



Prescription Medicines: International Costs in Context

March 2017



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

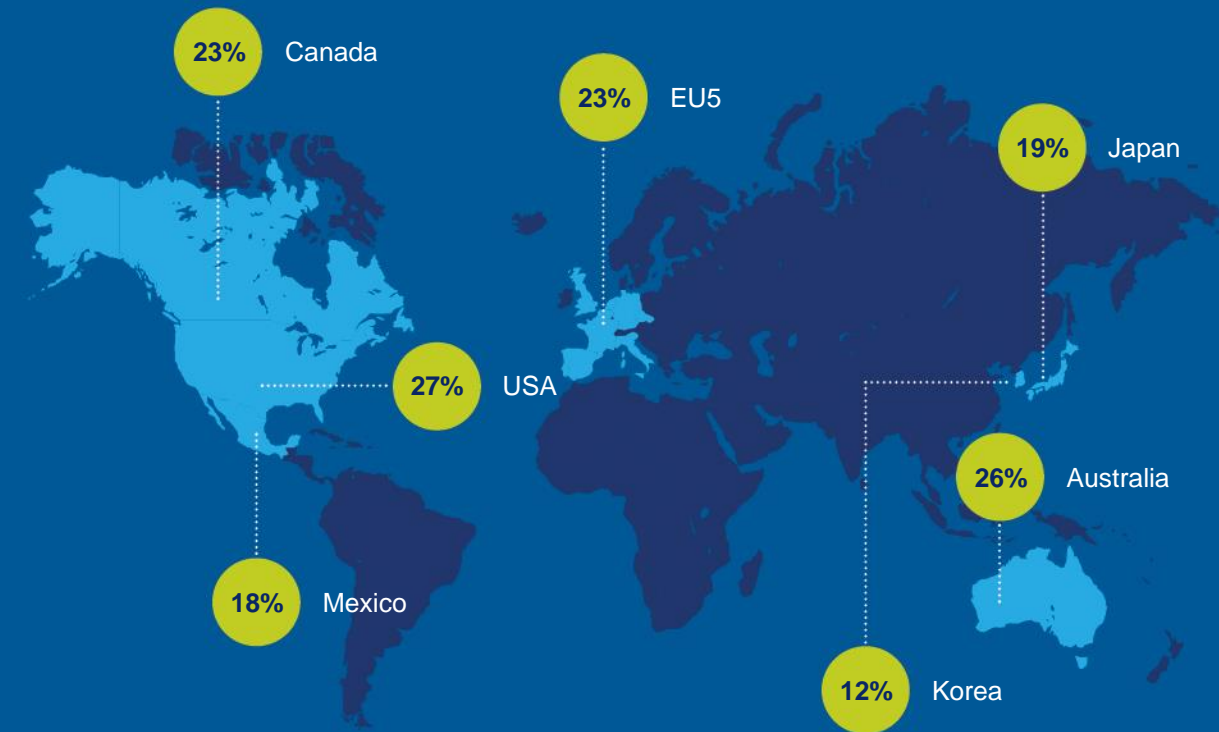


Today, 2 out of 3 people diagnosed with cancer survive at least 5 years²

Approximately 83% of survival gains in cancer are attributable to new treatments³

Percent Decline in Cancer Mortality Rates Since 1991

1991 to 2014 – All Cancers¹



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



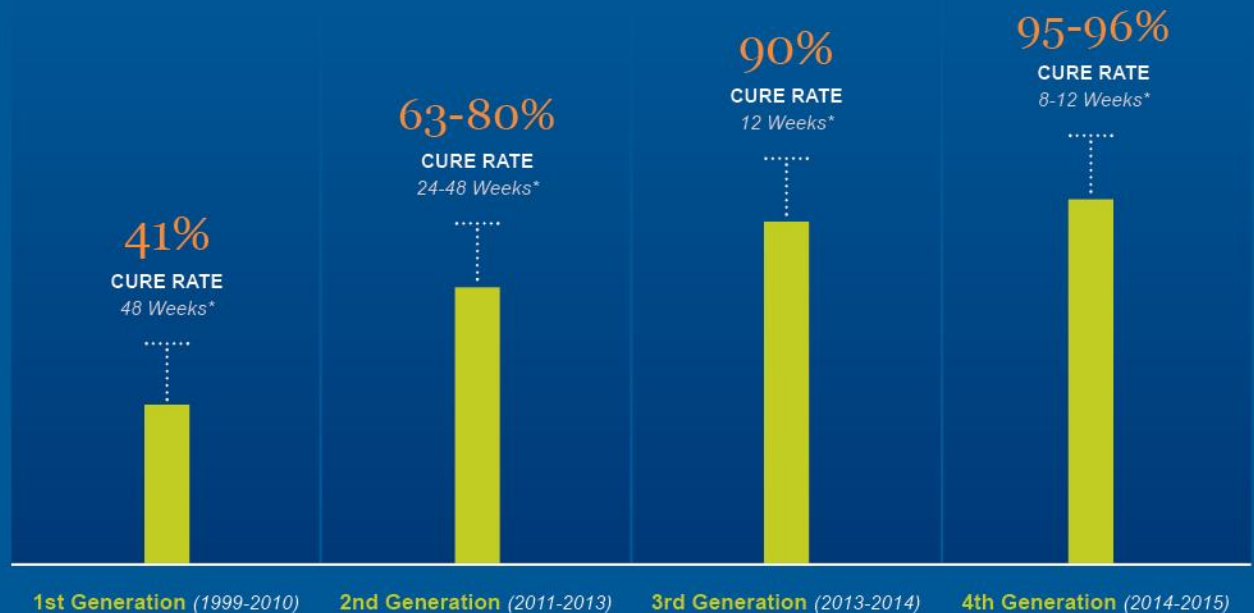
HEPATITIS C VIRUS

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



of treated patients with only 8-12 weeks of treatment

+133% cure rate increase for patients in Europe¹



IMPROVED TOLERANCE AND EASE OF TREATMENT



Interferon and Ribavirin (IFN-R) Injection



Protease Inhibitors with IFN Injection



Polymerase Inhibitors with IFN Injection



Oral Combination Therapies

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 treatment¹



Diabetes

Between 2000 and 2012, new therapies contributed to a 48% and 31% decline in the diabetes death rate in Korea and Canada, respectively²



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 disease³



Death rates for
non-communicable diseases

declined nearly
20%

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

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 program¹



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 2010²

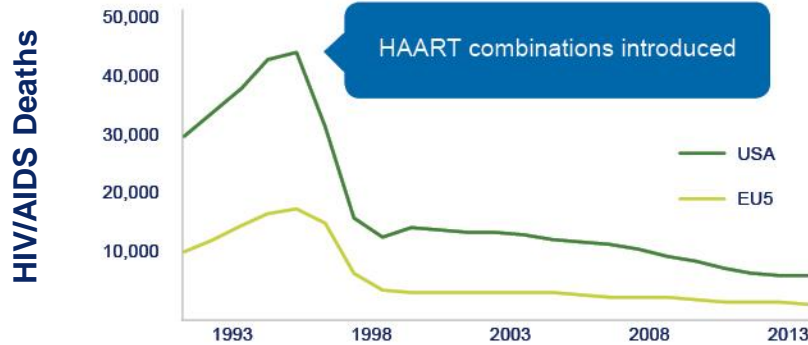


Mexico

In Mexico, the introduction of the rotavirus vaccine in 2007 led to a **46% reduction** in annual diarrhea-related mortality among children under five³

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

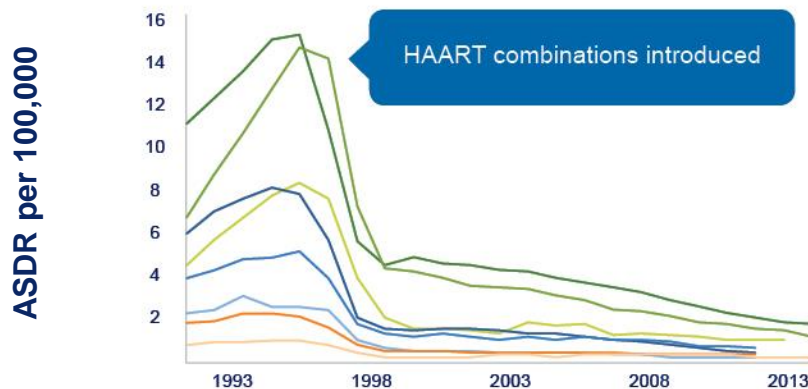
HIV/AIDS Deaths, USA and EU5¹



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%

Biopharmaceutical Companies Have Driven A Decade of Advances in Medicines

2005

- First new kidney cancer medicine in over a decade
- 3 new therapies for diabetes

2007

- New class of medicines to treat high blood pressure
- First treatment for fibromyalgia

2009

- First treatment for peripheral T-cell lymphoma
- First new medicine for gout in 40 years

2011

- First lupus drug in 50 years
- 2 new personalized medicines

2013

- 2 new personalized medicines to treat the most dangerous forms of skin cancer
- A new oral treatment for multiple sclerosis

2015

- 2 new drugs for difficult-to-treat forms of high cholesterol
- New cystic fibrosis treatment for patients with a genetic mutation that is the most common cause of the disease

2006

- First vaccine for the prevention of cervical cancer
- First medicine for chronic chest pain in 20 years
- First once-a-day HIV medicine

2008

- A new type of treatment for Crohn's disease
- The first medicine for symptoms of Huntington's disease

2010

- 2 new multiple sclerosis drugs
- First therapeutic cancer vaccine

2012

- First drug to target root cause of cystic fibrosis
- First drug to treat Cushing's disease

2014

- Oral treatments for HepC provide cure rates upwards of 90%
- 17 new drugs to treat patients with rare diseases

Improved Understanding of Disease and Personalized Medicines Have Increased Patient Survival

Personalized medicines have improved the outlook for patients with blood cancers in Europe¹

Chronic Lymphocytic Leukemia

5-year survival rates have grown to 70%³

Hodgkin's Lymphoma

5-year survival rates have grown to 80%³

INCREASED SURVIVAL RATE

Today,
230 medicines
are in development for
blood cancers in Europe*²

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

Biopharmaceutical Companies Have Made Continued Progress Against Rare Diseases



There are approximately

7,000

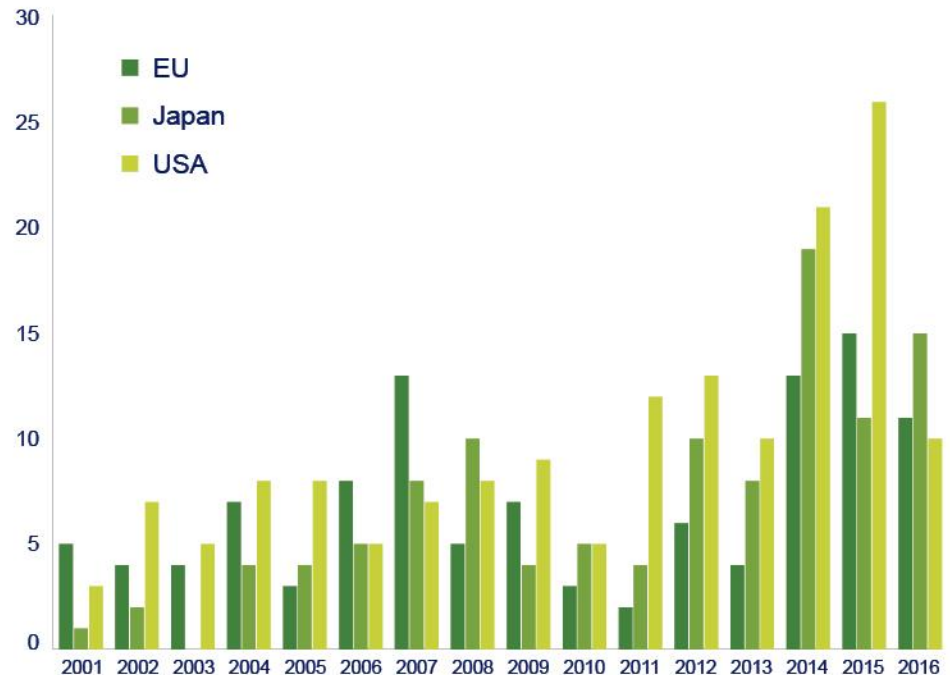
different rare diseases worldwide

1 in 10

individuals in the USA and Europe are living with a rare disease²



Growth in Orphan Drug Approvals¹



Medicines Often Demonstrate Far Greater Benefits than Understood at Initial Approval

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



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

Medicines in Development





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



The US health care system could
save \$215 billion annually
if medicines were used properly¹

In Europe, medication non-adherence
costs governments an estimated
€125 billion
and contributes to the premature
deaths of nearly 200,000
Europeans a year²



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 Europe¹



€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 Europe¹

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 1995–2004²

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



United States

\$376 billion

Costs avoided by 2050 from the development of a new medicine that delays the onset of Alzheimer's disease¹ by

just five years



England

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 dementia²



Germany

€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%**



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

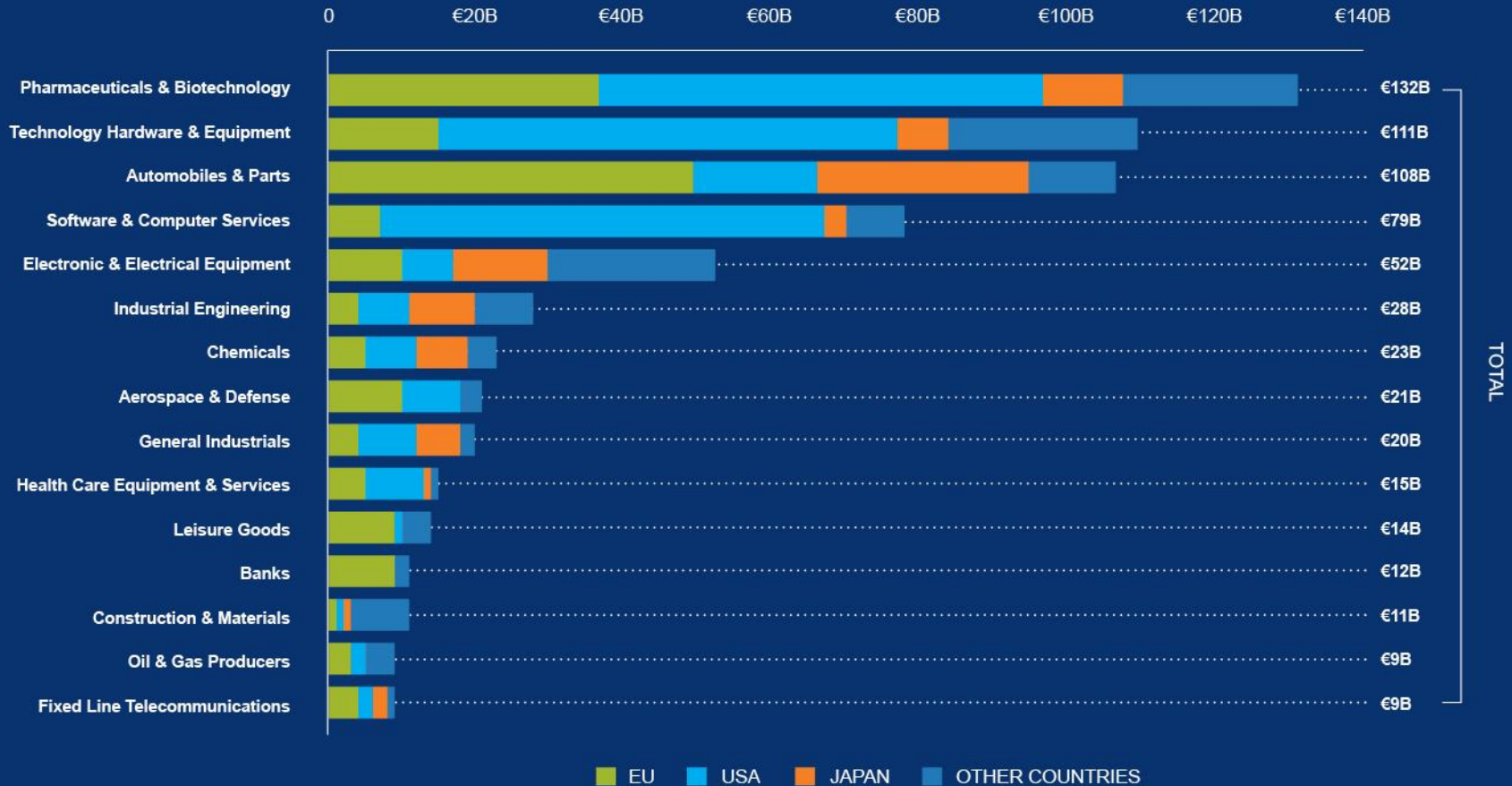
MEXICO
680,000
jobs

CANADA
80,000
jobs

AUSTRALIA
64,000
jobs

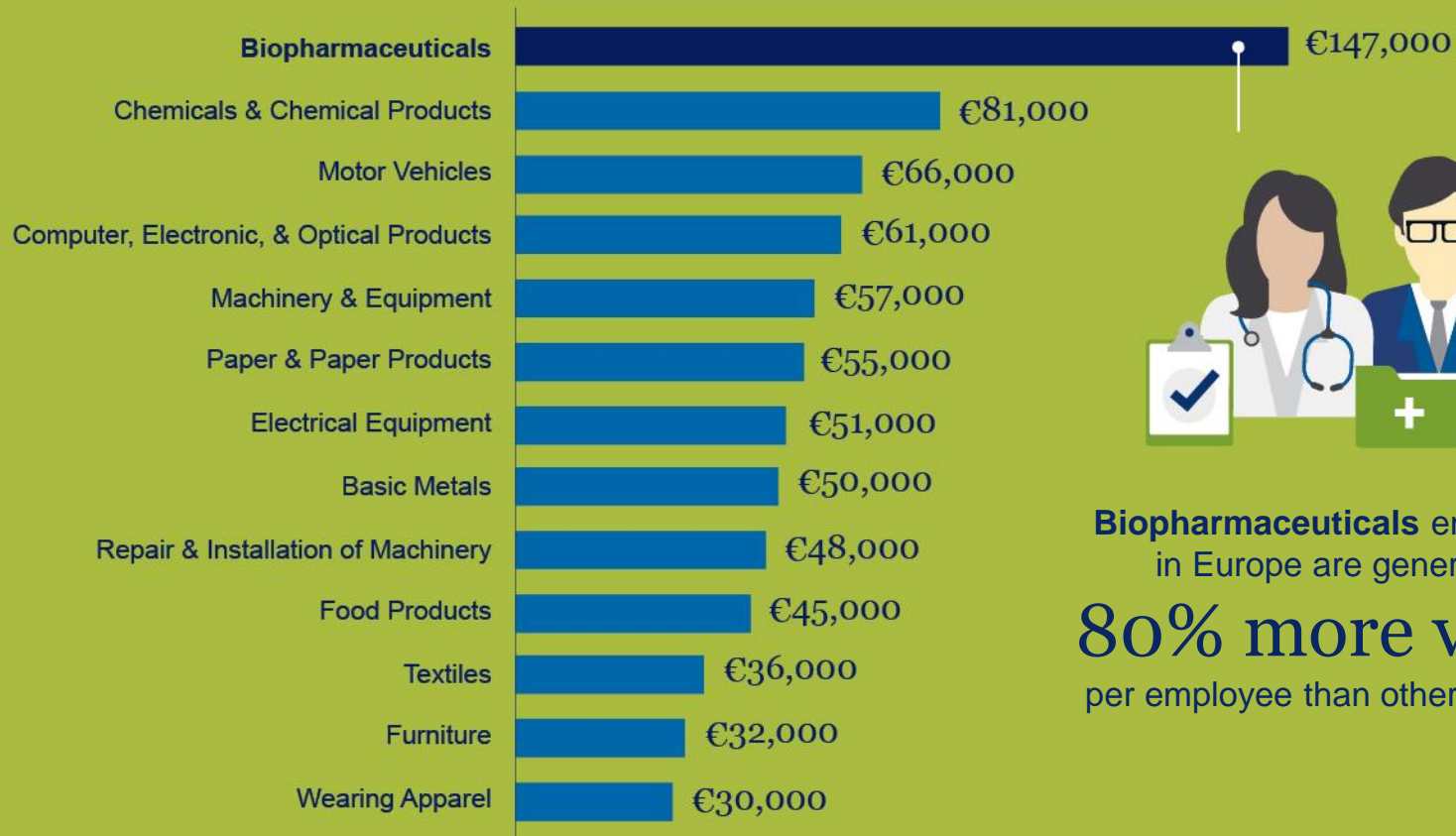
The Biopharmaceutical Sector Is the Single Largest Funder of Business R&D in the World

R&D Investment by Sector



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

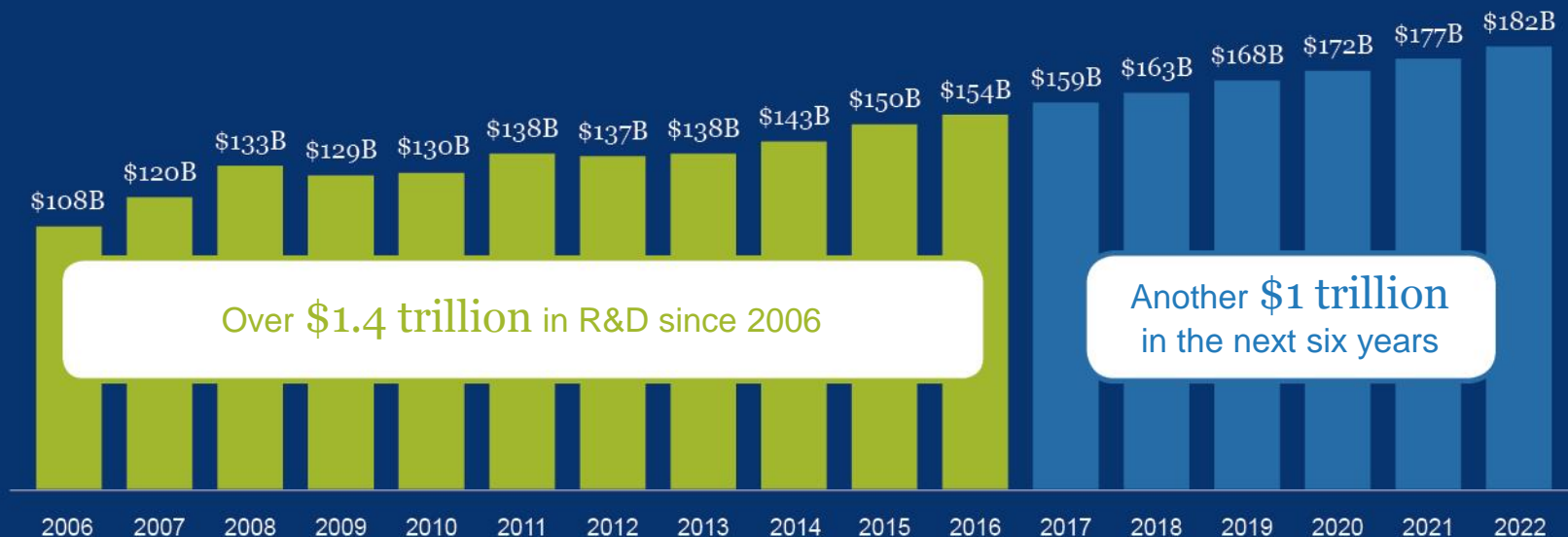
Gross Value Added per Employee in Europe, 2012



Biopharmaceuticals employees in Europe are generating **80% more value** per employee than other industries

Biopharmaceutical Companies Have Invested Billions to Bring Innovative Therapies to Market

Worldwide Pharmaceutical R&D Investment¹



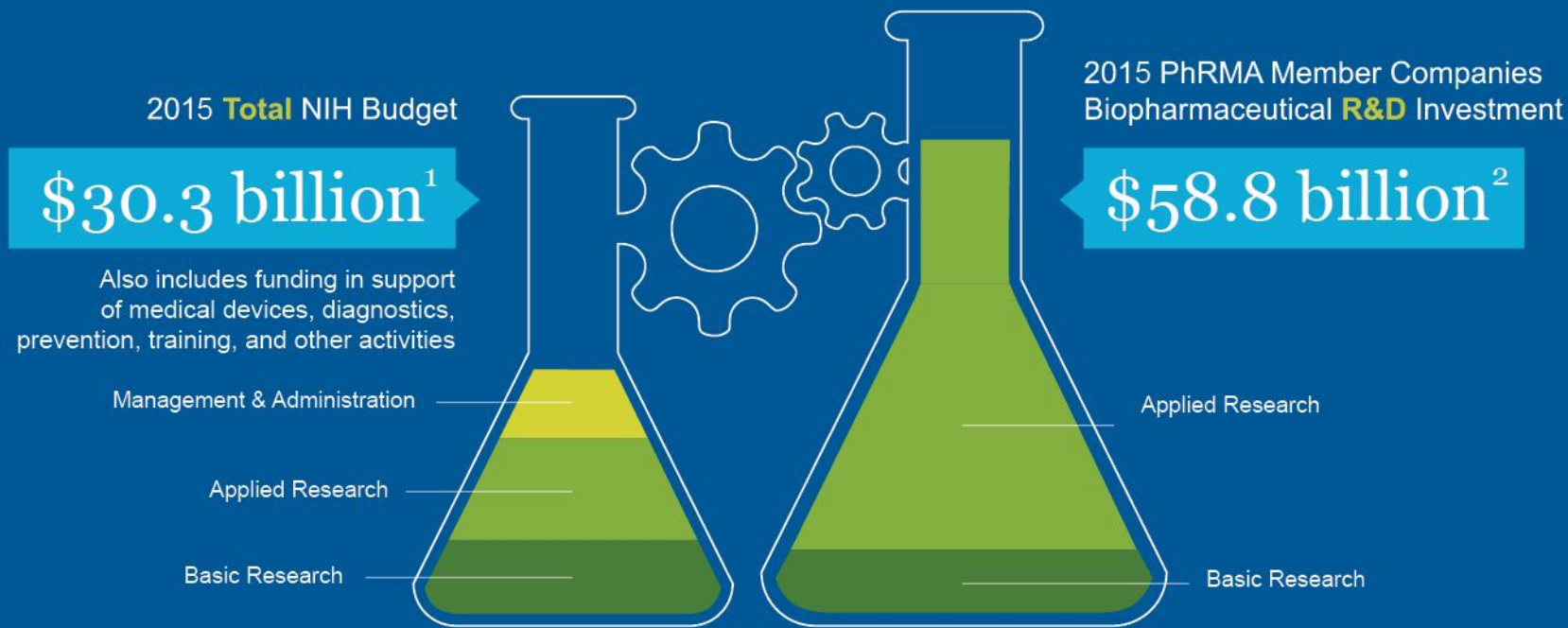
“

“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

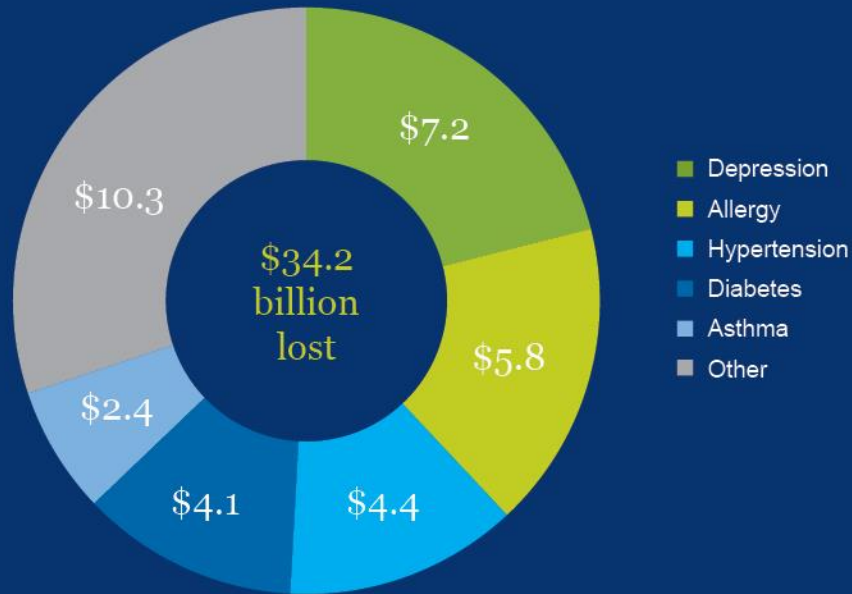
Biopharmaceutical R&D Investment in the United States, 2015



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

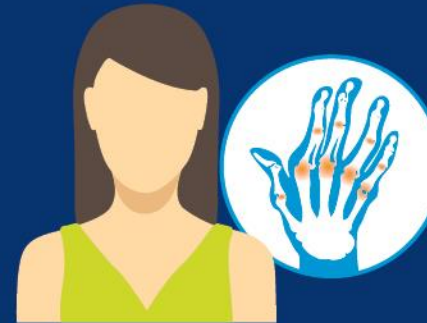
Innovative Medicines Address Health Needs While Also Supporting Economic Growth

POOR HEALTH IS A MAJOR CAUSE OF WORKPLACE PRODUCTIVITY LOSS¹



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

NOVEL TREATMENTS ALLOW PATIENTS TO WORK LONGER AND MORE PRODUCTIVELY²



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

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 productivity¹



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}

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 individuals¹, however



4 out of 5
cancer patients
around the world today
are returning to work
following diagnosis due to
innovative therapies²

NETHERLANDS

83% of working individuals diagnosed with head and neck cancer returned to work, and most often within 6 months after treatment⁵

FRANCE

82% of working women diagnosed with breast cancer returned to work after a median sick leave of 10.8 months⁴

JAPAN

81% of patients diagnosed with cancer returned to work within 12 months of their initial sick leave³



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





PART 2:

Putting Prescription Medicine Spending in Context

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

AGING POPULATION

PERSISTENCE OF RISK FACTORS

GROWING CHRONIC DISEASE BURDEN

POLITICAL AND ECONOMIC PRESSURES

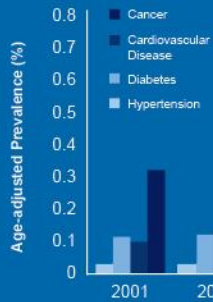
CONSTRAINED BUDGETS

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 year¹



Two thirds of Canada's direct health care costs are spent on chronic disease, amounting to \$190 billion annually¹



USA

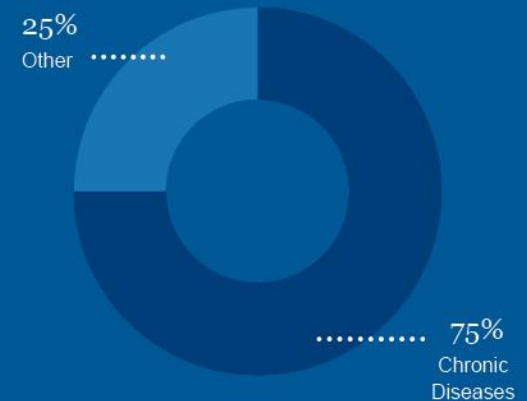
The prevalence of chronic diseases in the US will grow 42% from 2003 to 2023, significantly increasing health care costs²

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



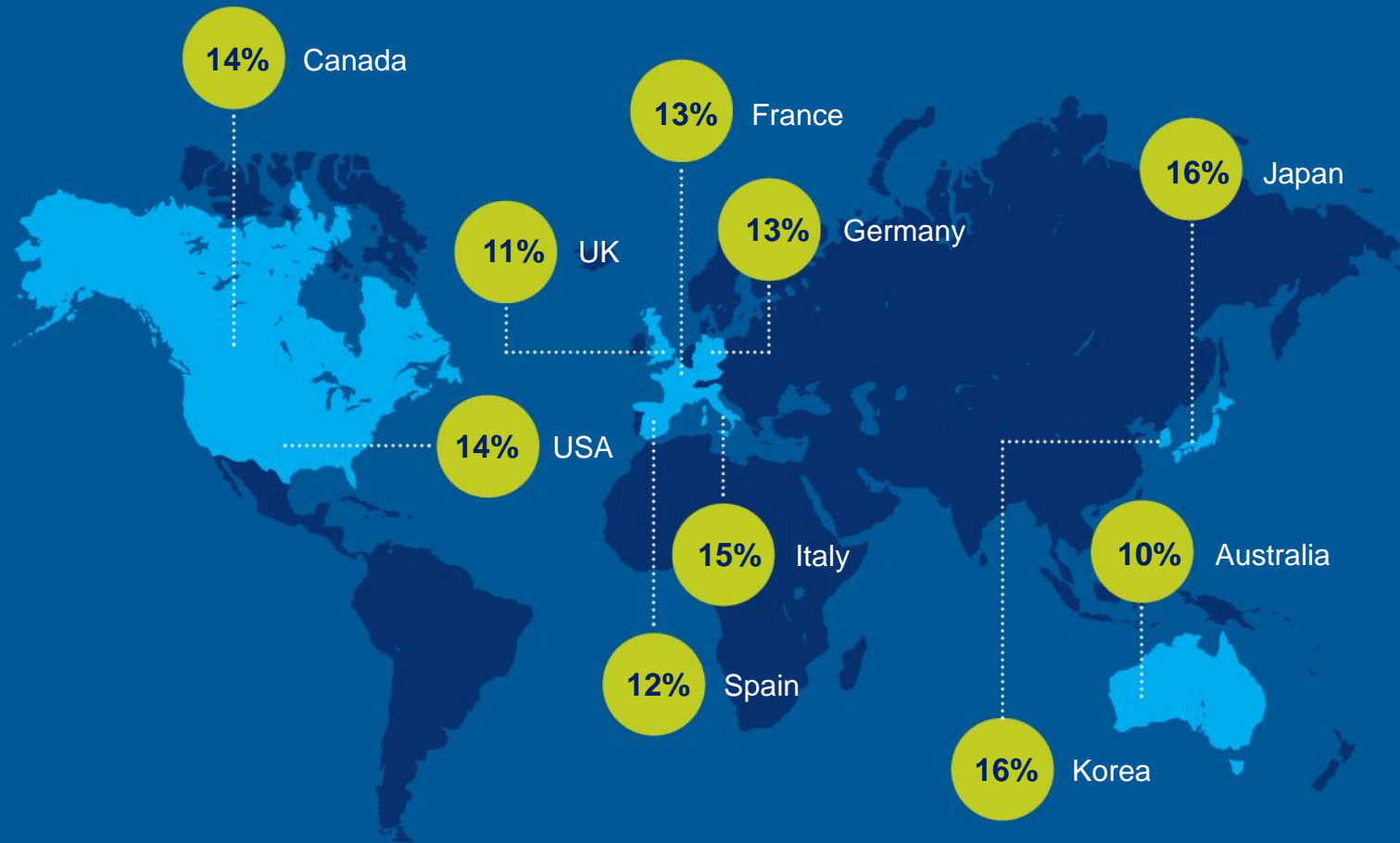
Europe

Nearly all Europeans will suffer from a chronic condition before retirement³



Three quarters of Europe's health care bill is spent on chronic disease, amounting to €700 billion annually²

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

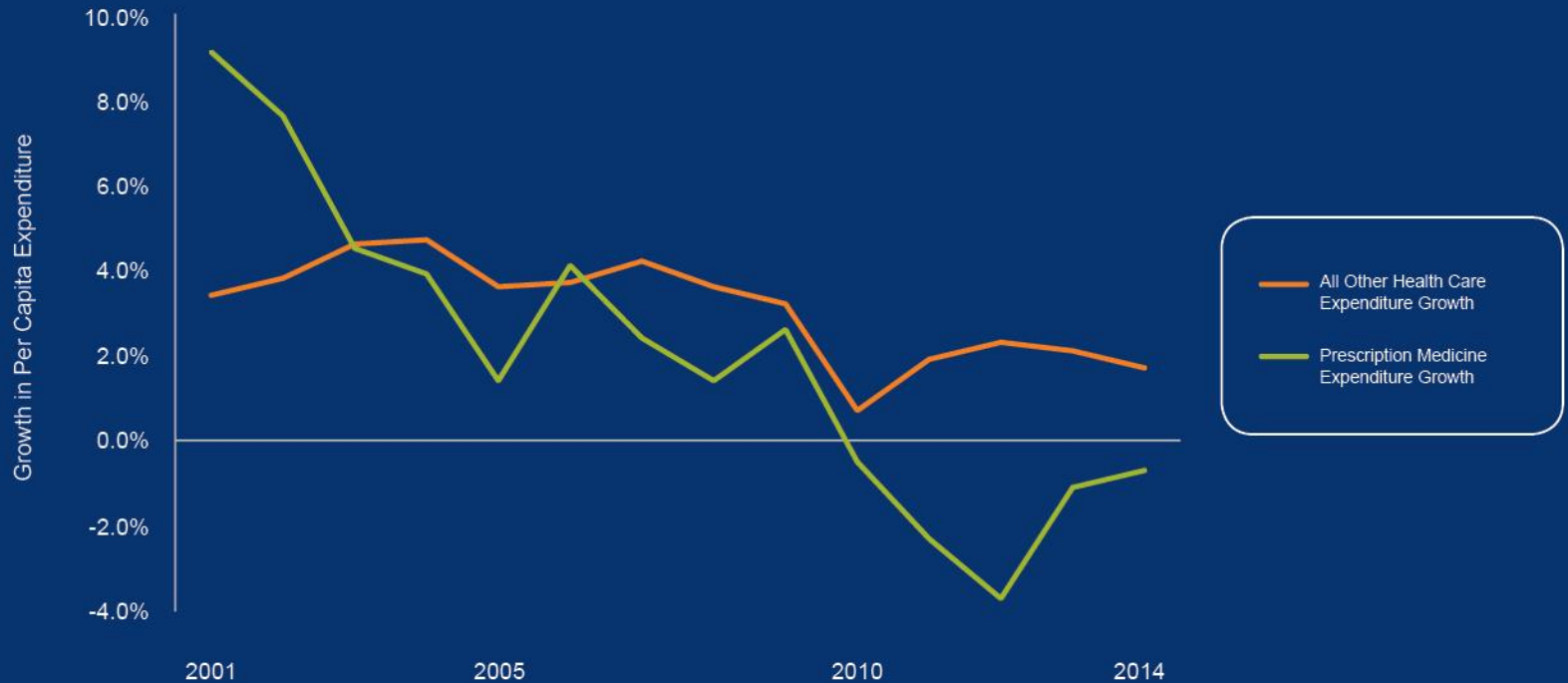


Prescription Medicines as a Percentage of Total Health Care Spending

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

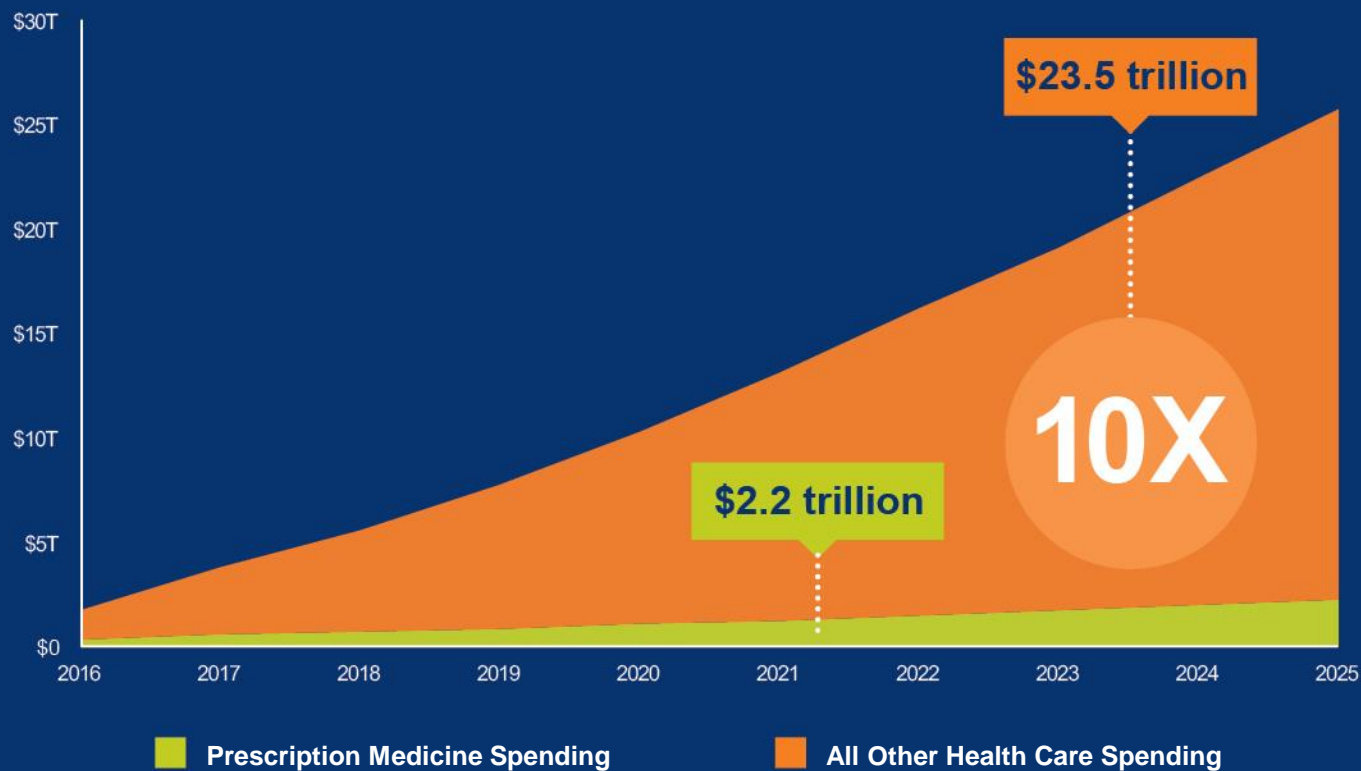
Other health care expenditures are growing faster than prescription medicine expenditures

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











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



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

Cancer Medicines Are a Small Share of Treatment Costs

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



...and only 1/4 of Total Spending on Cancer Care¹



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. Malcolm Kendrick, 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)*

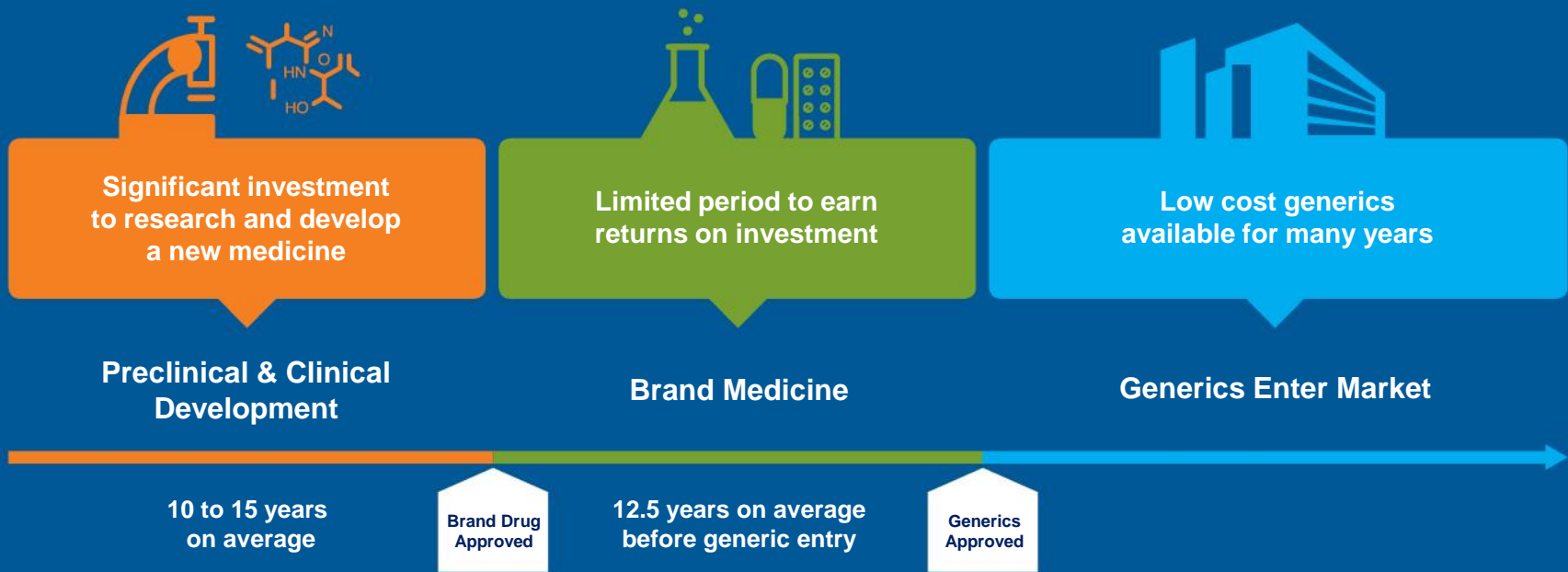
“We feel very confident we can manage this and this won't mess up our clients' budgets in 2016.”

– *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



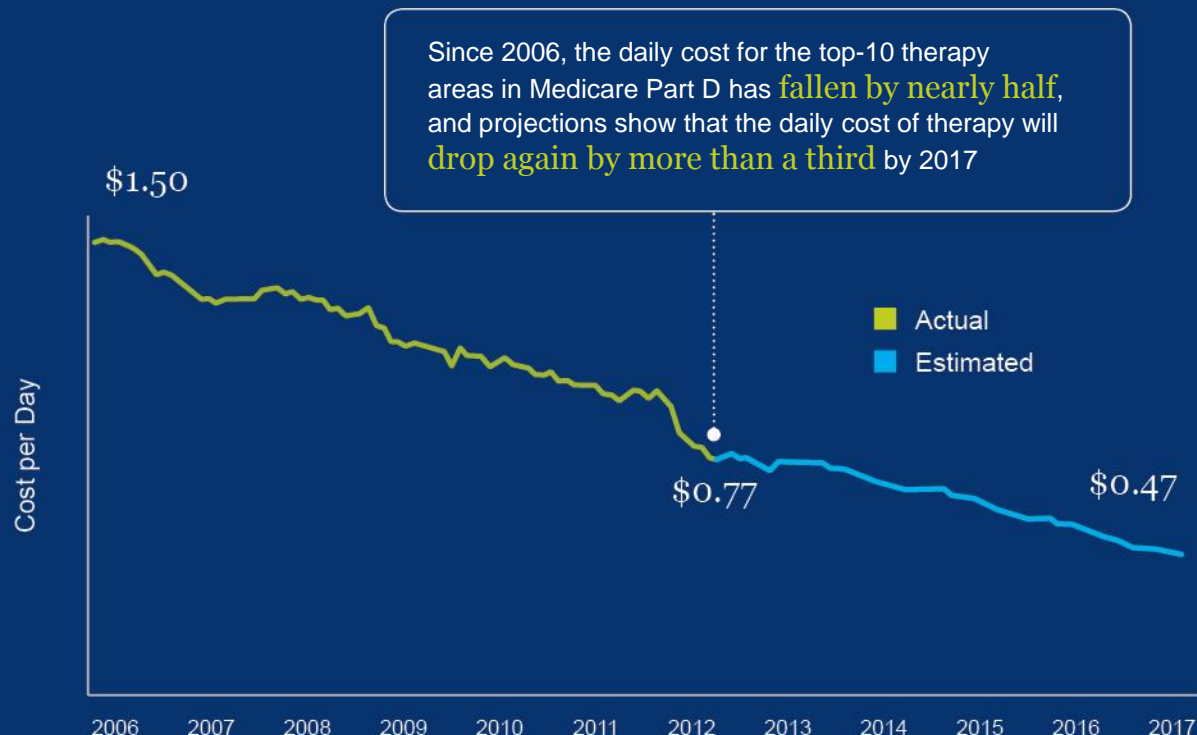
Most brand medicines face competition from other brands long before a generic enters the market

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

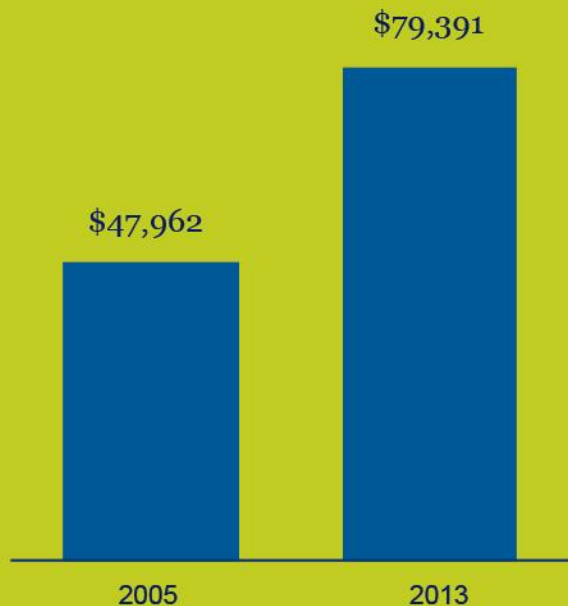


Medical Procedures Become More Expensive Over Time, But Cost Containment Is Built into the Pharmaceutical Life Cycle

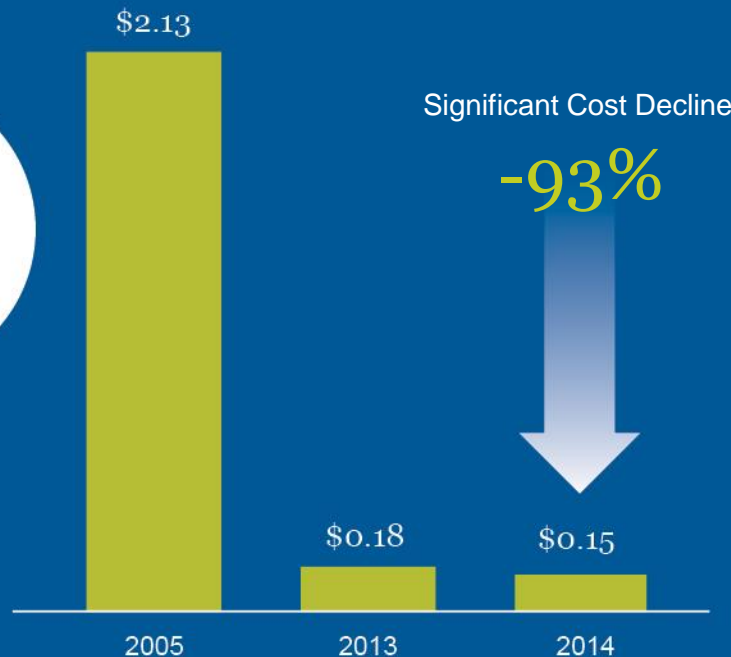


Two Approaches to Cardiovascular Disease Management in the **United States**

Medical Procedure Percutaneous Coronary Angioplasty (PTCA)



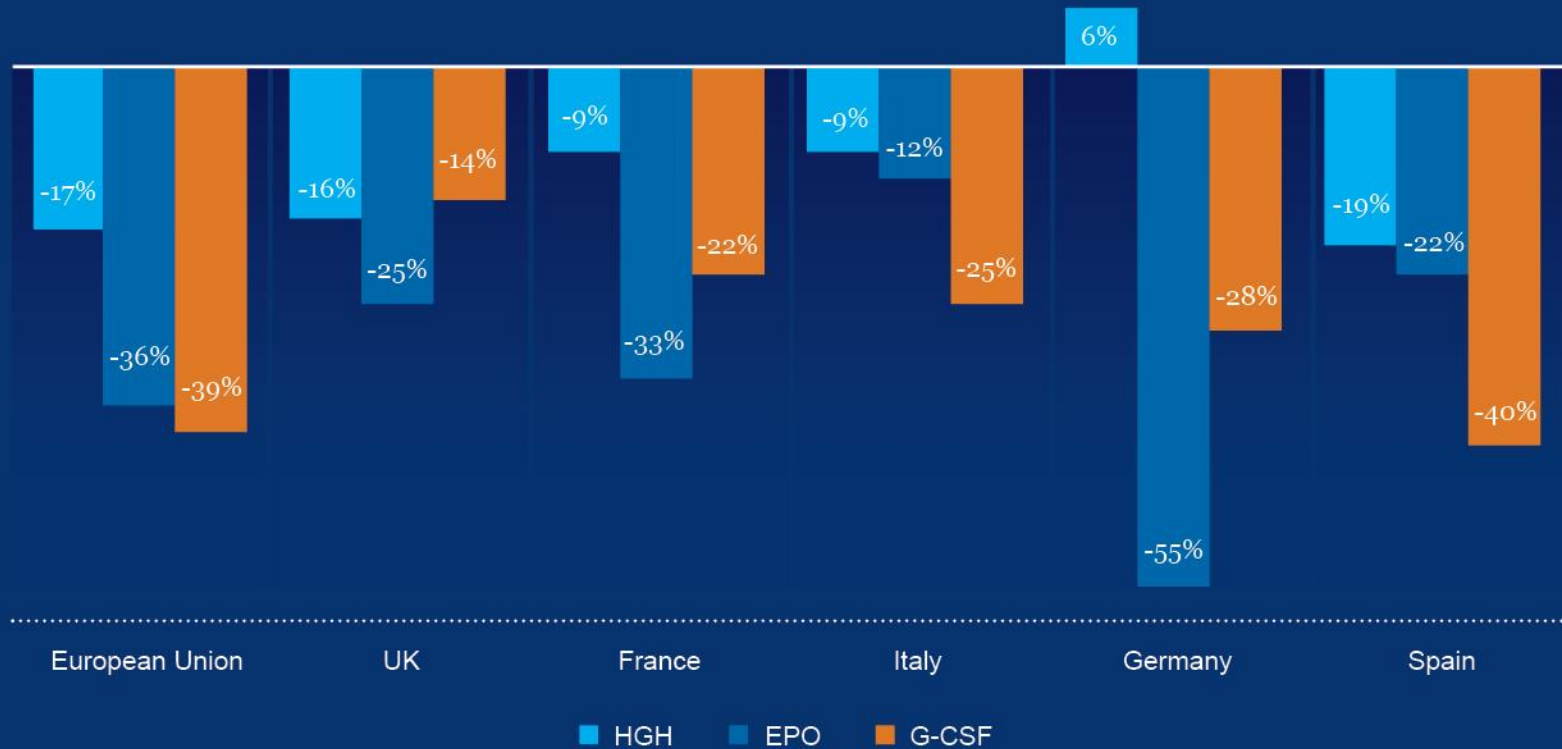
Pharmaceutical Intervention Atorvastatin 10mg



Safe and Effective Biosimilars Can Lead to Long Term Cost Savings

Biosimilar entry decreased the average cost of therapy in Europe

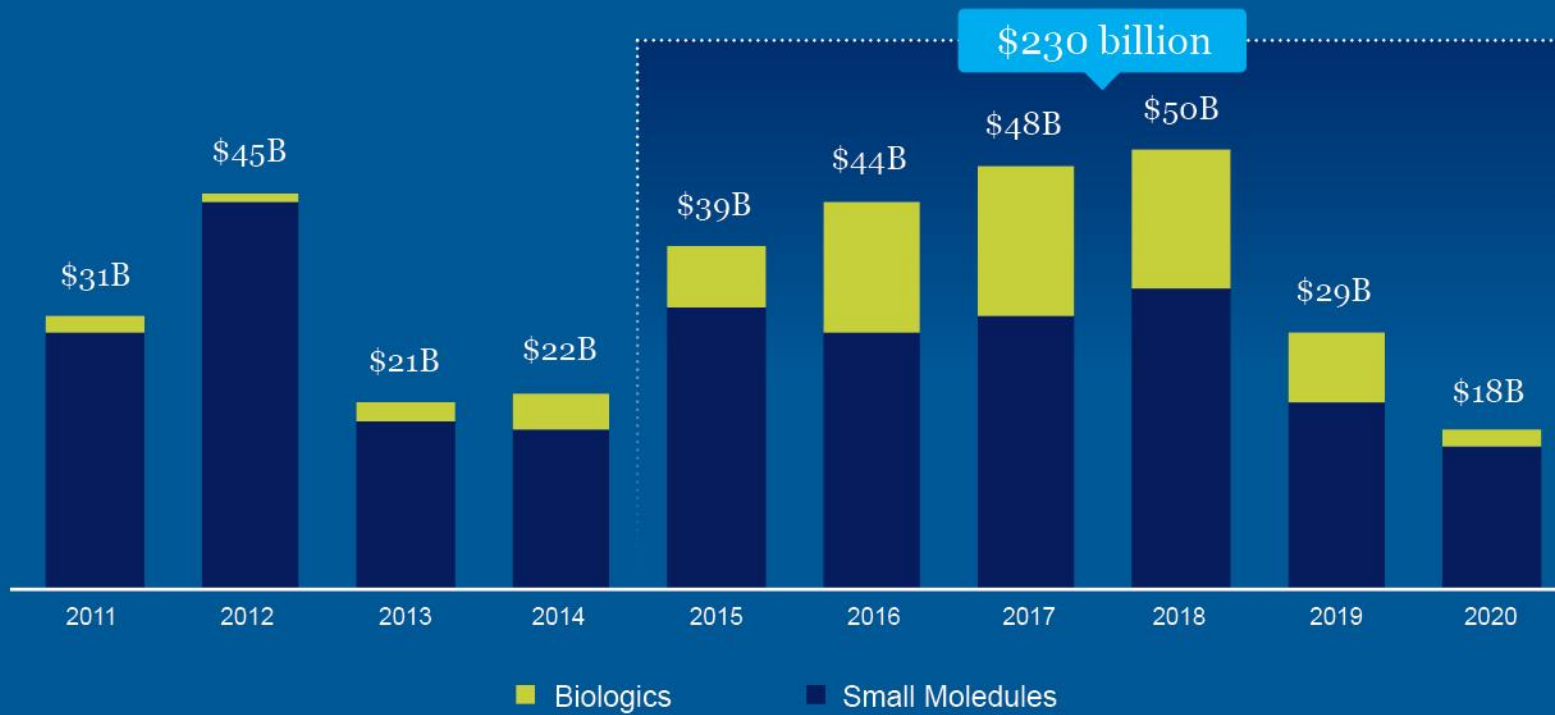
2013 vs. 2006 Cost of Therapy



\$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

Pre-Expiry Value of Branded Products at Risk, 2011-2020



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



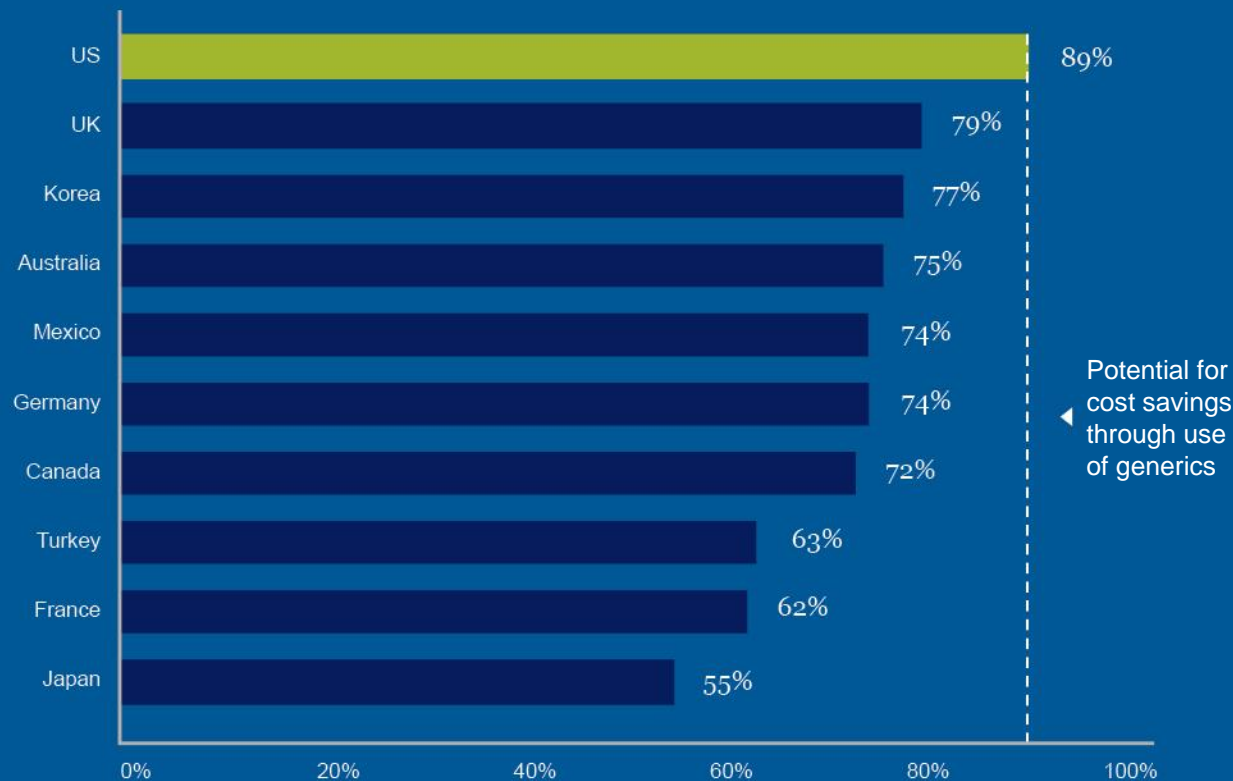
While Nearly

9 out of every **10**

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

Cost Savings

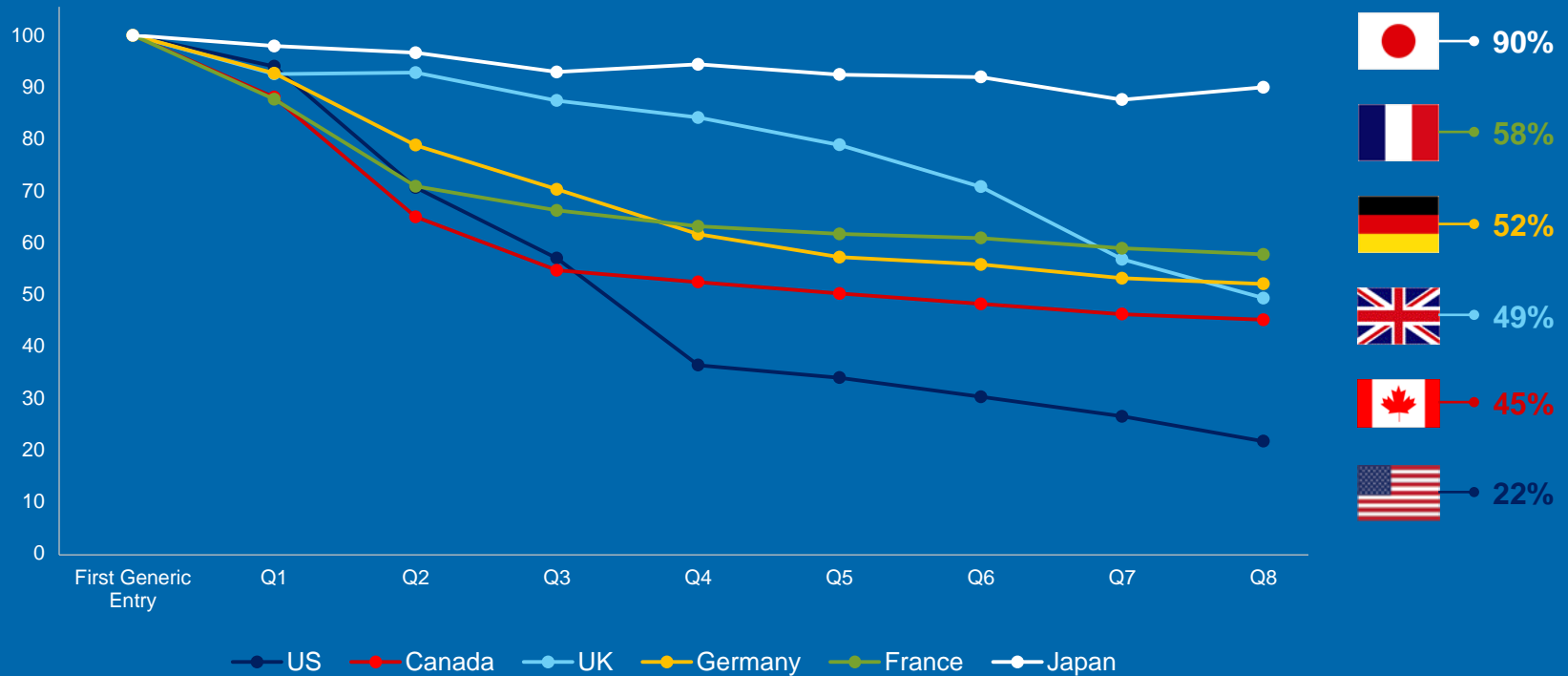
Generic Medicine Share of the Total Pharmaceutical Market, 2015



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.

Change in Average Price per Molecule Following Generic Entry
2009-2014





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

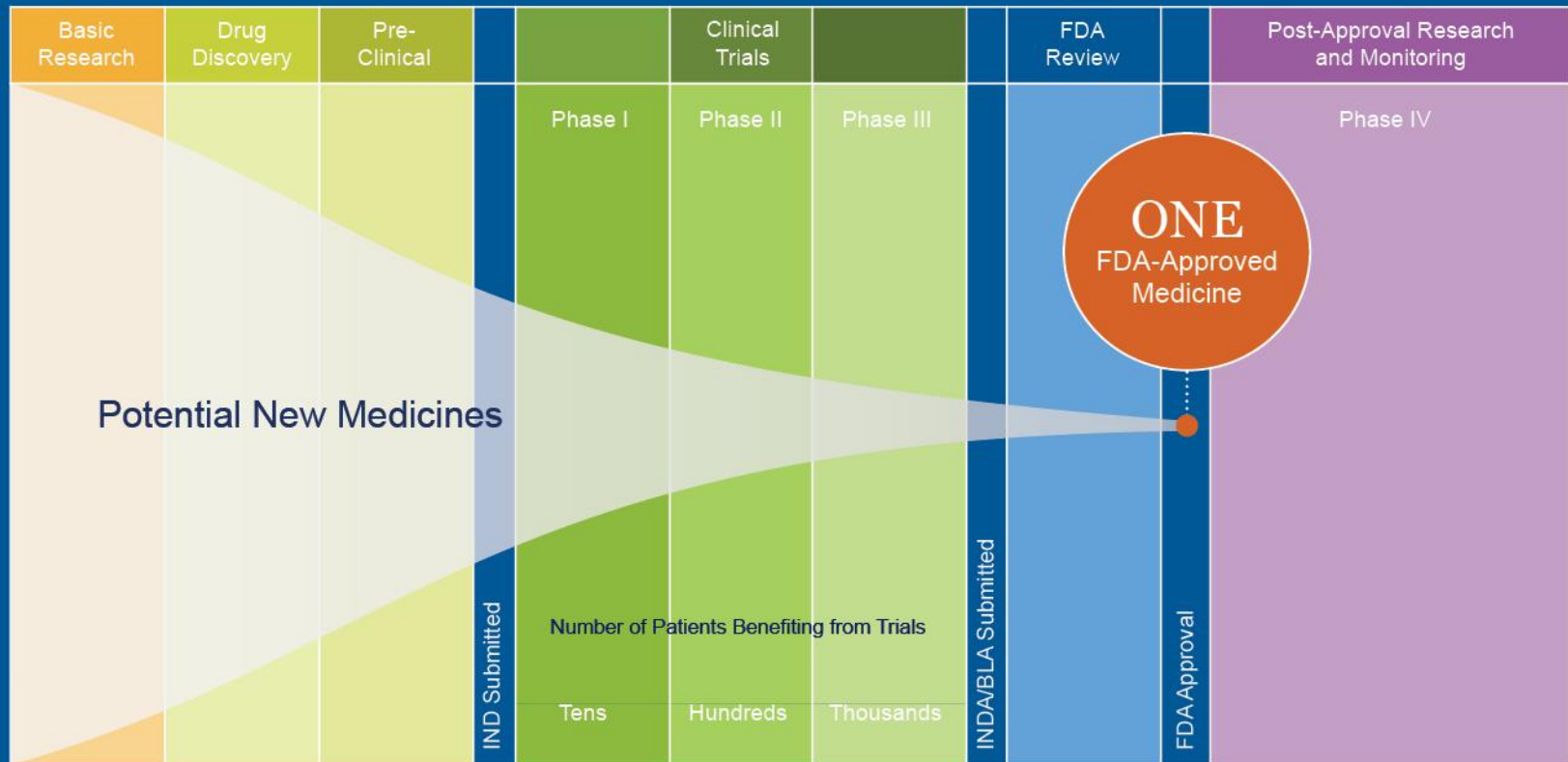
Eroding intellectual property protections

Increased reference pricing and parallel trade

Payers mandating off-label use to reduce costs

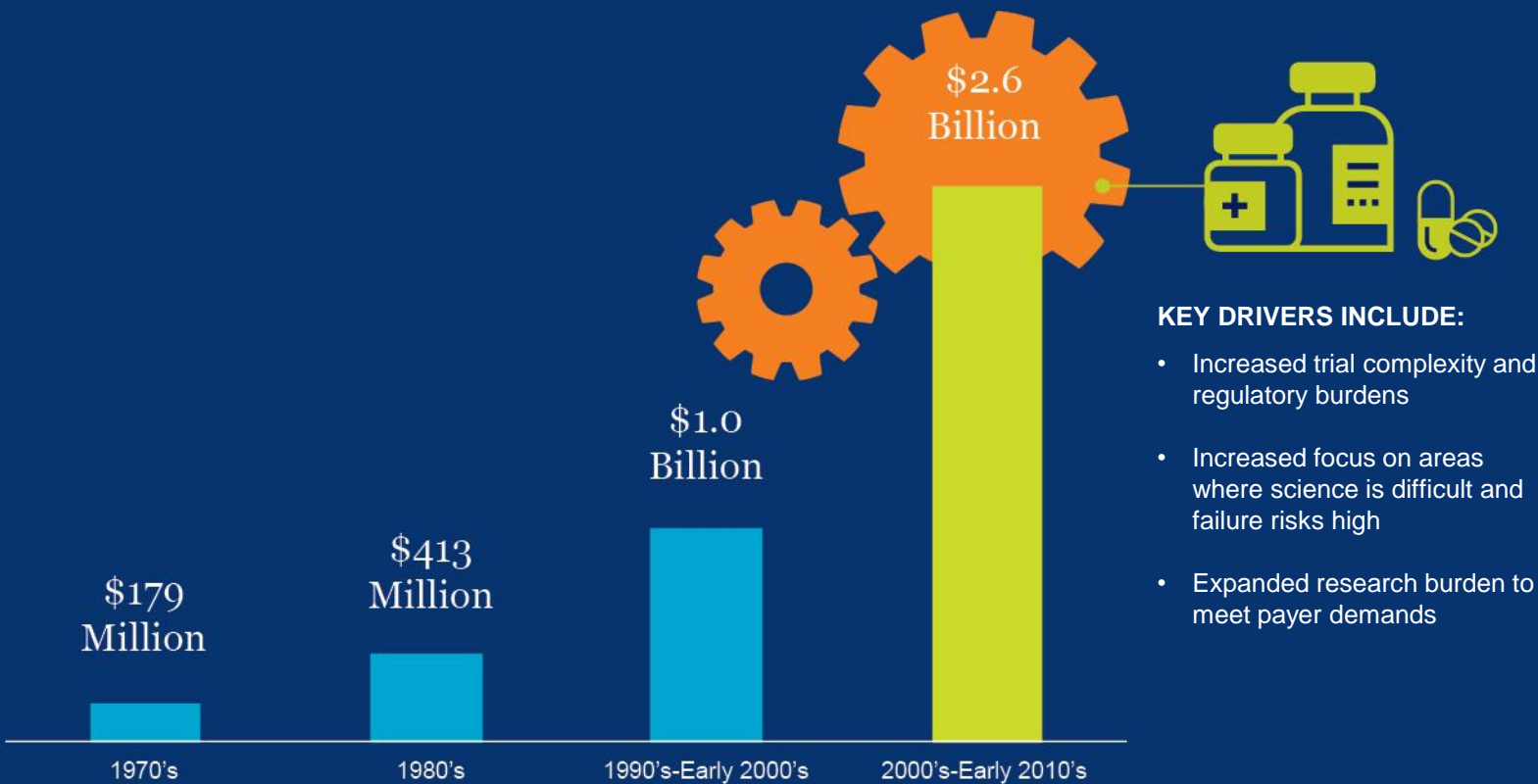
The Biopharmaceutical Research and Development Process

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

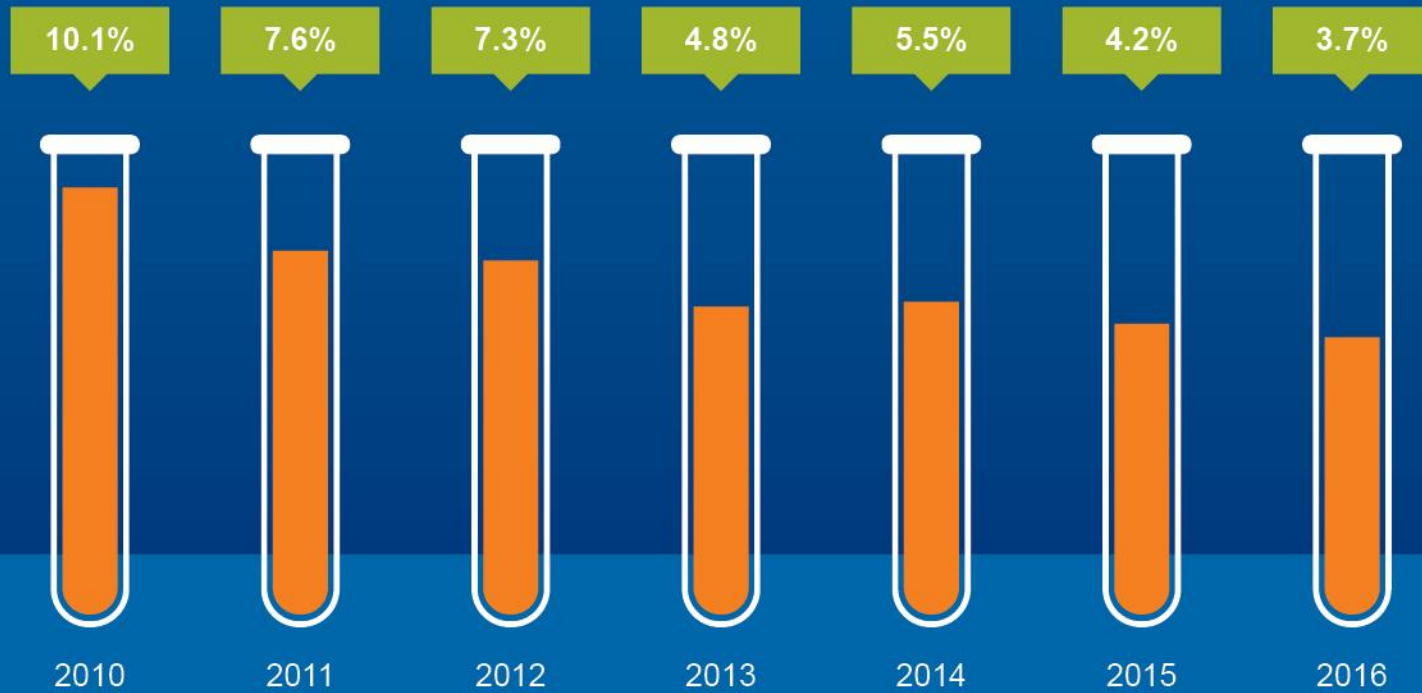


The Cost to Develop a New Medicine More Than Doubled Over the Past Decade

Average Cost to Develop an Approved Medicine – Including Setbacks



Returns on Biopharmaceutical R&D Continue to Decline

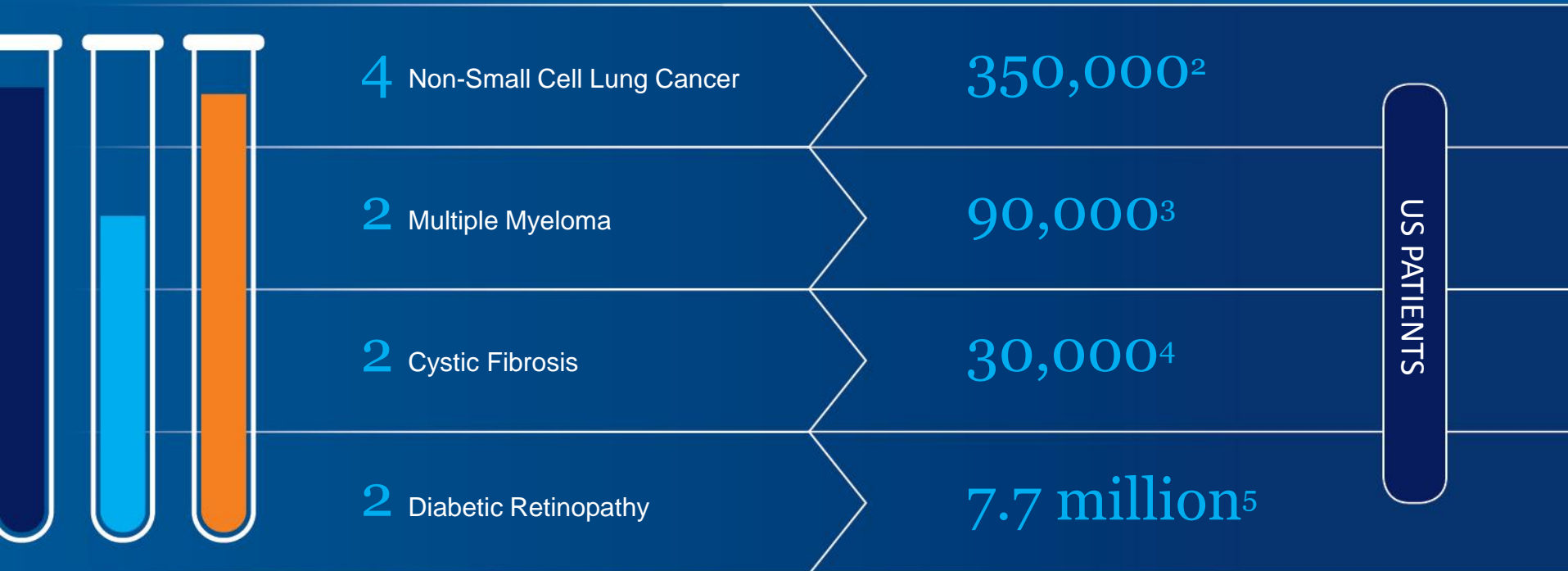


Projected Return on Late-Stage Pipelines of Leading Biopharmaceutical Companies

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 2015¹...

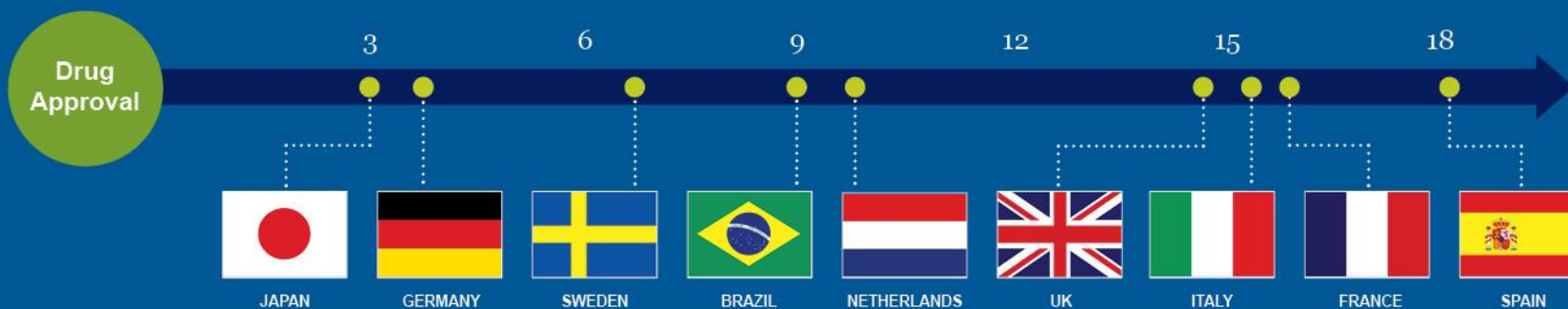
...which have the ability to change the lives of millions of patients



And there are 7,000 more medicines in development

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) program¹

UNITED KINGDOM

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

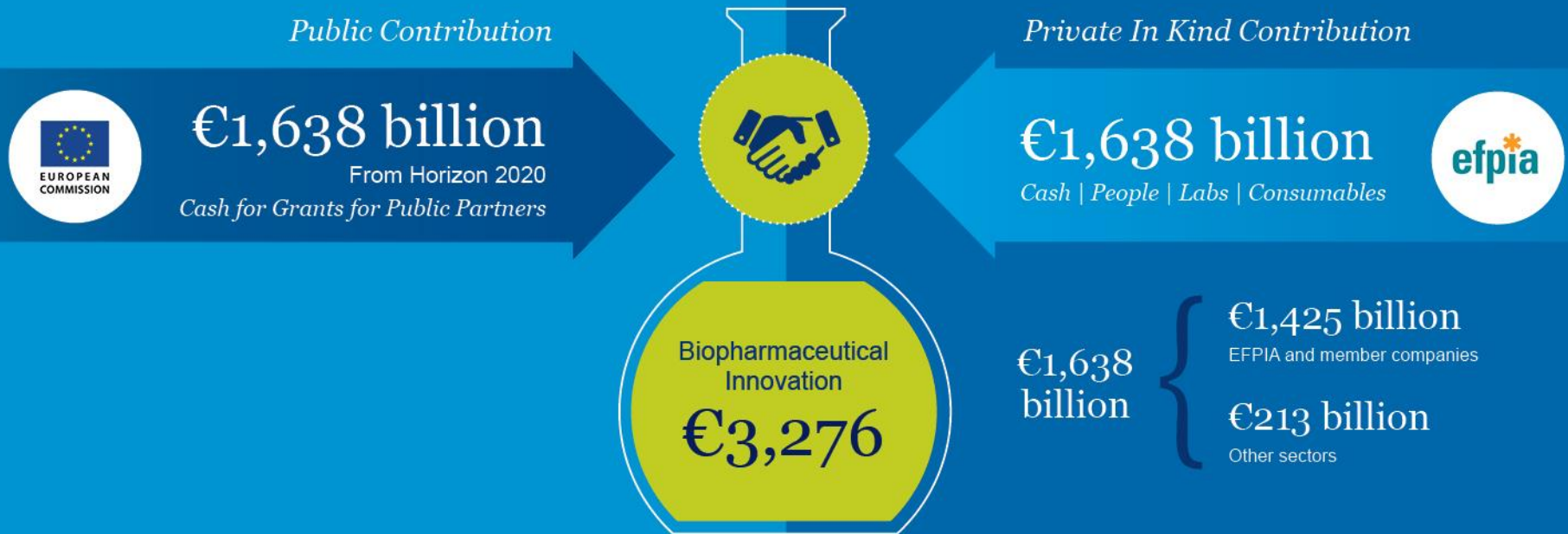
approved four months before market authorization was granted²



Industry Helps Patients Get New Medicines Despite Process Delays

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

IMI 2 Partnership and Funding Overview¹



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

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



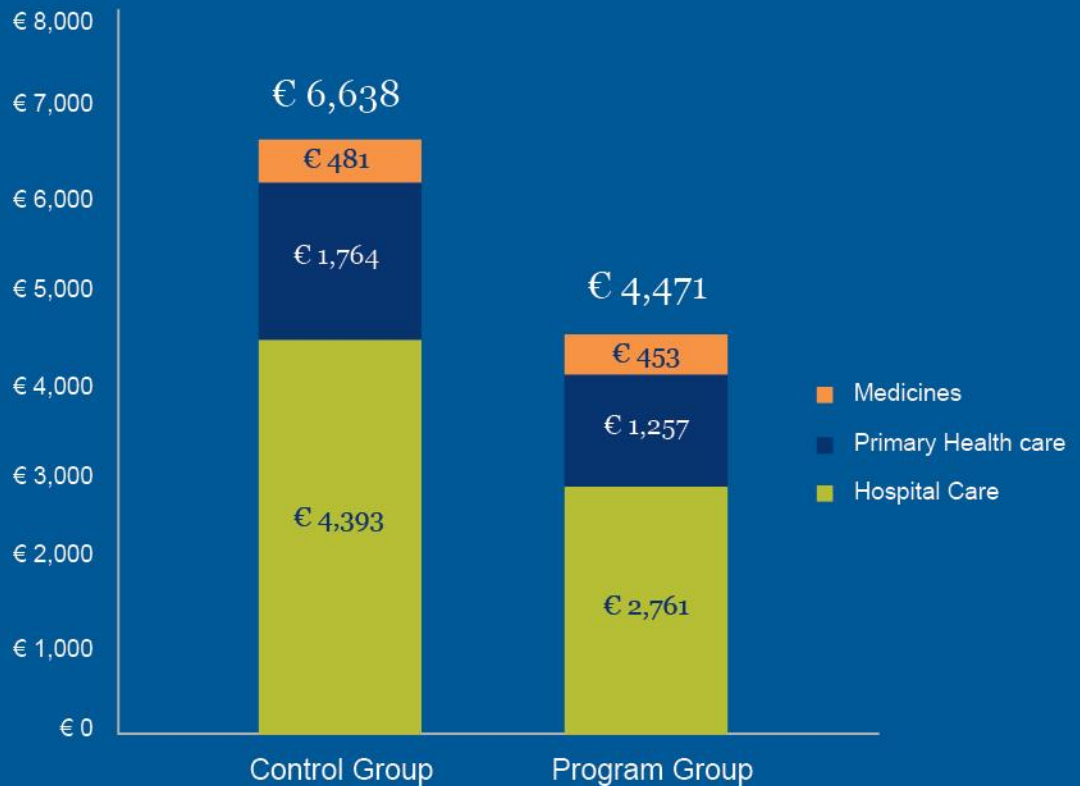
A recent study in Sweden targeting disease management found that patients enrolled in a heart failure program involving regular follow-up* with specialized nurses led to

30%

reduced costs and improved outcomes

through fewer hospital admissions and GP visits

Total Health Care Costs per Patient



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

