Cancer Medicines: Value in Context

May 2019

PhRMA
RESEARCH • PROGRESS • HOPE

Table of Contents

Key Takeaways

- We have made remarkable progress in the fight against the more than 200 diseases we call cancer and current research holds enormous promise to address the great unmet need.

- Too many cancer patients face financial burdens, and these come from a variety of sources including treatment costs, non-medical costs, and insurance benefit design.

- The cost of cancer treatment comes from a range of sources including medicines, hospital and ED visits, diagnostics, and physician services.

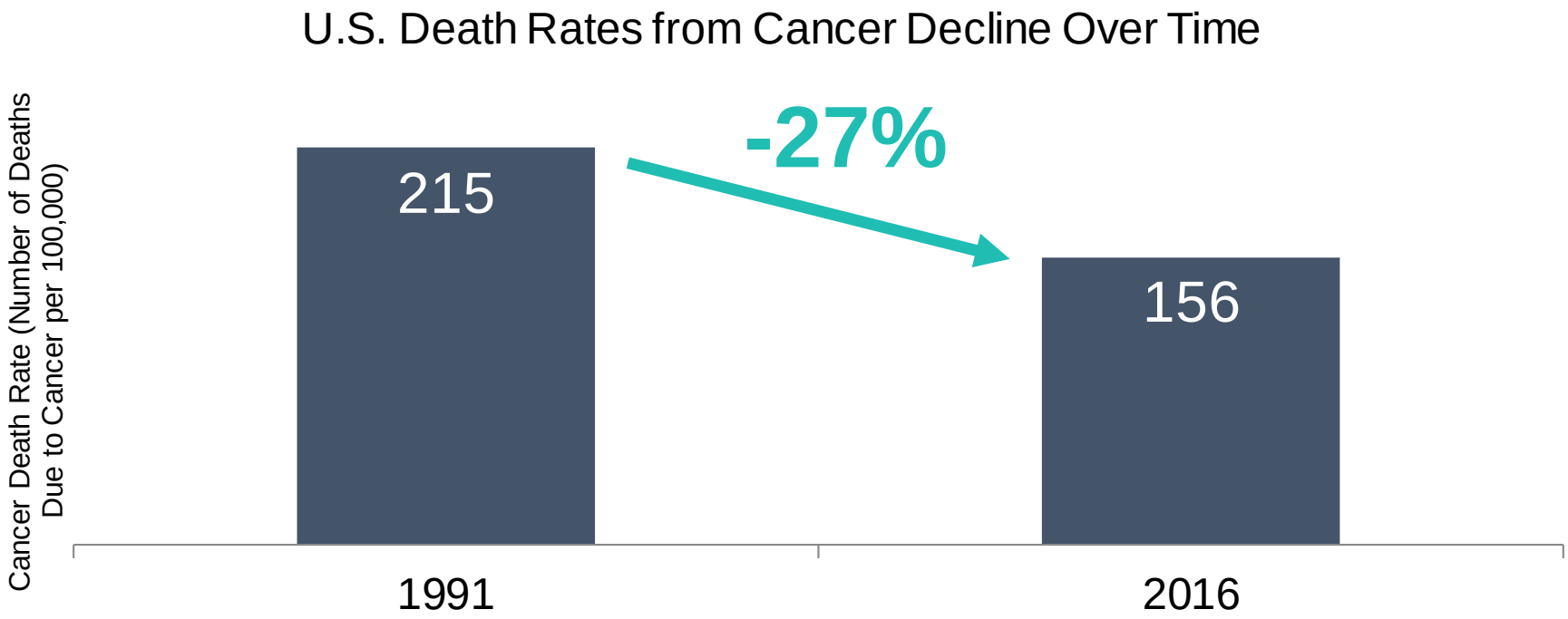
- The oncology market is working to control spending on cancer medicines and overall treatment costs.

- Reforms are needed to accelerate the development path for cancer medicines and promote a delivery system that is increasingly patient-centered and value-based.

1. Advances in Cancer Treatment

Since Peaking in the Early 1990s, Cancer Death Rates Have Declined 27%

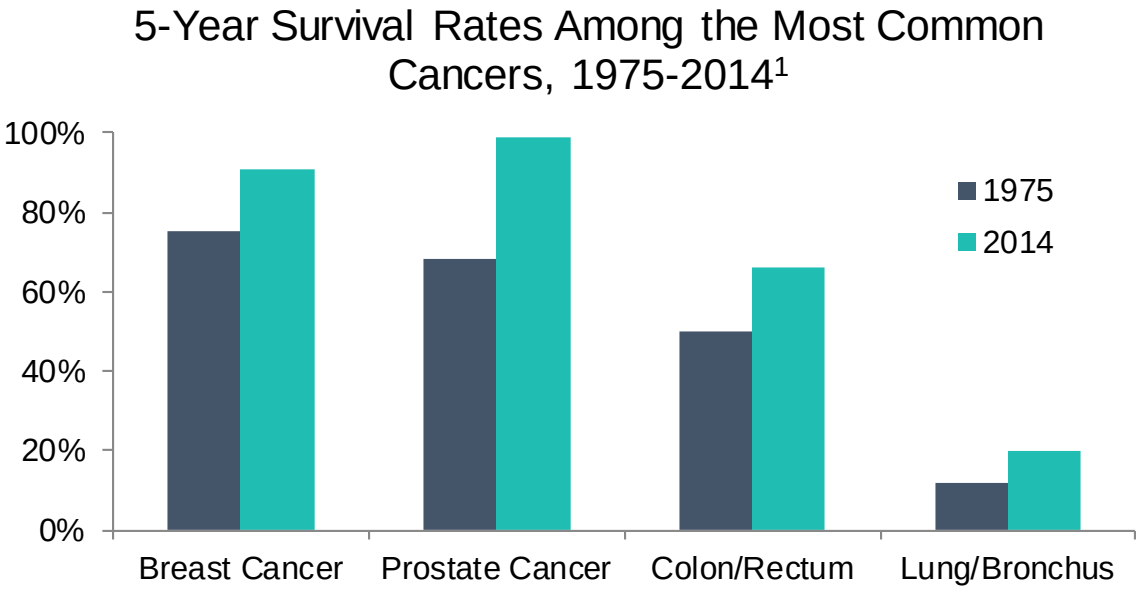
Increases in cancer survival are estimated to translate to the avoidance of nearly 2.6 million cancer deaths.



Source: American Cancer Society, "Cancer Facts & Figures 2019," https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2019.html.

Five-Year Survival is Increasing for Many Types of Cancer

Since 1975, the chances that a cancer patient will live 5 years or more have increased by 41% across cancers.[1]



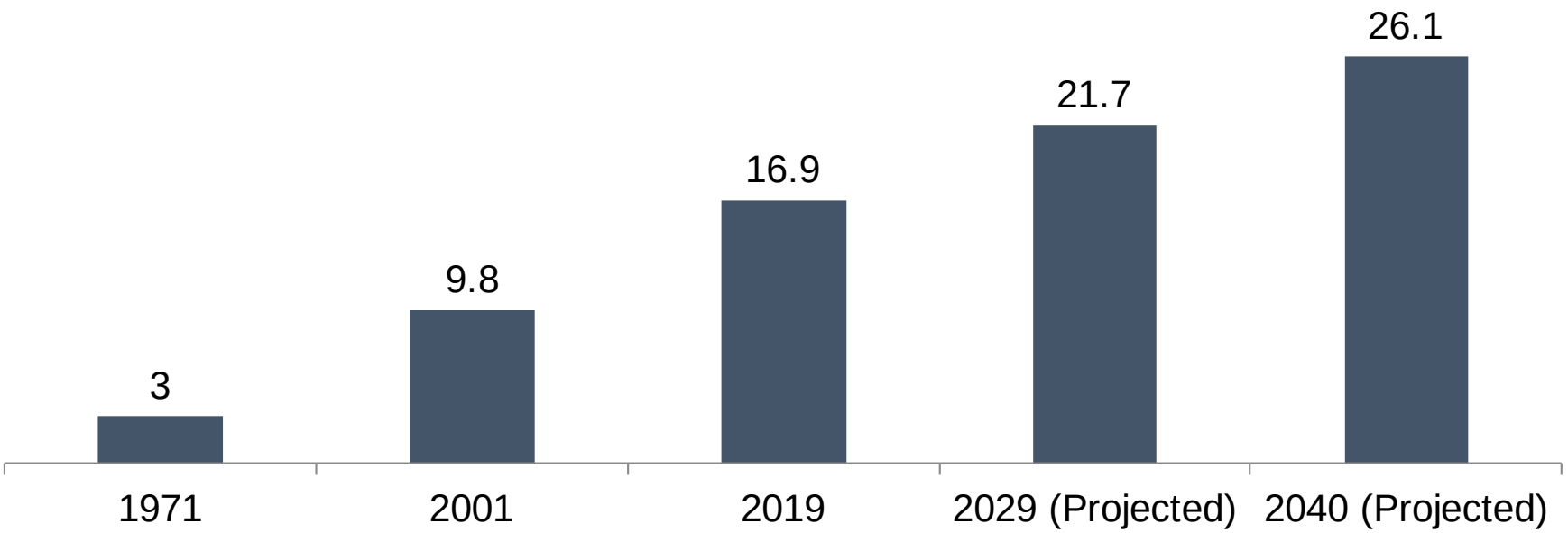
73% *of recent survival gains in cancer are attributable to treatment advances including new medicines.*[2]

Sources: 1) American Cancer Society, "Cancer Facts & Figures 2019," https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf. 2) S. Seabury, "Quantifying Gains in the War on Cancer Due to Improved Treatment and Earlier Detection," *Forum for Health Economics and Policy* 2016; 19(1): 141–156.

The Number of Cancer Survivors is Steadily Rising

The continued increase in survival rates is in large part attributable to earlier detection and better treatments.[1]

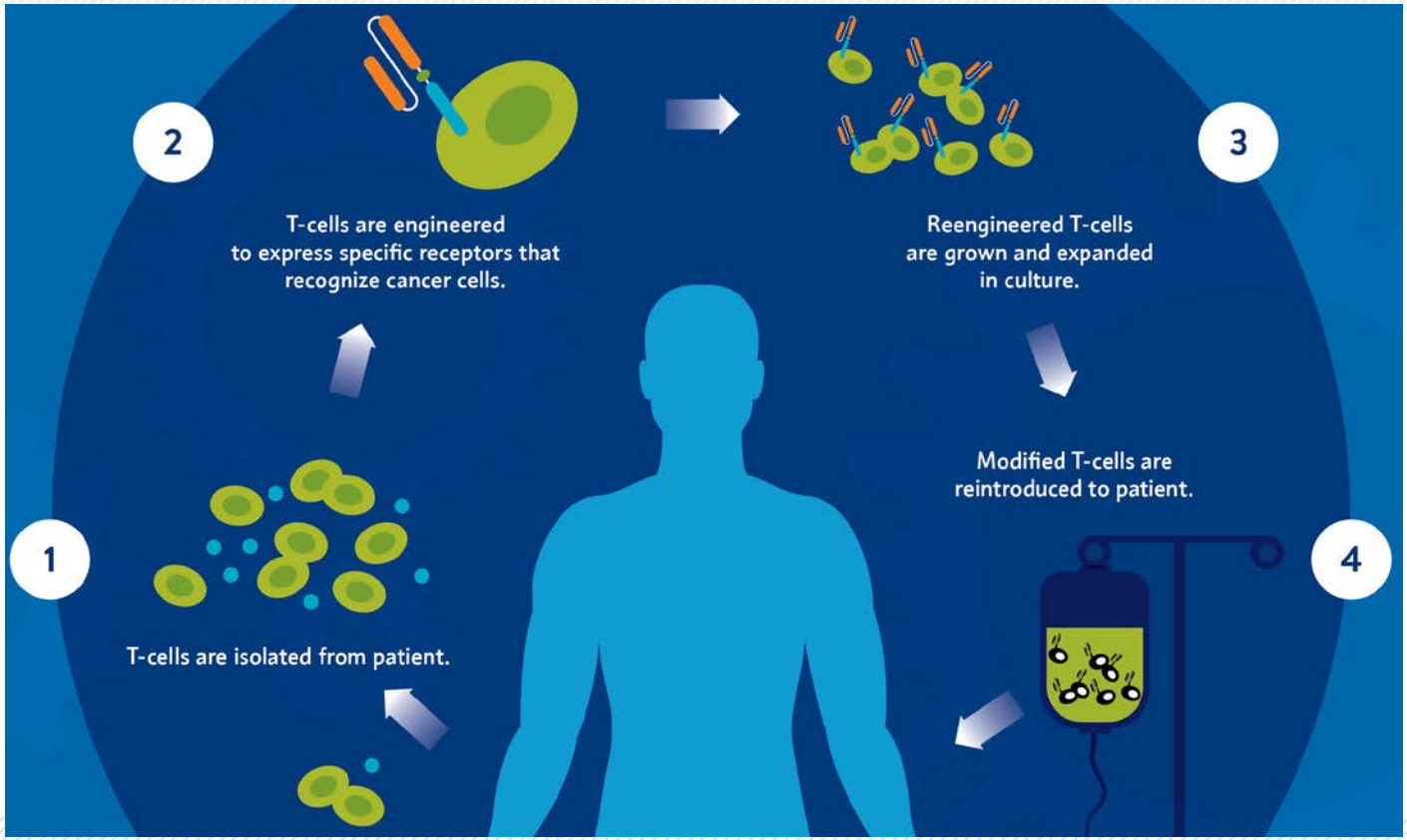
U.S Cancer Survivors Over Time (millions)[1,2,3]



Sources: 1) American Cancer Society, "Cancer Treatment and Survivorship Facts & Figures, 2016-2017," http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-048074.pdf. 2) Centers for Disease Control and Prevention, "Cancer Survivors-United States, 2007," 10 March 2011, http://www.cdc.gov/cancer/survivorship/what_cdc_is_doing/research/survivors_article.htm. 3) National Institutes of Health, National Cancer Institute, Office of Cancer Survivorship Statistics, https://cancercontrol.cancer.gov/ocs/statistics/statistics.html#ref1 (accessed May 2019).

CAR-T Therapy Driving Breakthroughs for Cancer Patients

Engineered immune T-cells can recognize, zero in on and kill cancer cells.



Immunotherapy is Revolutionizing the Treatment of Many Advanced Cancers: Metastatic Melanoma

Note: Data from KEYNOTE-001 pembrolizumab clinical study

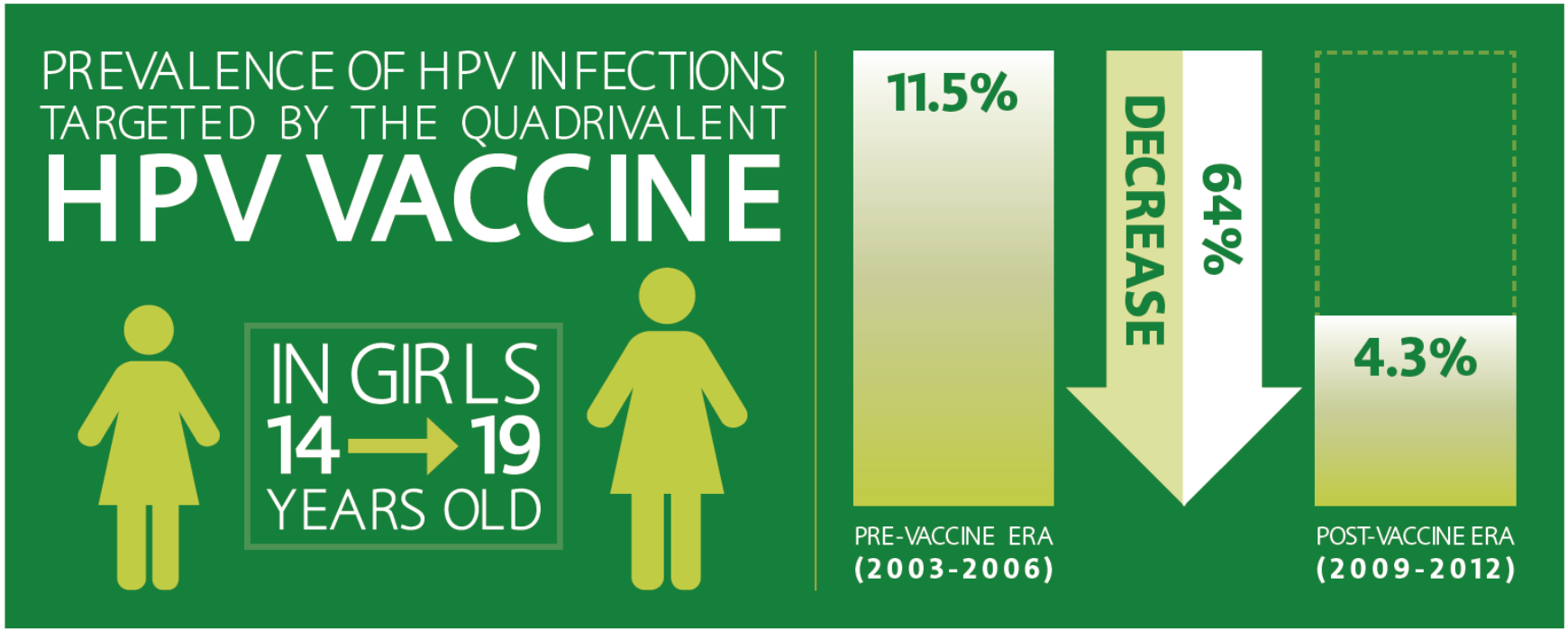
"No recent cancer advance has been more transformative than immunotherapy."

- Dr. Julie M. Vose, former President of the American Society of Clinical Oncology[3]

Sources: 1) ASCO, "PD-1 Inhibitor Pembrolizumab Provides Long-Term Survival Benefit for Patients With Advanced Melanoma," May 18, 2016, https://www.asco.org/about-asco/press-center/news-releases/pd-1-inhibitor-pembrolizumab-provides-long-term-survival; 2) The ASCO Post. "ASCO Names Advance of the Year, Highlights Major Top Research Trends." February 10 2016. http://www.ascopost.com/issues/february-10-2016/asco-names-advance-of-the-year-highlights-major-top-research-trends/; 3)Southall, A. "Former President Jimmy Carter Says He is Free of Cancer." http://www.nytimes.com/2015/12/07/us/jimmy-carter-cancer.html. Dec. 6, 2015.

Cervical Cancer: Reduced Incidence of Cancer-Causing HPV Infections

Among teenage girls, widespread use of the quadrivalent human papilloma virus (HPV) vaccine has driven down infection rates by nearly two-thirds.



Source: Markowitz, L, et al. "Prevalence of HPV After Introduction of the Vaccination Program in the United States." *Pediatrics.* March 2016. http://pediatrics.aappublications.org/content/early/2016/02/19/peds.2015-1968.

Transformation in Cancer Diagnosis Has Led to More Precise Treatment

A greater understanding of the molecular basis of disease has transformed what was once known collectively as "disease of the blood," into multiple subtypes of leukemias and lymphomas, opening up new treatment approaches.

60 YEARS AGO

"Disease of the Blood"

50 YEARS AGO

Leukemia

Lymphoma

40 YEARS AGO

Chronic Leukemia

Acute Leukemia

Pre-leukemia

Indolent Lymphoma

Aggressive Lymphoma

TODAY

~ **40** Unique **Leukemia** types identified

~ **50** Unique **Lymphoma** types identified

5 year **survival** rates have grown to **70%**

There are nearly **340** **medicines** in development for blood cancers

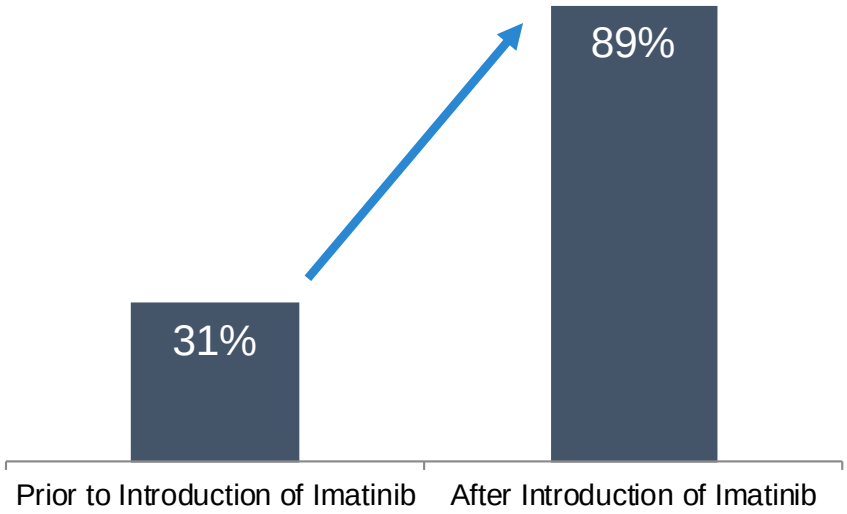
Source: M Aspinal, former President Genzyme Genetics (http://www.comtecmed.com/biomarker/2014/Uploads/Editor/PDF/ppt/Edward%20Abrahams_Key%20Note%20Lecture.pdf)); National Cancer Institute,; SEER Cancer Statistics Review, 1975-2011, http://seer.cancer.gov/csr/1975_2011/, based on November 2013 SEER data submission, posted to the SEER web site, April 2014; PhRMA, Medicines in Development for Cancer, May 2018.

Targeted Therapies Drive Survival Gains in Chronic Leukemias

Since the approval of the first tyrosine kinase inhibitor (TKI) for chronic myeloid leukemia (CML), survival rates have improved dramatically and patients are living close to normal life spans.[1]

- Imatinib—the first TKI—was approved in 2001 to treat CML. The transformative impact of this class of medicines had not been completely realized.
- After initial approval, continued research revealed that imatinib had a greater impact when initiated earlier in the progression of the disease.
- Further research also revealed that imatinib was effective in combating other types of cancer.
- Additional TKIs have since been approved for CML and offer alternatives to imatinib.

5-Year Survival Rates for CML Patients Nearly Triple After Introduction of Imatinib[2]

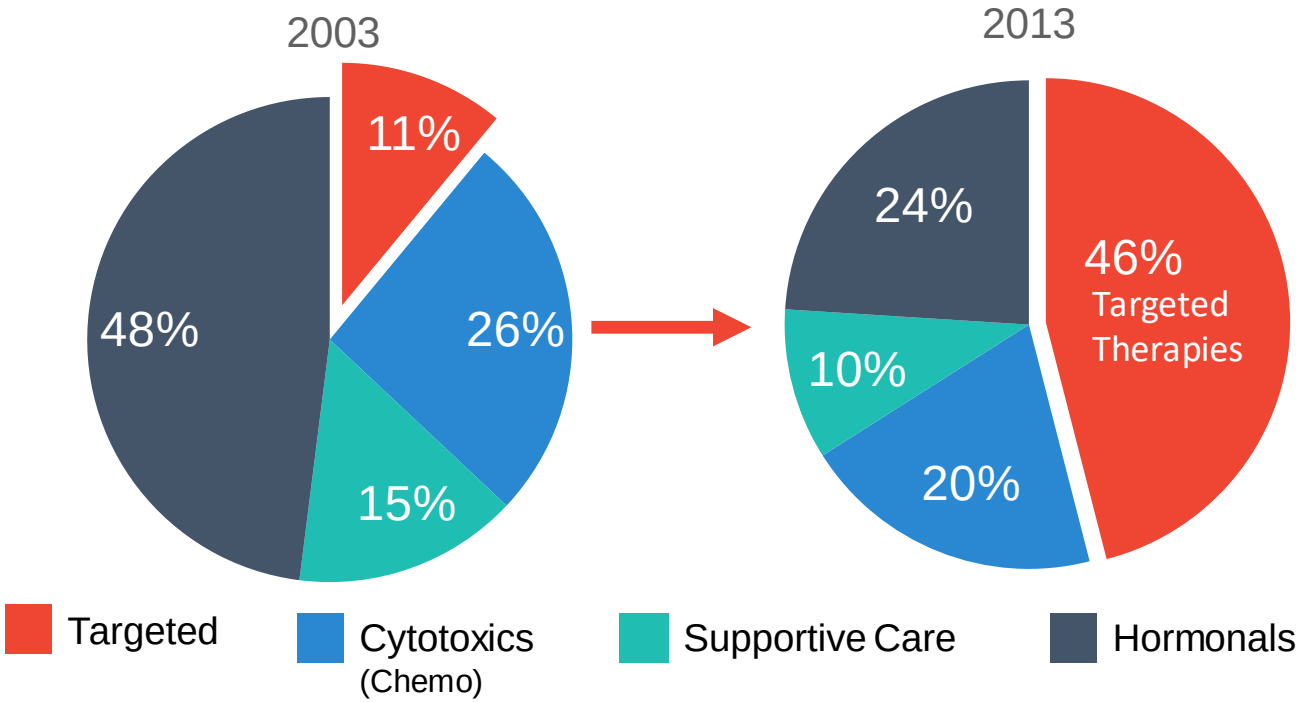


Sources: 1) PhRMA, "A Decade of Innovation in Cancer: 2006-2016," http://phrma-docs.phrma.org/sites/default/files/pdf/decade-of-innovation-cancer.pdf, 2016; 2) BJ Druker, et al., "Five-year follow-up of patients receiving imatinib for chronic myeloid leukemia," *N Engl J Med.* 2006; 355(23):2408-17.

The Role of Personalized Medicines Is Rapidly Growing

Personalized medicines provide effective and efficient care by targeting the right medicine to the right patient.

Oncology Treatment Modalities in Top Pharmaceutical Markets, Share of Sales, 2003-2013



Source: IMS Institute for Healthcare Informatics, "Innovation in Cancer Care and Implications for Health Systems: Global Oncology Trend Report," May 2014.

Cancer Treatment Advances Result in Substantial Gains to Society

Between 1988 and 2000:

23 million

years of life saved due to cancer treatment advances

$1.9 trillion

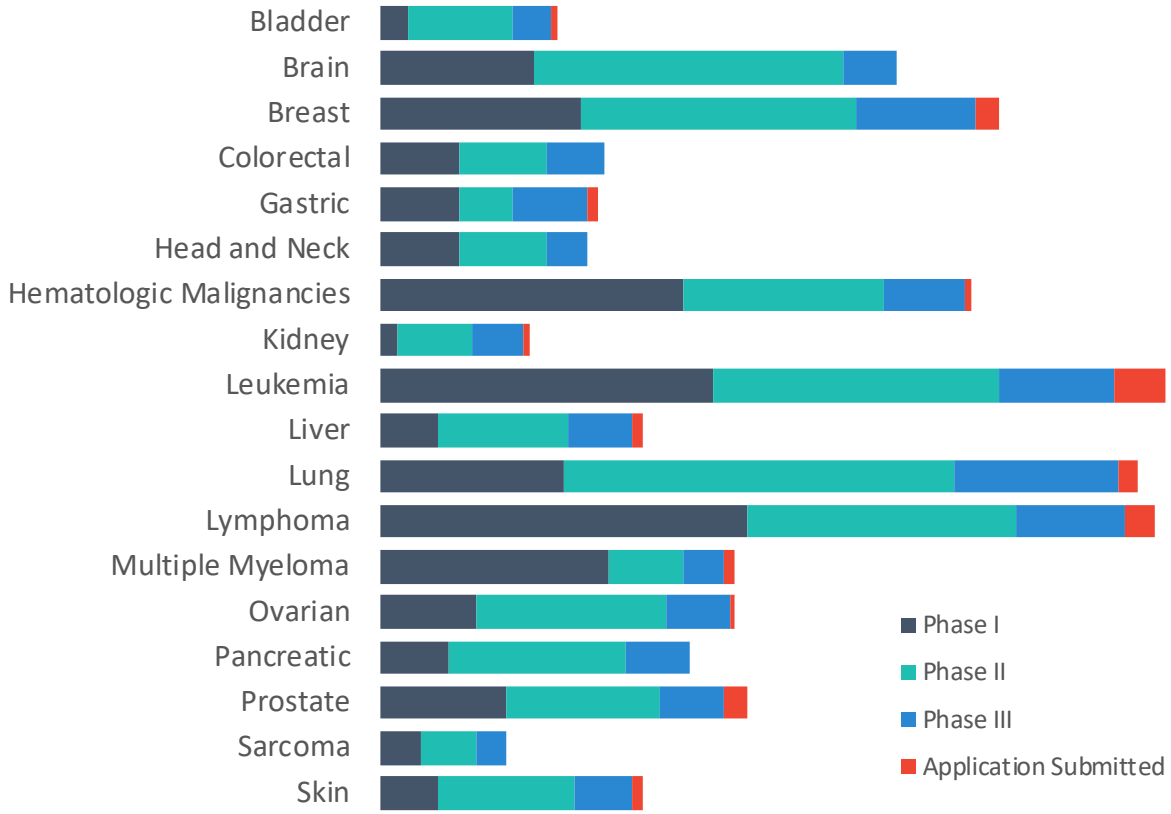
value of improved cancer treatment to society based on improved productivity, extended life and other factors

Source: DN Lakdawala , et al., "An economic evaluation of the war on cancer," *Journal of Health Economics*. May 2010. 29(3):333-346.

2. Innovation in the Cancer Medicine Pipeline

Promise in the Pipeline: More than 1,100 Medicines in Development for Various Cancers

Medicines and Vaccines in Development for Cancer by Tissue of Origin (Selected) – May 2018



"These are exciting times… the pace of discovery and application of new knowledge to patient care is rapidly accelerating."

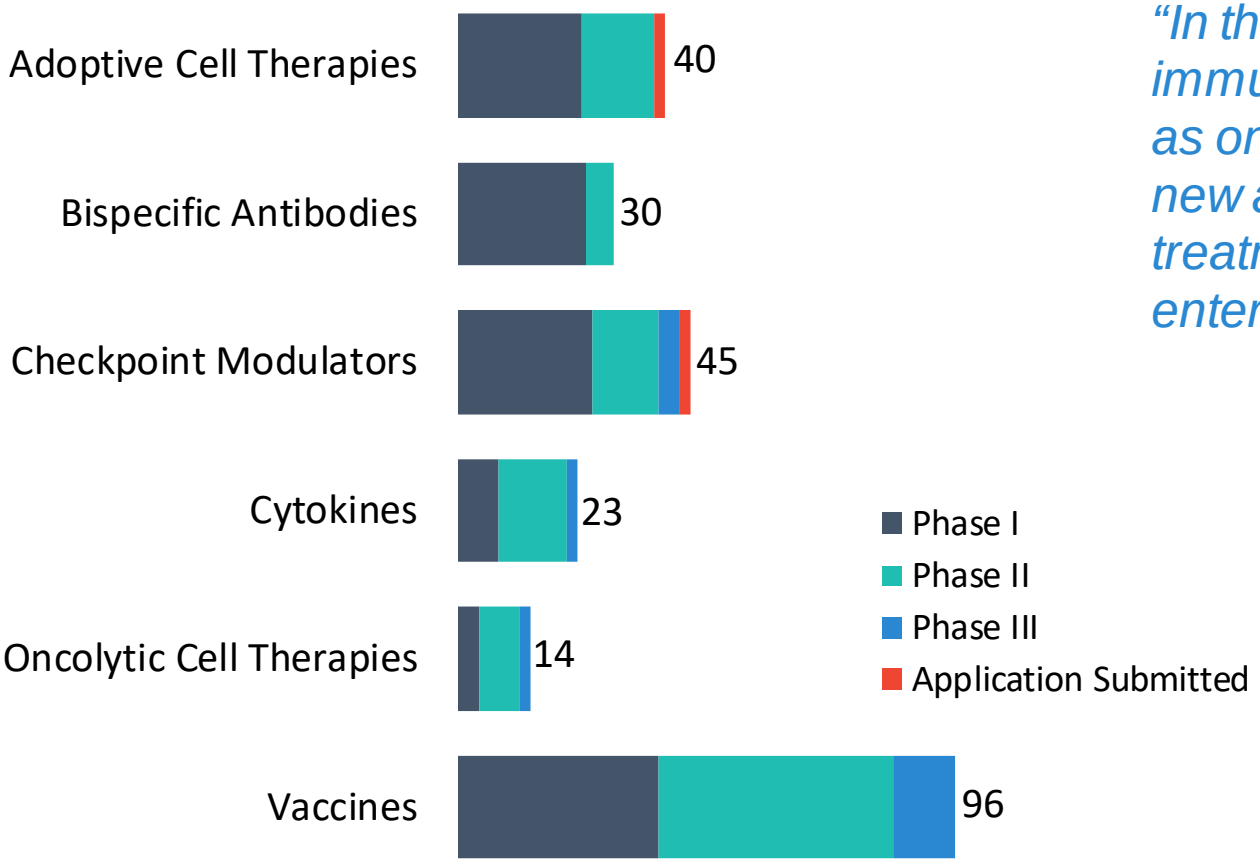
— Dr. Jose Baselga, Physician-in-Chief, Memorial Sloan Kettering Cancer Center

*Some medicines may be in more than one therapeutic category.

Sources: PhRMA, Medicines in Development for Cancer, May 2018; American Association for Cancer Research. "Jose Baselga, MD, PhD" http://cancerprogressreport.org/2015/Pages/baselga.aspx .

Promise in the Pipeline: More than 200 Immuno-oncology Medicines in Development

Number of Medicines in Development in the United States, May 2017, Selected Classes of Immunotherapy



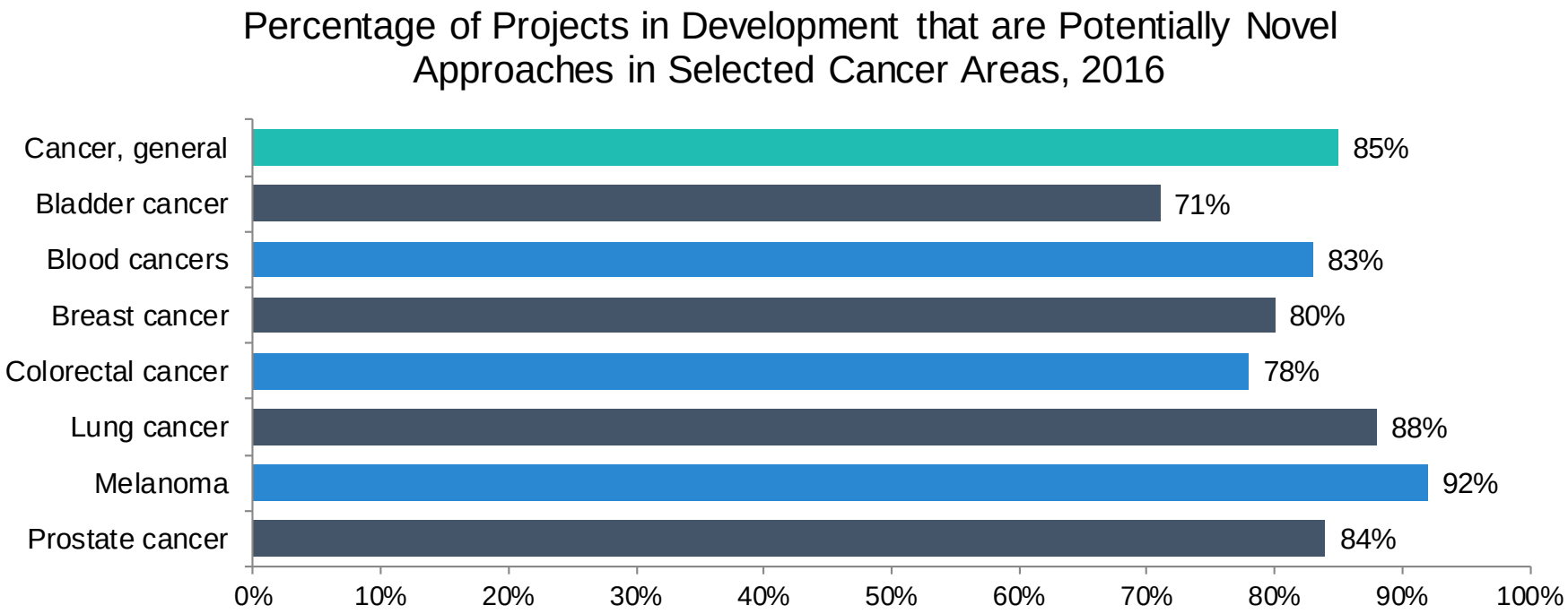
"In the past 5 years, immunotherapy has emerged as one of the most exciting new approaches to cancer treatment that has ever entered the clinic."

- American Association for Cancer Research

Sources: PhRMA, "Medicines in Development for Immuno-oncology," June 2017, https://www.phrma.org/medicines-in-development-immuno-oncology; American Association for Cancer Research. "Jose Baselga, MD, PhD" http://cancerprogressreport.org/2015/Pages/baselga.aspx .

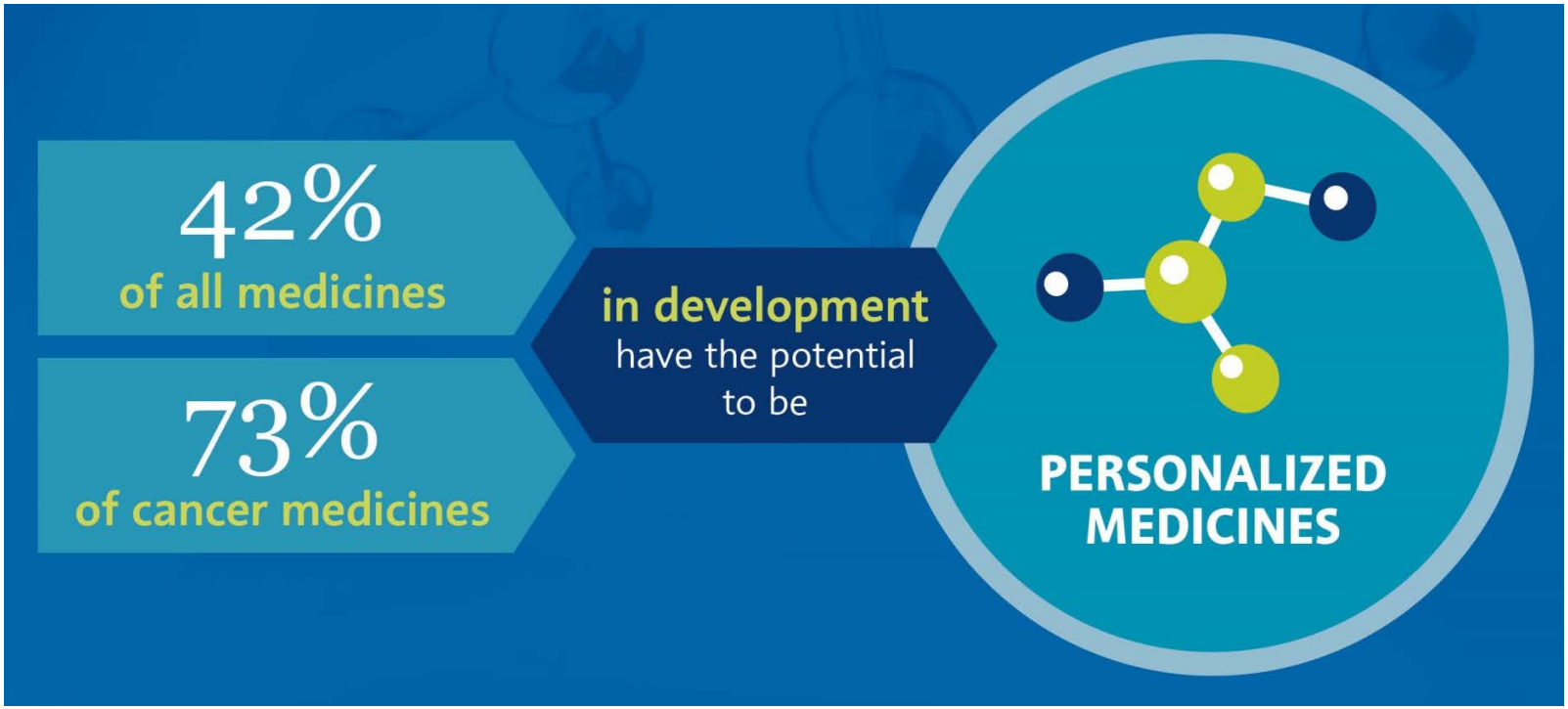
New Approaches to Treating Cancers Represent the Majority of Medicines in the Oncology Pipeline

Researchers are using novel approaches to attack cancer at the molecular level. An average of 85% of drugs in the oncology pipeline, including 79% in the clinical research phase, have the potential to be first-in-class medicines.



Source: Long, G. "The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development" Analysis Group. June 2017.

Biopharmaceutical Companies are Researching New Targeted Cancer Therapies



Sources: Tufts Center for the Study of Drug Development (CSDD). Personalized medicine gains traction but still faces multiple challenges. Tufts CSDD Impact Rep. 2015.

Major Scientific Advances in Cancer Treatment Pipeline Give Patients Hope

The cancer pipeline is ripe with innovative therapeutic options. Emerging combinations of medicines hold particular promise for controlling and killing cancer cells.

Oncolytic viral therapies zero in on cancer cells, replicate, and cause them to rupture.

CRISPR/Cas9 gene editing allows researchers to manipulate cancer cell function.

PARP inhibitors interrupt cancer's hyperactive DNA repair systems, thus allowing tumors to be crippled and die.

Immunotherapies help target and kill cancer cells by unleashing the immune system. (e.g. CAR-T)

"We are in the midst of a sea change in how we are treating cancer. We're really seeing the fruits of many years of research into what drives cancer and how it interacts with the immune system to defeat it and survive."

- Dr. Louis Weiner, director of the Georgetown Lombardi Comprehensive Cancer Center

Sources: World Medical Innovation Forum: Cancer. "Disruptive Dozen 2016." http://worldmedicalinnovation.org/wp-content/uploads/2016/04/Partners-FORUM-2016-BROCHURE-D12-Cancer-160422_0942-FREV1-WEB-X3-SM-SPREADS.pdf; McGinley, L. "The list of cancers that can be treated by immunotherapy keeps growing." The Washington Post. https://www.washingtonpost.com/news/to-your-health/wp/2016/04/19/breakthrough-cancer-therapy-shows-growing-promise/; M. Eisenstein, "Top 40 Drugs in the Pipeline – 2016," C&EN Supplement, September 2016, http://cen.acs.org/content/dam/cen/supplements/09435-cens-web.pdf (Accessed 14 March 2017).

Cancer Researchers Build on Knowledge Gained from Setbacks to Inform Advances

Developing a new cancer medicine is a complex process, fraught with setbacks, but these so called "failures" are not wasted efforts. Researchers learn from them to inform future study.

MELANOMA

- 96 unsuccessful attempts
- 7 new medicines

BRAIN CANCER

- 75 unsuccessful attempts
- 3 new medicines

LUNG CANCER

- 167 unsuccessful attempts
- 10 new medicines

*Setbacks and advances from 1998 to 2014

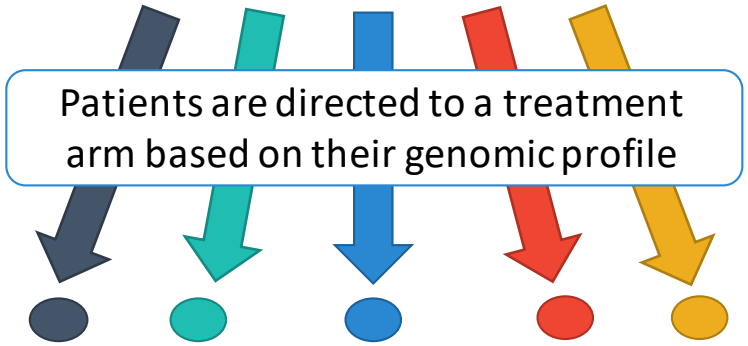
Source: PhRMA, "Researching Cancer Medicines: Setbacks and Stepping Stones," http://www.phrma.org/sites/default/files/pdf/2014-cancer-setbacks-report.pdf, 2014.

Lung-MAP: Innovative Clinical Trial Takes New Approach to Cancer Drug Development

Lung-MAP (Lung Cancer Master Protocol) matches patients to specific investigational medicines based on genomic screening. Shared infrastructure accelerates drug development and increases efficiency.

HOW IT WORKS:

Patients undergo genomic profiling to identify mutations that may cause non-small cell lung cancer



Patients receive highly targeted therapies and researchers collect data to advance the study of new medicines

THE PARTNERS:

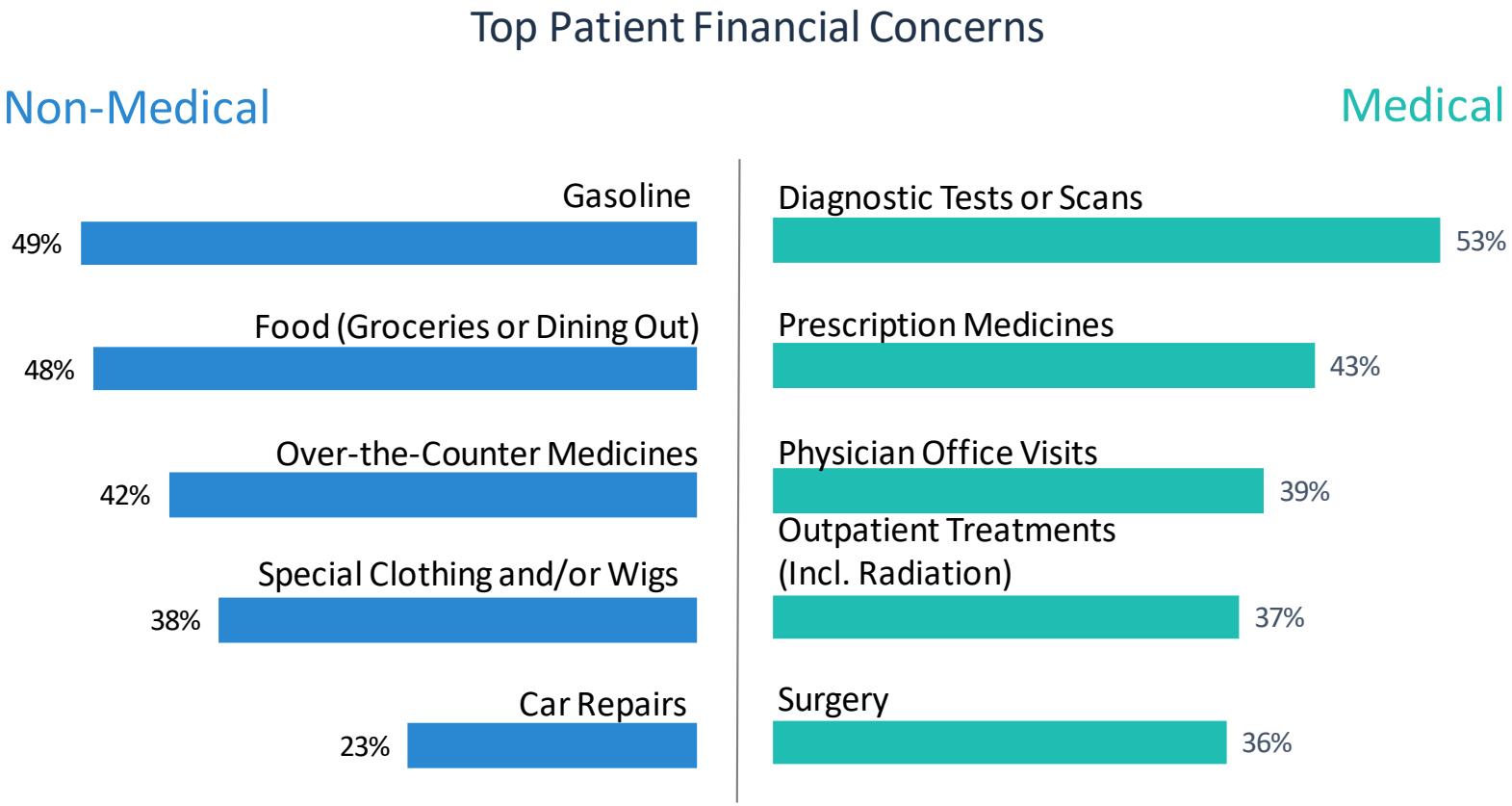
Lung-MAP is a unique public-private partnership between:

- Patient and disease advocacy groups
- Biopharmaceutical companies
- National Cancer Institute
- Foundation for the National Institutes of Health

Source: Lung Cancer Master Protocol, http://www.lung-map.org/ (accessed May 2019).

3. Cancer Patient Spending and Financial Burden

Multiple Factors Contribute to the Financial Burden Faced by Cancer Patients



Source: Financial Hardship Associated with Cancer. CancerCare, 2017.

A Cancer Diagnosis Impacts Productivity and Employment for Patients and Caregivers

Patients

67%

of patients who were employed full-time when diagnosed either **stopped working or reduced their work hours**

Caregivers

More than

25%

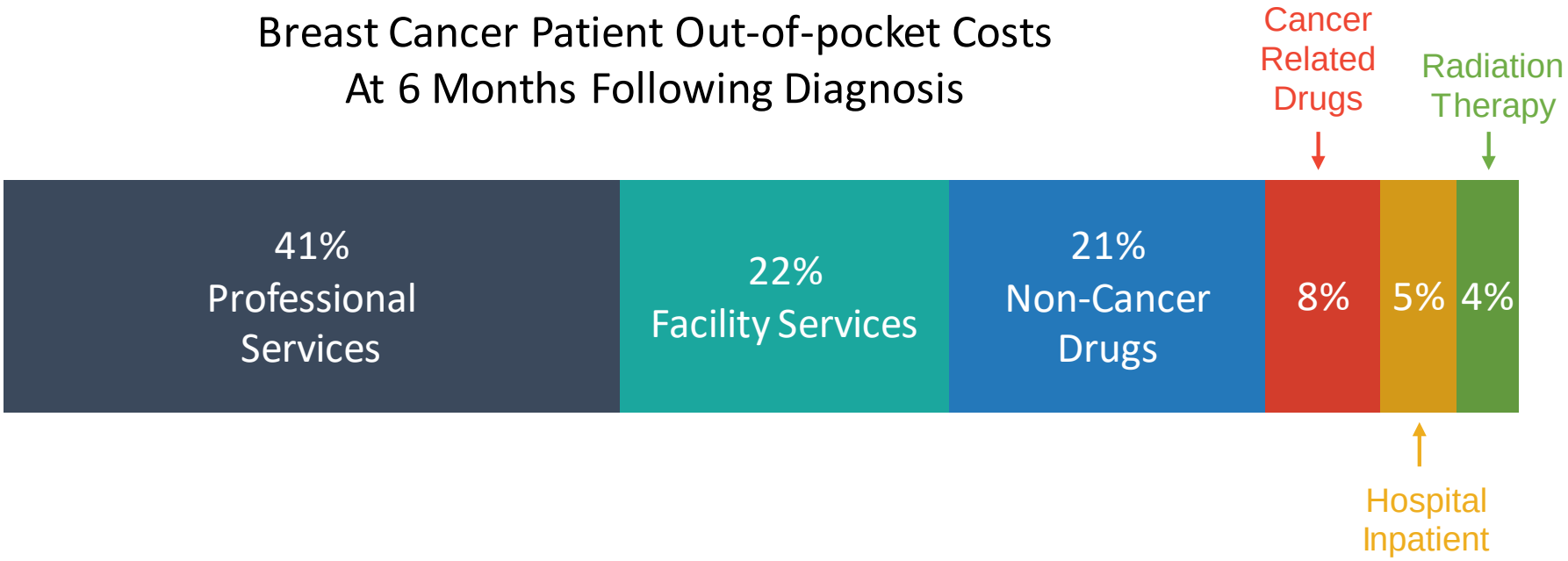
of caregivers made **extended employment changes**

Sources: Financial Hardship Associated with Cancer. CancerCare, 2017.; Yabroff et al. Financial Hardship Associated with Cancer in the United States: Findings from a Population-Based Sample of Adult Cancer Survivors (2016), deMoor et al. 2016. Employment implications of informal cancer caregiving; Yabroff & Kim. 2009. Time costs associated with informal caregiving for cancer survivors.

Out-of-Pocket Costs Are Not Driven by Cancer Medicines

At 6 months post-diagnosis, 60-70% of out-of-pocket costs are driven by physician and facility care for commercially insured patients with breast, lung and colorectal cancer on average.

Breast Cancer Patient Out-of-pocket Costs
At 6 Months Following Diagnosis

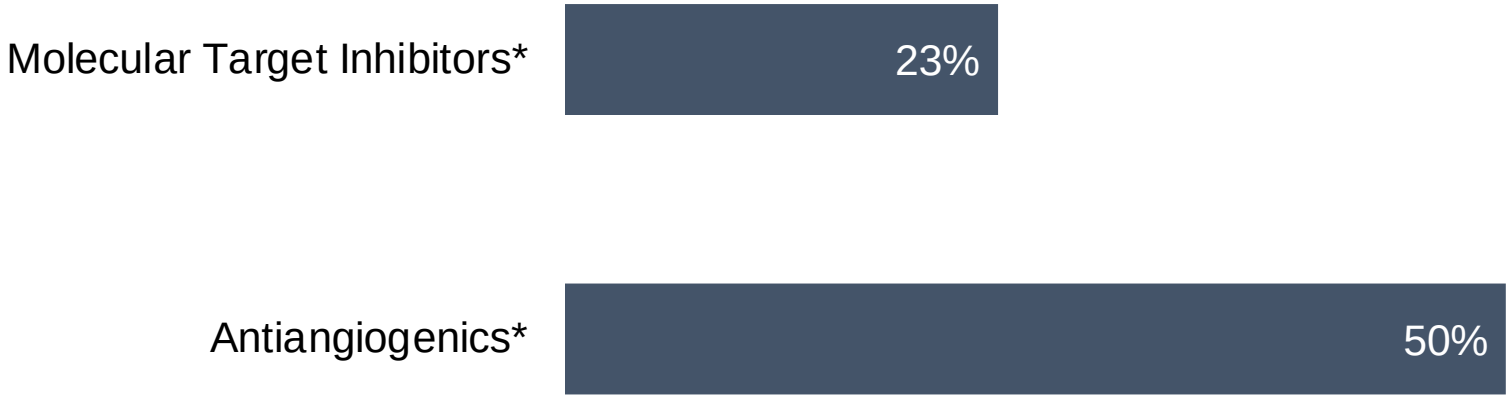


Source: G. Dieguez, et al, Milliman Research Report: "A Multi-Year Look at the Cost Burden of Cancer Care," 11 April 2017

Benefit Design Hinders Access to Cancer Medicines in Some New Classes

Some plans place treatments for certain high-cost conditions on the highest drug formulary cost sharing tier.

Percentage of Silver Plans Placing All Drugs per Class on Specialty Tier, 2016

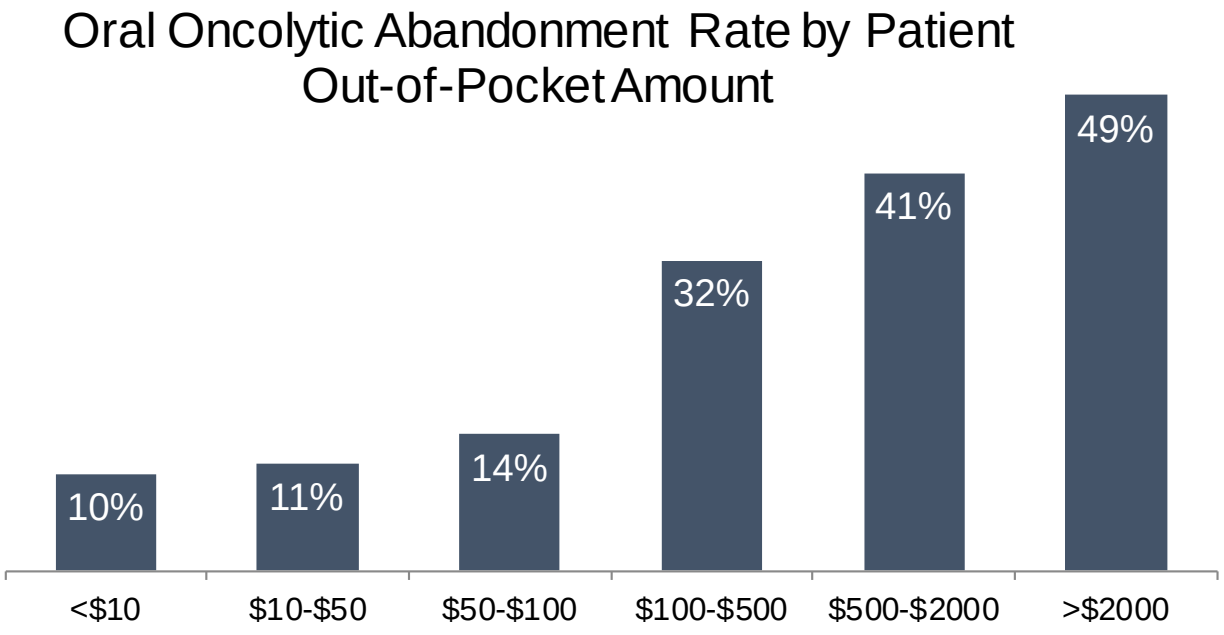


*There are no generic drugs available in this class. All products are single-source.

Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, April 2016. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

High Cost Sharing Leads to Abandonment or Delays in Cancer Treatment

Patients with highest co-pay were 5 times more likely to abandon treatment than the lowest co-pay group

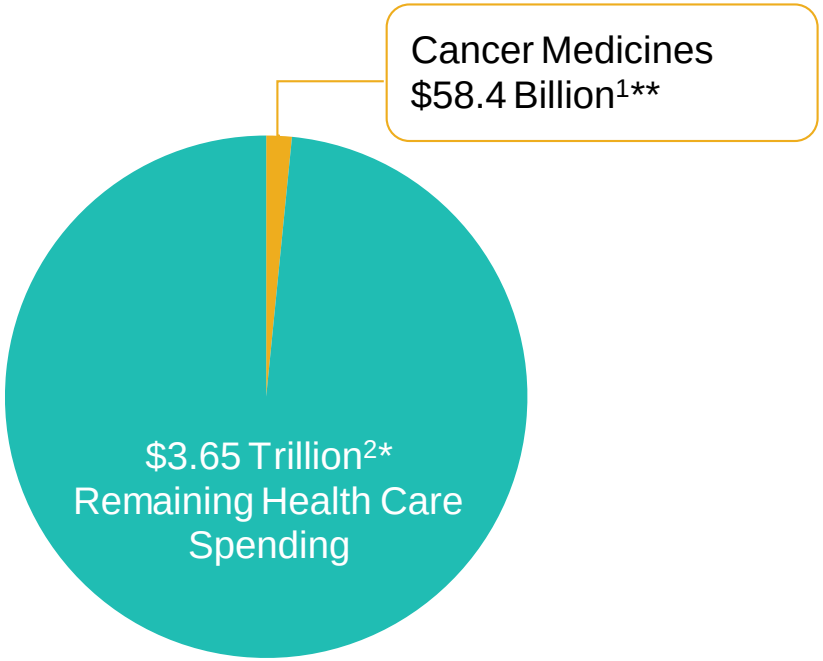


Source: Doshi JA, Li P, Huo H, Pettit AR, Armstrong KA. Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. Journal of Clinical Oncology. 2017 Dec 20:JCO-2017. Available online at: http://ascopubs.org/doi/pdf/10.1200/JCO.2017.74.5091

4. Cancer Costs in Context

Spending on Cancer Medicines Represents Less than 2% of Overall Health Care Spending

Cancer Medicines as a Portion of
Total U.S. Health Care Spending, 2018*

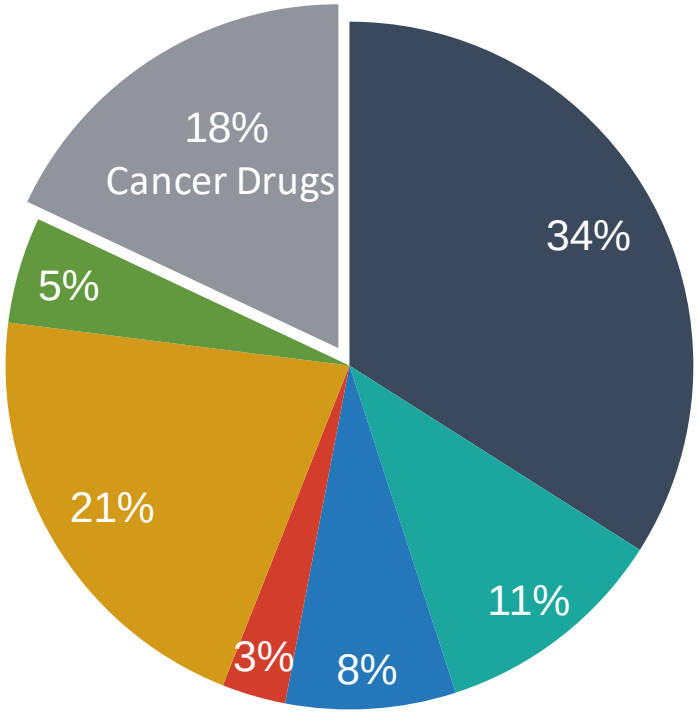


* 2018 CMS total National Health Expenditures is a projection
** Cancer drug invoice spending and does not include discounts

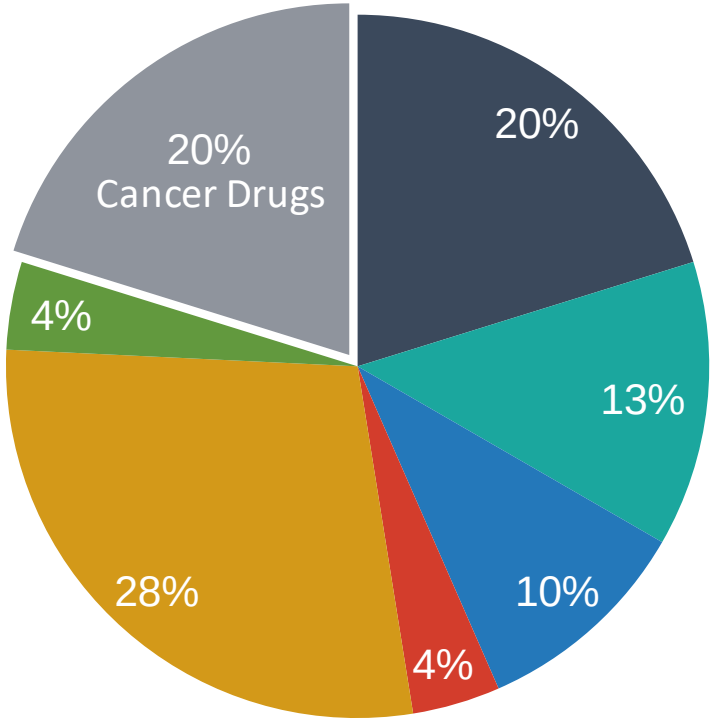
Sources: 1) IQVIA Institute. Medicine Use and Spending in the U.S. A Review of 2018 and Outlook to 2023. https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023. Published May 2019. 2) Centers for Medicare & Medicaid Services (CMS) data. National health expenditures (NHE) table 2 Amounts and Annual Percent Change by Type of Expenditure. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html. Accessed April 2019.

Cancer Medicines Represent About 20% of Cancer Spending

Medicare, Actively Treated Cancer Population, 2014



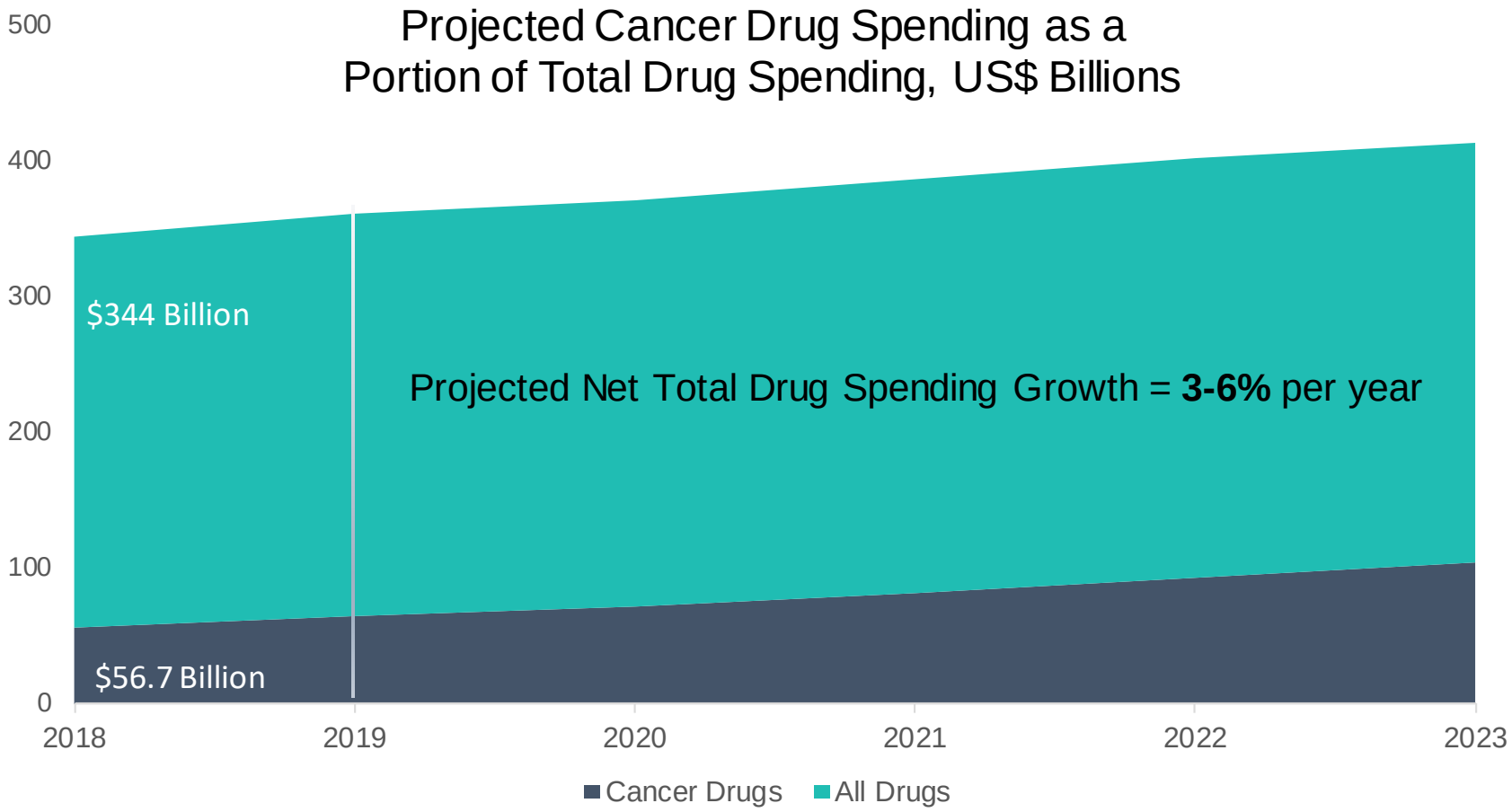
Commercially Insured, Actively Treated Cancer Population, 2014



Hospital Inpatient | Cancer Surgeries | Radiology | Radiation Oncology | Other Out Pt Services | Professional Services | Cancer Drugs

Source: K. Fitch, *et al*. Milliman, "Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014," April 2016, http://www.milliman.com/uploadedFiles/insight/2016/trends-in-cancer-care.pdf.

Overall Drug Spending Growth Expected to be Moderate as Cancer Progress Continues

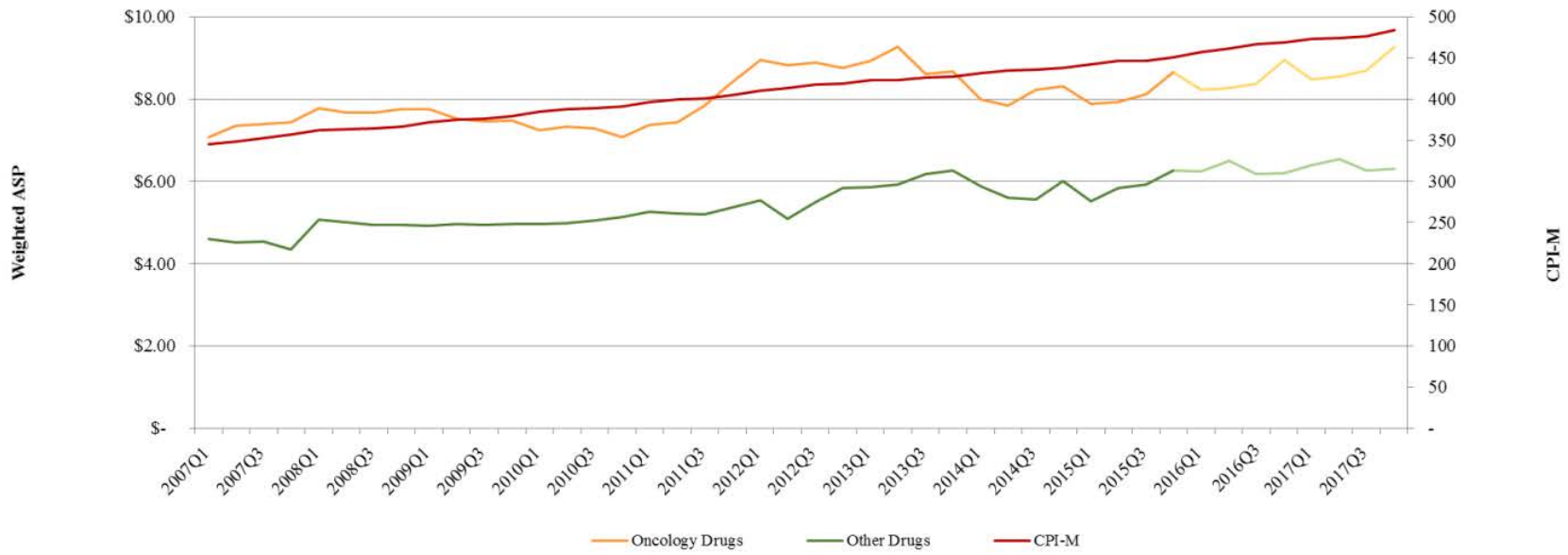


Sources: IQVIA Institute. Global Oncology Trends 2019: Therapeutics, Clinical Development and Health System Implications. Published May 2019 and IQVIA Institute. "Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023" Published May 2019.

Prices of Cancer Medicines in Medicare Part B Growing Slowly

The volume-weighted Average Sales Price (ASP) for cancer drugs administered through Medicare Part B has been growing in line with medical inflation.

Weighted ASP (Oncology Drugs vs. All Other Drugs) vs Consumer Price Index – Medical (CPI-M)

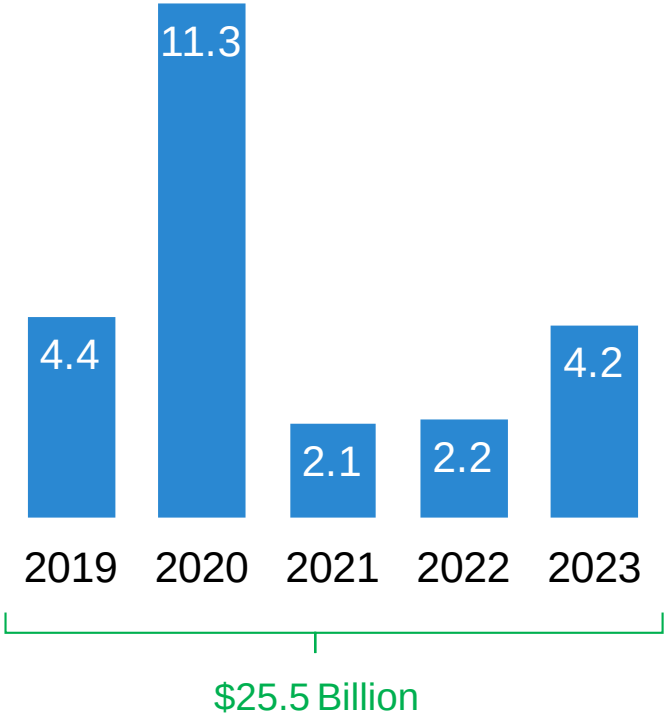


* 2016 and 2017 Weighted ASP numbers are projections.

Source: The Moran Company. Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2006-2017. December 2017.

Cancer Treatments Face Growing Competition from Generics and Biosimilars

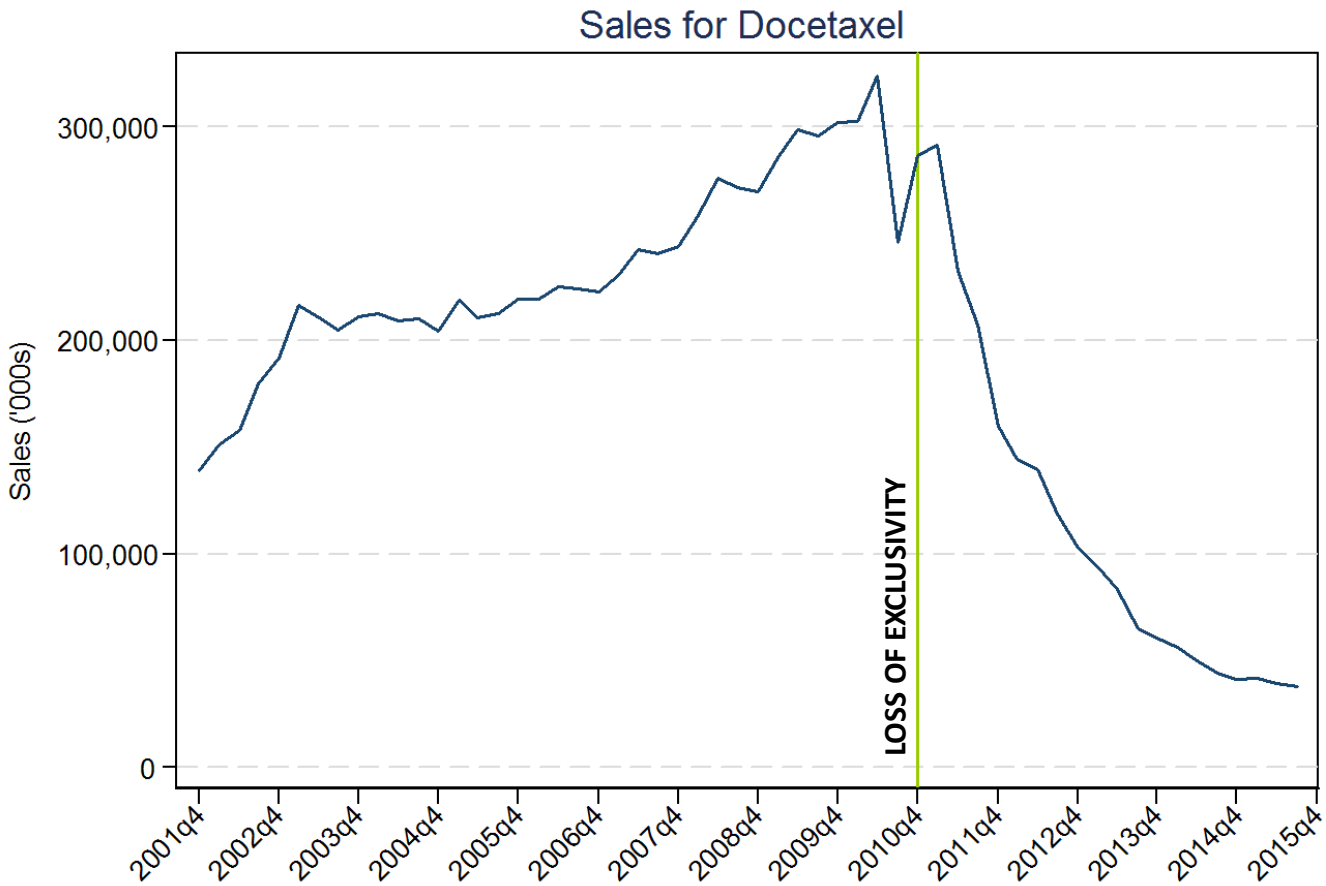
Global Oncology Sales at Risk of Reduction Due to Estimated Loss of Exclusivity
(Billions of US Dollars)*



*Pre-Expiry spending is the actual and estimated spending in the 12 months prior to loss of exclusivity (LOE) and is shown for developed markets only. Estimates are based on patent expiry dates or expected generic/biosimilar availability, and historic analogues where available. Biologics and small molecules are modeled separately. Biologic brand sales at risk are based on any non-original biologic competitor, regardless of approval type.

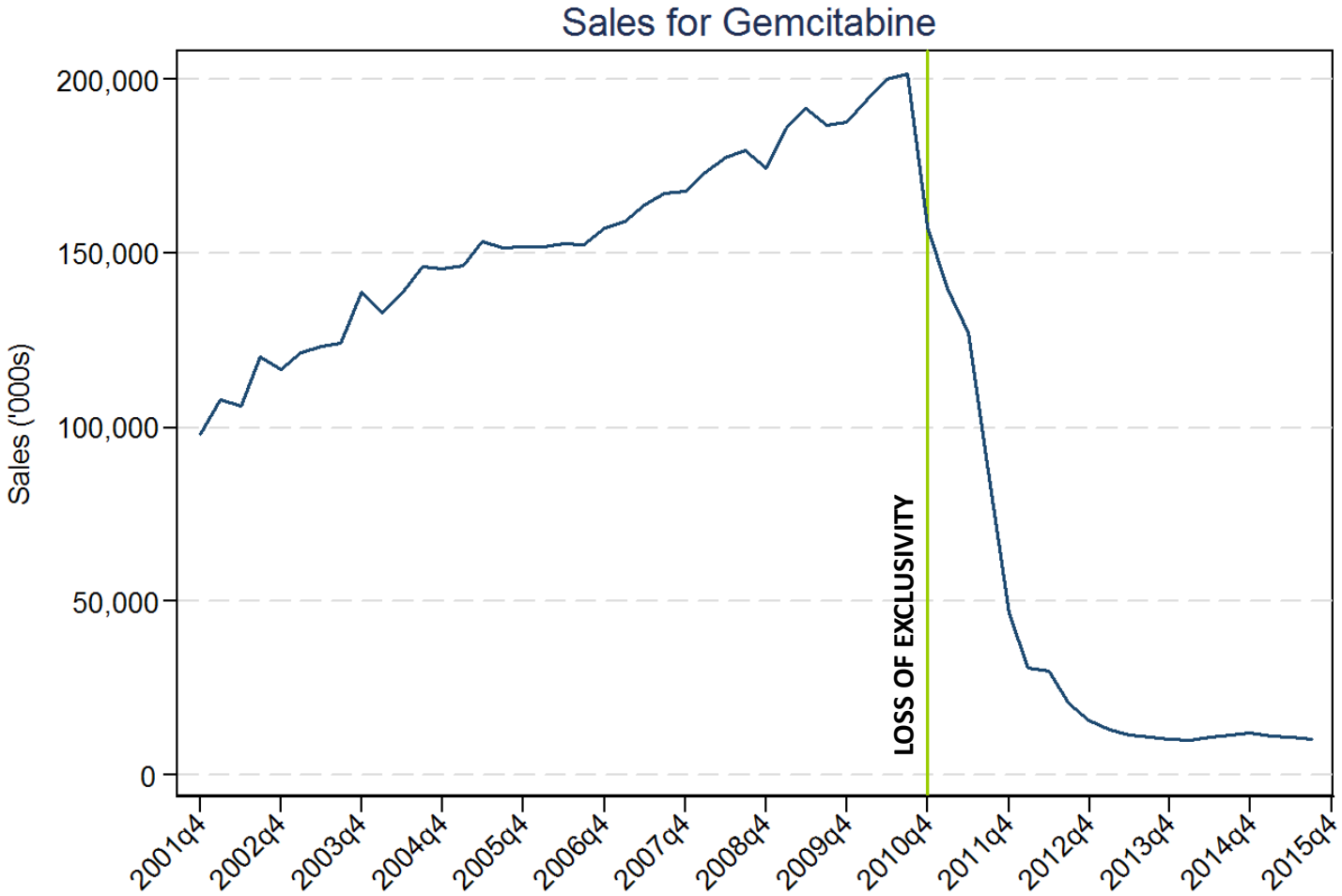
Sources: IQVIA Market Prognosis, National Sales Perspectives, Quintiles IMS Institute, May 2019. Includes small and large molecules.

Market Drives Rapid Switch to Generic Medicines: Example - Injectable Cancer Medicine Docetaxel



Sources: Bates White Economic Consulting, "Oncology Product Sales and Patent Expiration: A Policy Brief," May 2017.

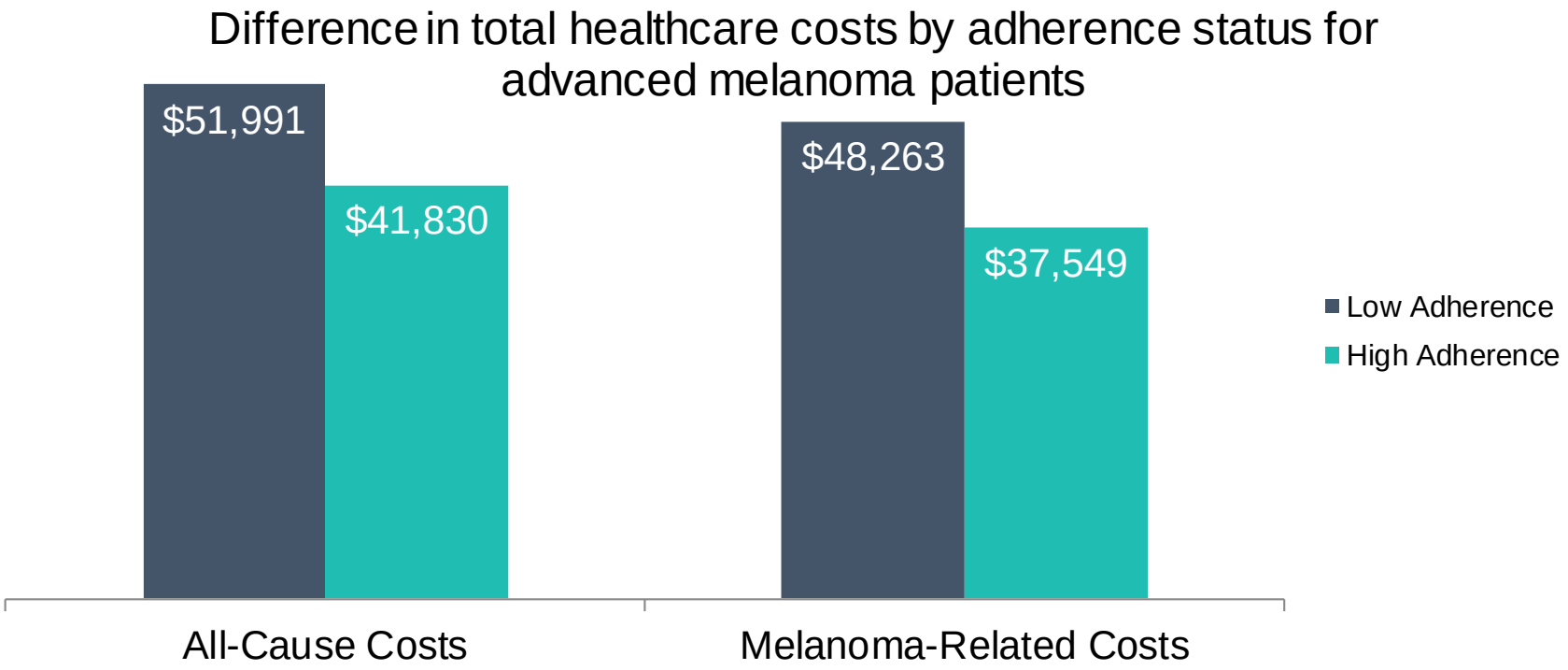
Market Drives Rapid Switch to Generic Medicines: Example - Injectable Cancer Medicine Gemcitabine



Sources: Bates White Economic Consulting, "Oncology Product Sales and Patent Expiration: A Policy Brief," May 2017.

Better Use of Cancer Medicines Can Reduce Health Care Costs

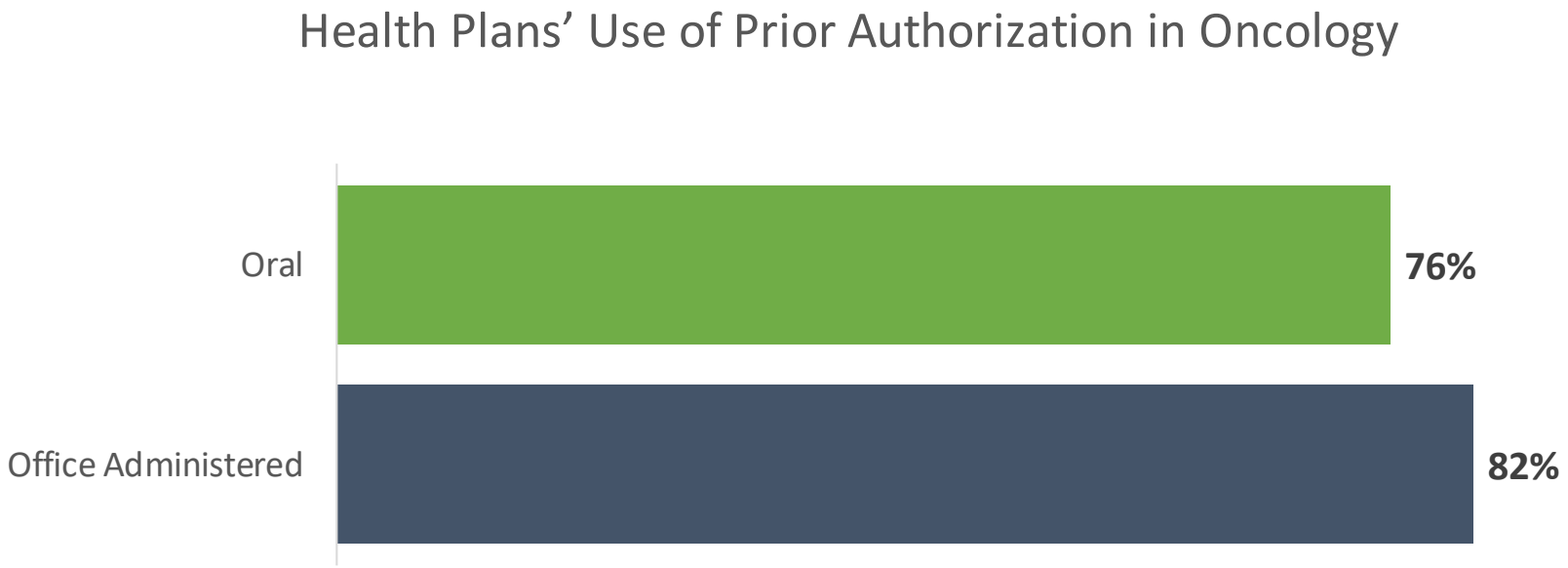
Advanced melanoma patients who were adherent to immunotherapy experienced 10% lower health care costs.



Source: Gupte-Singh K, Lin J, Lingohr-Smith M, Menges BL, Rao S. Adherence to cancer therapies and the impact on healthcare costs among patients with advanced melanoma in the USA. Proceedings of the 22nd Annual International Meeting International Society of Pharmacoeconomics and Outcomes Research; 2017 May; Boston, MA. Abstract available at: https://www.ispor.org/ScientificPresentationsDatabase/Presentation/70971?pdfid=49558.

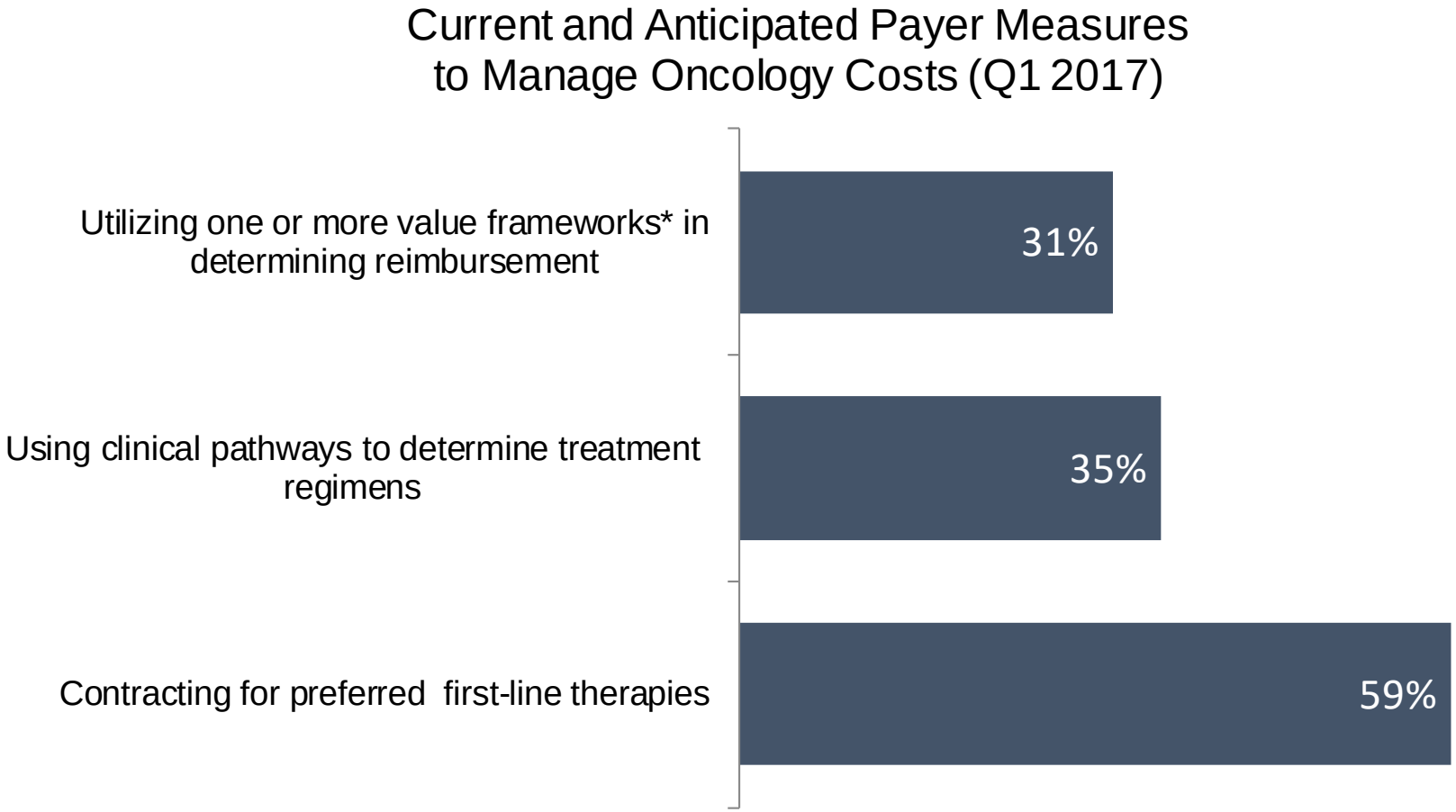
5. Evolving Cancer Market Dynamics

Health Plans Make Extensive Use of Prior Authorization in Oncology



Source: Health Strategies Group. Cost Containment in the Market for Branded Pharmaceuticals. August 2018. https://www.healthstrategies.com/executive-briefs.

Health Plans Deploy a Range of Tools to Manage Cancer Drug Spending

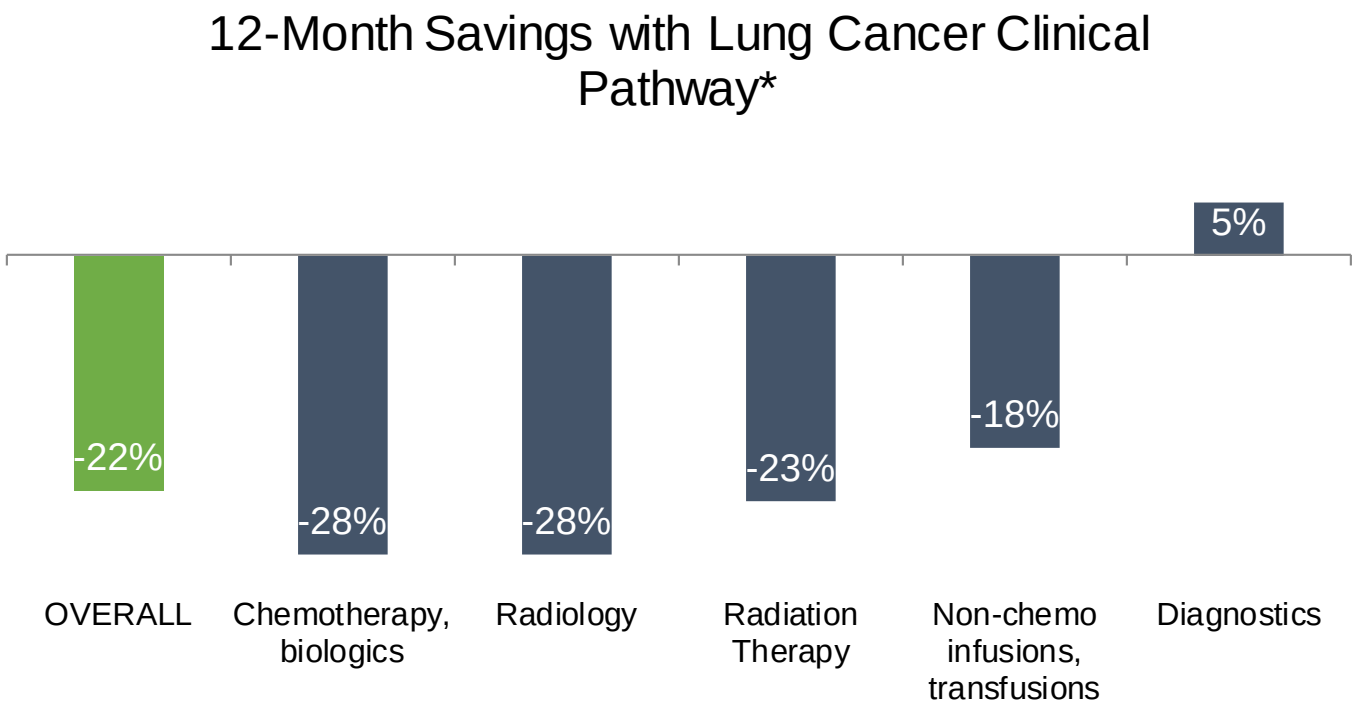


*Value Frameworks: NCCN Evidence Blocks, ASCO Value Framework, etc.

Source: Zitter Health Insights, Managed Care Oncology Index, 2016.

Plans and Providers Rapidly Adopting Clinical Pathways

Non-small cell lung cancer patients treated according to a clinical pathway incurred lower drug and total costs.



*Clinical pathways are care plans that provide specific guidance on the sequencing of care steps and the timeline of interventions. They often consider evidence on the benefits and harms of alternati care options and take the cost therapy into account.

Source: DM Jackman *et al* "Cost and Survival Analysis Before and After Implementation of Dana-Farber Clinical Pathways for Patients with Stage IV Non-Small Cell Lung Cancer, " *Journal of Oncology Practice*, April 2017, http://ascopubs.org/doi/abs/10.1200/JOP.2017.021741

Plans Realize Savings via New Payment Models

Early results from oncology medical homes, bundled payment and specialty Accountable Care Organizations (ACOs) show potential for reducing total cancer costs.

Patient-centered medical homes	Pilot reduced total costs 35% annually
Episode- or bundled payment	Pilot reduced total costs of care 34%
Specialty ACOs	Reduce drug spending 5%, total spending 2% +

"Notably, all those interviewed suggested that the use of clinical pathways was a driver of financial savings, either through reduced drug spending or indirectly through more appropriate patient treatment."

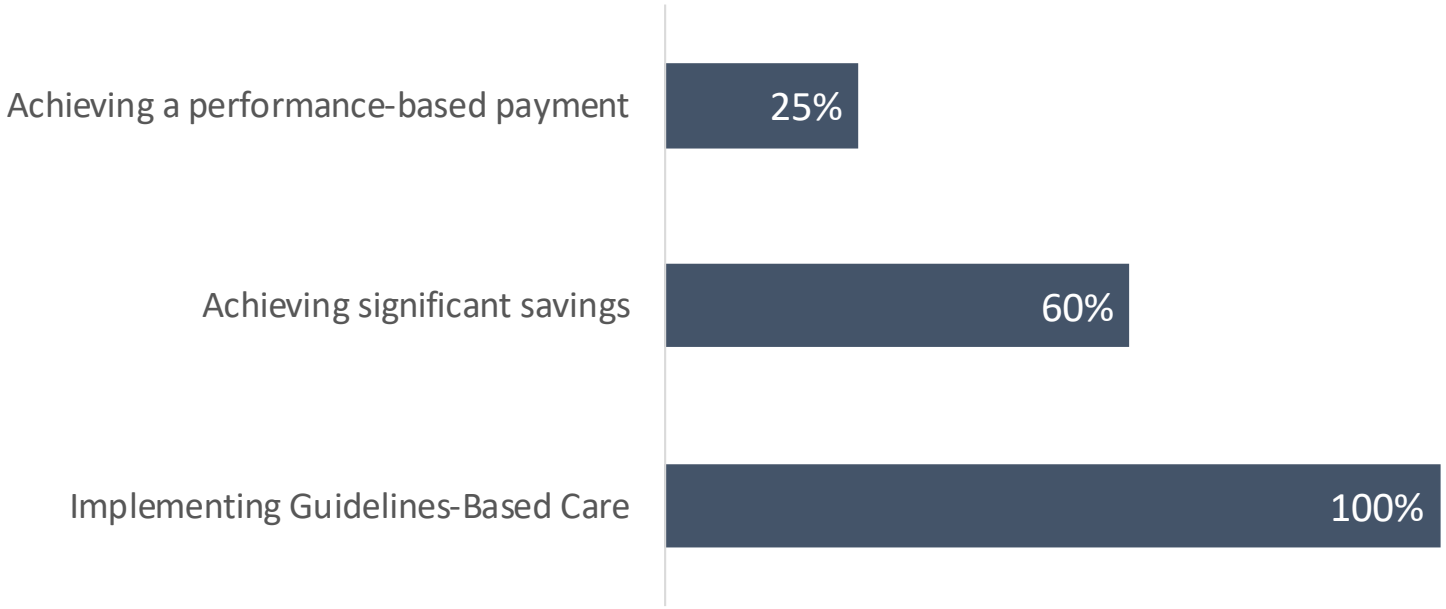
- Sonal Shah, PharmD, and Greg Reh, *American Journal of Managed Care*

Source: S. Shah, G. Reh, "Value-Based Payment Models in Oncology: Will They Help or Hinder Patient Access to New Treatments?" AJMC, 18 April 2017, http://www.ajmc.com/journals/evidence-based-oncology/2017/april-2017/value-based-payment-models-in-oncology-will-they-help-or-hinder-patient-access-to-new-treatments

Market Shift to New Payment Models: CMS' Oncology Care Model

Nearly 200 oncology practices are participating in the Oncology Care Model (OCM) to improve quality an reduce the cost of cancer care in Medicare Part B.

OCM* Practice Results – Performance Period One



*The Oncology Care Model (OCM) aims to provide higher quality, more highly coordinated oncology care at the same or lower cost to Medicare. Under OCM, physician practices have entered into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. The practices participating in OCM have committed to providing enhanced services to Medicare beneficiaries such as care coordination, navigation, and national treatment guidelines for care. CMS is also partnering with commercial payers in the model.

Source: Journal of Clinical Pathways. "Early Data Show Positive Trend in OCM Cost Savings" March 27, 2018.

Manufacturers and Insurers Pursuing Outcomes-Based Contracts in Oncology

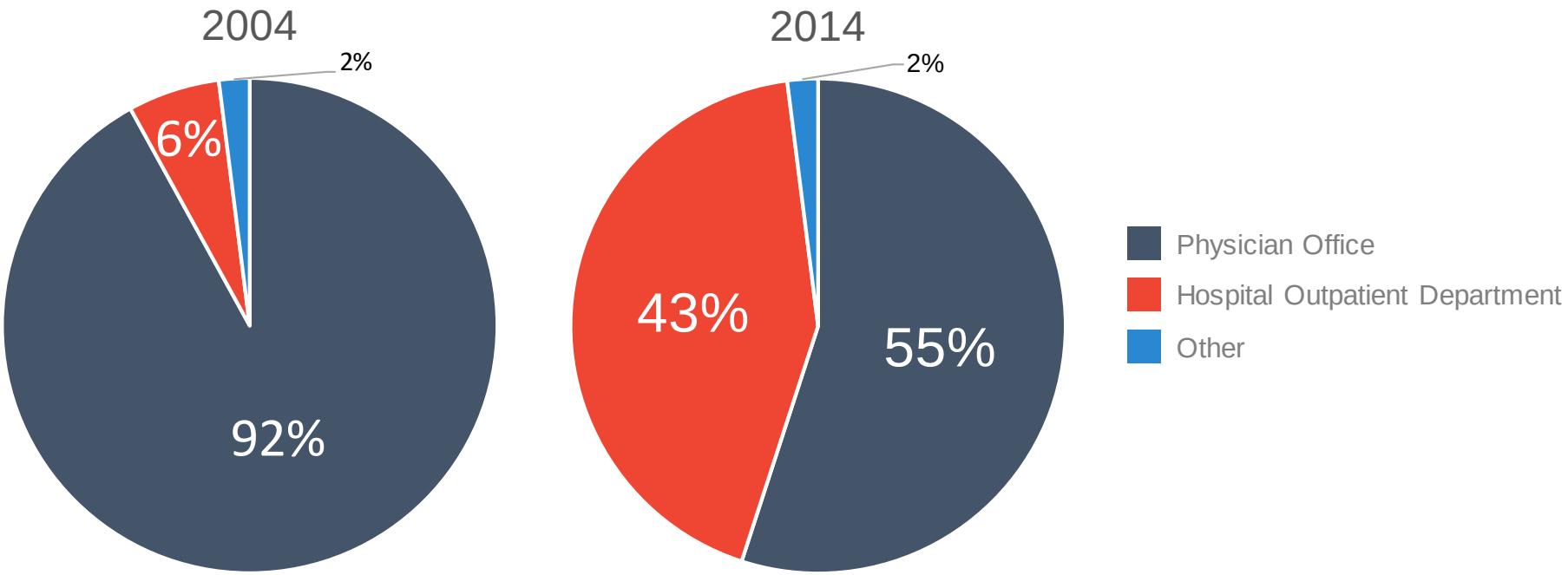
Shared risk or outcomes-based contracts (OBCs) between health insurers and manufacturers are becoming more common across diseases, including oncology.

More than **40%** of the 65 outcomes-based contracts projected between 2018-2022 are expected to be in oncology.

Source: IQVIA. 2018 and Beyond: Outlook and Turning Points. March 2018. Available online at: https://www.iqvia.com/institute/reports/2018-and-beyond-outlook-and-turning-points

Site of Care Shifts Drive Higher Cancer Costs

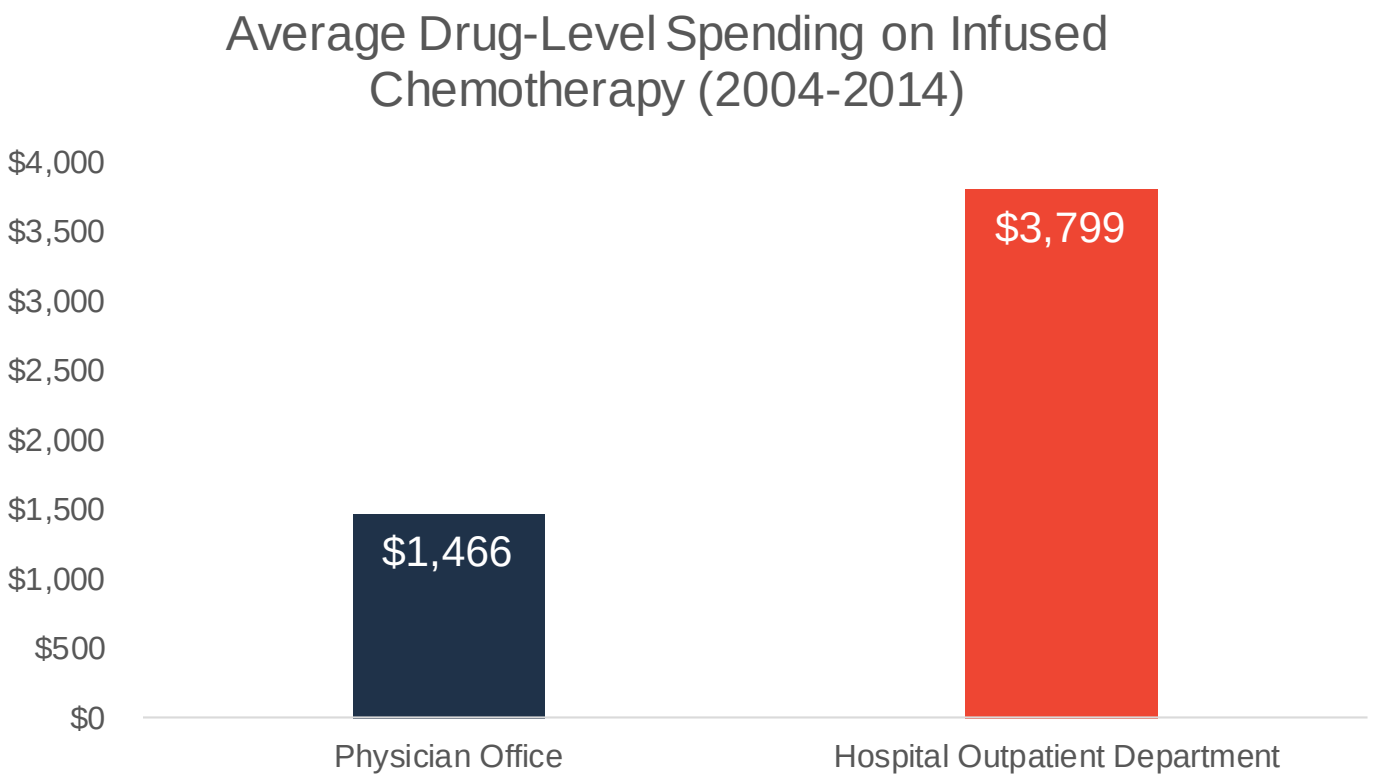
The rate of commercially insured patients receiving infused chemotherapy in hospitals increased from 6% of transfusions in 2004 to 43% in 2014.



Source: Winn AN, Keating NL, Trogdon JG, Basch EM, Dusetzina SB. Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014. JAMA oncology. 2018 Apr 1;4(4):580-1. Available online at: https://jamanetwork.com/journals/jamaoncology/fullarticle/2673075.

Site of Care Shifts Drive Higher Cancer Costs

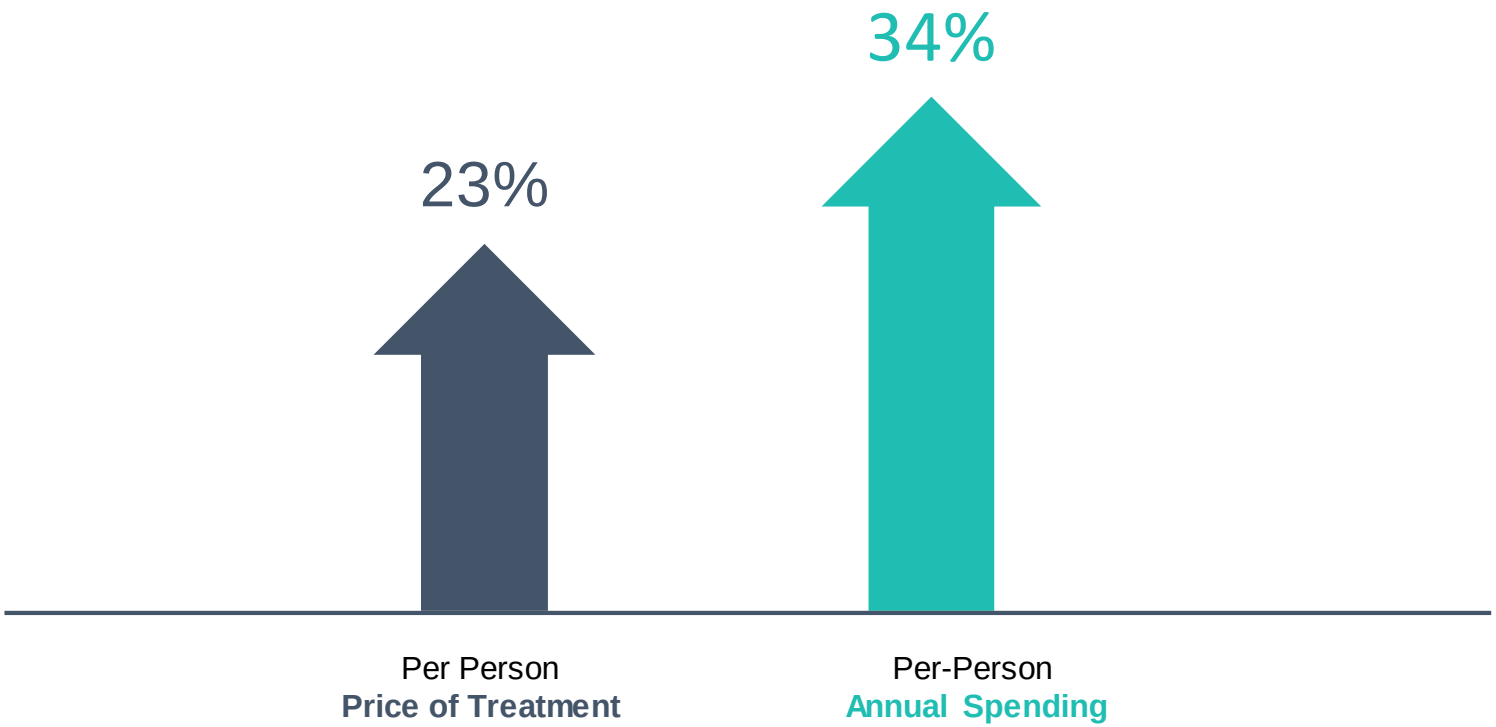
Commercial spending on chemotherapy infusions and oncology 6-month treatment episodes are twice as high in the hospital outpatient department compared to the physician office setting.



Source: Winn AN, Keating NL, Trogdon JG, Basch EM, Dusetzina SB. Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014. JAMA oncology. 2018 Apr 1;4(4):580-1. Available online at: https://jamanetwork.com/journals/jamaoncology/fullarticle/2673075.

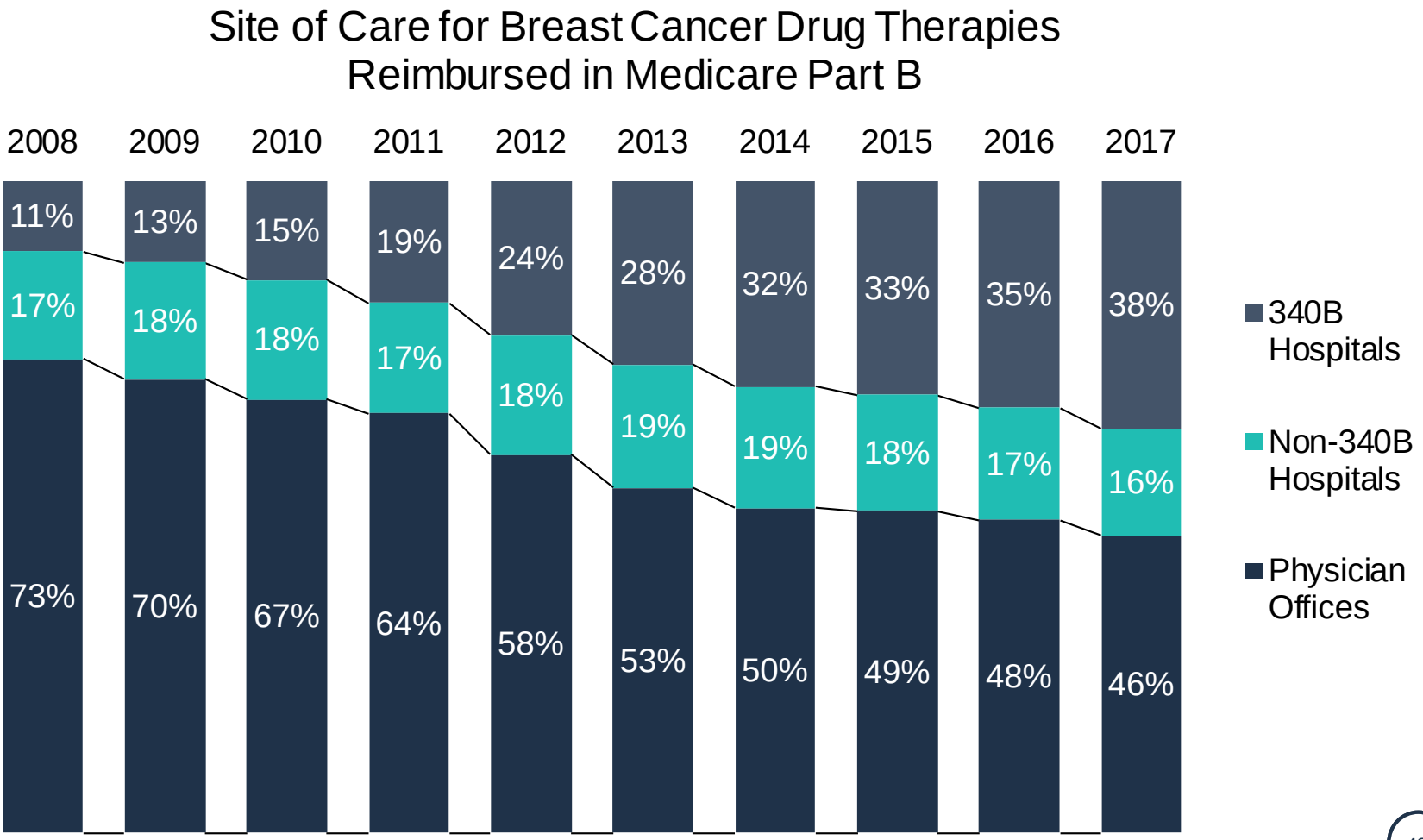
Hospital Consolidation Associated with Increases in Cancer Spending

Spending increases associated with just a 1% increase in the proportion of medical providers affiliated with hospitals and/or health systems.



Source: Conti RM, Landrum MB, and Jacobson M. The impact of provider consolidation on outpatient prescription drug-based cancer care spending. 2016.

340B Creates Incentives to Shift Delivery of Physician-Administered Cancer Medicines to More Expensive Hospital Settings



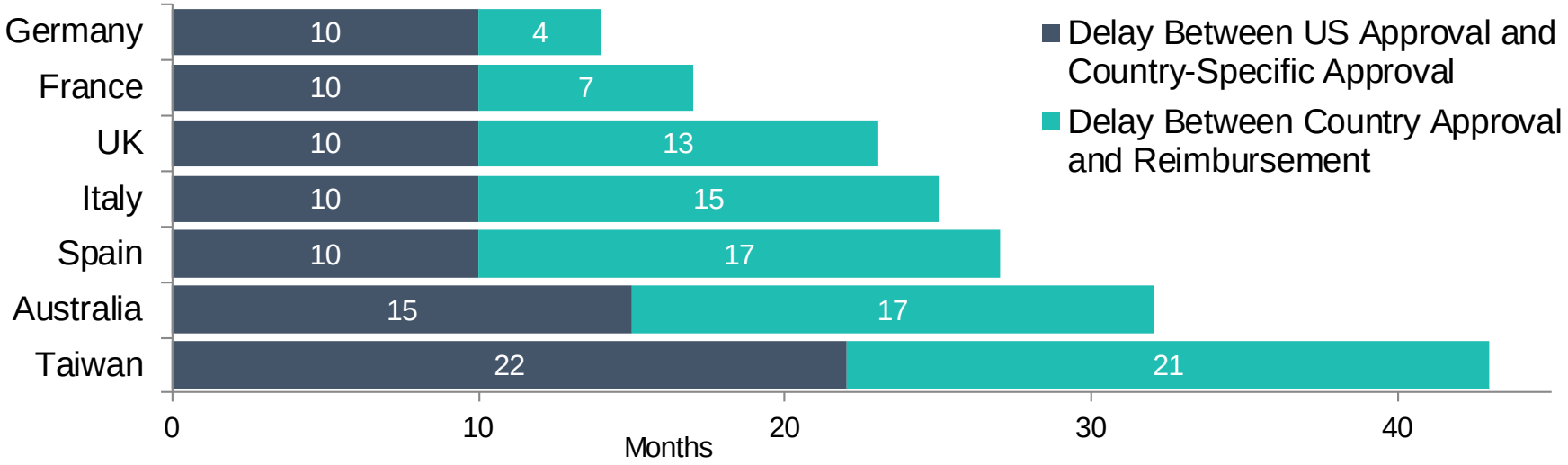
Source: Berkeley Research Group, Site of Care Shift for Physician-Administered Drug Therapies, March 2019.

6. US System in Context

US Patients Have Access to Cancer Medicines on Average Two Years Earlier Than Patients in Other Developed Countries

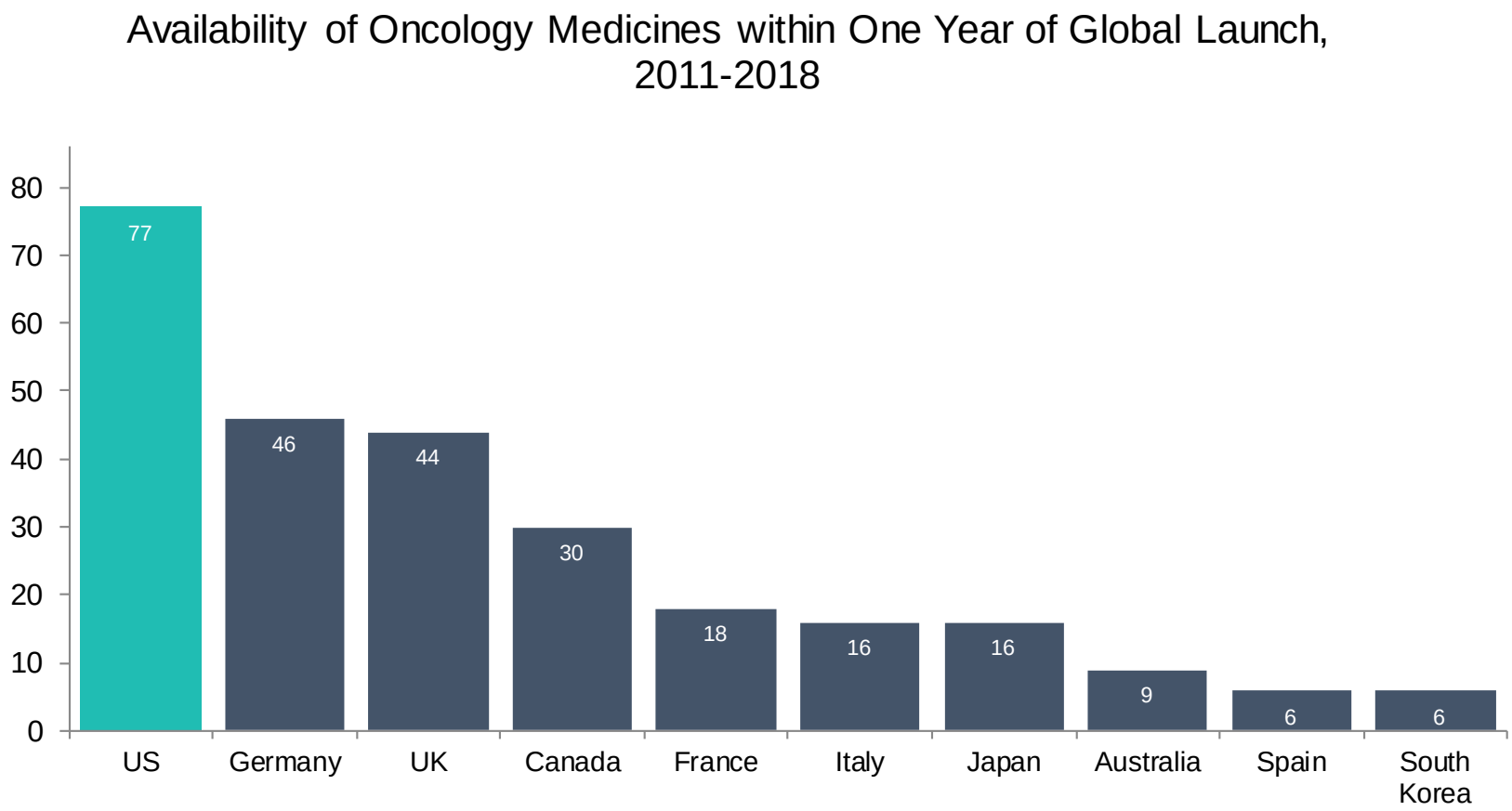
Other developed countries use centralized government price setting and coverage decisions to manage drug spending, resulting in significantly slower access to medicines than in the US.

Average Time Delay Compared to the US in the Approval and Reimbursement of Oncology Medicines from 2010 to 2014



Source: PhRMA analysis of IMS Consulting Group "Patient Access to Innovative Oncology Medicines Across Developed Markets". June 2016

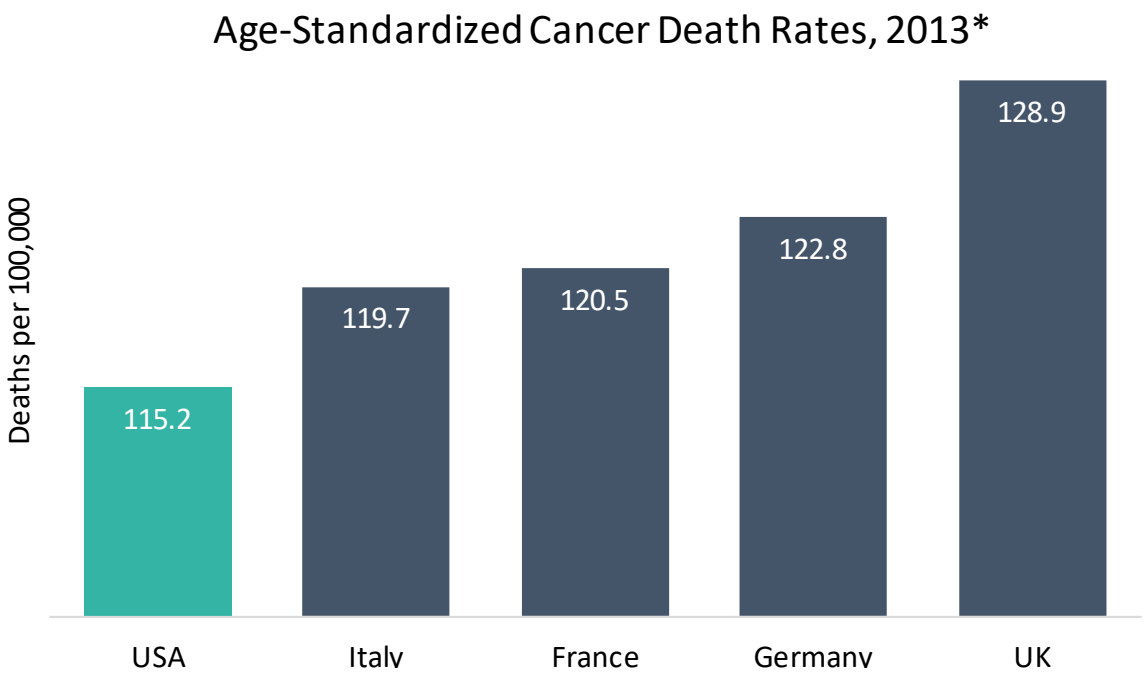
More Cancer Medicines are Available to US Patients



Source: PhRMA analysis of IQVIA Analytics Link and FDA, European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) data on oncology new active substances first launched globally from 2011 to 2018, June 2019.

US Patients Have Better Outcomes in Cancer

Cancer death rates are lower in the US where patients have access to cancer medicines about 2 years earlier than in other developed countries

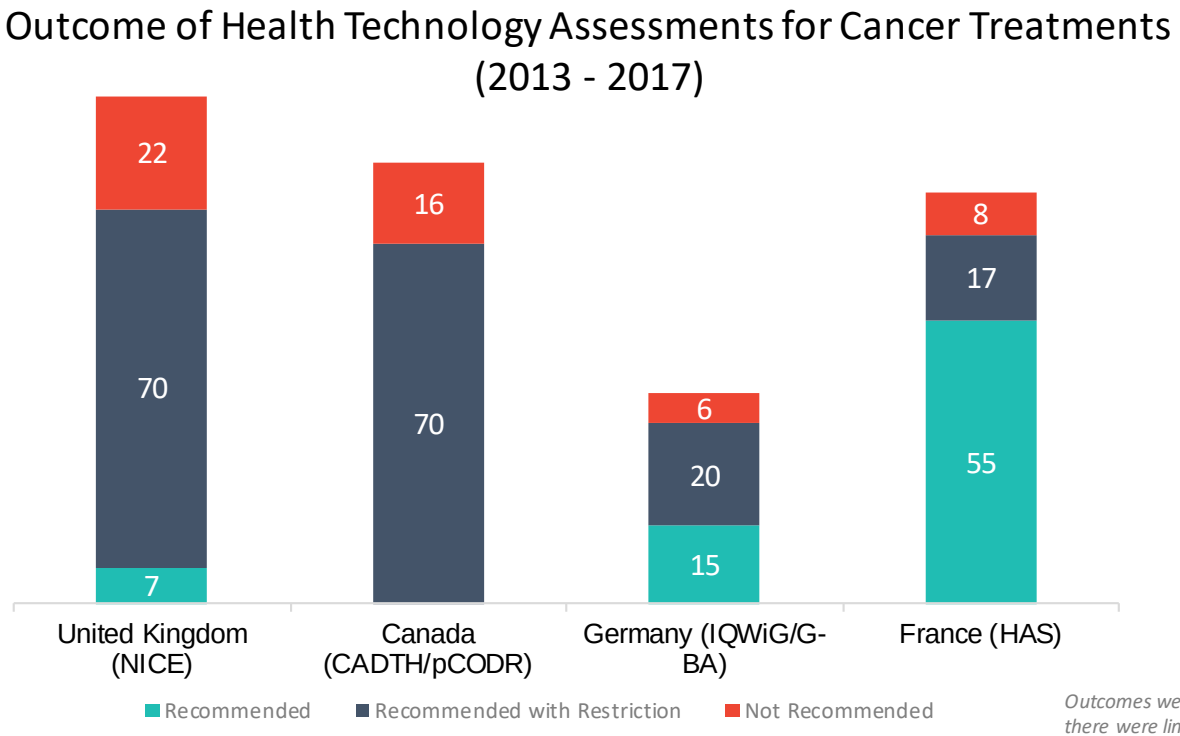


*2013 is the latest year for which data are available for all listed countries.

Source: PhRMA analysis of WHO Mortality Database, May 2019. Note: 2013 data was used because some countries lack newer data.

In Other Countries, Governments Restrict Access to Cancer Medicines

Health technology assessment (HTA) recommendations across countries show little consistency, highlighting the effect of cultural factors on HTA design and implementation, and that a "one-size-fits-all" approach is not realistic in determining access to needed medicines.



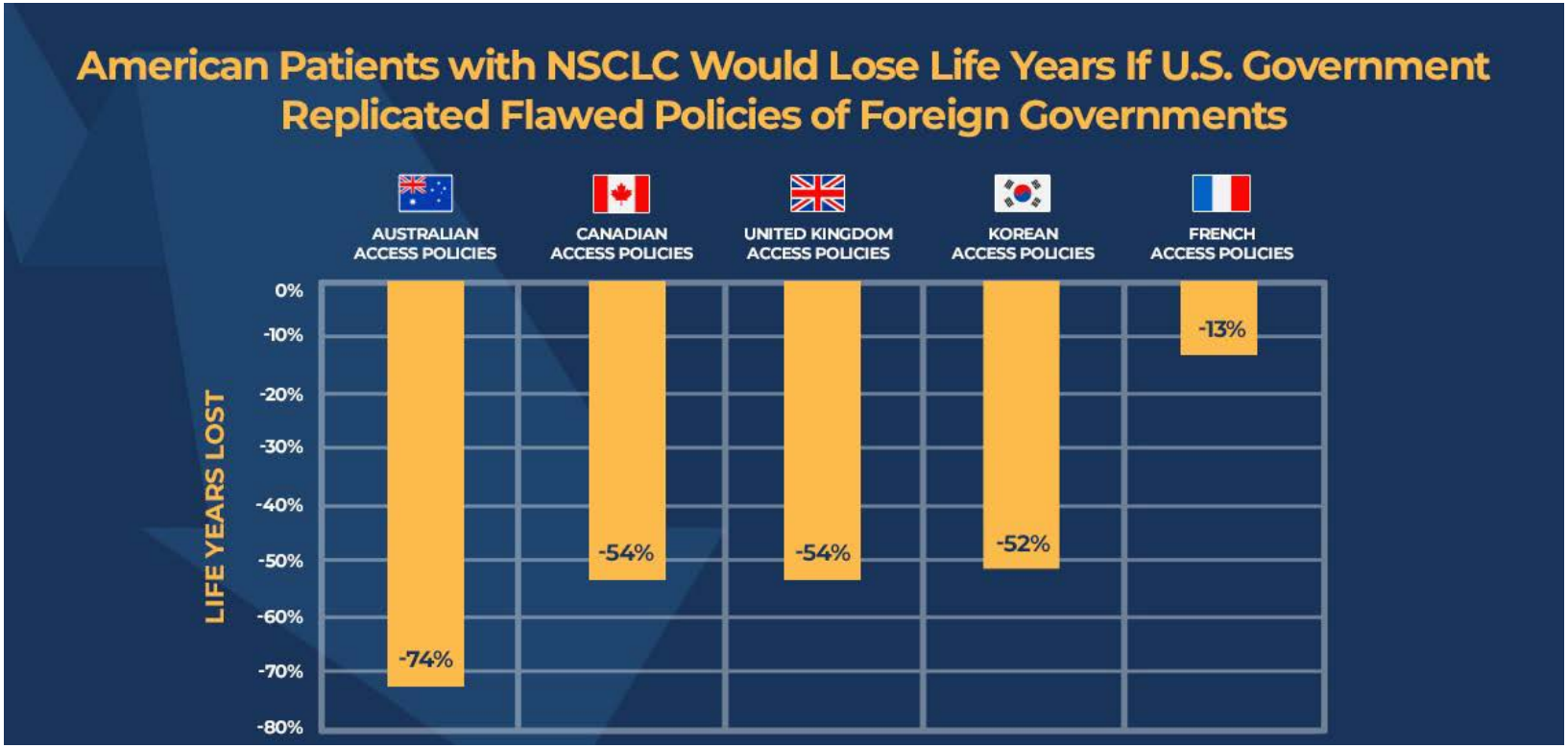
In the U.K. only 7 government assessments recommended without restrictions.

Outcomes were classified as "Recommended with Restrictions" if there were limitations that may impact access.

Source: Data provided by Avalere Health (citation forthcoming).

Lung Cancer Patients Experience Better Survival Under the Market Access Policies in the United States

Americans diagnosed late-stage non-small cell lung cancer gained an estimated 201,700 life years from 2006 to 2017 due to innovative medicines being made available with little to no delay after regulatory approval. Patients would have lost half of these survival gains if the United States had adopted HTA frameworks like those used by foreign governments to determine access to care.



Source; IHS Markit. Comparing Health Outcome Differences Due to Drug Access: A Model in Non-Small Cell Lung Cancer. December 2018. https://ihsmarkit.com/research-analysis/population-health-outcomes-american-patients.html

7. Solutions For Advancing Value in Cancer Care

Advancing the Path for Development of New Cancer Medicines

Advances in regulatory science are creating efficiencies and enhancing the tools needed to drive innovative cancer drug discovery, development and approval.

Solutions For Accelerating Cancer Progress

Integrating Patient Perspective	Accelerating Qualification & Use of Biomarkers	Advancing Use of Real-World Evidence	Increasing Acceptance of Novel Clinical Trial Designs
Incorporate patient input & increase patient engagement.	*Increase acceptance of novel outcome measures*	*Enable use of both safety & efficacy data in regulatory decision making.*	*Enhance use of adaptive & other flexible study designs*

Biopharmaceutical Companies Advancing Patient-Centered Solutions for Better Value

Enabling the Cancer Drug Market's Move to Value

Value Based Contracts

Expand value-based contracts by modernizing outdated regulations.

"[R]egulatory reforms can address these concerns and encourage more robust competition within the drug market."

- Scott Gottlieb & Kavita Patel

Value Frameworks

Develop better data and tools to support informed decision-making by patients, physicians and payers.

"[E]merging approaches for assessing drug value are welcome….The frameworks will require refinement, however, before they're ready to be broadly applied."

- Peter Neumann & Joshua Cohen

Quality Measures

Close gaps in clinical and patient-focused quality measures.

"All phases of the cancer care continuum…need new measures."

- National Academy of Medicine

Sources: S Gottlieb, K. Patel, "A Fair Plan for Fairer Drug Prices," *Health Affairs*, 11 July 2016; Institute of Medicine, "Delivering High-Quality Cancer Care: P. Neumann, J. Cohen, "Measuring the Value of Prescription Drugs," NEJM, December 2015; Institute of Medicine, "Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis," 2013.