Prescription Medicines: International Costs in Context

March 2017

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PART 1:

Medicines Benefit Patients, Health Care Systems, and Economies

Medicines Benefit Patients, Health Care Systems, and Economies

Patients

Patients all around the world are living longer, healthier, and more productive lives

Health Care Systems

Medicines can put health care systems on more sustainable paths by reducing need for more expensive services

Economies

The biopharmaceutical industry creates jobs, R&D investment, and medicines that improve worker productivity

VALUE OF MEDICINES

Value to Patients

Patients all around the world are living longer, healthier, and more productive lives

Medicines Have Significantly Increased Chances of Survival

Cancer

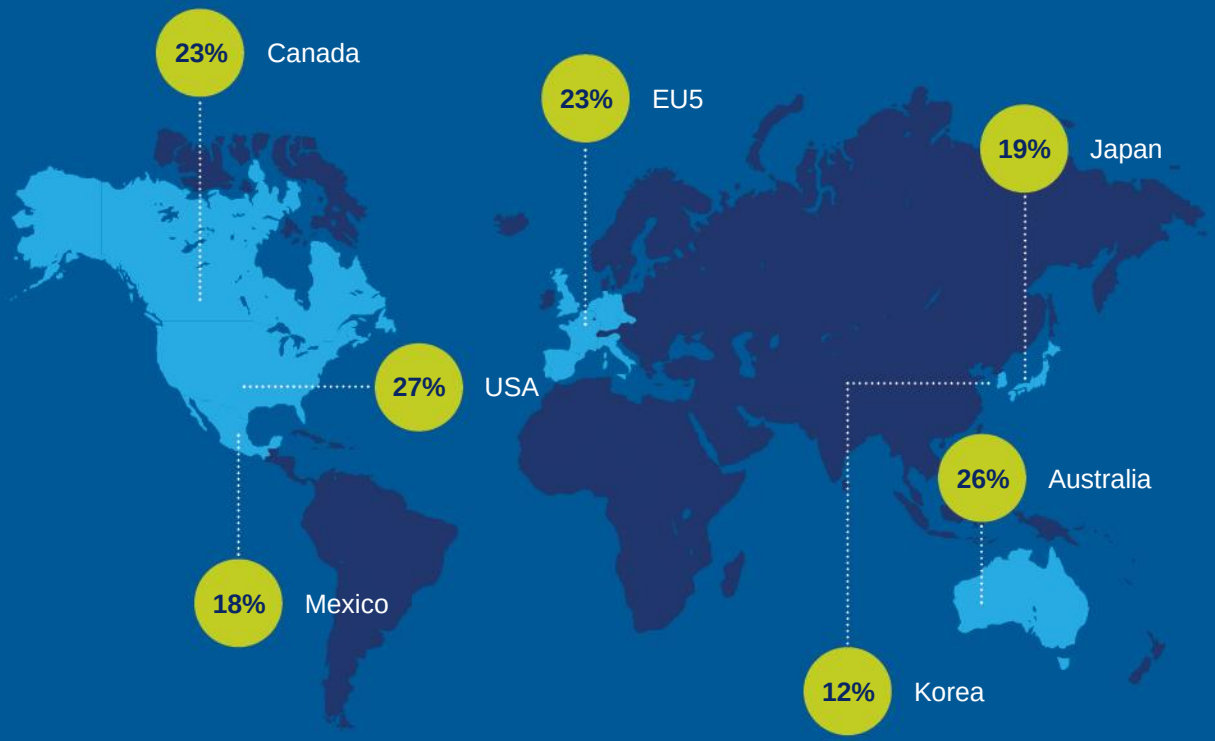
New therapies have contributed to significant declines in cancer mortality rates around the world since its peak in 1991

Today, 2 out of 3 people
diagnosed with cancer survive
at least 5 years[2]

Approximately
83% of survival gains
in cancer are attributable
to new treatments[3]

Percent Decline in Cancer Mortality Rates Since 1991

1991 to 2014 – All Cancers[1]



Source: Health Advances analysis; [1]WHO Mortality Database (accessed January 2017); [2]American Cancer Society Cancer Statistics Center; [3]Sun et al., 2008, "The determinants of recent gains cancer survival: an analysis of the surveillance, epidemiology, and end results (SEER) database," Journal of Clinical Oncology.

Medicines Are Some of the Most Powerful Tools to Treat and Cure Deadly Diseases

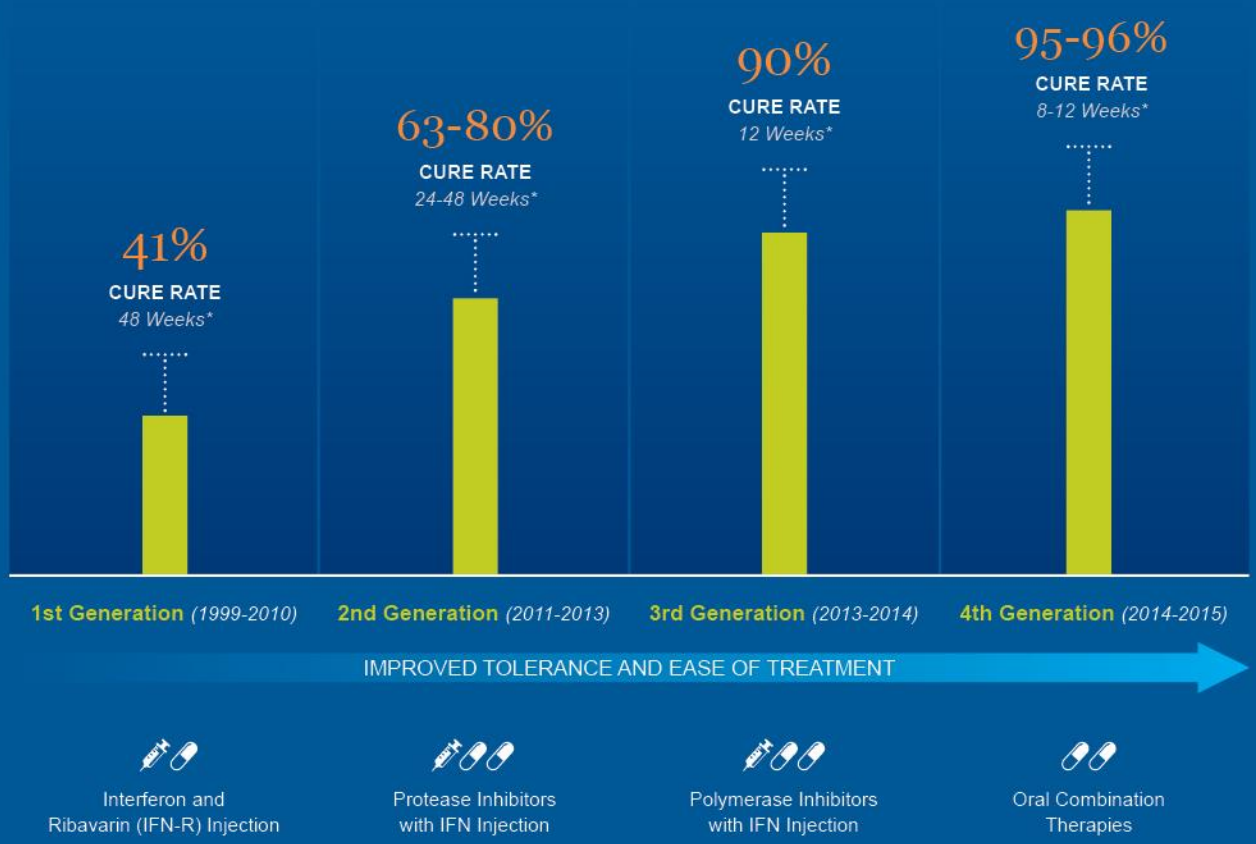
HEPATITIS C VIRUS

The leading cause of liver transplants and the reason liver cancer is on the rise – is now curable in more than

90%

of treated patients with only 8-12 weeks of treatment

+133% cure rate increase for patients in Europe[1]



*Treatment duration.
Note: European Medicines Agency approval dates. Cure rates based upon clinical trial results reported in US Food and Drug Administration labels for: interferon; telaprevir; boceprevir; simeprevir; sofosbuvir; sofosbuvir and ledipasvir combination; and ombitasvir, paritaprevir, ritonavir, and dasabuvir combination.
Source: [1]PhRMA, 2014, 25 years of progress against hepatitis C; PhRMA, 2015, Biopharmaceutical research industry profile.

Medicines Are Transforming the Treatment of Many Chronic Diseases

Cardiovascular Disease

Innovative biopharmaceutical companies are currently developing 190 medicines to treat heart disease, stroke and other cardiovascular diseases. New PCSK9 inhibitors have revolutionized high cholesterol treatment[1]

Diabetes

Between 2000 and 2012, new therapies contributed to a 48% and 31% decline in the diabetes death rate in Korea and Canada, respectively[2]

Rheumatoid Arthritis

The recent introduction of disease-modifying therapies has dramatically improved the lives of patients and caregivers by slowing and sometimes even reversing negative physical symptoms of the disease[3]

Death rates for non-communicable diseases

declined nearly 20%

in the EU5, Australia, Canada and Japan from 2000 to 2012

Note: The four main types of chronic diseases defined by WHO are cardiovascular diseases (e.g. heart attacks and stroke), cancers, chronic respiratory diseases (e.g. chronic obstructed pulmonary disease and asthma) and diabetes.
Source: Health Advances analysis; [1]US Food and Drug Administration; [2]WHO Mortality Database (accessed February 2016); [3]Kremer, 2008, "COMET's path, and the new biologicals in rheumatoid arthritis," Lancet.

Vaccines Are Helping to Win the Fight Against Communicable Diseases

England

In England, infant deaths

declined 79%

from 2012 to 2013 as a result of a maternal pertussis vaccination program[1]

Italy

Italy was the first industrialized country to introduce a program for routine vaccination against hepatitis B virus (HBV); this program led to an

82% decline

in the incidence of HBV from 1991 to 2010[2]

Mexico

In Mexico, the introduction of the rotavirus vaccine in 2007 led to a

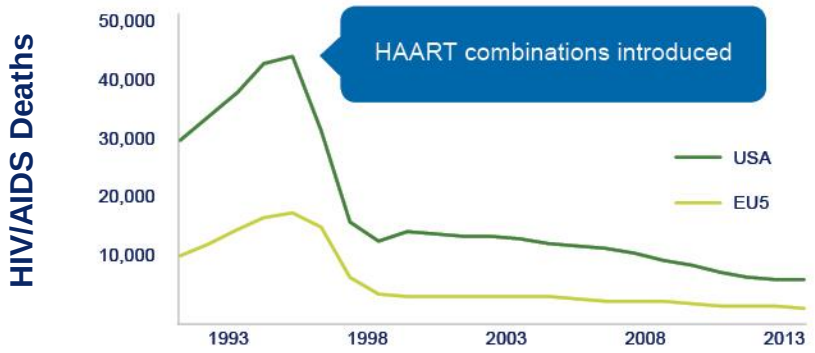
46% reduction

in annual diarrhea-related mortality among children under five[3]

Source: Health Advances analysis; [1]Amirthalingam, 2014, "Effectiveness of Maternal Pertussis Vaccination in England," Lancet; [2]Boccalini, 2013, "Economic analysis of the first 20 years of universal hepatitis B vaccination program in Italy," Human Vaccines and Immunotherapeutics; [3]Richardson, 2011, "Childhood diarrhea deaths after rotavirus vaccination in Mexico," New England Journal of Medicine.

Medicines Have Transformed HIV/AIDS From a Death Sentence to a Manageable Disease

HIV/AIDS Deaths, USA and EU5[1]



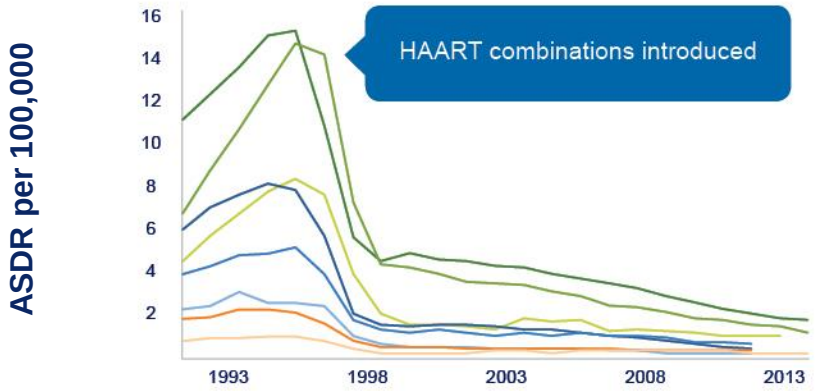
HIV/AIDS

The number of deaths from HIV/AIDS has

dropped by 85%

since its peak in 1995 in the USA and EU5

HIV/AIDS Age-Standardized Death Rates (ASDR) *By Country*



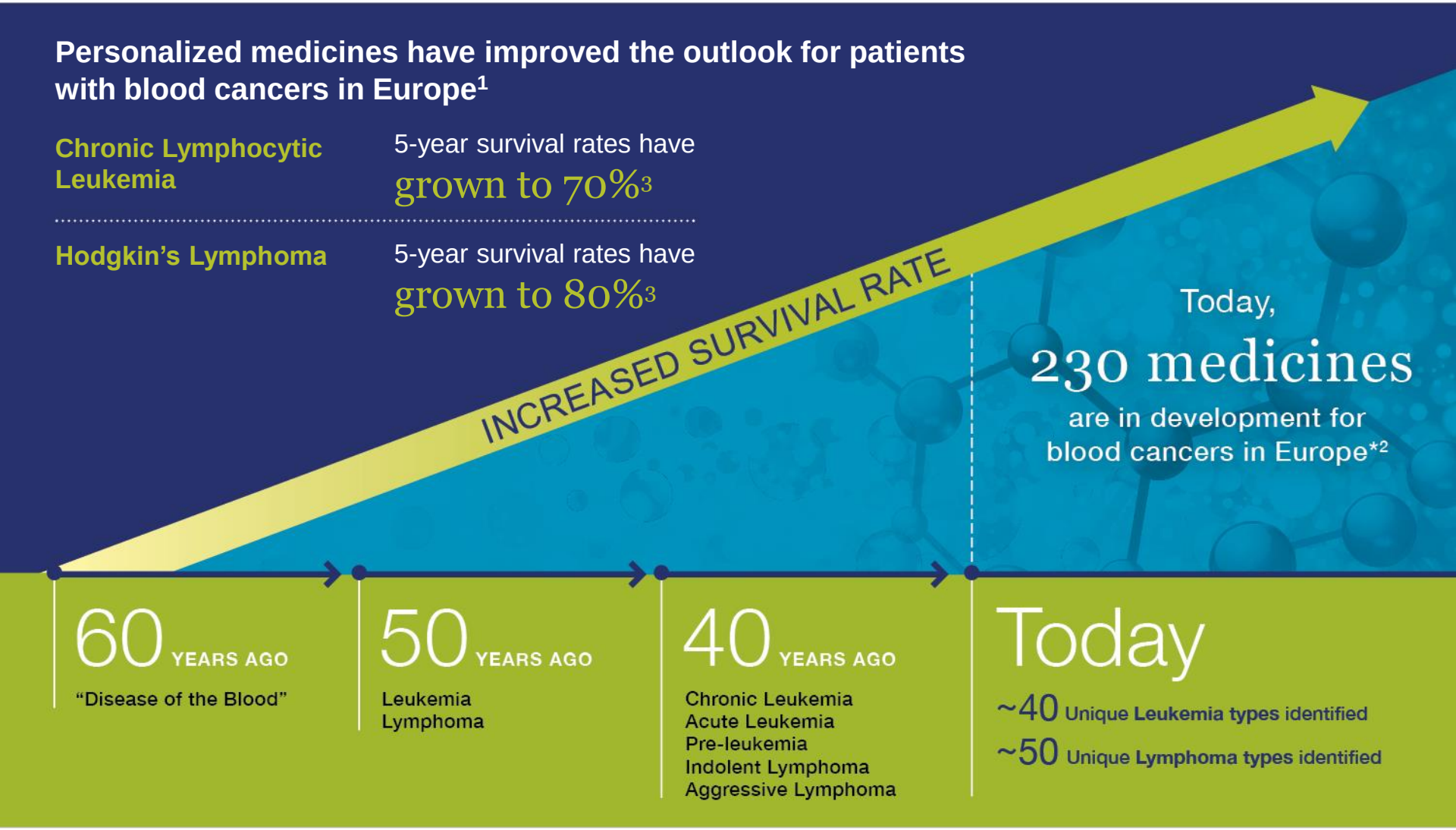
COUNTRY	Decline in ASDR (1995-2013*)
USA	-88%
SPAIN	-92%
ITALY	-87%
FRANCE	-94%
CANADA	-87%
AUSTRALIA	-88%
GERMANY	-82%
UNITED KINGDOM	-73%

*Or latest year of available data: Italy (2012), France (2011), Canada (2011), Australia (2011), Germany (2011).
Note: HIV/AIDS ASDR extrapolated for Italy in 2004-2005 and Australia in 2005.
Source: Health Advances analysis; [1]WHO Mortality Database (accessed February 2016).

Biopharmaceutical Companies Have Driven A Decade of Advances in Medicines

Note: Dates of innovation provided by the US Food and Drug Administration.
Source: US Food and Drug Administration, Drugs@FDA: FDA approved drug products (accessed April 2016).

Improved Understanding of Disease and Personalized Medicines Have Increased Patient Survival



*Medicines in Phase I through Phase III for the treatment of all types of leukemia and lymphoma.
Source: [1]National Cancer Institute SEER Cancer Statistics Review; [2]Eurocare 5 Database on cancer survival in Europe; [3]PharmaProjects (accessed February 2016).

Biopharmaceutical Companies Have Made Continued Progress Against Rare Diseases

There are approximately

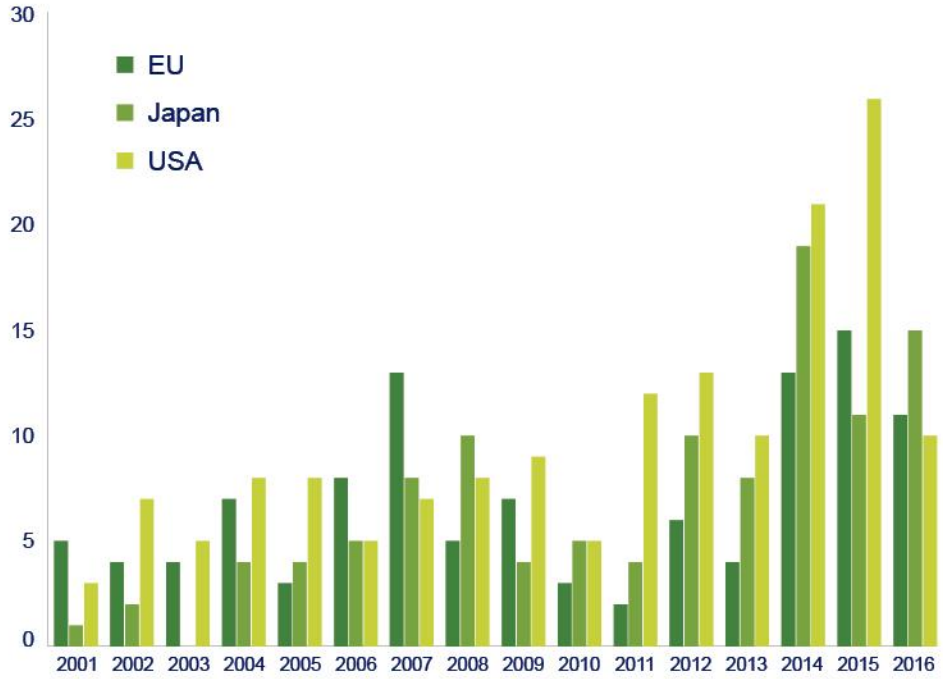
7,000

different rare diseases worldwide

1 in 10

individuals in the USA and Europe are living with a rare disease[2]

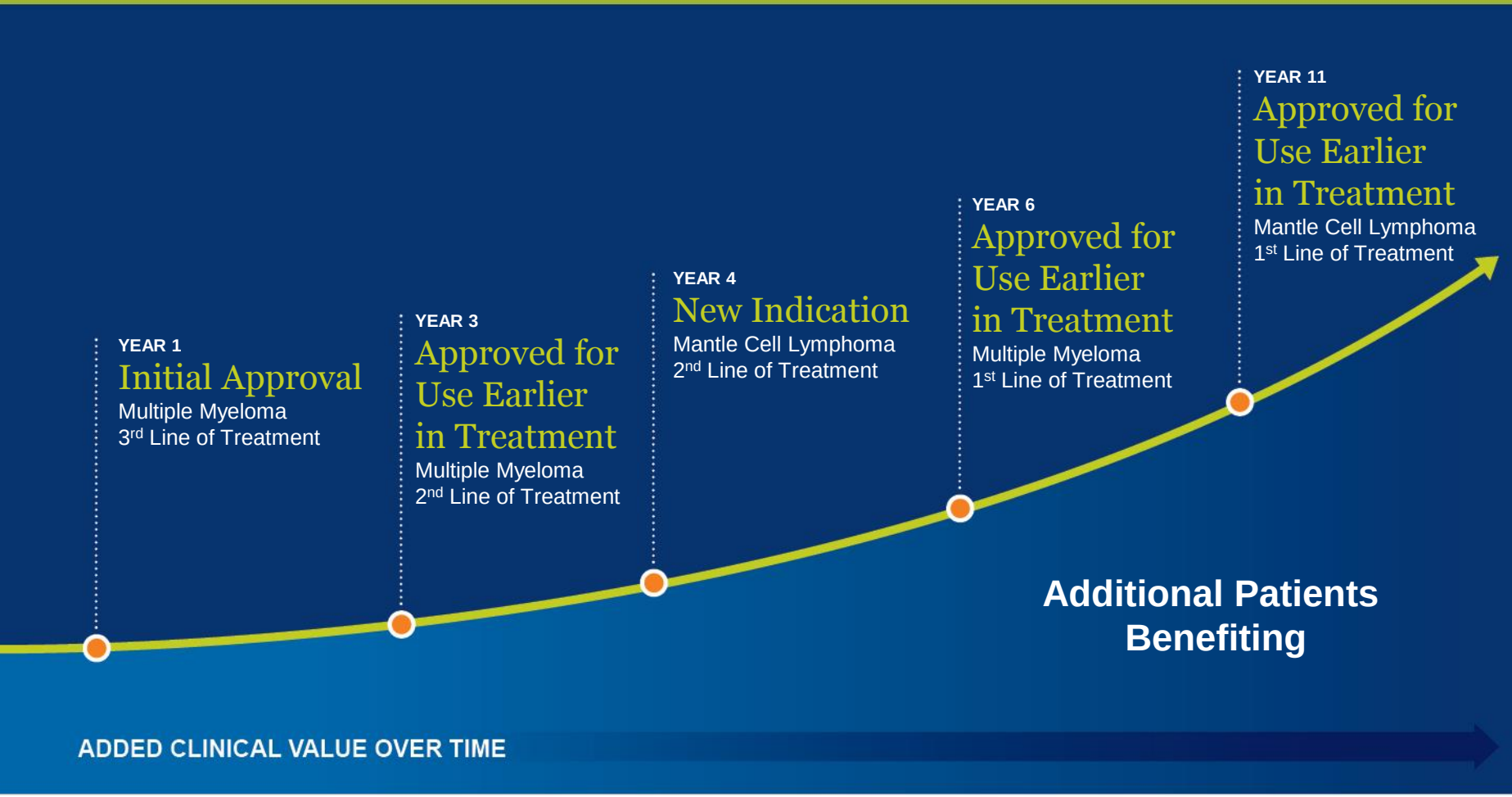
Growth in Orphan Drug Approvals[1]



Note: 2016 data is still undergoing audit as of January 2017.
Source: [1]CIRS, 2017, Analysis of FDA, EMA and PMDA orphan designations for new active substances; [2]Global Genes, 2015, Rare Disease: Facts and Statistics.

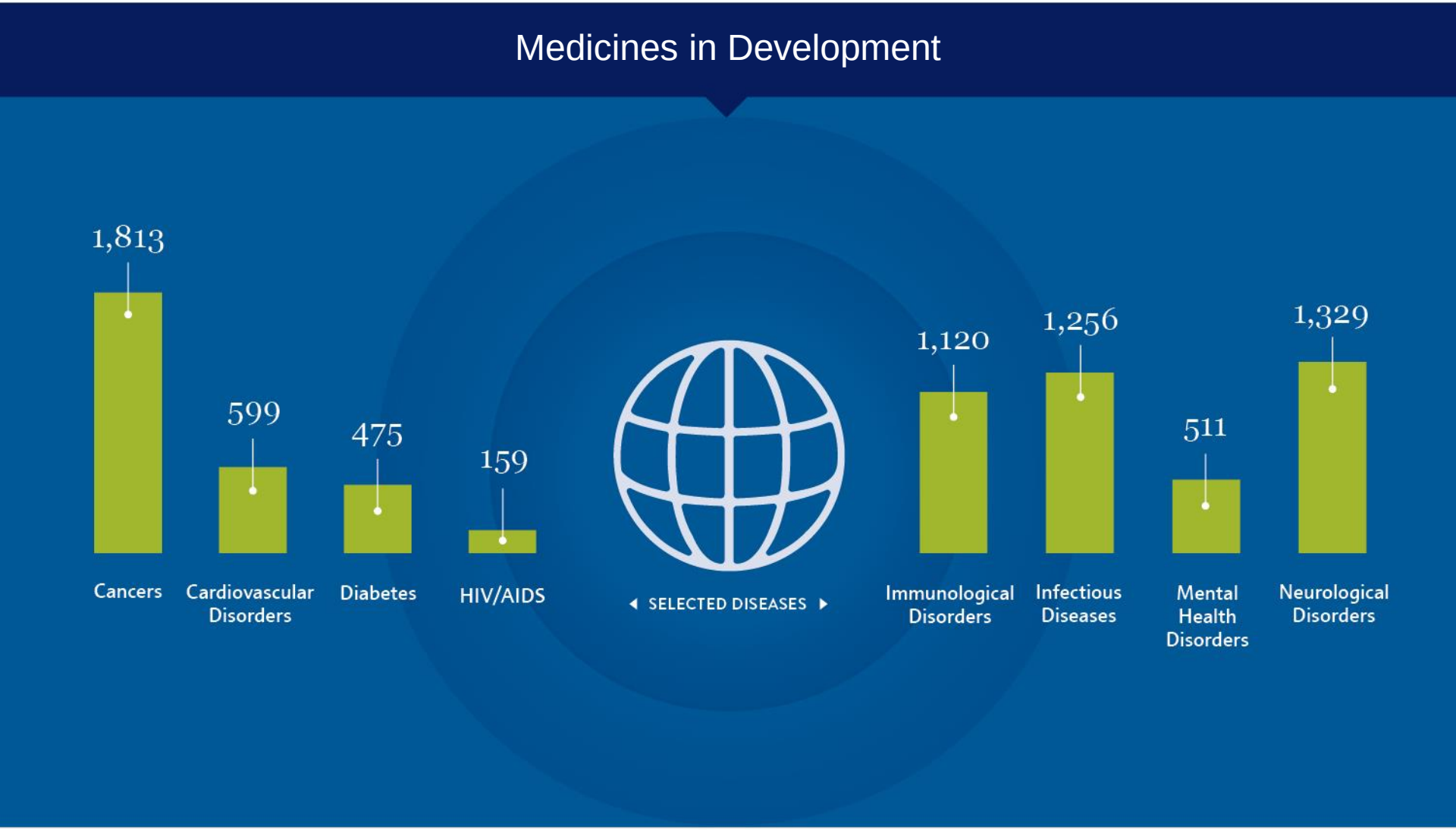
Medicines Often Demonstrate Far Greater Benefits than Understood at Initial Approval

Cancer medicines demonstrate **increasing clinical value over time** long after initial approval



Note: Representation of the change in clinical value over time in the US as additional data and evidence became available for bortezomib.
Source: Boston Healthcare Associates, 2015, The value of innovation in oncology: recognizing emerging benefits over time.

More Than 7,000 Medicines Are in Development Around the World



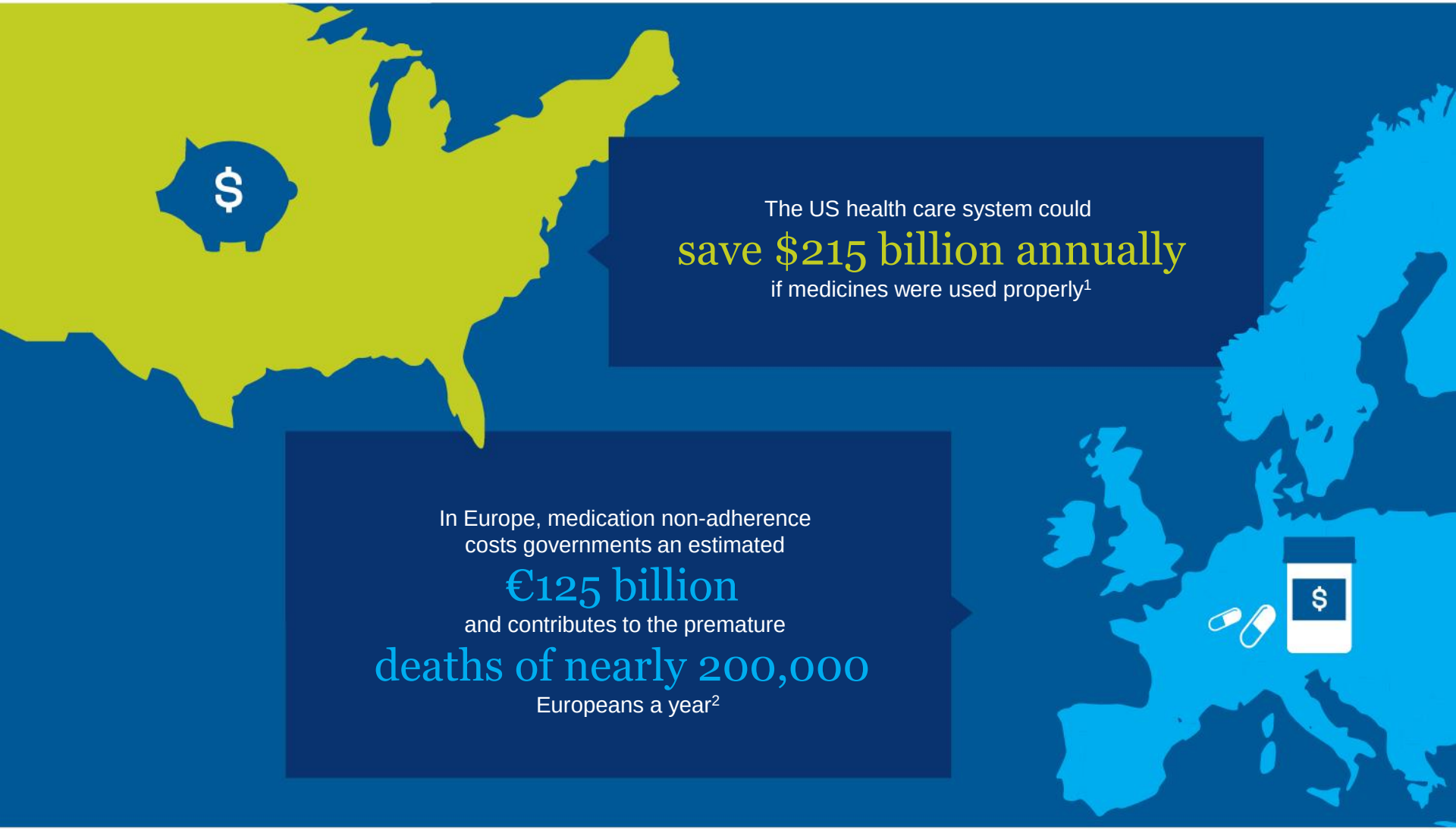
Note: Each product is counted exactly once, regardless of the number of indications pursued.
Source: Adis R&D Insight Database.

VALUE OF MEDICINES

Value to Health Care Systems

Medicines can put health care systems on more sustainable paths by reducing need for more expensive services

Medicines Provide Critical Savings for Health Care Systems



Source: Health Advances analysis; [1]IMS Institute for Health Care Informatics, 2013, Avoidable costs in US health care: the $200 billion opportunity from using medicines more responsibly; [2]EFPIA, 2011, Annual review of 2011 and outlook for 2012.

Medicines Reduce Spending on Hospitalizations and Other Health Services

1.6-2.1 million

The number of influenza cases averted with the current use of seasonal influenza vaccination in Europe[1]

€250-330 million

Total influenza-related costs saved annually from averted GP visits, hospitalizations, and lost days of work as a result of the current use of seasonal influenza vaccination in Europe[1]

New Cardiovascular Medicines Led to Direct Savings on Hospitalizations in 20 OECD Countries*, 1995-2004

Per capita expenditure on cardiovascular hospitalizations would have been

$89 (70%) higher

in 2004 had new cardiovascular medicines not been introduced in the period 1995–2004[2]

*Countries include Australia, Austria, Belgium, Canada, Czech Republic, Finland, France, Germany, Hungary, Italy, Japan, Korea, New Zealand, Norway, Poland, Slovak Republic, Spain, Switzerland, Turkey, UK and US.

Source: Health Advances analysis; [1]Preaud, 2014, "Annual public health and economic benefits of seasonal influenza vaccination," BMC Public Health; [2]Lichtenberg, 2009, "Have newer CV drugs reduced hospitalizations in 20 OECD countries? Evidence from longitudinal country-level data on 20 OECD countries, 1995-2003," Health Economics.

New Medicines Are Part of the Solution to Hold Down Future Health Care Costs

$376 billion

Costs avoided by 2050 from the development of a new medicine that delays the onset of Alzheimer's disease[1] by

just five years

In the UK, a treatment delaying the onset of dementia by 5 years* would result in:

666,000

fewer people with dementia

566,000

fewer informal cares required

£21.2 billion

reduction in the cost of dementia[2]

€22 billion

savings in Germany by 2040 from the development of new medicine that **halts the progression** of Parkinson's Disease (PD)[3]

€3.9 billion

savings if medicine **slows progression by 20%**

*Study duration and savings modeled through 2050 for an intervention that would delay the onset of dementia by 5 years and would become available in 2020.
Source: Health Advances analysis; [1]Alzheimer's Association; [2]Alzheimer's Research UK, 2014, Defeat dementia: The evidence and a vision for action; [3]Johnson, 2012, "Economic value of slowing Parkinson's disease in Germany: modeling progression through Hoehn and Yahr stages," ISPOR 15th Annual European Congress.

VALUE OF MEDICINES

Value to Economies

The biopharmaceutical industry creates jobs, R&D investment, and medicines that improve worker productivity

The Innovative Biopharmaceutical Industry Has a Major Impact on Economies

Jobs across the US, EU5, Japan, Korea, Mexico, Canada, and Australia

1,600,000
direct jobs

Innovative Biopharmaceutical Industry

6,400,000
jobs downstream

Vendors and Suppliers

8 million
TOTAL JOBS

US
4,500,000
jobs

EU5
1,700,000
jobs

JAPAN
630,000
jobs

KOREA
440,000
jobs

MEXICO
680,000
jobs

CANADA
80,000
jobs

AUSTRALIA
64,000
jobs

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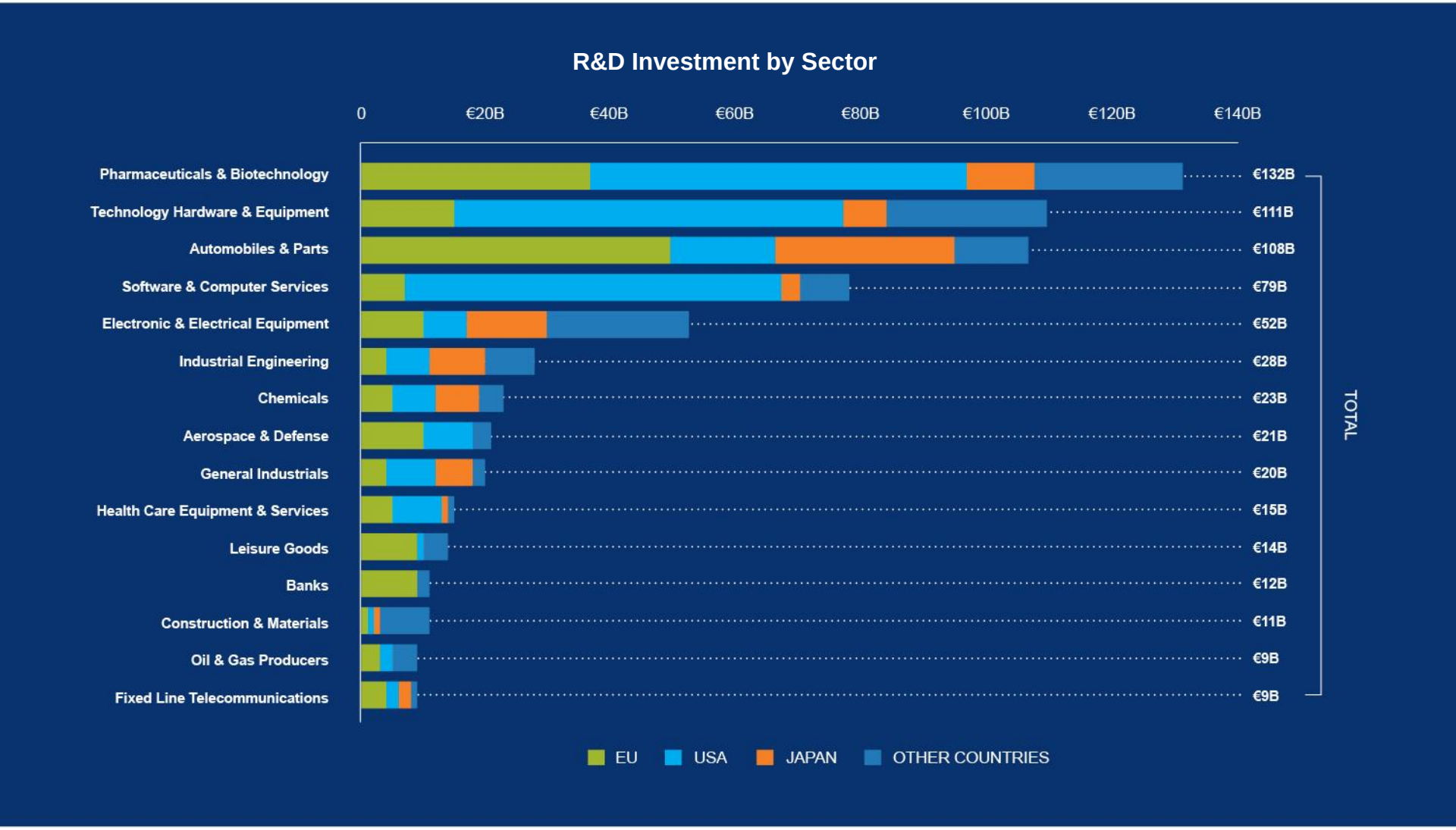
Source: Health Advances analysis; PhRMA and TEConomy Partners LLC, 2016, The economic impact of the US biopharmaceutical industry: national and state estimates; EFPIA, 2015, Pharmaceutical industry in figures; JPMA, 2016, Pharmaceutical industry outlook; Invest Korea, 2015, Investment opportunities in Korea: biopharmaceutical; WifOR, 2016, Supporting the value proposition of the pharmaceutical industry in Mexico; Statistics Canada CANSIM Database (accessed January 2017); Australian Bureau of Statistics Australian Industry Database (accessed January 2017).

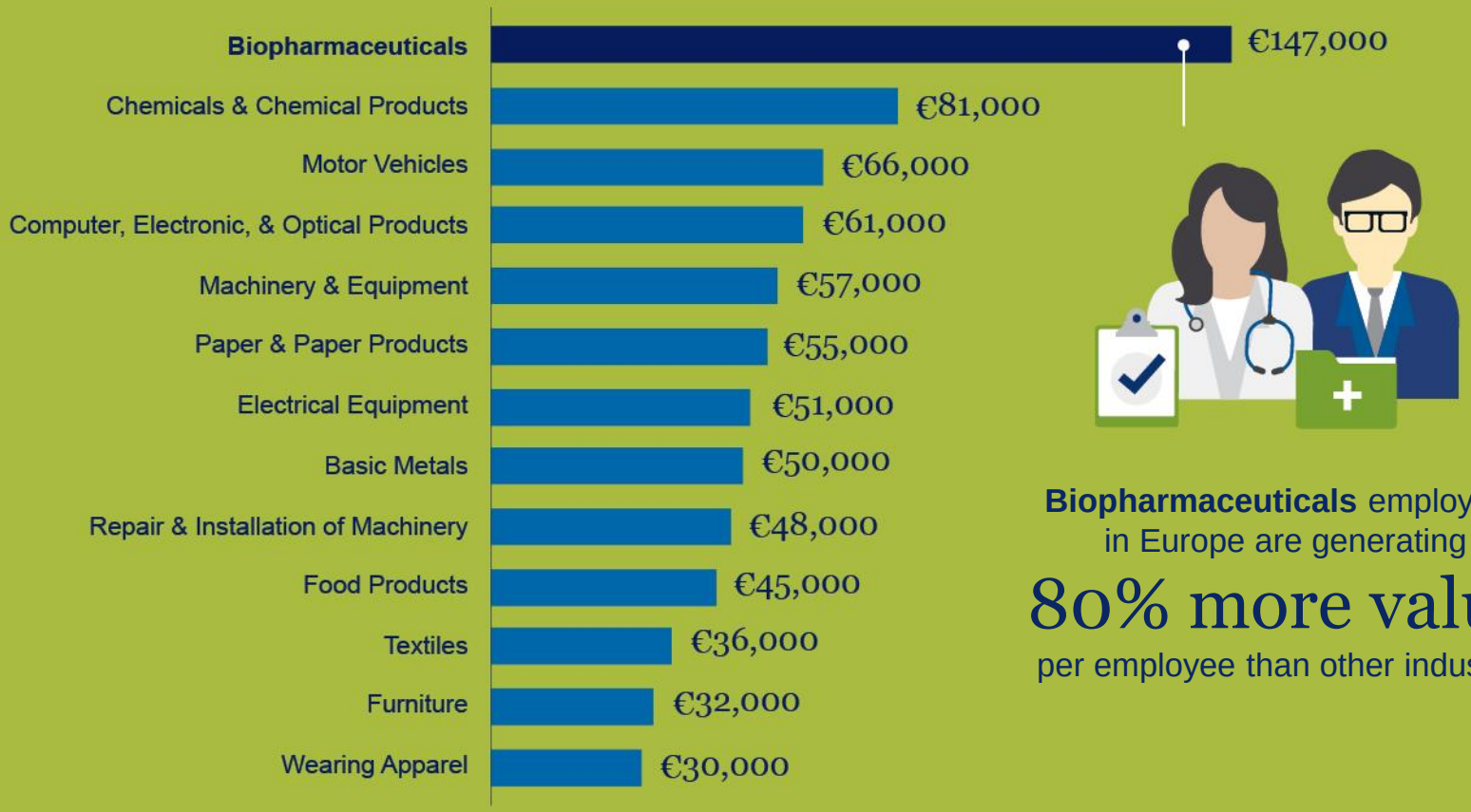
The Biopharmaceutical Sector Is the Single Largest Funder of Business R&D in the World



Source: European Commission, 2016, The 2016 EU industrial R&D investment scoreboard.

The Biopharmaceutical Sector Adds the Most Value to the Economy per Employee

Gross Value Added per Employee in Europe, 2012



Biopharmaceuticals employees in Europe are generating

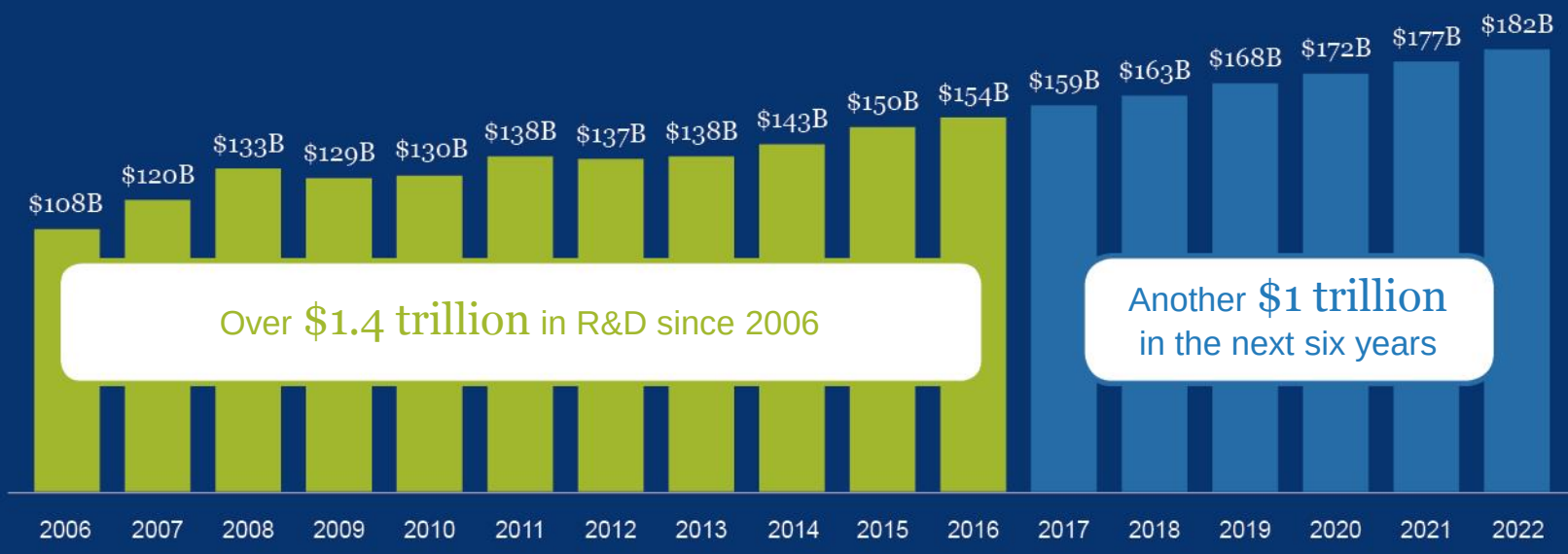
80% more value

per employee than other industries

Note: Gross value added is defined as the gross income from operating activities per employee in the EU-28 and Norway.
Source: Health Advances analysis; Eurostat Database (accessed February 2016).

Biopharmaceutical Companies Have Invested Billions to Bring Innovative Therapies to Market

Worldwide Pharmaceutical R&D Investment[1]

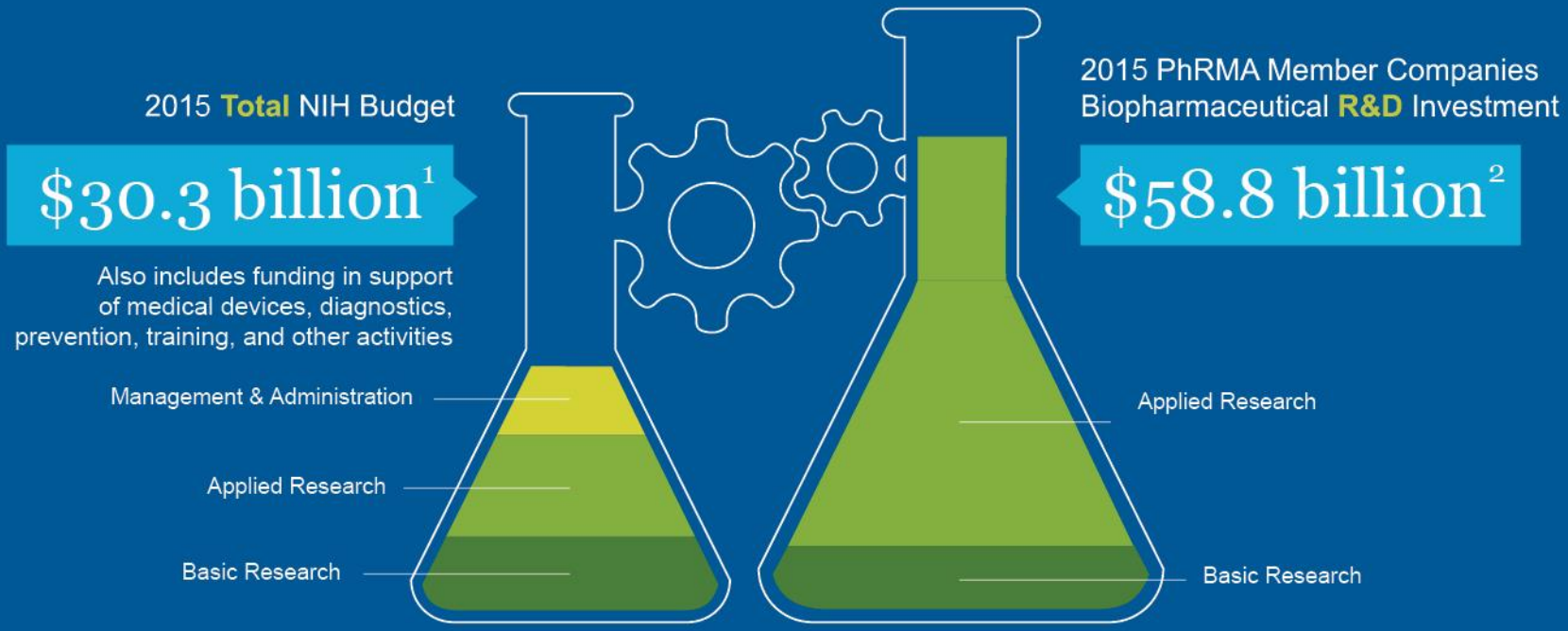


"The most important challenge facing the global research community is ensuring that populations regard its contributions as positive, responsible and legitimate. R&D policy is not just about throwing money at scientists and engineers – it is also about ensuring that their innovations can be brought into use, which is a quite different challenge."

– DOMESTIC CORPORATION, UK (DECEMBER 2013)[2]

Biopharmaceutical Companies Do the Vast Majority of Research to Translate Basic Science into New Medicines

Biopharmaceutical R&D Investment in the United States, 2015

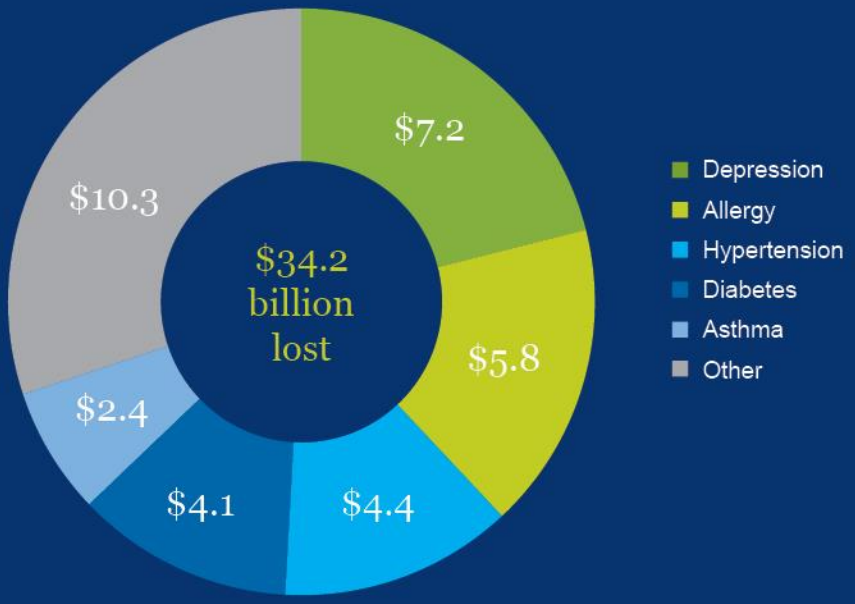


While basic science is often initiated in academia, biopharmaceutical firms provide the necessary critical mass, expertise, and experience needed to develop new medicines

Source: [1]Total National Institutes of Health (NIH) spending is for fiscal year 2015. In addition to funding for basic and applied research, the total NIH budget includes funding in support of prevention (e.g., suicide prevention), diagnostics and medical devices, Superfund Research Program activities, training and education (e.g., dental), program evaluation, management and support, buildings and facilities, and other activities; [2]PhRMA member companies' R&D spending is estimated for calendar year 2015. PhRMA member companies account for the majority of private biopharmaceutical R&D spending. Nonmember company data are not included.

Innovative Medicines Address Health Needs While Also Supporting Economic Growth

POOR HEALTH IS A MAJOR CAUSE OF WORKPLACE PRODUCTIVITY LOSS[1]



Total cost of productivity loss due to presenteeism in Australia, 2009-2010

NOVEL TREATMENTS ALLOW PATIENTS TO WORK LONGER AND MORE PRODUCTIVELY[2]

Ability to work 31 weeks longer and earn

€26,000

more than a patient on conventional therapy

When comparing worker productivity for European, Australian, and Canadian patients with rheumatoid arthritis (RA), researchers found that patients were able to work longer and earn more money when treated with a novel biologic rather than conventional therapy* over the study period of 2 years

Note: Conventional therapy refers to conventional disease-modifying anti-rheumatic drugs. Presenteeism is the act of attending work while sick.
Source: Health Advances analysis; [1]Victoria Institute of Strategic Economic Studies, 2014, Impact of health on worker attendance and productivity in APEC region; [2]Halpern et al., 2009, "Impact of adalimumab on work participation in rheumatoid arthritis: comparison of an open-label extension study and a registry-based control group," Annals of the Rheumatic Diseases.

Chronic Disease Is a Health and Economic Issue

$190 billion

The Canadian economy loses $190 billion annually due to chronic disease: $90 billion on treatment and $100 billion on lost productivity[1]

10% loss

in workforce productivity

The Australian economy loses 537,000 full-time person years and 47,000 part-time person years annually due to chronic diseases, reducing productivity by 10%[2,3]

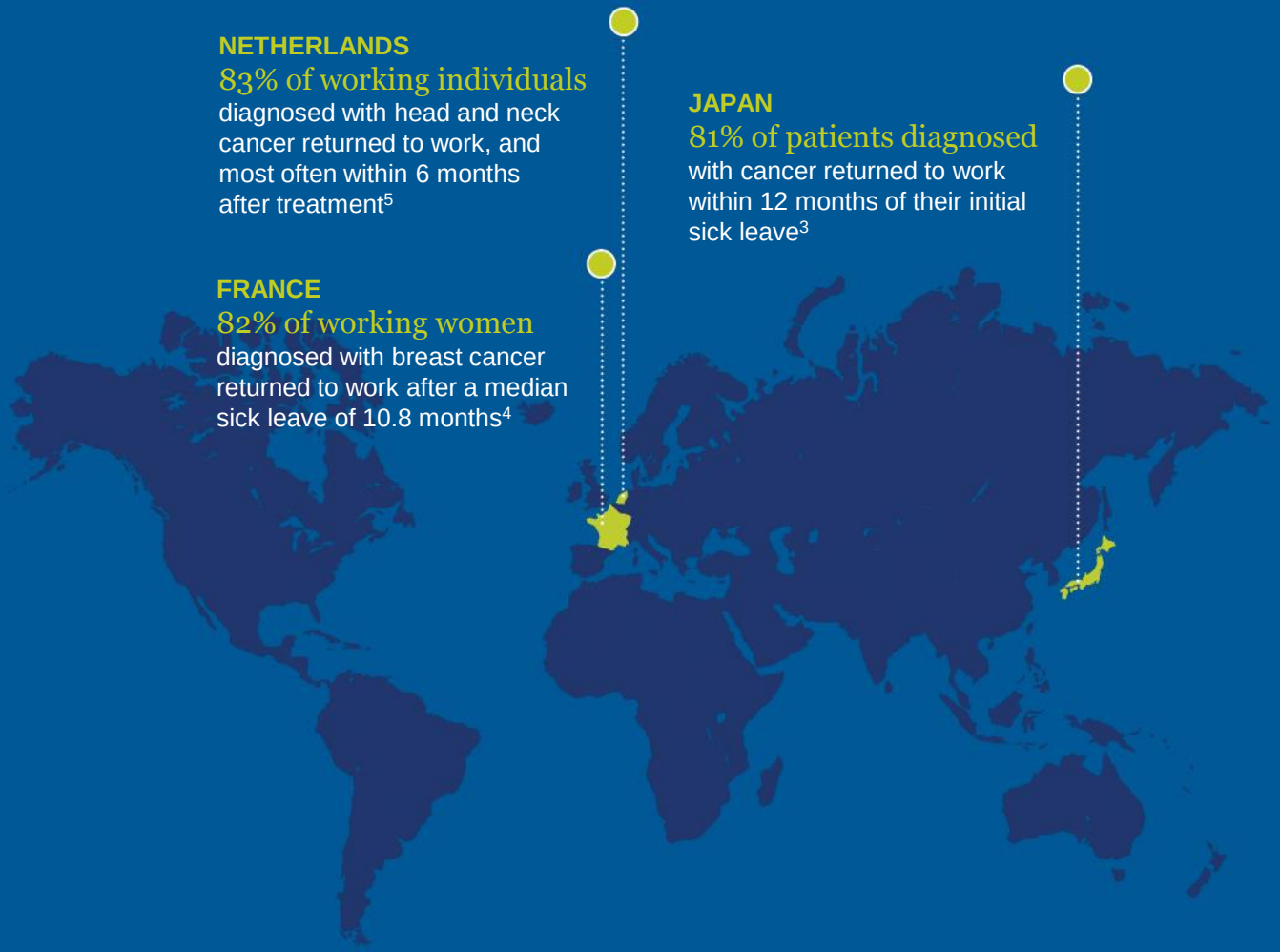
Note: Costs to Canadian economy are in Canadian dollars. Lost person years from chronic disease include workforce non-participation, absenteeism, and death.
Source: Health Advances analysis; [1]Public Health Agency of Canada (PHAC) evidence presented to the Canada Standing Committee on Health, May 2012; [2]Australian Health Policy Collaboration, 2014, Chronic Disease in Australia; [3]Business Council of Australia, 2011, Facts and statistics on Australia's healthcare sector.

Innovative New Therapies Have Enabled Patients to Continue Contributing to Society

Cancer

Cancer survivors are 1.4 times more likely to be unemployed than healthy individuals[1], however

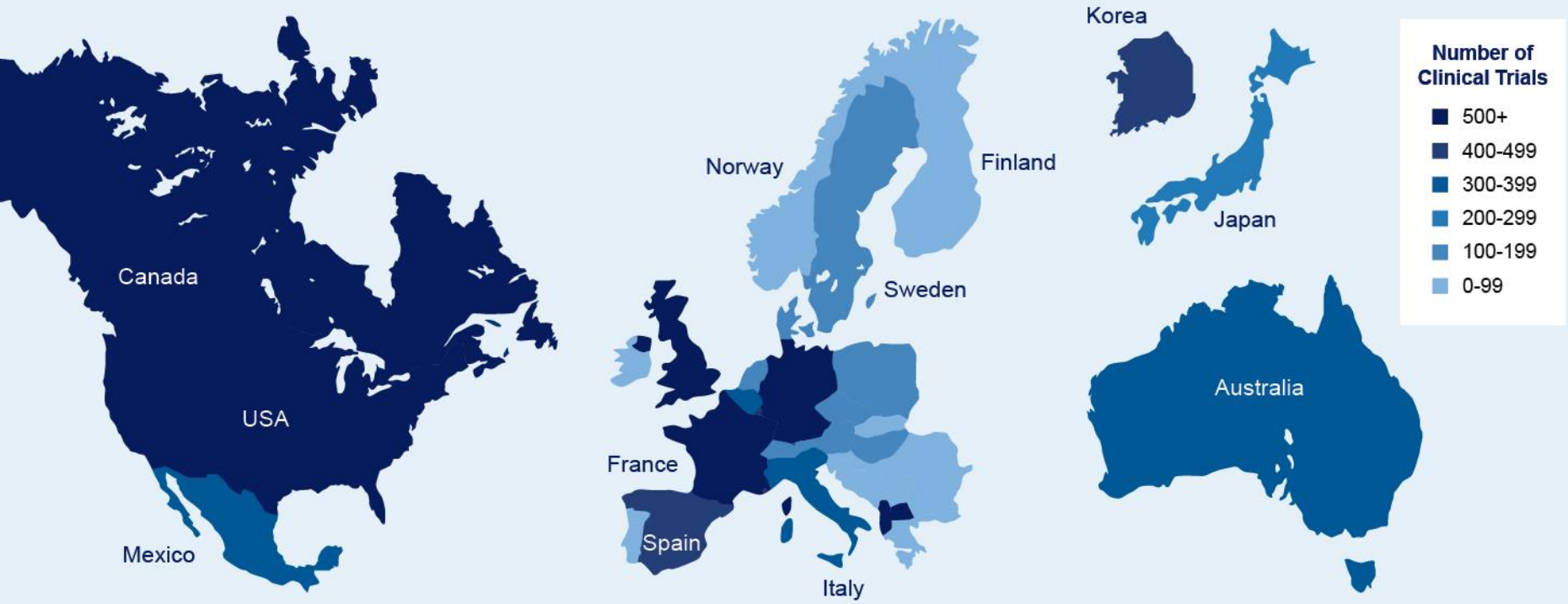
4 out of 5 cancer patients around the world today are returning to work following diagnosis due to innovative therapies[2]



Note: In all three studies, return to work included full-time and part-time work.
Source: Health Advances analysis; [1]de Boer, 2009, "Cancer survivors and unemployment: a meta-analysis and meta-regression," Journal of the American Medical Association; [2]Amir and Brocky, 2009, "Cancer survivorship and employment: epidemiology," Occupational Medicine; [3]Endo et al., 2015, "Returning to work after sick leave due to cancer: a 365-day cohort study of Japanese cancer survivors," Journal of Cancer Survivorship; [4]Fantoni, 2010, "Factors related to return to work by women with breast cancer in Northern France," Journal of Occupational Rehabilitation; [5]Verdonck-de Leeuw, 2010, "Employment and return to work in head and neck cancer survivors," Oral Oncology.

Industry-Sponsored Clinical Trials Contribute Significant Value to the Countries in Which They Are Located

In 2015, the biopharmaceutical industry sponsored 9,059 clinical trials around the world

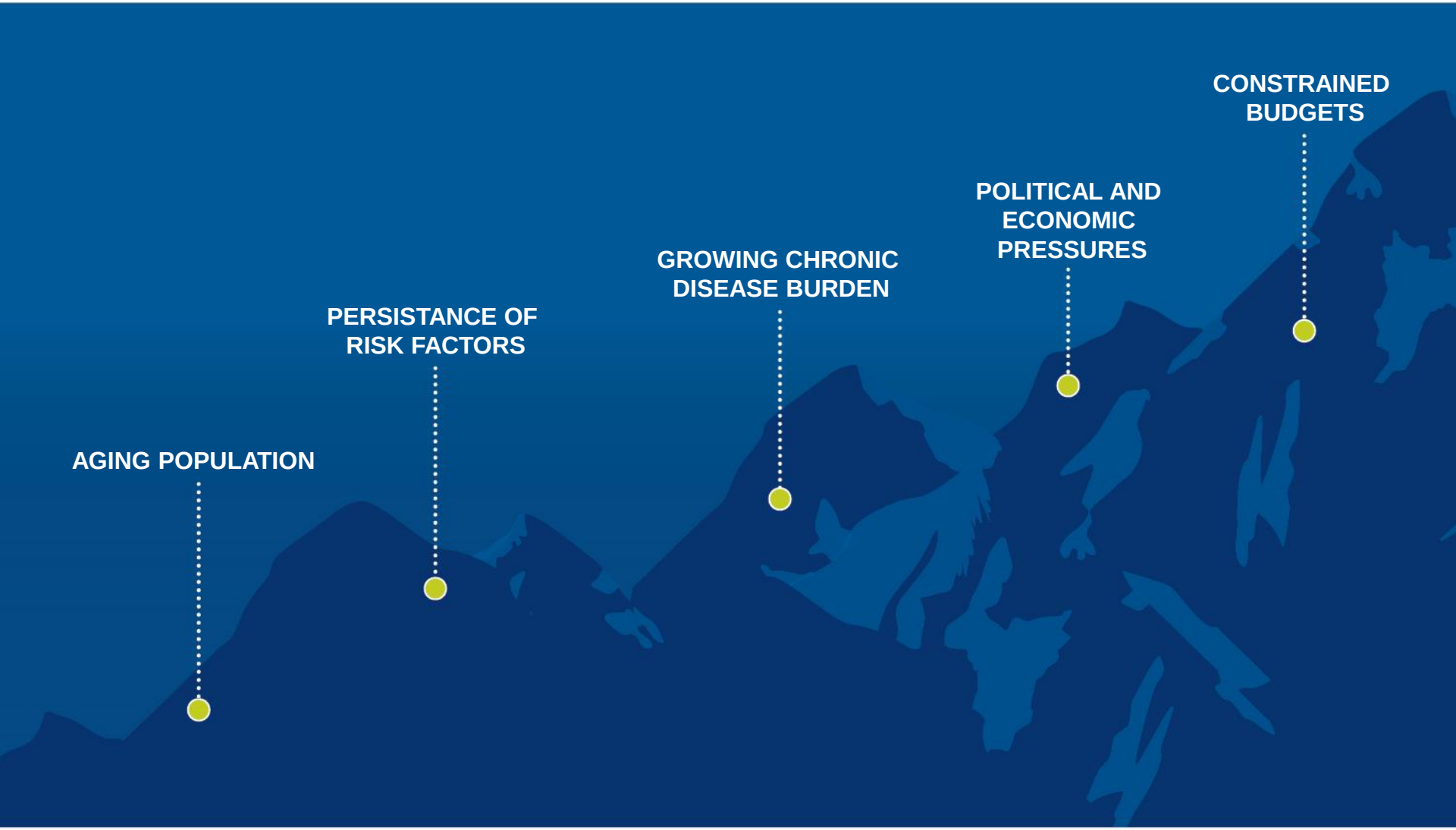


Note: Represents all Phase 0 through Phase IV clinical trials registered with ClinicalTrials.gov Database in 2015.
Source: Health Advances analysis; Clinicaltrials.gov Database (accessed February 2016).

PART 2:

Putting Prescription Medicine Spending in Context

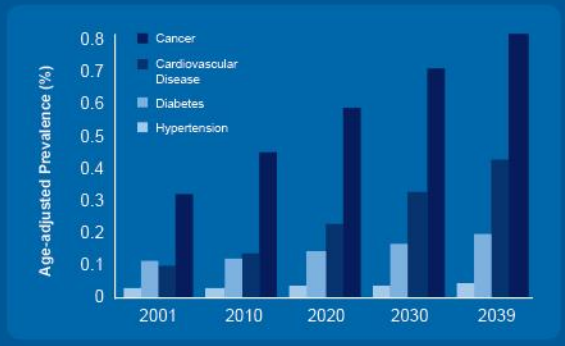
Societies Face Significant Challenges Expanding Access to Health Care While Managing Constrained Budgets



Increasing Prevalence of Chronic Disease Is the Main Driver of Rising Health Care Costs

Canada

3 out of 5 Canadian adults have a chronic disease and rates are increasing by 14% each year[1]



Two thirds of Canada's direct health care costs are spent on chronic disease, amounting to $190 billion annually[1]

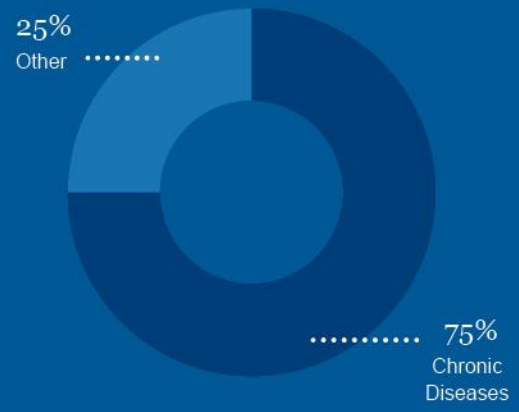
USA

The prevalence of chronic diseases in the US will grow 42% from 2003 to 2023, significantly increasing health care costs[2]

Chronic Disease	2003 Costs	2023 Costs
Overall	$1,300B	$4,200B
Cancers	$319B	$1,106B
Hypertension	$312B	$927B
Diabetes	$132B	$430B

Europe

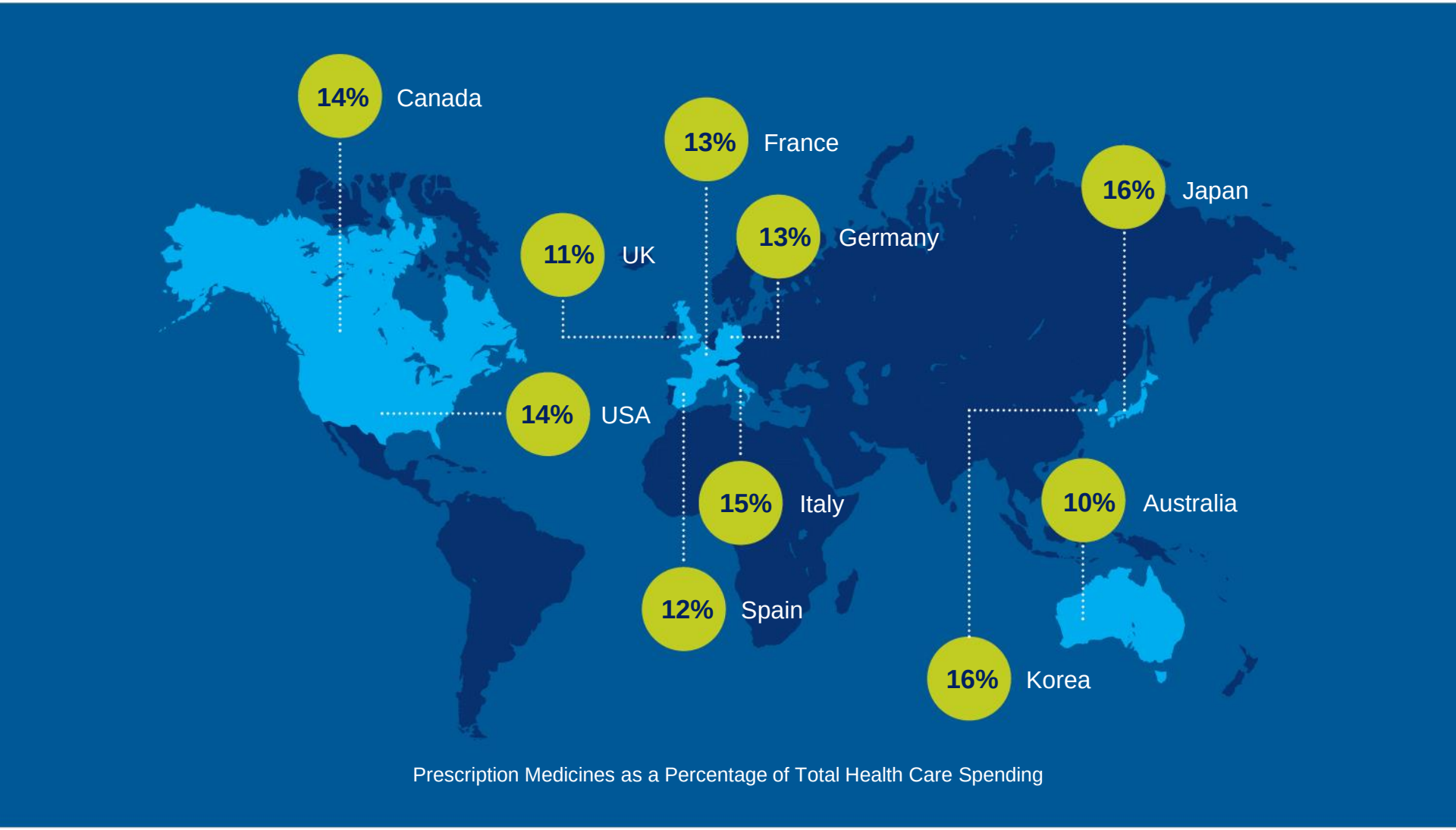
Nearly all Europeans will suffer from a chronic condition before retirement[3]



Three quarters of Europe's health care bill is spent on chronic disease, amounting to €700 billion annually[2]

Source: Health Advances analysis; [1]Public Health Agency of Canada, 2013, Against the growing burden of disease; [2]Bodenheimer, 2009, "Confronting the growing burden of chronic disease," Health Affairs; [3]The Economist Intelligence Unit, 2012, Never too early: Tackling chronic disease to extend healthy life years.

Spending on Prescription Medicines Is a Small Share of Total Health Care Spending



Prescription Medicines as a Percentage of Total Health Care Spending

Note: Total health care spending includes hospital care, physician and clinical services, home health and nursing home care, government administration and net cost of private health insurance, dental, home health and other professional services as well as durable medical equipment.
Source: Health Advances analysis; OECD Health Statistics Database (accessed February 2016); Altarum Institute, 2015, A ten year projection of the prescription drug share of national health expenditures including non-retail; ABPI analysis of UK National Health Service data. Farmindustria analysis of Italian Medicines Agency (AIFA) and National Institute for Statistics (Istat) data.

Spending on Prescription Medicines Is Not the Driver of Total Health Care Expenditure Growth

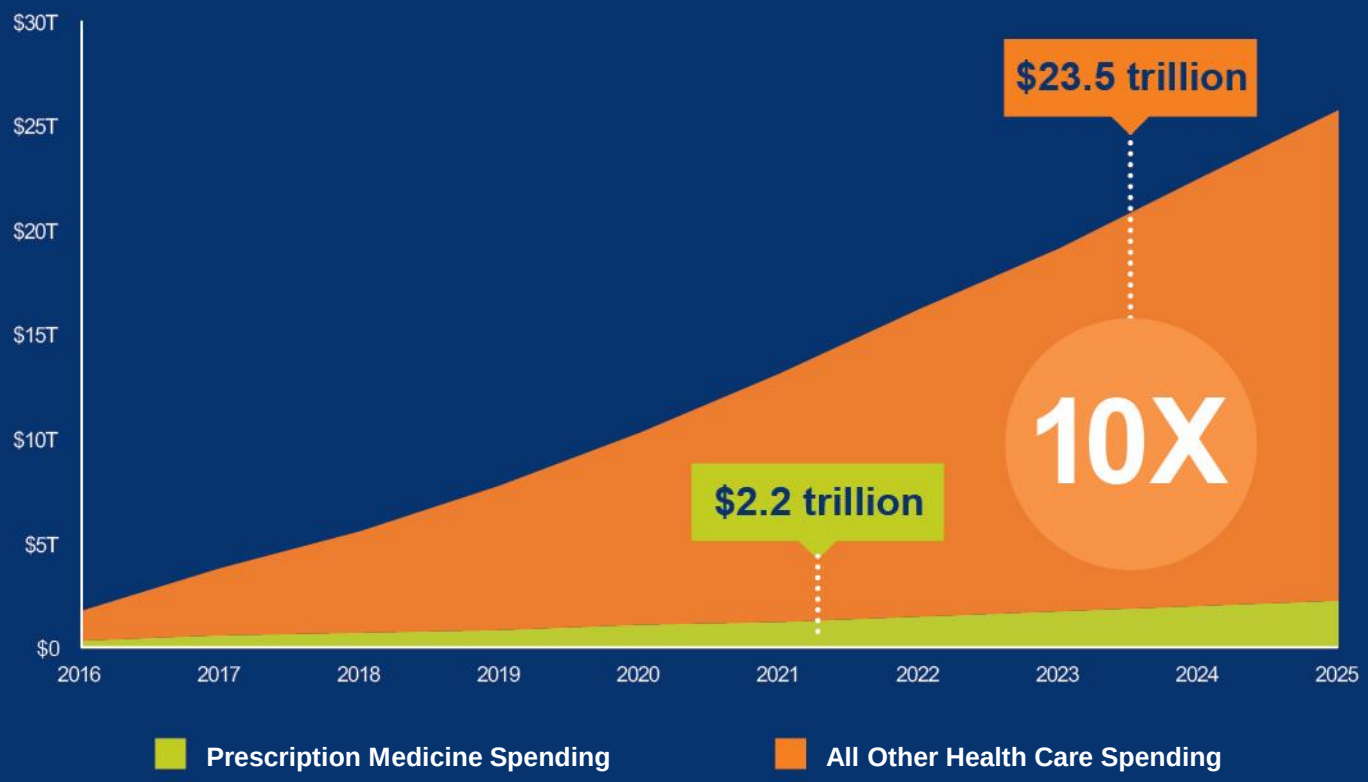
Other health care expenditures are growing faster than prescription medicine expenditures

Average Annual Growth in Per Capita Health Care Expenditure across OECD Countries, 2001-2014

Note: Countries include Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Japan, Korea, Latvia, Luxembourg, Mexico, Norway, Poland, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and US.
Source: Health Advances analysis; OECD Health Statistics Database (accessed October 2016).

Growth in Other Health Care Services Will Be Ten Times Prescription Medicine Spending Growth through Next Decade

Projected Cumulative Growth in Health Care Spending across OECD Countries



Source: Business Monitor International (accessed November 2016).

Putting Spending on Prescription Medicines in Perspective across Key Developed Markets

	USA	Japan	Germany	France	UK	Italy	Canada	Spain
Total Spending on Hospital Care, 2014	$1,786B	$271B	$191B	$124B	$117B	$92B	$70B	$73B
Total Spending on Prescription Medicines, 2014	$277B	$82B	$49B	$34B	$29B	$29B	$22B	$16B
Ratio (Hospital Care / Prescription Medicines)	**6.4**	**3.3**	**3.9**	**3.6**	**4.0**	**3.2**	**3.2**	**4.6**

SPENDING ON
Prescription Medicines

SPENDING ON
Hospital Care

Expenditure on hospital care across countries is
3-6 times the total spending
on prescription medicines

Note: Top seven countries ranked by total health care spending in the OECD. Hospital care includes all curative and rehabilitative care. Pharmaceutical spending for Japan is from 2013, the most recent year reported.
Source: Health Advances analysis; OECD Health Statistics Database (accessed October 2016); ABPI analysis of UK National Health Service data; Farmindustria analysis of Italian Medicines Agency (AIFA) and Italian National Institute for Statistics (Istat) data.

Cancer Medicines Are a Small Share of Treatment Costs

Spending on cancer medicines across the EU represents only
1% of Overall Health Care Spending…

Total Health care Spending
99%

Cancer Drugs
1%

…and only 1/4 of Total Spending on Cancer Care[1]

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Source: Health Advances analysis; Luengo-Fernandez et al., 2013, "Economic burden of cancer across the European Union: a population-based cost analysis," Lancet Oncology.

Case Study

Critics Proved Wrong on Hepatitis C Medicine Spending in the US

What US Payers Claimed Would Happen

"What they have done with this particular drug will break the country… it will make pharmacy benefits no longer sustainable. Companies just aren't going to be able to handle paying for this drug."

–Express Scripts (April 2014)

"This pricing, which Gilead attempts to justify as the cost of medical advancement, will have a tsunami effect across our entire health care system."

–America's Health Insurance Plans (July 2014)

What Actually Happened

"The price is sufficiently low that we can go to our clients and say that they can treat every patient with hepatitis C."

–Express Scripts (January 2015)

"We are receiving market-leading rates from both companies. Neither company wanted to be left off the formulary."

–Prime Therapeutics (January 2015)

"Competitive market forces and hard-nosed bargaining" make 'tremendously effective' new hepatitis C medicines not just more accessible to ailing patients – but also offer good value to the US health care system."

–The New York Times Editorial Board (September 2015)

Case Study

Critics Proved Wrong on New High Cholesterol Medicine Spending

What Critics Claimed Would Happen

"These drugs are not only expensive but they present a financial challenge to the health care industry."

– Harvard Pilgrim Health Care (September 2015)

"While these drugs are being viewed as breakthroughs, they also have the potential to wreck financial havoc on clients who do not proactively manage."

– Express Scripts (July 2015)

"Given the number of people potentially eligible for treatment with PCSK9 will number in the millions, the potential overall expenditures by payers are huge."

– CVS Health (July 2015)

"Imagine if everyone on statins in the UK, around seven million, changed to PCSK9 inhibitors. This would cost £56 billion pounds a year. A tidy little sum. Half of the entire NHS budget."

– Dr. Malcomn Kendrik, UK General Practitioner (December 2015)

What Actually Happened

"We are in a situation where we can bargain with the drug manufacturers to get a significant discount in return for an exclusive deal."

– CVS Health (November 2015)

"We were able over the course of tough negotiations to get good economics on both products."

– Express Scripts (October 2015)

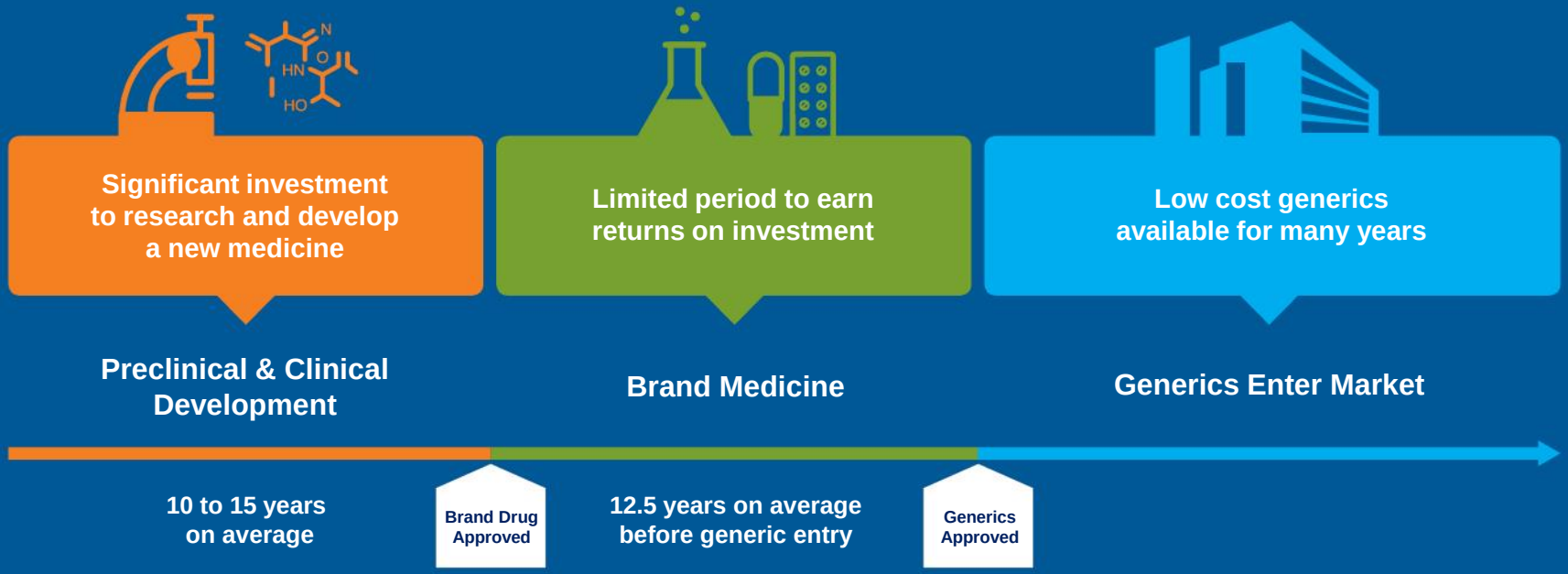
"We feel very confident we can manage this and this won't mess up our clients' budgets in 2016."

– Express Scripts (October 2015)

The Pharmaceutical Life Cycle Promotes Innovation and Long Term Savings

Innovators pave the way for low cost generics to enter the market

ILLUSTRATIVE PHARMACEUTICAL LIFE CYCLE



Most brand medicines face competition from other brands long before a generic enters the market

Note: Average brand medicine lifespan prior to generic entry is based on brand medicines with more than $250 million in U.S. annual sales, which account for 92% of sales of the brand medicines analyzed.
Source: PhRMA, 2014, Drug discovery and development: understanding the R&D process; Grabowski et al., 2016, Updated trends in US brand-name and generic drug competition, Journal of Medical Economics; Tufts Center for the Study of Drug Development, 2014, Costs of developing a new drug.

Savings from the Pharmaceutical Life Cycle Reduce Treatment Costs for the Most Common Conditions

Innovator biopharmaceutical companies produce medical advances leading to improved health and — *eventually* — lower cost generics that bring long-term value

Daily Cost of Top-10 Therapeutic Classes Most Commonly Used by Medicare Part D Enrollees

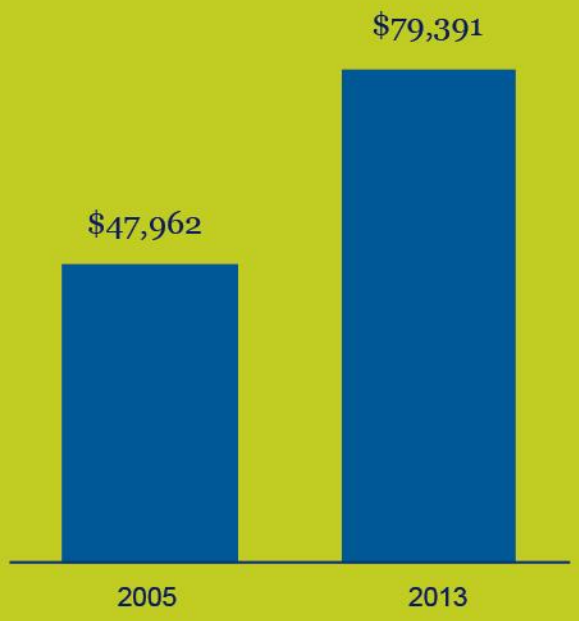
Since 2006, the daily cost for the top-10 therapy areas in Medicare Part D has fallen by nearly half, and projections show that the daily cost of therapy will drop again by more than a third by 2017

Note: The ten therapeutic classes most commonly used by Part D enrollees in 2006 were lipid regulators, angiotensin-converting-enzyme inhibitors, calcium channel blockers, beta blockers, proton pump inhibitors, thyroid hormone, angiotensin II, codeine and combination products, antidepressants and seizure disorder medications.
Source: Kleinrock, 2013, Daily cost of Medicare Part D, IMS Institute for Health Care Informatics.

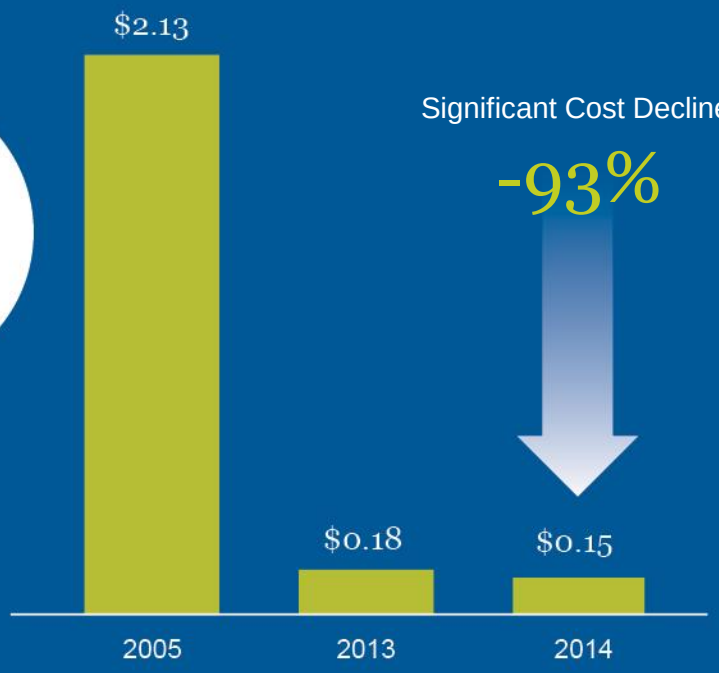
Medical Procedures Become More Expensive Over Time, But Cost Containment Is Built into the Pharmaceutical Life Cycle

Two Approaches to Cardiovascular Disease Management in the United States

Medical Procedure
Percutaneous Coronary Angioplasty (PTCA)



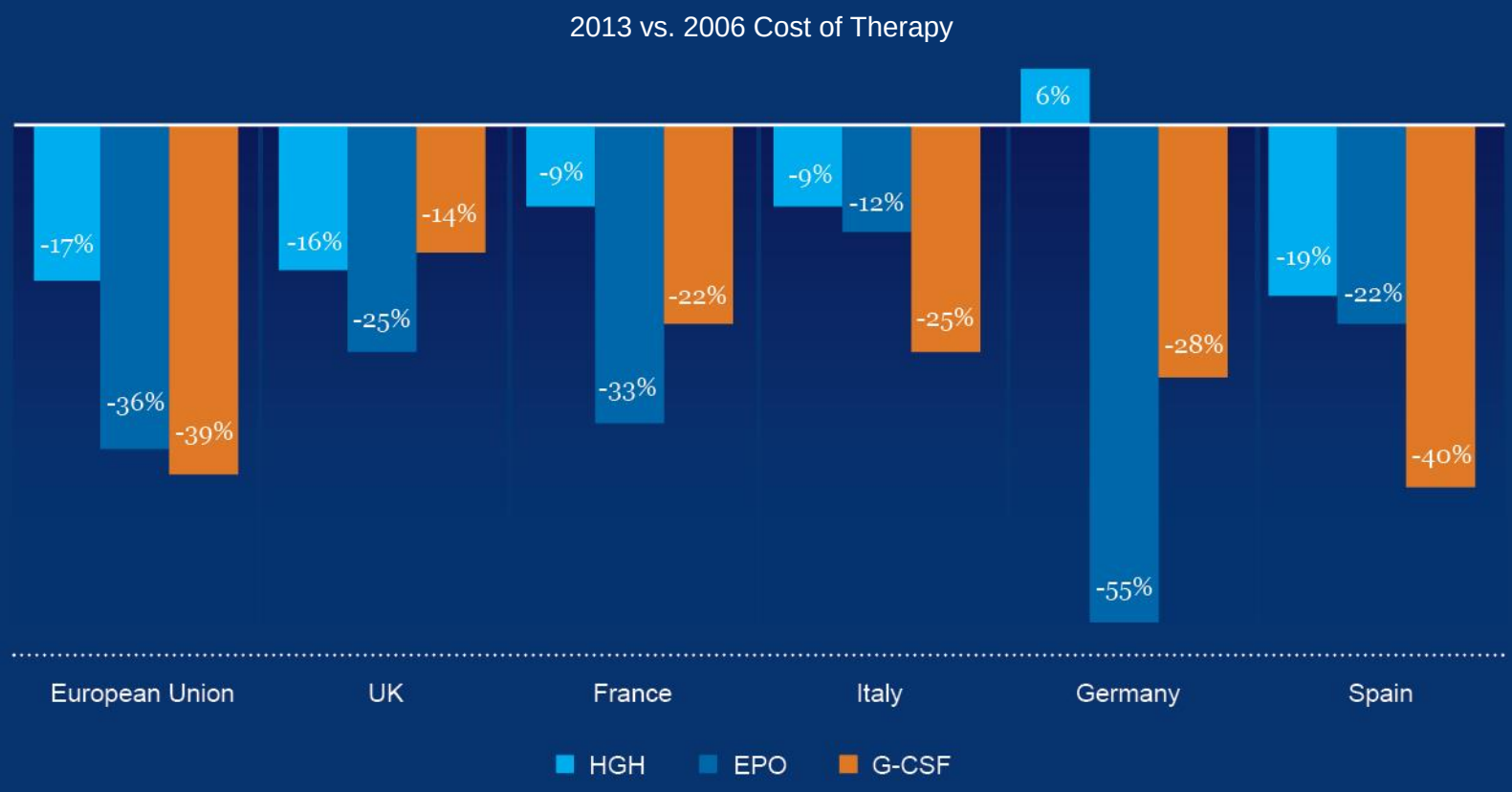
Pharmaceutical Intervention
Atorvastatin 10mg



Source: Average hospital charges for atorvastatin 10mg data adapted from HCUP Hospital Charge database 2005 and 2013; IMS National Sales Perspective invoice price in 2005 (branded Lipitor), 2013 (generic), and 2014 (generic).

Safe and Effective Biosimilars Can Lead to Long Term Cost Savings

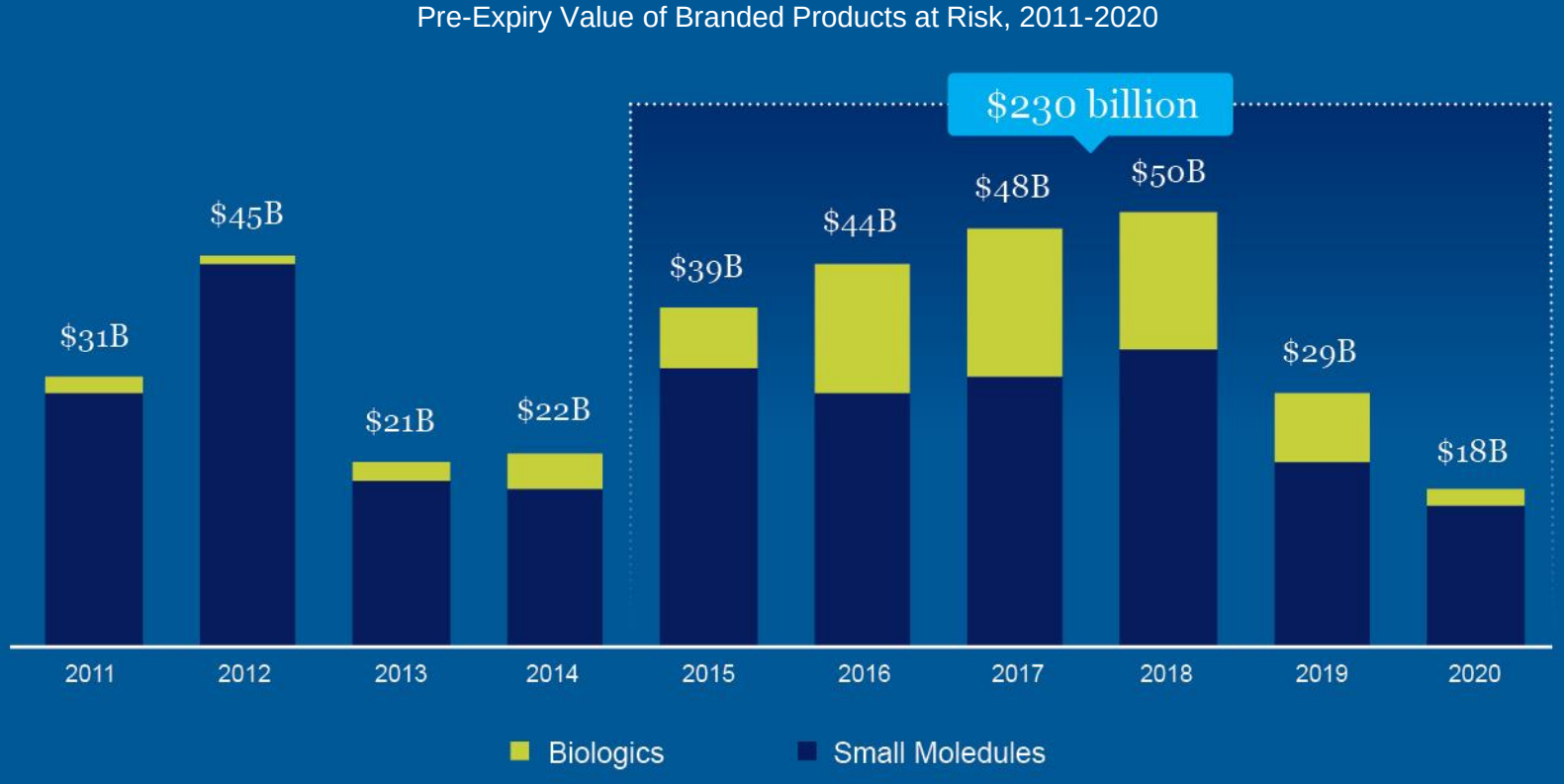
Biosimilar entry decreased the average cost of therapy in Europe



Note: Countries include Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Norway, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, and UK. HGH = Human Growth Hormone (somatropin), EPO = Erythropoietin, G-CSF = Granulocyte Colony-Stimulating Factor.
Source: Health Advances analysis; IMS Institute for Health Care Informatics, 2014, Assessing biosimilar uptake and competition in European markets.

$230 Billion of Developed Market Brand Sales Are Projected to Face Generic Competition from 2015 to 2020

Projections underscore cost savings from the pharmaceutical lifecycle



Note: 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 and biosimilar availability, and historic analogues where available. Biologics and small molecules are modeled separately. Biologic brand losses are based on any non-original biologic competitor, regardless of approval type.
Source: IMS Institute for Health Care Informatics, 2015, Global Medicines Use in 2020: Outlook and Implications.

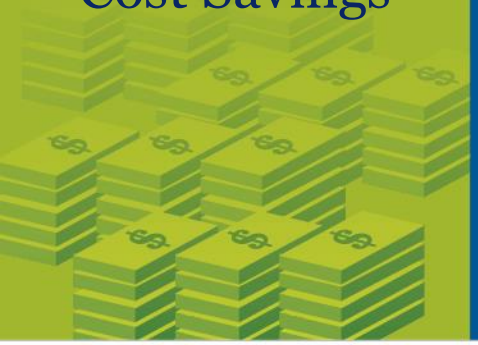
Greater Use of Generics in Many Countries Could Produce Additional Cost Savings

While Nearly

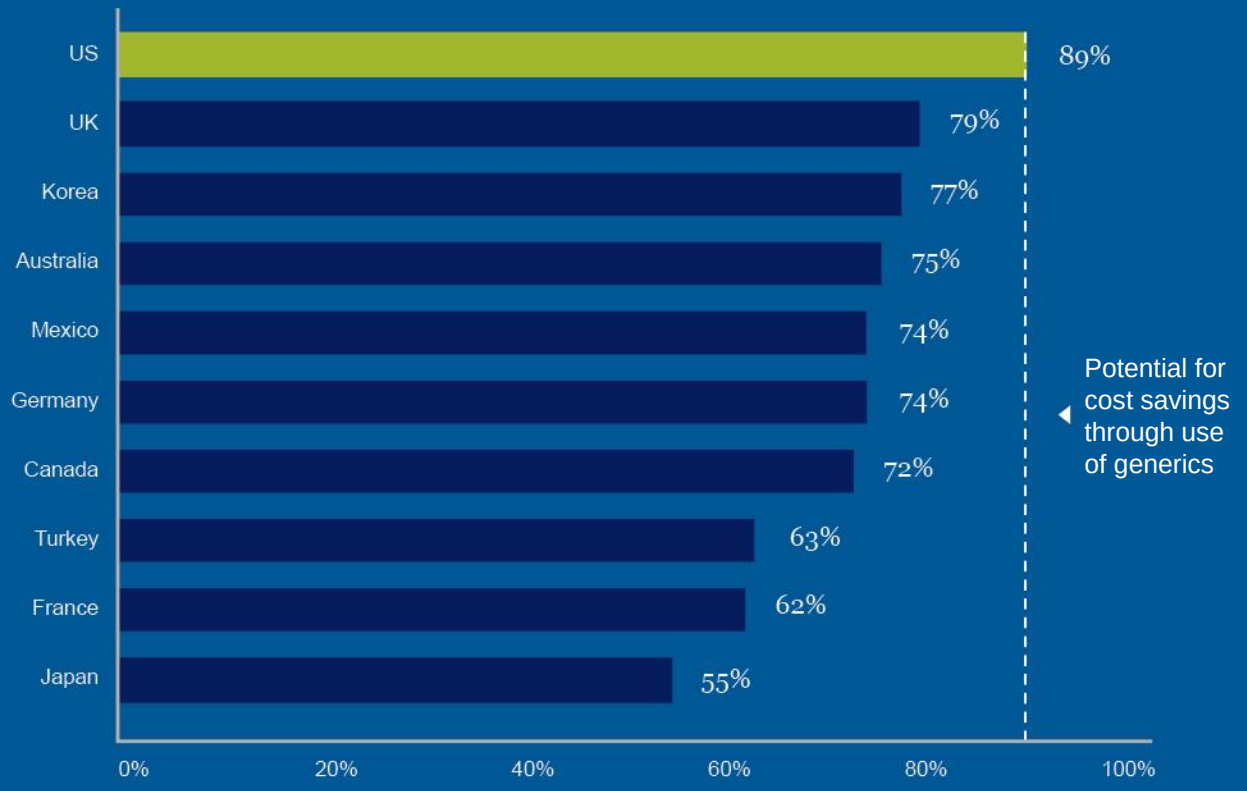
9 out of every **10**

US prescriptions are filled with generics, other developed markets are not taking advantage of potential generic

Cost Savings



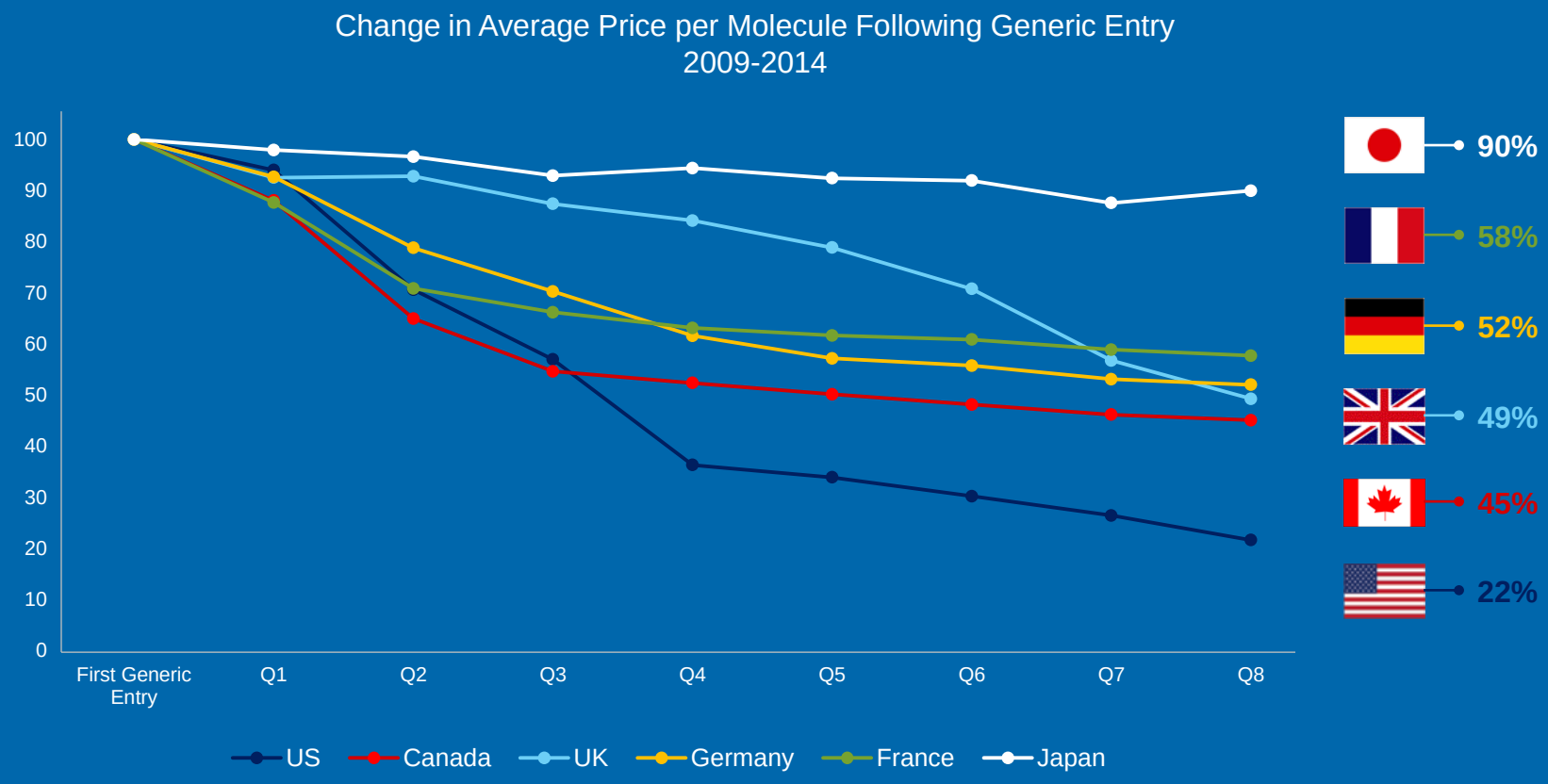
Generic Medicine Share of the Total Pharmaceutical Market, 2015



Source: IMS National Sales Perspectives and IMS MIDAS audited data.

Many Countries Could Achieve Lower Costs With a More Competitive Generics Market

Prices in Many Markets Do Not Fall as Far or as Fast as Those in the U.S.



Note: Sample includes all oral solid products that lost market exclusivity in a given country from 2009-2014.
Source: PhRMA analysis of IMS Analogue Planner: Off Patent (accessed December 2016).

PART 3:

Challenges and Opportunities in the Marketplace

The Economics of Medicine Has Changed Markedly in Recent Years

Biopharmaceutical Innovation

THE SCIENCE IS HARDER AND MORE COSTLY

Researchers targeting more complex diseases

Rise of personalized medicine

Higher regulatory hurdles

Longer, more complex trials

Genomics and molecular medicine are complex new frontiers

Increased costs of R&D

THE MARKET IS RISKIER AND TOUGHER

Ad-hoc fiscal austerity measures

Greater cost-sharing and coverage restrictions

Complex HTA processes delaying or denying patient access to the best care

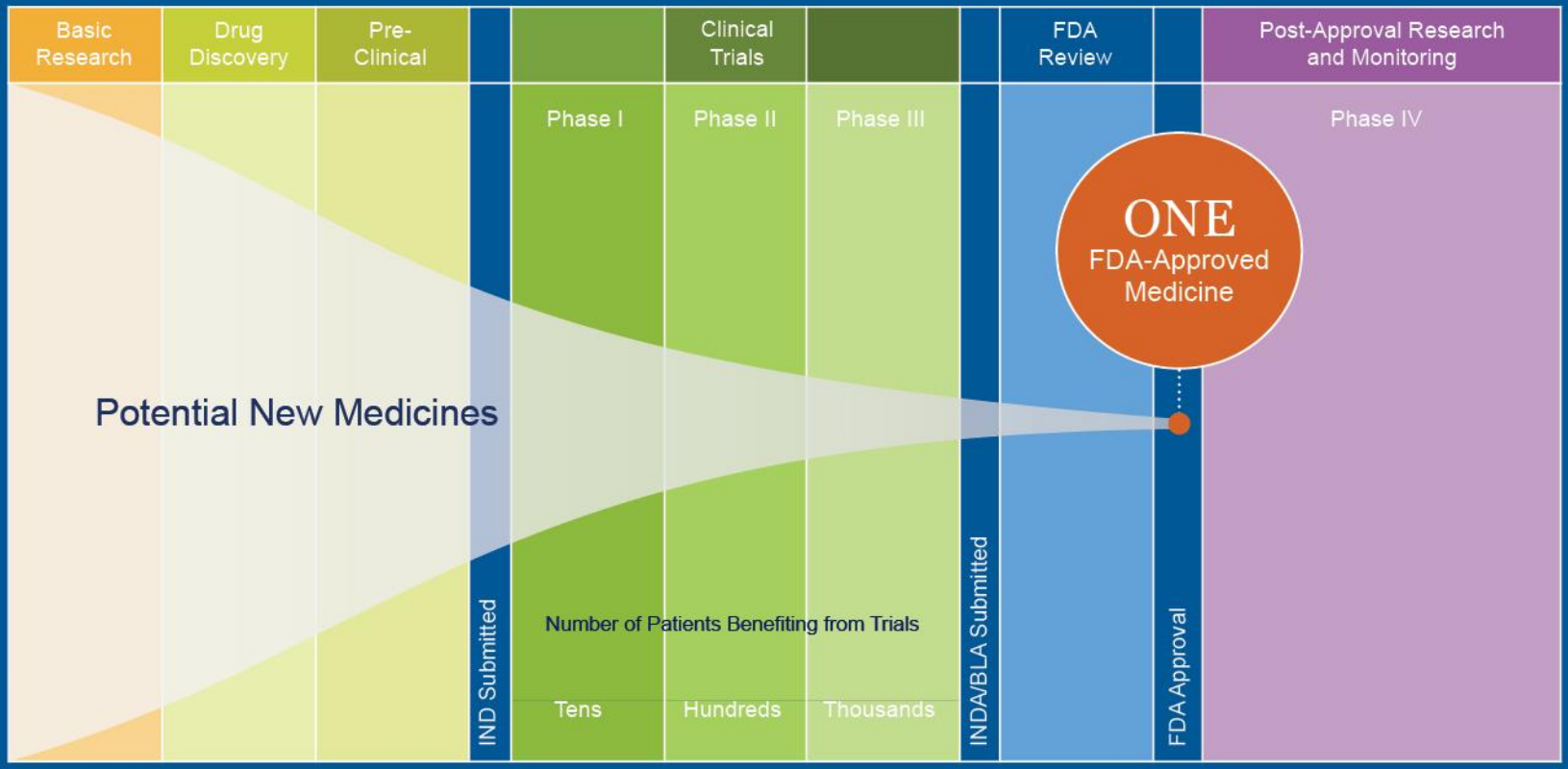
Eroding intellectual property protections

Increased reference pricing and parallel trade

Payers mandating off-label use to reduce costs

The Biopharmaceutical Research and Development Process

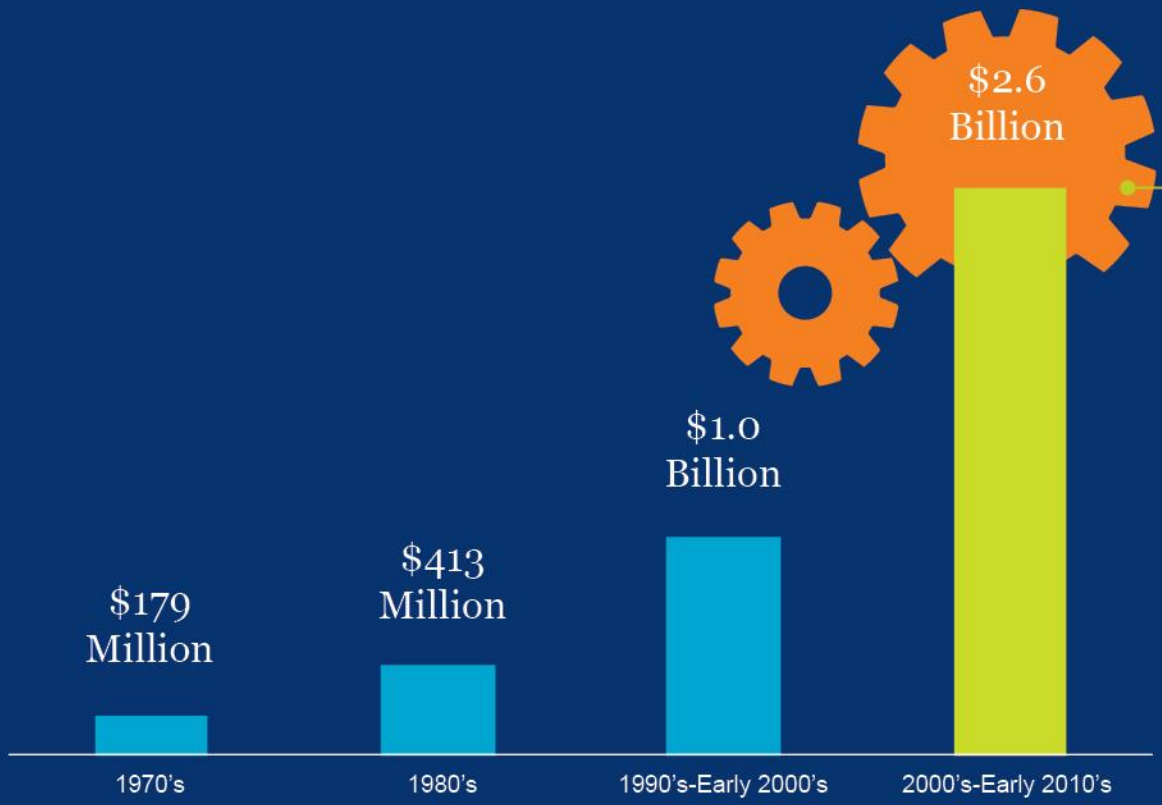
From drug discovery to regulatory approval, developing a new medicine on average takes 10 to 15 years and costs $2.6 billion



Note: The average R&D cost required to bring a new, US Food and Drug Administration approved medicine to patients is estimated to be $2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval. IND = Investigational New Drug Application, NOA = New Drug Application, BLA = Biologics License Application.
Source: Tufts Center for the Study of Drug Development.

The Cost to Develop a New Medicine More Than Doubled Over the Past Decade

Average Cost to Develop an Approved Medicine – Including Setbacks

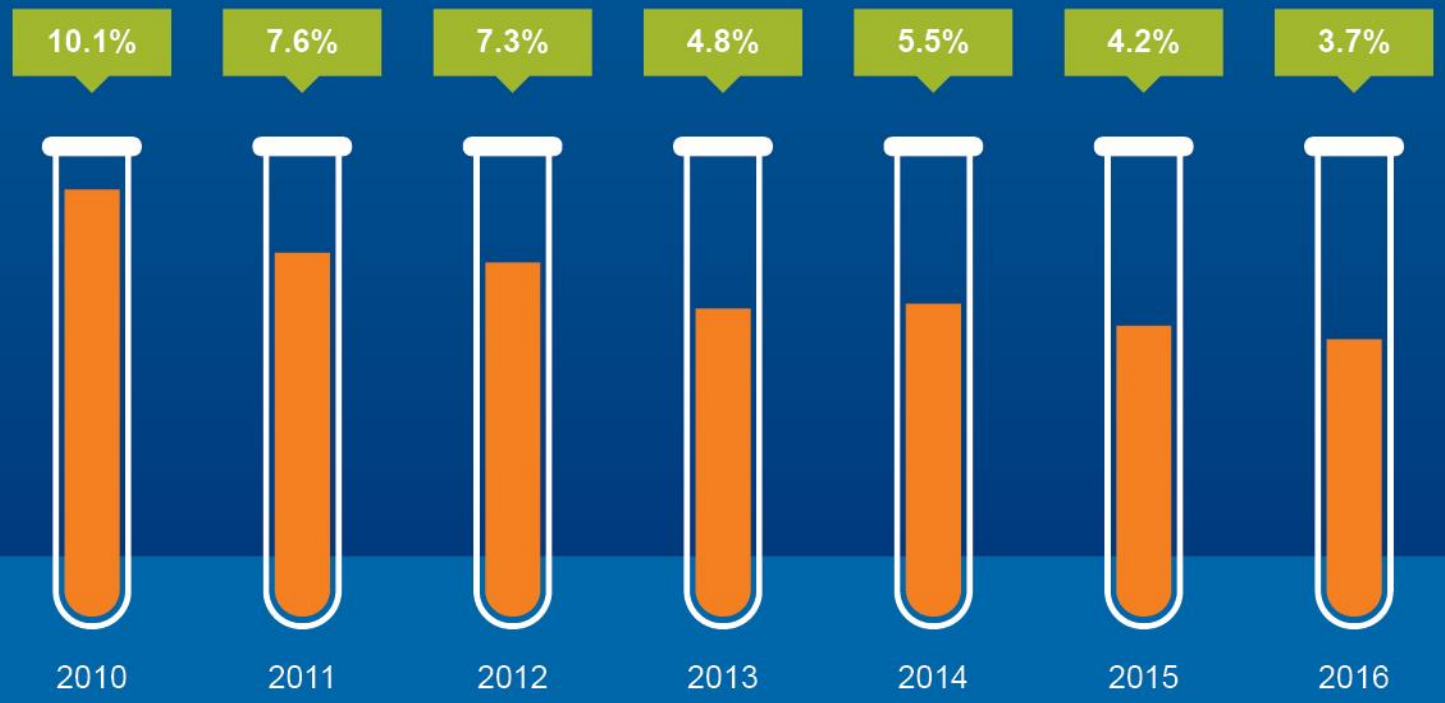


KEY DRIVERS INCLUDE:

- Increased trial complexity and regulatory burdens
- Increased focus on areas where science is difficult and failure risks high
- Expanded research burden to meet payer demands

Note: In constant 2013 dollars.
Source: Tufts Center for the Study of Drug Development.

Returns on Biopharmaceutical R&D Continue to Decline



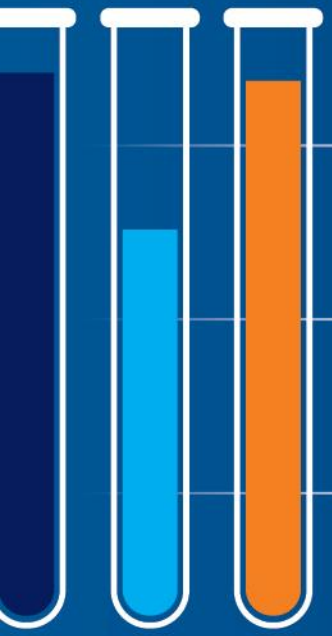
Projected Return on Late-Stage Pipelines of Leading Biopharmaceutical Companies

Source: Deloitte, 2016, Measuring the return from pharmaceutical innovation.

Despite Inherent Risk and Challenges of Drug Development, New Treatments and Cures Are Giving Hope to Patients

Pharmaceutical development in the US led to 21 breakthrough therapy approvals in 2015[1]…

…which have the ability to change the lives of millions of patients



4	Non-Small Cell Lung Cancer	350,000[2]
2	Multiple Myeloma	90,000[3]
2	Cystic Fibrosis	30,000[4]
2	Diabetic Retinopathy	7.7 million[5]

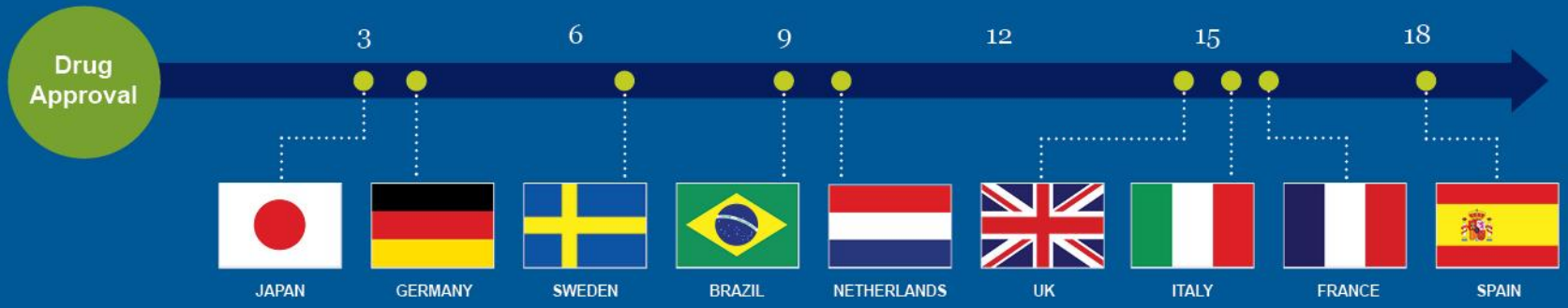
US PATIENTS

And there are 7,000 more medicines in development

Note: Based on US prevalence rates.
Source: Health Advances analysis; [1]US Food and Drug Administration, 2015, CDER breakthrough therapy designation approvals as of December 31, 2015; [2]American Cancer Society, 2015, Lung cancer report; [3]SEER Cancer Statistics Database (accessed March 2016); [4]Cystic Fibrosis Foundation website; [5]National Eye Institute website.

Industry-Sponsored Early Access Programs Mitigate Delays from Lengthy Regulatory and Reimbursement Review Processes

Average Months of Delay in National Patient Access Following Drug Approval



FRANCE

Over 12,000 patients received new medicines in 2014

through industry-sponsored early access programs in collaboration with the French ATU (temporary authorization for use) program[1]

UNITED KINGDOM

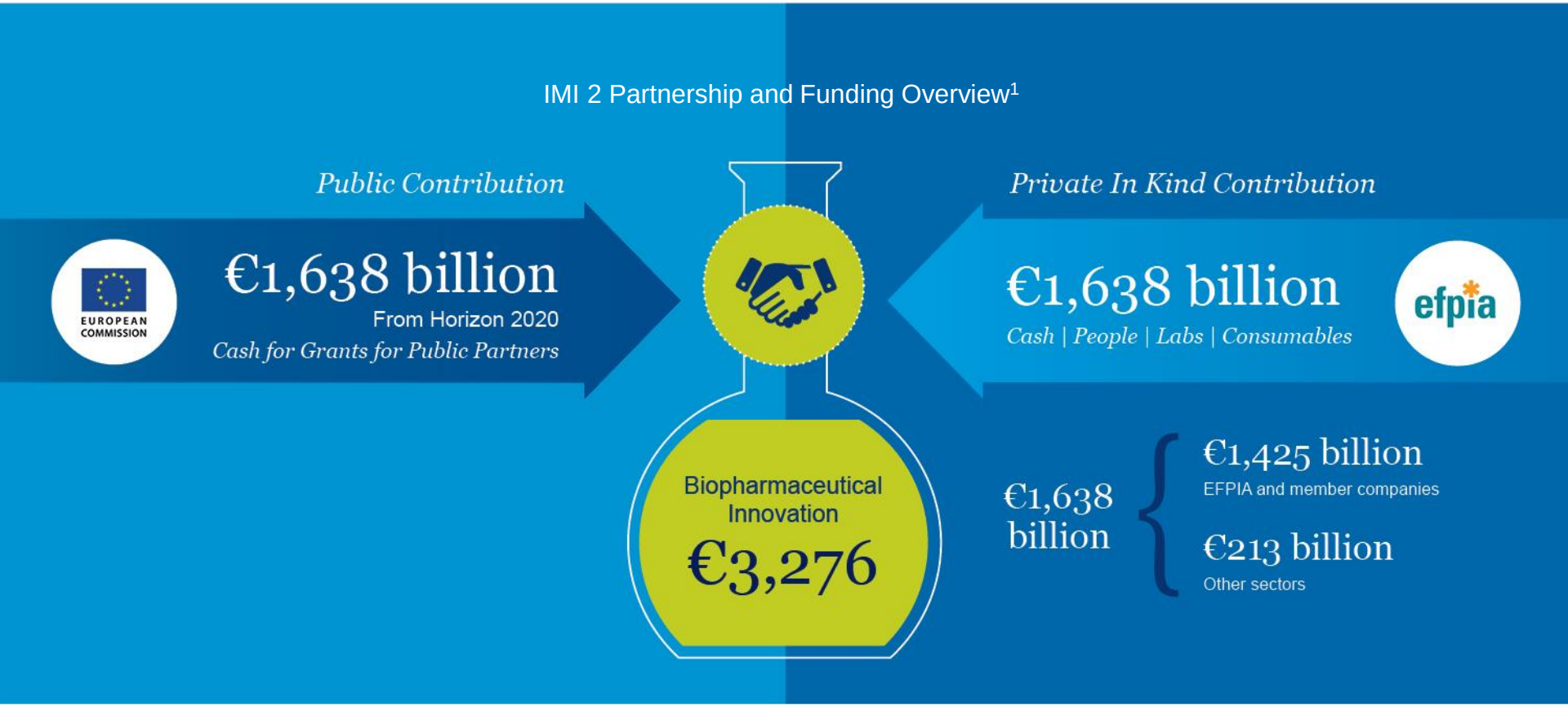
Early access to a new medicine for patients suffering from melanoma was

approved four months before market authorization was granted[2]

Industry Helps Patients Get New Medicines Despite Process Delays

Note: Timelines for EU5 countries are based on products with first sales in 2014. Timelines for Spain, Italy, UK, and France represent time to reimbursement approval. Additional time may be required in Italy and Spain for regional or local negotiations. Timeline for Japan may range from 2-3 months based on publicly-available descriptions of the reimbursement approval process.
Source: Health Advances analysis; [1]French National Agency for Medicines and Health Products Safety, 2014, Annual Report; [2]Medicines and Healthcare Products Regulatory Agency, 2015, Early access to medicines scheme: Scientific opinion for pembrolizumab.

The Challenges Facing Health Care Systems and Innovators Must Be Addressed through Successful Collaboration



Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI) is the **world's largest public-private initiative in the life sciences**. IMI 2, a joint undertaking between the European Union and EFPIA, will support collaborative research projects and build networks of industrial and academic experts to boost pharmaceutical innovation in Europe

Source: [1]EFPIA, 2014, Annual report.

International Experience Shows that Key Policies Are Needed to Promote Value-Based Health Care

Industry Supports Pragmatic Solutions to Address Cost Concerns

Better quality measurement and value assessment tools

Outcomes-based incentives and innovative financing

Appropriate use of medicines

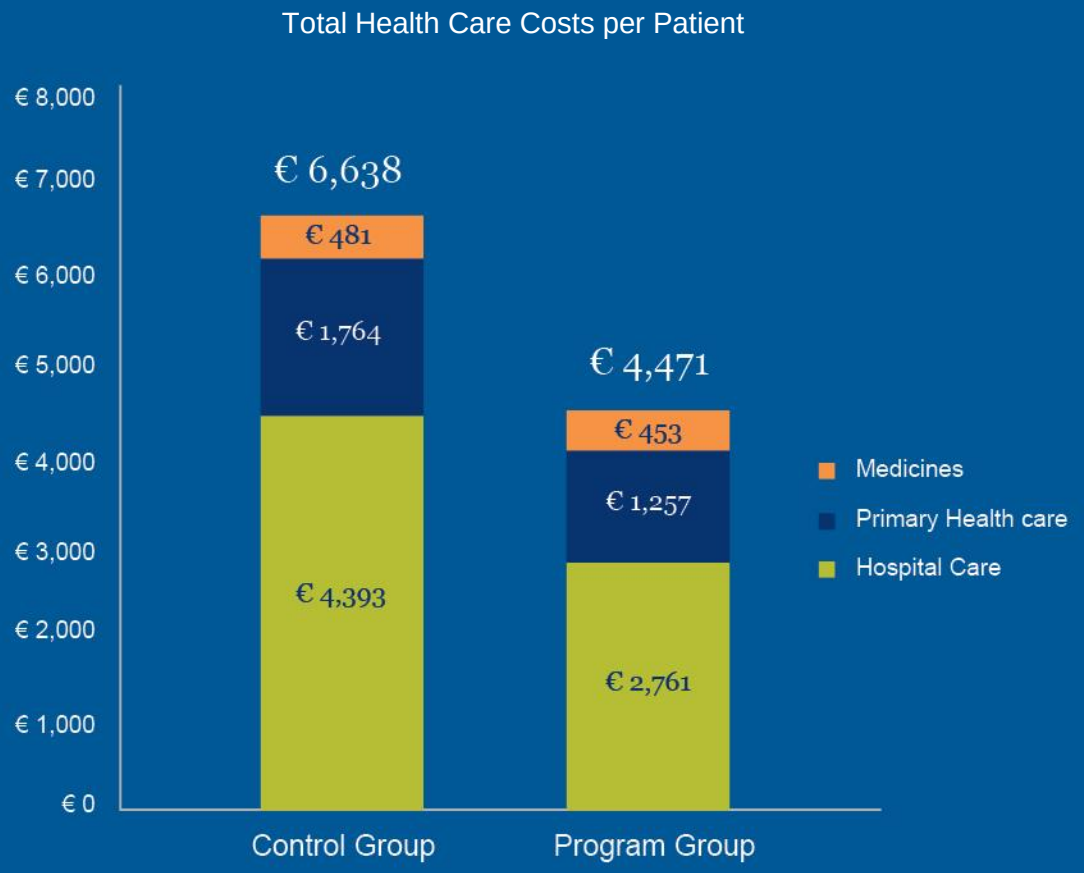
Initiatives Focused on Health Outcomes Instead of Only Cost Containment Can Improve Quality of Care and Reduce Overall Costs

A recent study in Sweden targeting disease management found that patients enrolled in a heart failure program involving regular follow-up* with specialized nurses led to

30%

reduced costs and improved outcomes

through fewer hospital admissions and GP visits



*Regular follow-up included frequent phone and in-person contact with nurses and physicians to optimize patient's heart failure treatment according to current guidelines, as well as receipt of information about heart failure from a validated computer-based awareness program.
Source: Agvall, 2014, "Resource use and cost implications of implementing a heart failure program for patients with systolic heart failure in Swedish primary health care," International Journal of Cardiology.

Medicines Are Part of the Solution and More Can Be Done Together

Governments, Providers, and Payers

Improve Efficiency

Look at all health care costs, reduce administrative costs and waste, and improve efficiency

Pay for Value

Support evidence-based care and empowered patients and providers, backed by sound research and quality measures

Find Solutions

Avoid blanket policies that chill investment, and collaborate to find new approaches

Biopharmaceutical Companies

Continue developing innovative therapies, promote medication adherence, and maintain efforts to support broad patient access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