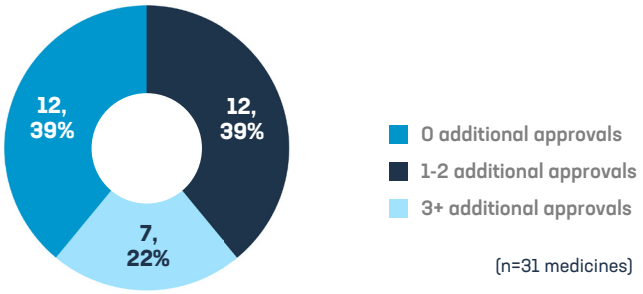
**New research from the Partnership for Health Analytics and Research (PHAR) demonstrates how price setting provisions in the IRA could have an acute impact on cancer medicines.[i] The study shows:**

**61%**

of the small molecule cancer products in this study received at least one post-approval indication and 22% received three or more.

## Number of cancer medicines by number of post-approval indications

For small molecule oncology medicines receiving initial FDA approval between 2006-2012



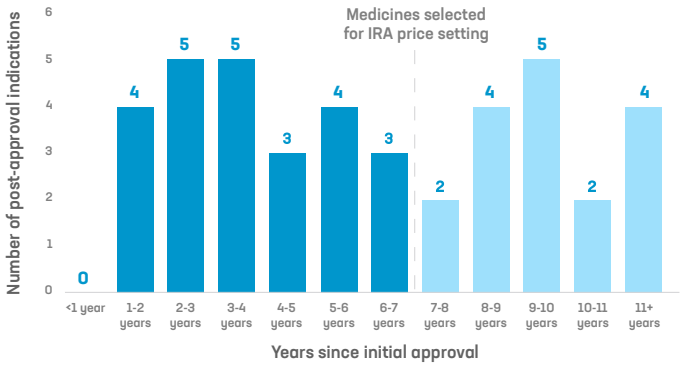

(n=31 medicines)

**41%**

of post-approval indications in cancer occurred seven or more years after a medicine's initial FDA approval. Advances like these that occur later in a medicine's lifecycle are most at risk under the IRA.

## Timing of post-approval indications

For small molecule oncology medicines receiving initial FDA approval between 2006-2012




(n=41 post-approval indications)

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**This threat to cancer R&D is particularly alarming considering post-approval indications in cancer medicines represent important advances for patients.**

Nearly **40%**

of post-approval indications for cancer medicines were for new disease targets, typically a different type or subtype of cancer.

Nearly **50%**

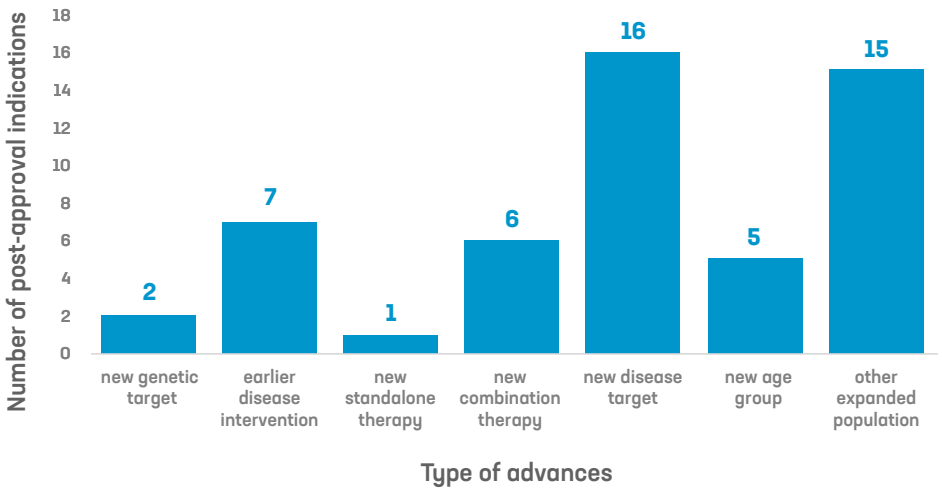
of post-approval indications were for a new age group or other populations, such as patients with different comorbidities.

**17%**

were for earlier intervention in the progression of the cancer.

## Types of advances represented by post-approval indications

For small molecule oncology medicines receiving initial FDA approval between 2006-2012




Categories not mutually exclusive

(n=41 post-approval indications)

Biopharmaceutical companies are committed to fighting the many diseases that comprise cancer. Given the nature of cancer research and the expansion of therapeutic value over time, the IRA's drug price setting provisions are projected to have an acute impact on the future of fighting cancers and other diseases. Instead, Congress should make it a priority to preserve innovation in lifesaving cancer medicines.

**Learn more at: PhRMA.org/Inflation-Reduction-Act**

*Analysis of small molecule prescription medicines receiving initial Food and Drug Administration (FDA) approval between January 1, 2006, and December 31, 2012, based on data published by FDA.[ii] Drug label data from Drugs@FDA was used to identify timing and characteristics of post-approval indications for each medicine in the sample.*


i Partnership for Health Analytic Research, Implications of the Inflation Reduction Act Price Setting Provisions on Post-Approval Indications for Small Molecule Medicines, June 2023

ii Center for Drug Evaluation and Research. Compilation of CDER New Molecular Entity (NME) Drug and New Biologic Approvals. FDA. Published online March 21, 2023. Accessed May 9, 2023. https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals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