

Access, Affordability and Innovation

Focus on High Cost Medicines: Facts and Potential Options

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Key Trends and Issues in Healthcare Worldwide

- Increasing Prevalence and Incidence of Chronic Diseases and Pandemics
- Increased Demand for Healthcare Products
- Access and Affordability for Healthcare Products/Services
- Emergence of New Healthcare Financing and Infrastructure Institutions
- Heterogeneous/Fragmented Regulatory and Reimbursement Landscape

What do healthcare decision-makers want?

- The most appropriate treatment of diseases and optimal allocation of healthcare resources
- Value for money in the use of drugs/medical technologies
- To address these concerns policy-makers are increasingly using:
 - Evidence-based medicine (EBM)
 - Health technology assessment (HTA)
 - CEA (cost-effectiveness analysis)
 - Pricing and reimbursement policies?
- But, are the fundamental issues being addressed appropriately?

Context and Themes

- **Perceptions of Pricing of Past and Present Drugs and Link to Economic Sustainability**
 - Recent high profile cases – Turing, Mylan, Valeant
- **Trends in prices and costs of pharmaceuticals worldwide**
- **Share of pharmaceuticals vs other healthcare costs**
- **Contributions and Value of Pharmaceuticals**
- **Present vs Future Patient and Societal Needs and Incentives for Innovation**
- **Evolving positions of innovative companies**

Perceptions of Pricing of Past and Present Drugs

Déjà vu?

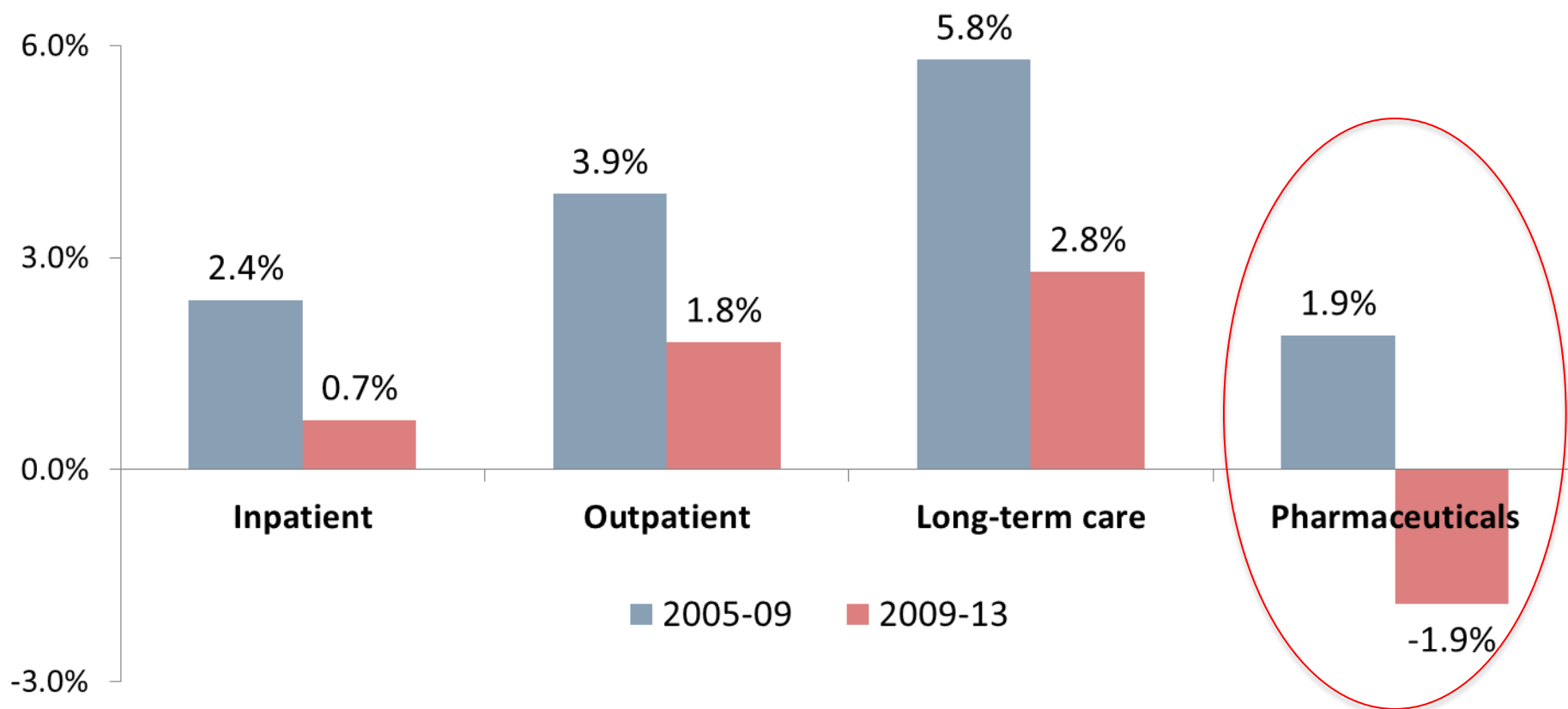
- For many disease areas in the past, the initial pharmaceutical innovations were viewed as potentially threatening the sustainability of affording them (H2s, PPIs, HIV drugs, Statins).

How are we going to be able to accommodate these drugs? How can we afford this?

- But when one looks over the last 10 years at the positive economic impact those medicines have had, it's actually in multiples of what those drugs cost in terms of lives saved. Those were very socially cost-effective investments.
- ***Today, we need to evaluate the issues in the larger context of managing overall healthcare costs and outcomes***

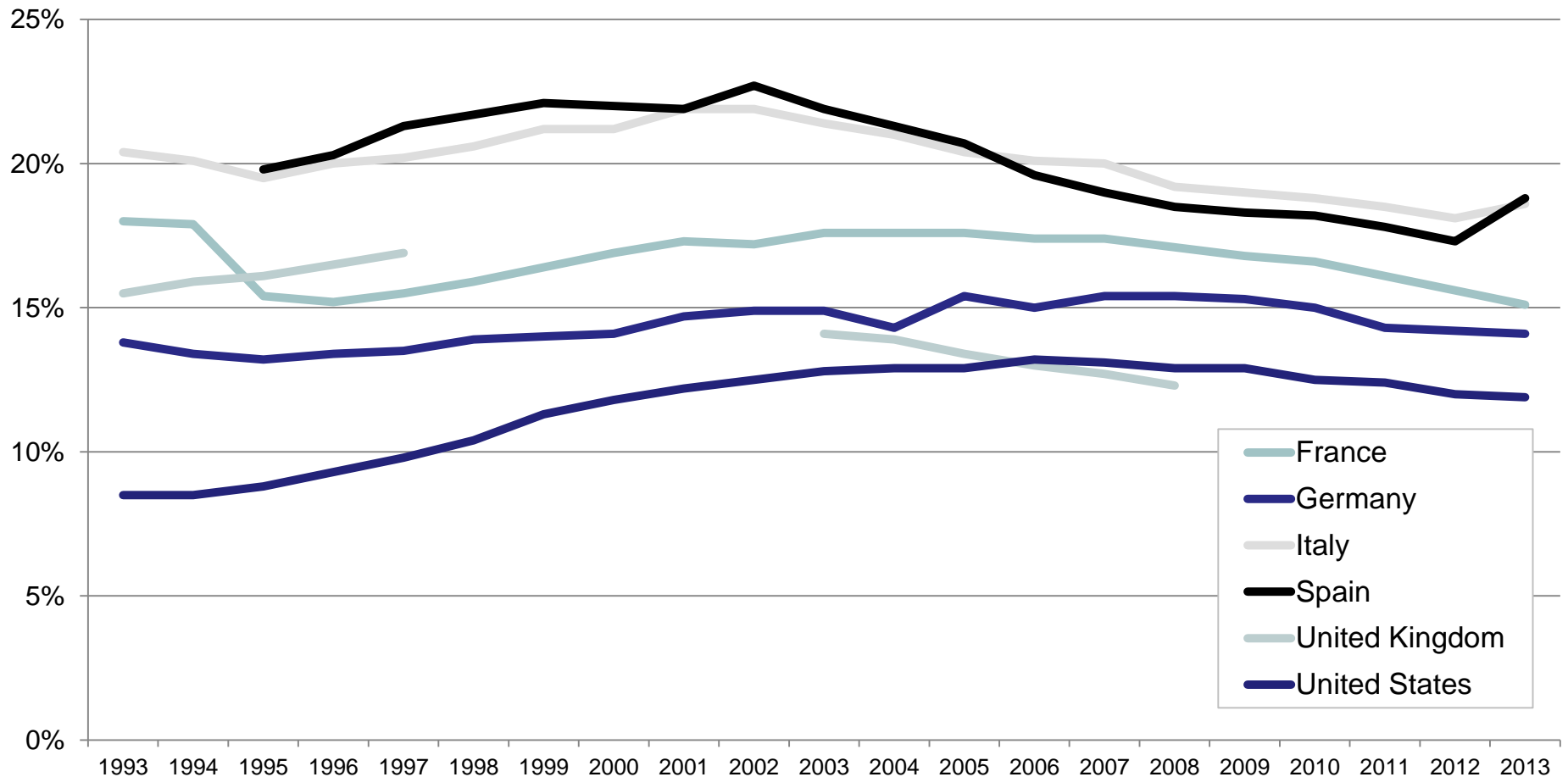
Pharmaceutical spending across OECD countries has actually been growing slower than other parts of the healthcare system

Average annual per capita growth rates
for health spending components, in real terms, 2005-2013



Source: OECD, Focus on Health Spending (July 2015) <http://www.oecd.org/health/health-systems/Focus-Health-Spending-2015.pdf>.

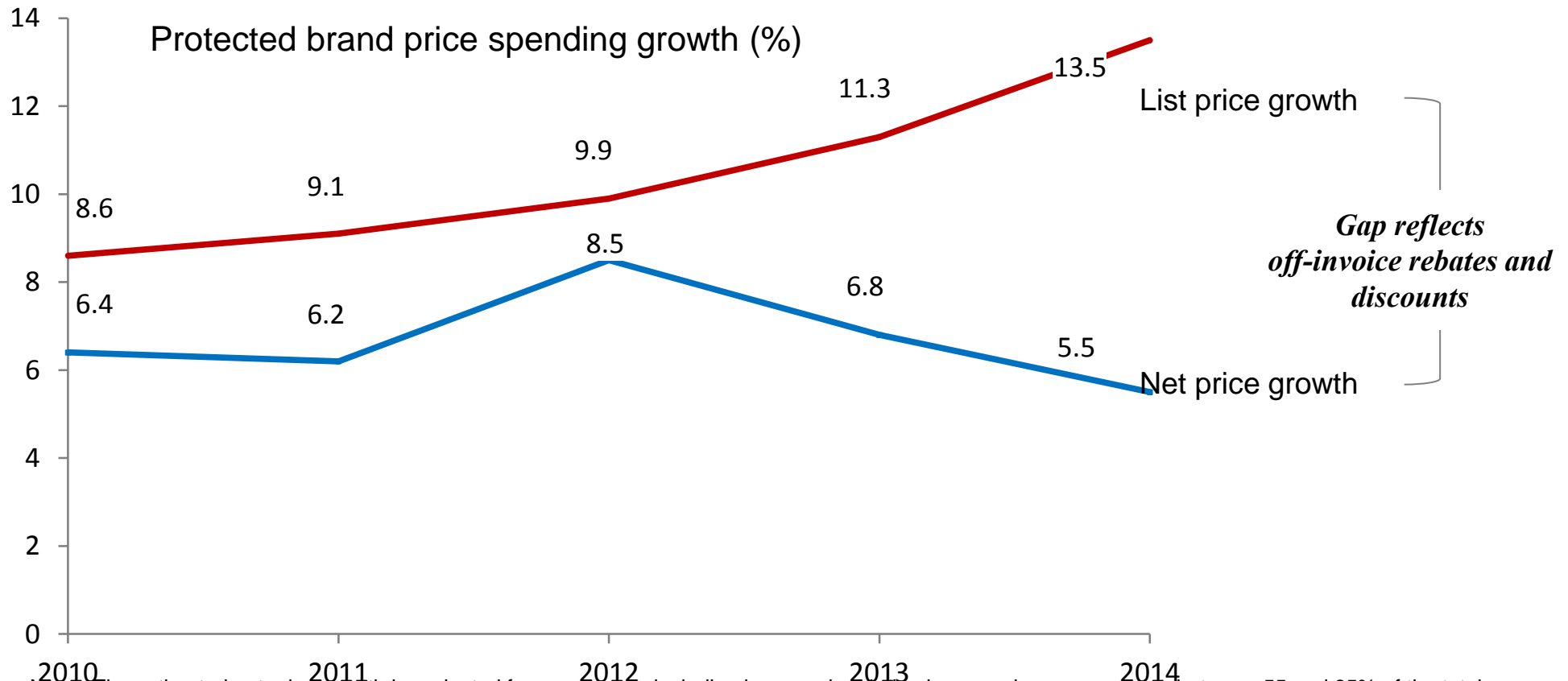
Pharmaceutical expenditures¹ as share of total health spending is consistently lower in the U.S. compared to other EU countries



1. Pharmaceutical expenditure includes pharmaceuticals and other medical non-durables such as medicinal preparations, patent, branded and generic drugs, serums and vaccines, vitamins and minerals and oral contraceptives. Drugs provided in hospitals are excluded – so the U.S. figure is lower than the 14% used elsewhere.

Source: OECD Health Statistics 2015 (<http://www.oecd.org/els/health-systems/health-data.htm>)

The cost of pharmaceuticals to payors is a net price, which grew at half the rate as the list price in 2014

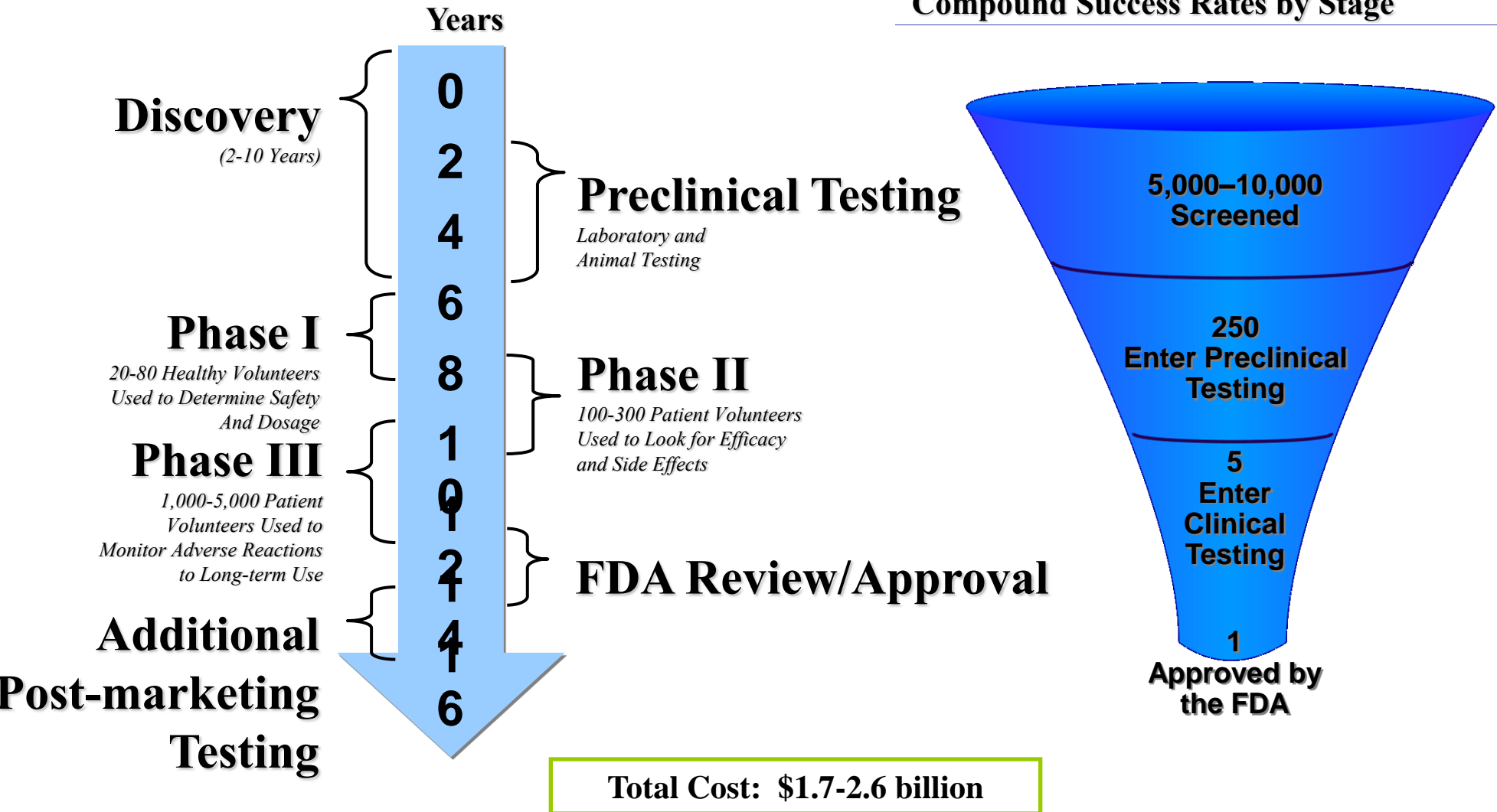


Note: The estimated net price growth is projected from a sample, including large and mid-sized companies, representing between 55 and 65% of the total market share for brands in years shown. Products are included in the samples based on financial filings with the SEC and if the volume of sales captured in IMS Health audits is consistent with information provided directly by manufacturers in support of IMS Health proprietary datasets.

Source: IMS

Innovation is Highly Expensive and Inherently Risky

Compound Success Rates by Stage



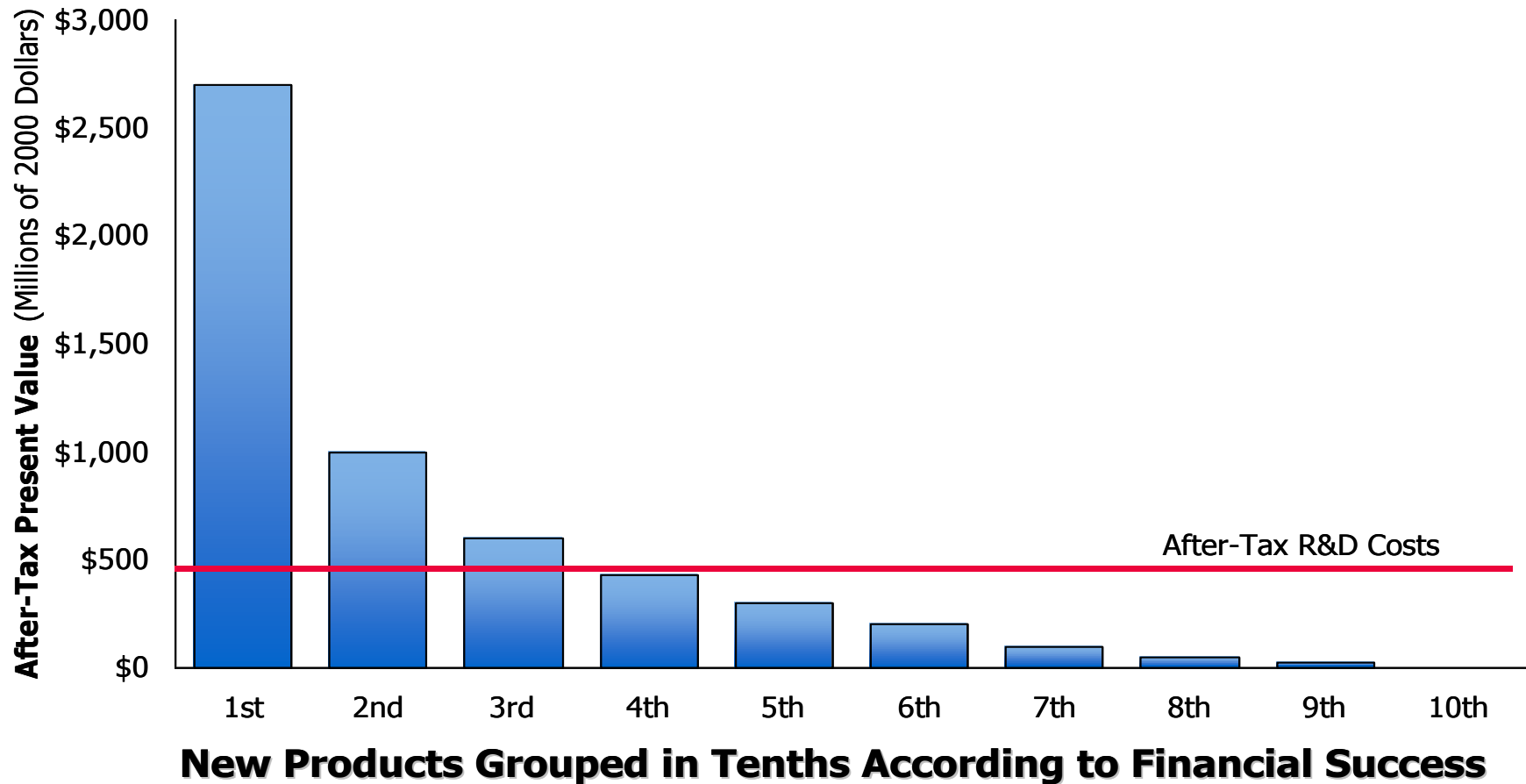
Importance of Intellectual Property and Patents to Risky Innovation

- Many economic studies have found that patent protection is a critical factor for pharmaceutical innovation.
- The length of the market exclusivity period is more important in pharmaceuticals than in other high-tech industries.
 - The basic reason is that the costs of innovation are high in pharmaceuticals, while the costs of imitation are low (transition point).
Fixed vs variable costs
- Contrary to popular misconception, on average, most marketed pioneer drugs do not recover their R&D costs.*

* Source: H. Grabowski and J. Vernon, 1984, 1994 and 1998

Most Products Never Make Enough to Recoup R&D Investment (2002 study cited below: updated data available)

Value of After-Tax Net Lifetime Sales of New Drugs (in \$Millions)

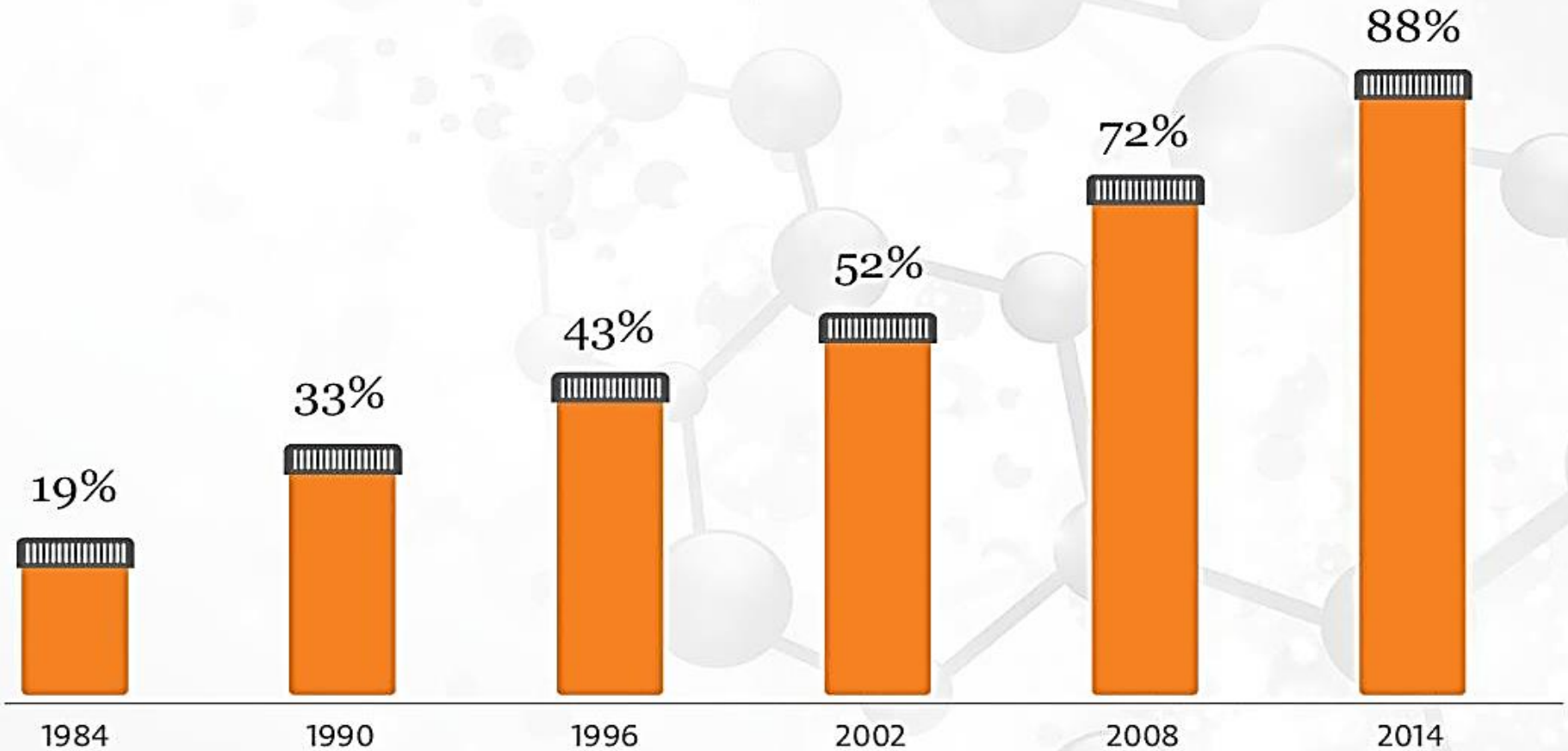


Cost of Drug Innovation versus Imitation

- Innovator Drug Development
 - Long and intensive drug development process – 10-12 years
 - High cost of failures or delays - enormous impact on market value
- Imitation Process
 - Short gestation process - 1 to 2 years
 - Low R&D costs – a few million (typically less than 5-10 million) to demonstrate bioequivalence*
- Biologics – unique structure and challenges
 - biosimilars vs generics

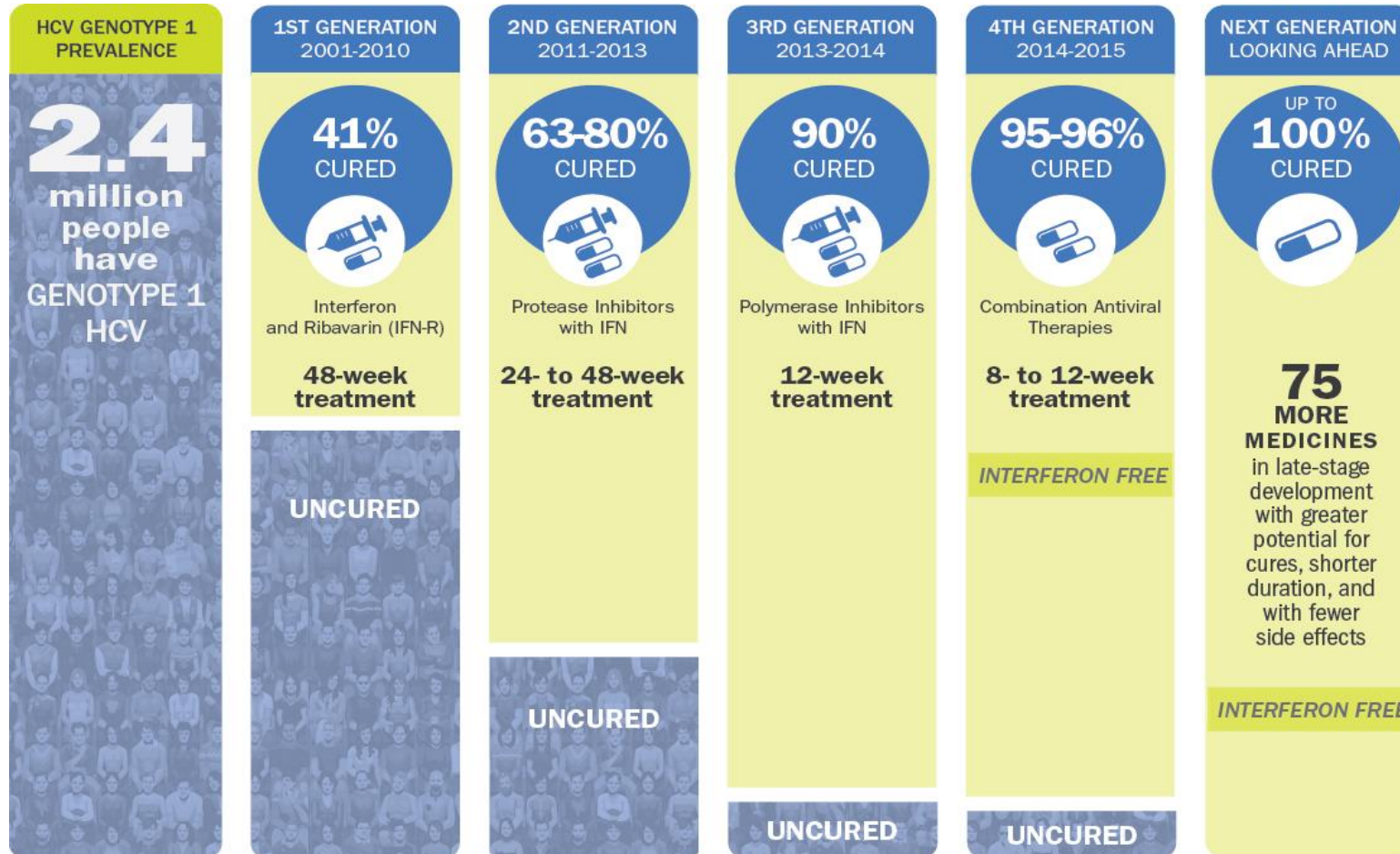
The share of generics as a proportion of prescriptions filled in the U.S. has continued to grow – in 2014, nearly 9 out of every 10 prescriptions were filled with generics

Generic Share* of Prescriptions Filled 1984-2014



Source: IMS Health

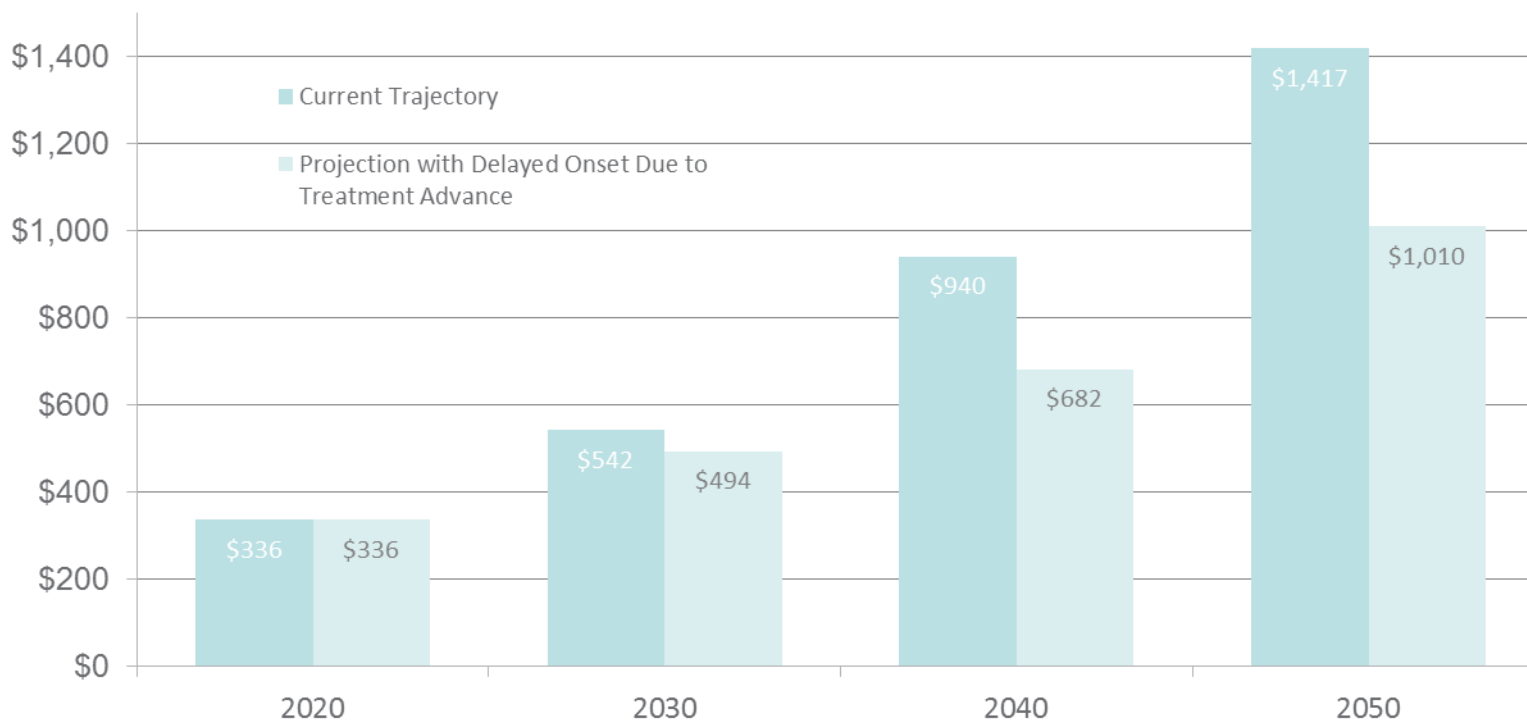
Hepatitis C (HCV): Cure Rates Are Rising



New Treatments for Alzheimer's Disease Could Yield Further Health Systems Savings

The development of a new treatment that delays the onset of Alzheimer's could reduce Medicare and Medicaid spending on patients with Alzheimer's by more than \$400 billion annually by 2050.*

*Projected Annual Medicare and Medicaid Spending, With and Without New Treatment Advances (Billions)***



*Assumes research advances that delay the average age of onset of Alzheimer's disease by 5 years beginning in 2025

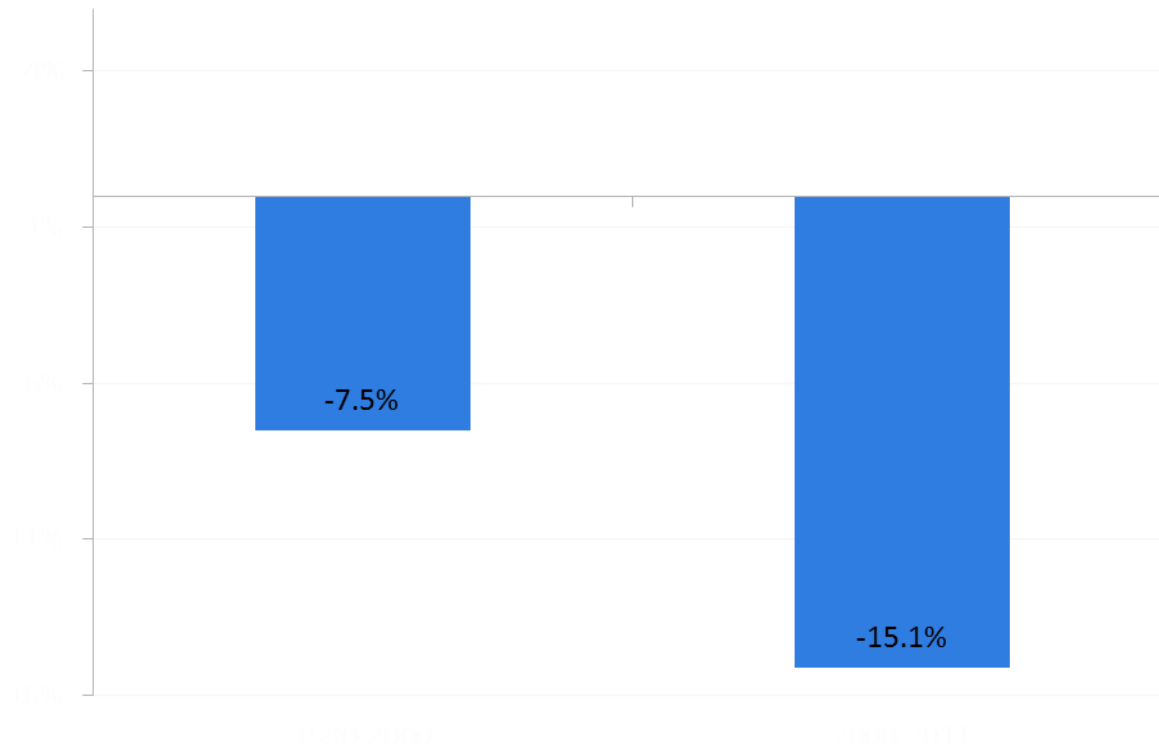
**Projected savings to Medicare and Medicaid assume research breakthroughs that slow the progression of Alzheimer's disease. This would dramatically reduce spending for comorbid conditions and expensive nursing home care.

• Source: Alzheimer's Association²⁹

Prescription Medicines Yield Important Advances Allowing Patients to Lead Longer, Healthier Lives

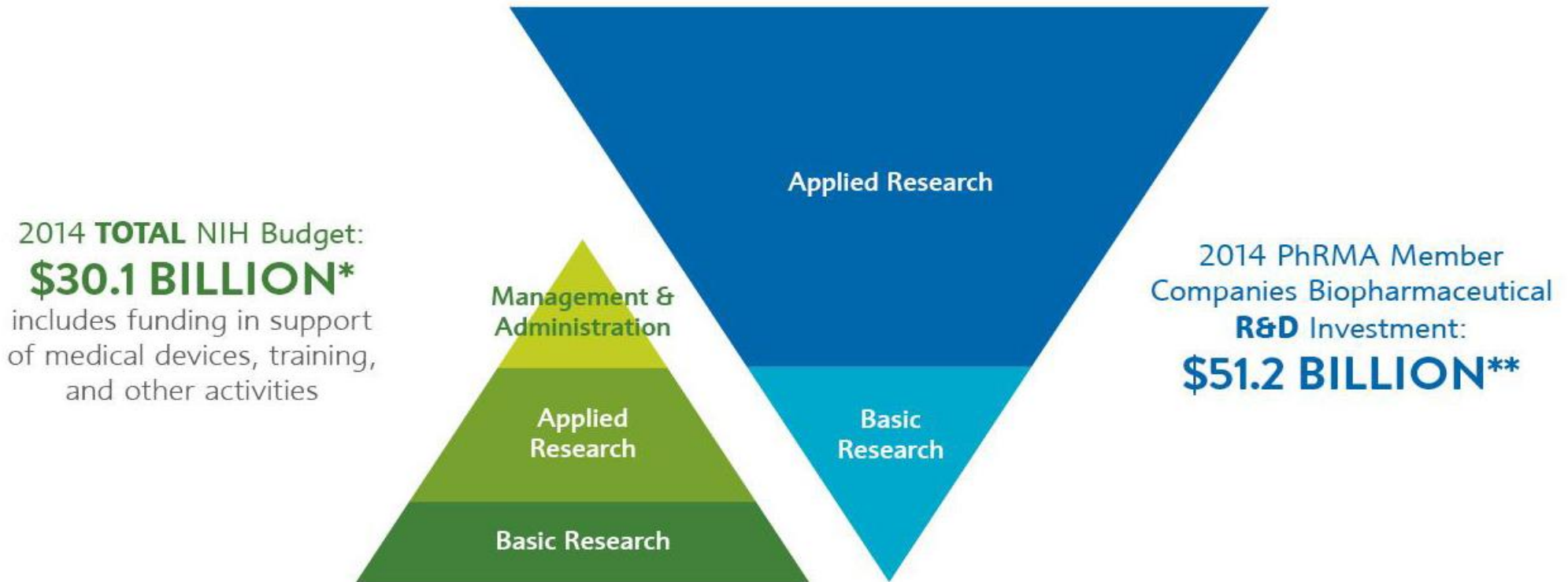
- Since peaking in the 1990s, cancer death rates have declined nearly 22 percent.¹⁴ Approximately 83% of survival gains in cancer are attributable to new treatments, including medicines.¹⁵

Percent Change by Decade in US Death Rates From Cancer¹⁴



• Sources: NCI¹⁴; Sun E, et al.¹⁵

The vast majority of research to translate basic science into new medicines is done by the biopharmaceutical industry



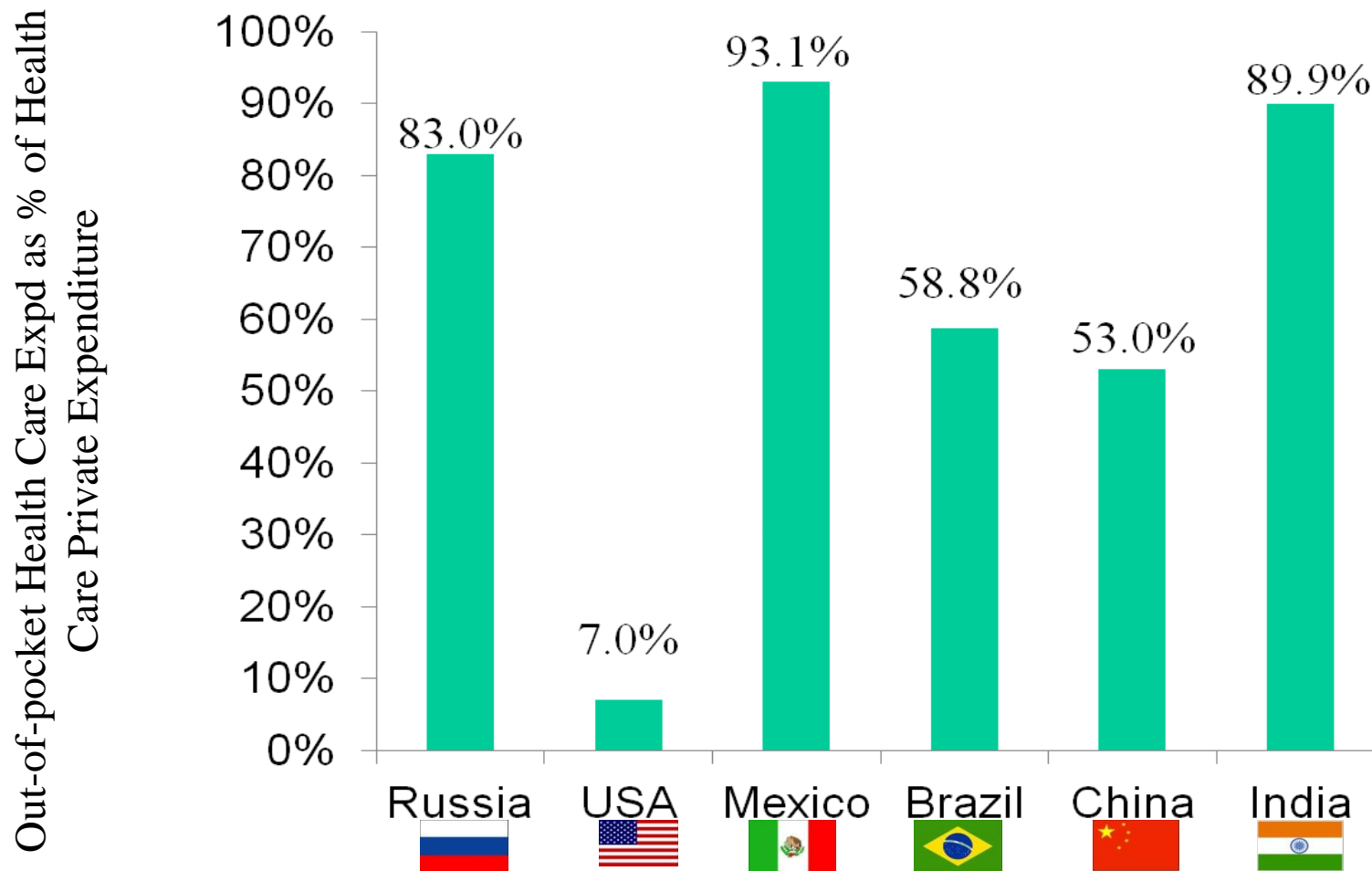
Note: Total NIH spending is for FY2014. In addition to funding for basic and applied research, the NIH budget includes support for prevention, medical devices, superfund activities and training and education, program evaluation, management and support, buildings and facilities and other activities. PhRMA companies' R&D spending is estimated for CY2014. PhRMA companies account for the majority of biopharm R&D spending; nonmember company data are not included.

Sources: PhRMA annual membership survey, Washington, DC: PhRMA 2015 and NIH, Office of Budget, http://www.nih.gov/about/director/budgetrequest/fy2016_directorsbudgetrequest_slides.pdf. Bethesda, MD: NIH 2015.

What potential solutions and options exist?

- Financing Models
- Pricing Models
- Feasibility Conditions?

Out of Pocket Health Expenditures as % of Healthcare Private Expenditure



Sources: WHO, World Health Statistics 2010
International Monetary Fund, statistics, 2009
China: Official Information

Complementary Insurance Models Offer Feasible and Efficient Options for the Economic Pyramid

- Public funding in most developing countries inadequate to provide financial protection to the majority of the population
- Limited ability to finance public insurance through taxation
- Need mixed models of funding: public, private and community along with limited out of pocket

Tiered Pricing, Feasibility Conditions

- Tiered Pricing: theory and rationale
- Challenges: Reference pricing, parallel trade and product diversion

Tiered or Differential Pricing

- Tiered pricing can increase both output, affordability in low income countries and maximize profit. But, for it to work, firms must be able
 - Identify groups of customers who have different elasticities of demand (might be a function of income and ability to pay)
 - Segment them into separate market segments; and
 - Limit their ability to resell its product between groups
 - (product diversion or parallel trade or even price referencing) .

Conclusions

- Given the demographics and chronic disease profile of all countries, including developing countries,
 - we can expect health care burden and cost trends to increase and converge to those observed for developed countries
- These trends will exert great pressure on the healthcare budget and fragmented infrastructure
- Among other solutions, medical technologies (drugs, devices, etc) can play a vital role in managing these pressures if used in a timely and efficient manner, recognizing their **total benefits and value.**