

# GOVERNMENT PRICE SETTING THREATENS THE MANY SIGNIFICANT INNOVATIONS GENERATED AFTER INITIAL FDA APPROVAL

Innovation doesn't stop when the U.S. Food and Drug Administration (FDA) approves a new prescription medicine. Biopharmaceutical companies continue to research treatments after FDA approval to see if they can be used in new ways to improve patient care, especially in disease areas like cancer.

## Additional FDA Approvals Resulting from Post-Approval Research and Development Can Include:



### NEW USES OR INDICATIONS

to treat a different medical condition



### NEW PATIENT POPULATIONS

such as children or patients with different stages of disease



### NEW FORMULATIONS

that offer significant advances in therapy



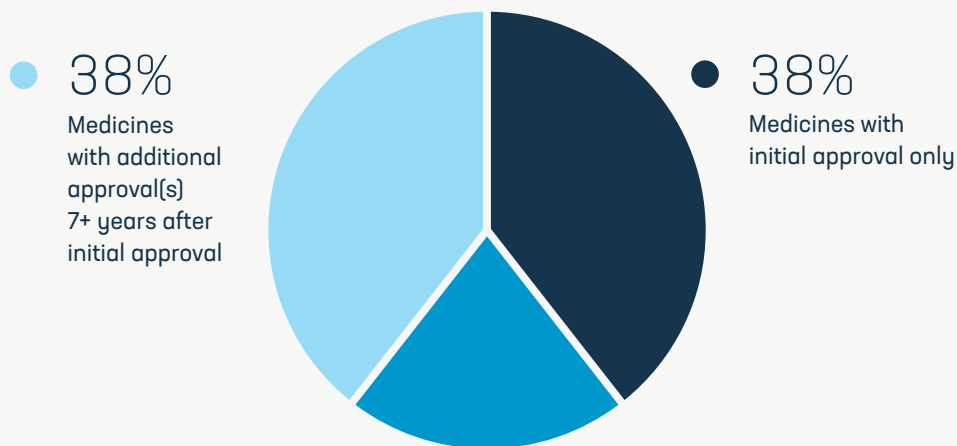
### NEW DOSAGE FORMS

that can help increase patient adherence

## 62% of oncology medicines approved a decade ago received additional approvals in later years.

Biopharmaceutical R&D generated most of these additional approvals 7 or more years after the initial approval, resulting in new indications or improved ways for patients to receive a therapy.

## Additional Approvals for Oncology Medicines Initially Approved from 2010 to 2012



Source: Partnership for Health Analytic Research, "Implications of the Inflation Reduction Act on Post-Approval Research & Development of Biopharmaceutical Medicines," November 2022

● 24%  
Medicines with additional approval(s) 1-6 years after initial approval

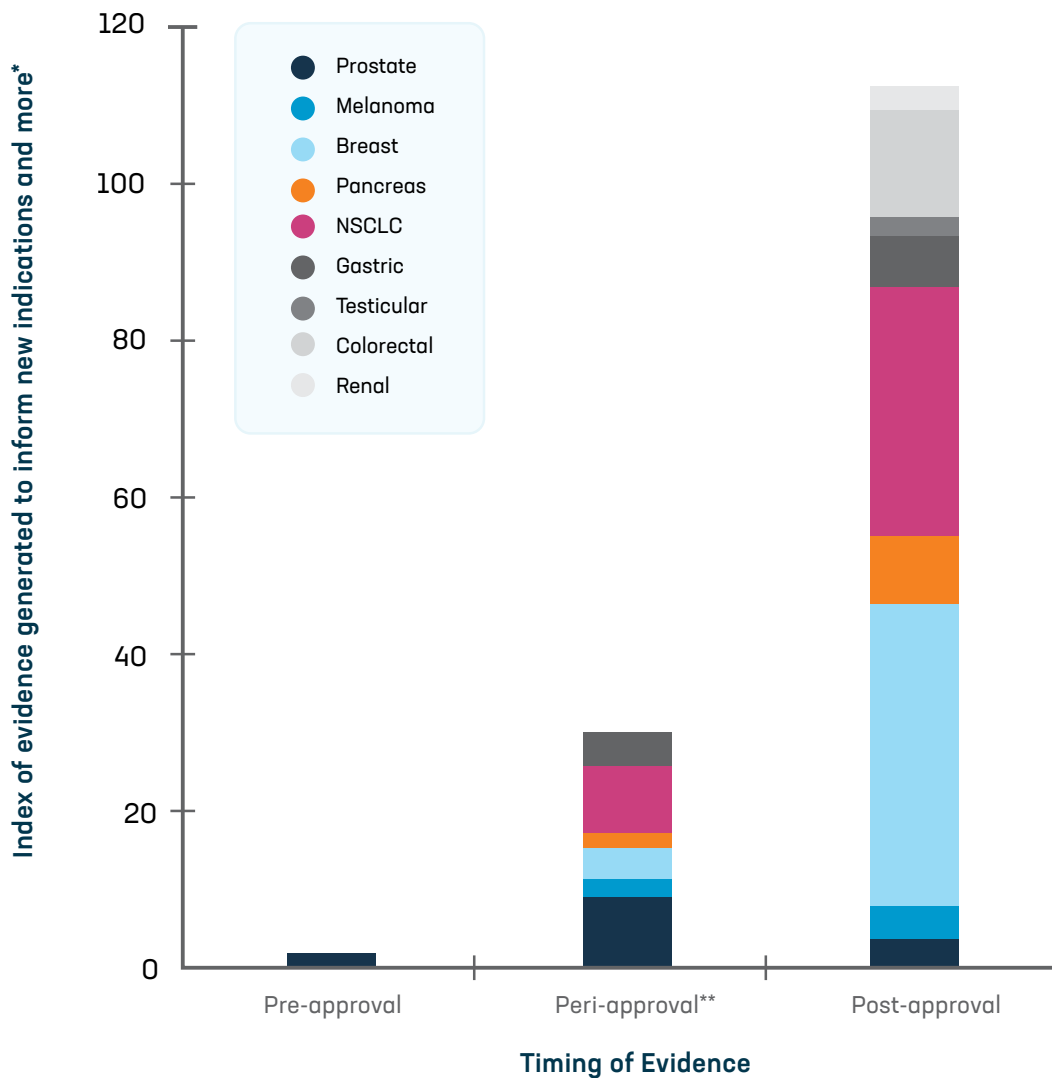
**Most of the research showing survival gains from cancer medicines is generated *after* a cancer medicine is initially approved.**

This post-approval research often leads to additional uses for the medicines that can benefit more patients.

Government price setting policies reduce biopharmaceutical companies' ability to invest in the post-approval research required to achieve these later survival gains.

Instead of undermining incentives for research, policymakers should encourage more progress in fighting disease.

**Timing of Research Evidence of Improved Overall Survival From Oncology Medicines**



\*Based on publications on selected solid tumor types from 1998-2015. Source: Paddock et al., "Dynamic value assessments in oncology supported by the PACE Continuous Innovation Indicators," *Future Oncol.* (2017) 13(25), 2253-2264.

\*\*Peri-approval spans 2 years pre- and post-approval to account for possible delays in publishing evidence in conjunction with the approval process.