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

- **38%** Medicines with additional approval(s) 7+ years after initial approval
- **38%** Medicines with initial approval only
- **24%** Medicines with additional approval(s) 1-6 years after initial approval

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

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.


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