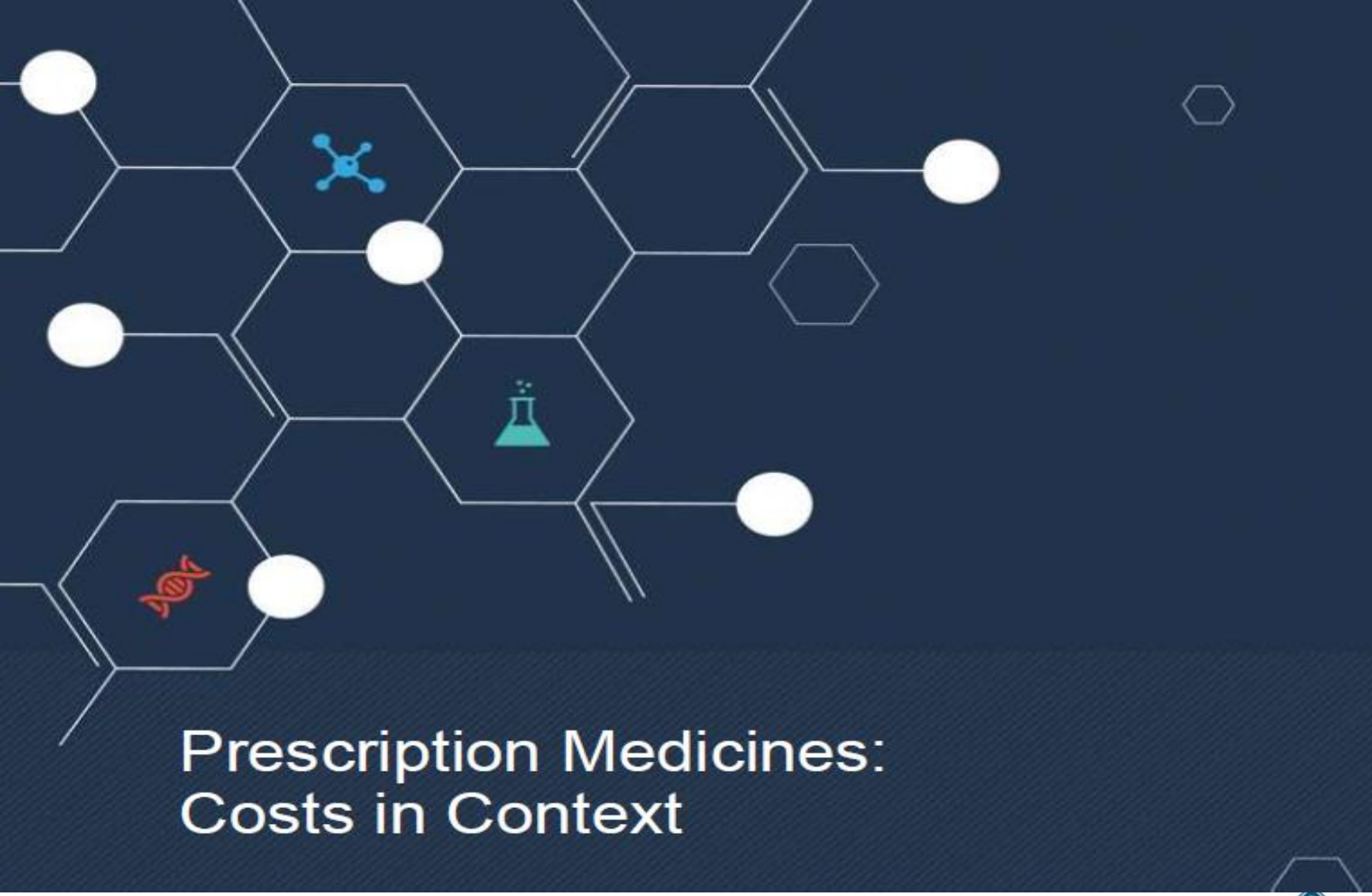
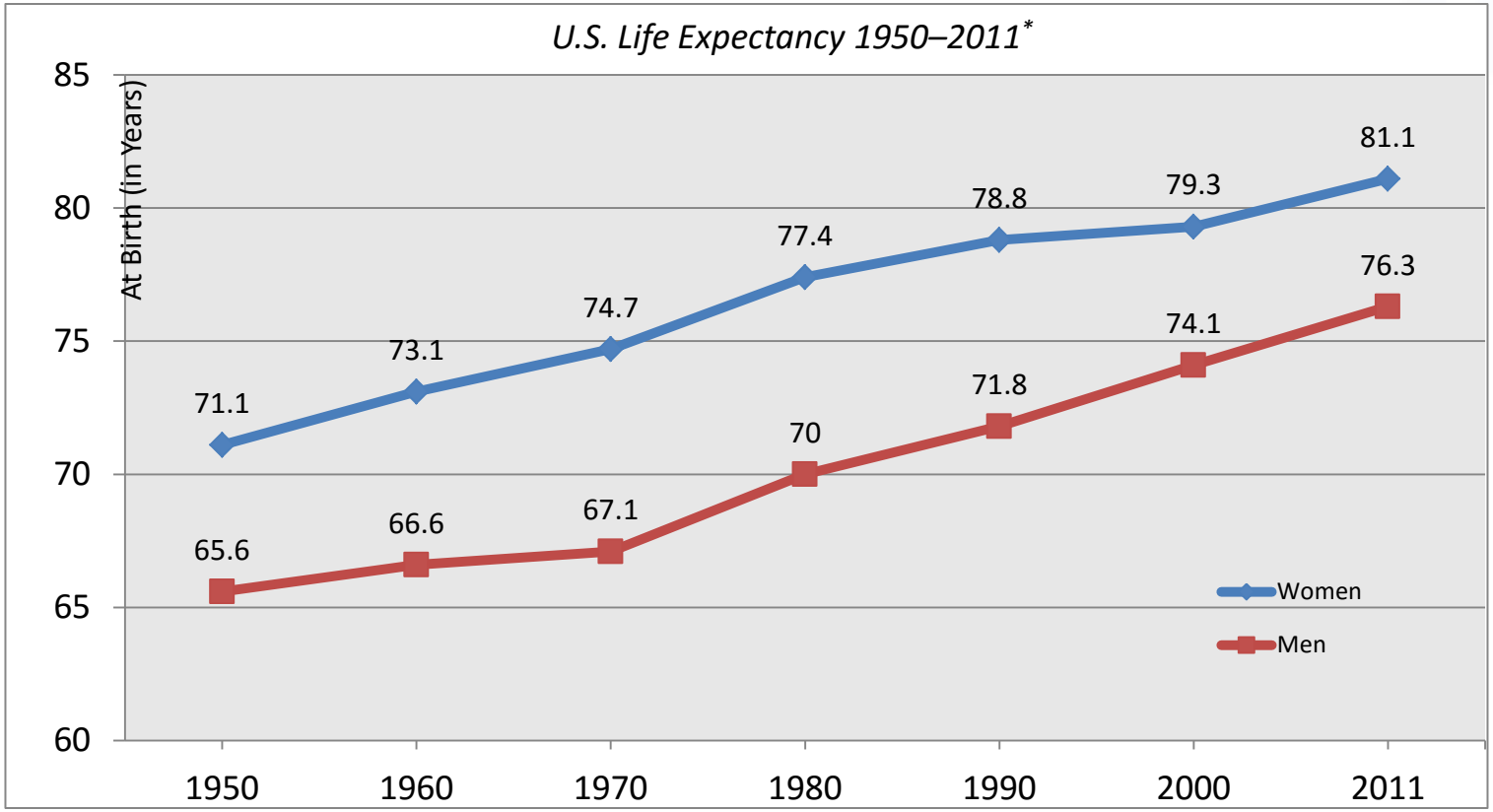


Prescription Medicines: Costs in Context

منتدى السياسات الصحية في الشرق الأوسط وشمال افريقيا
MIDDLE EAST AND NORTH AFRICA HEALTH POLICY FORUM

Increases in U.S. Life Expectancy

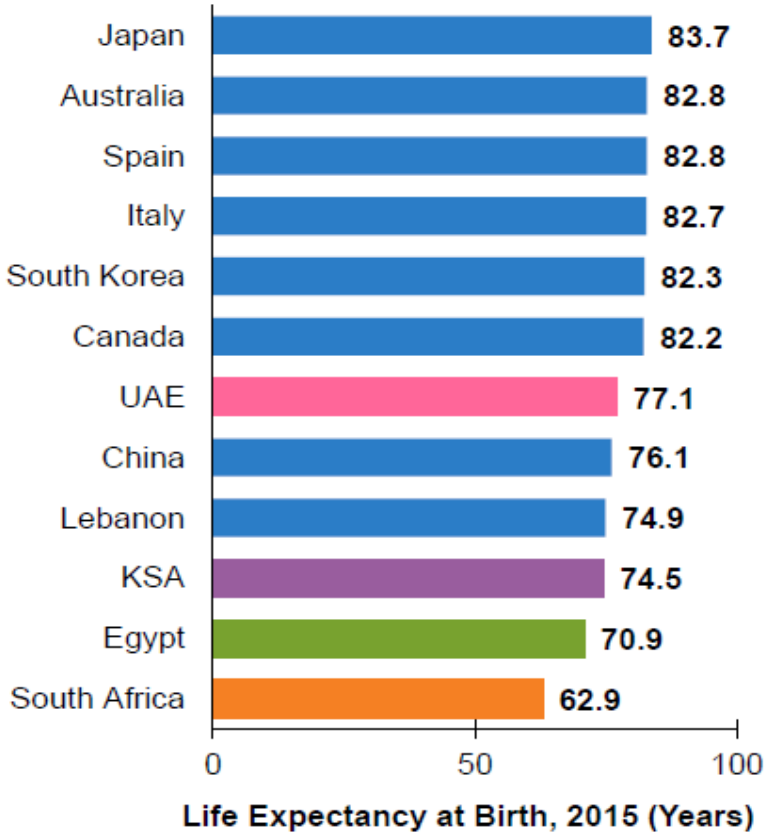
> *While nutrition, sanitation, other public health measures, and expanded access to care have been major sources of increasing human health, innovative medicines have also played a profound role in this progress.*
>
> — The President's Council of Advisors on Science and Technology[1]

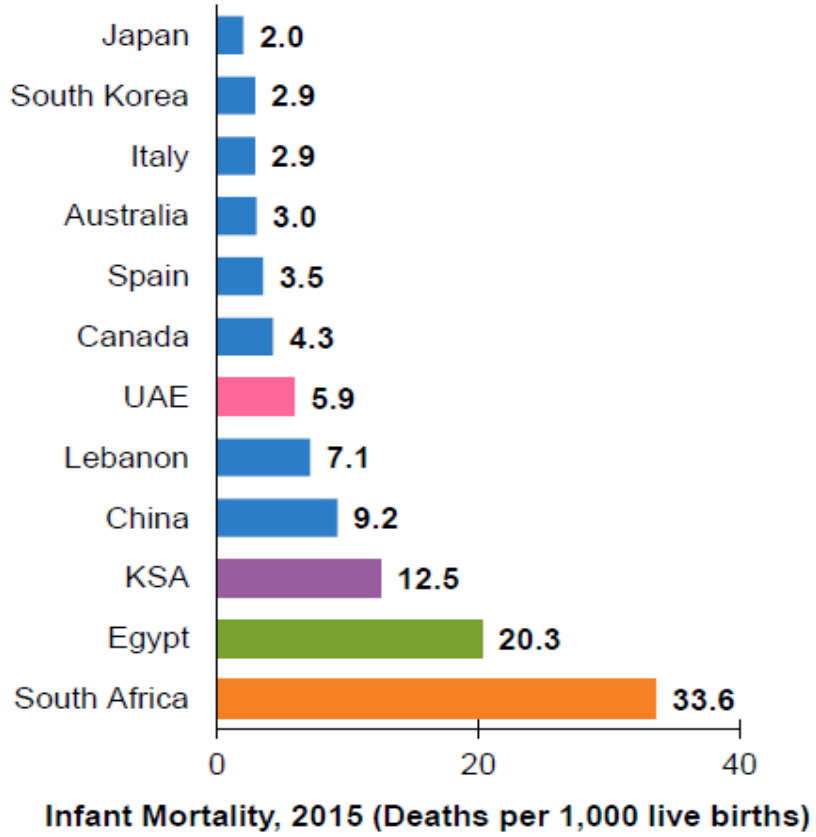


1. President's Council of Advisors on Science and Technology. "Report to the President on Propelling Innovation in Drug Discovery, Development, and Evaluation." Washington, DC: PCAST, September 2012.
2. U.S. Department of Health and Human Services (HHS), CDC, National Center for Health Statistics (NCHS). "Health, United States, 2008 with Chartbook." Hyattsville, MD: HHS, 2009; 1950–2006 data from M. Heron, et al. "Deaths: Final Data for 2006." *National Vital Statistics Reports* 2009; 57(14): 5. Hyattsville, MD: NCHS. Available at www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_14.pdf (accessed June 2010); 2007 data from J. Xu, et al. "Deaths: Final Data for 2007." *National Vital Statistics Reports* 2010; 58(19): 13. Hyattsville, MD: NCHS. Available at www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_19.pdf (accessed June 2010); 2008–2009 data from K. Kochanek, et al. "Deaths: Final Data for 2009." National Vital Statistics Reports 2011; 60(3): 1. Hyattsville, MD: NCHS. Available at www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60_03.pdf (accessed March 2013); 2010–2011 data from D.L. Hoyert and J. Xu. "Deaths: Preliminary Data for 2011." *National Vital Statistics Reports* 2012; 61(6): 5. Hyattsville, MD: NCHS. Available at www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_06.pdf (accessed December 2012).

ME&A Life Expectancy And Infant Mortality Rates Are Behind Developed Nations

Low investment in healthcare and innovative medicines contributes to lagging health outcomes

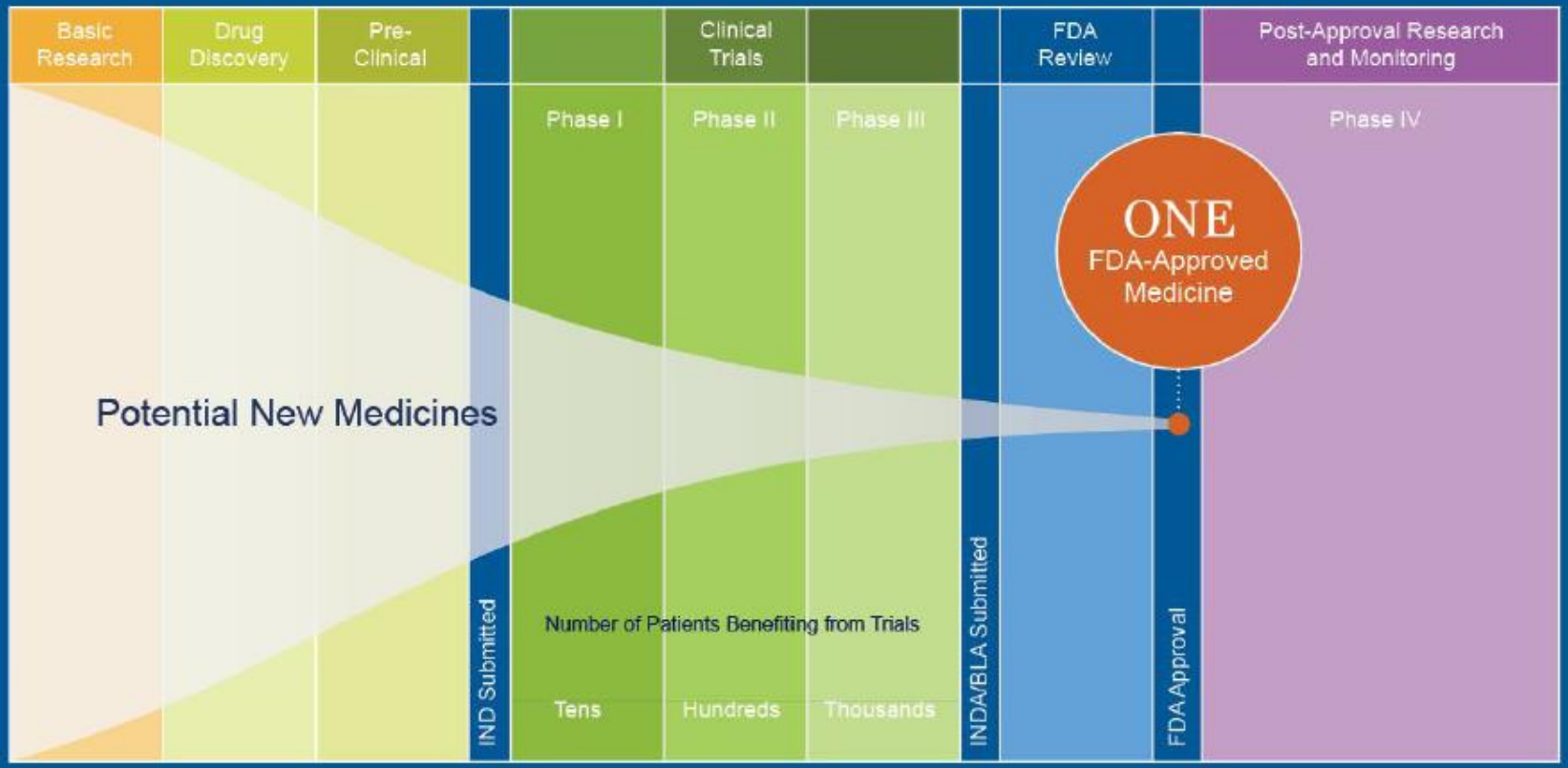




Source: Health Advances analysis; WHO Global Health Observatory Database (accessed September 2016).

The Biopharmaceutical Research and Development Process

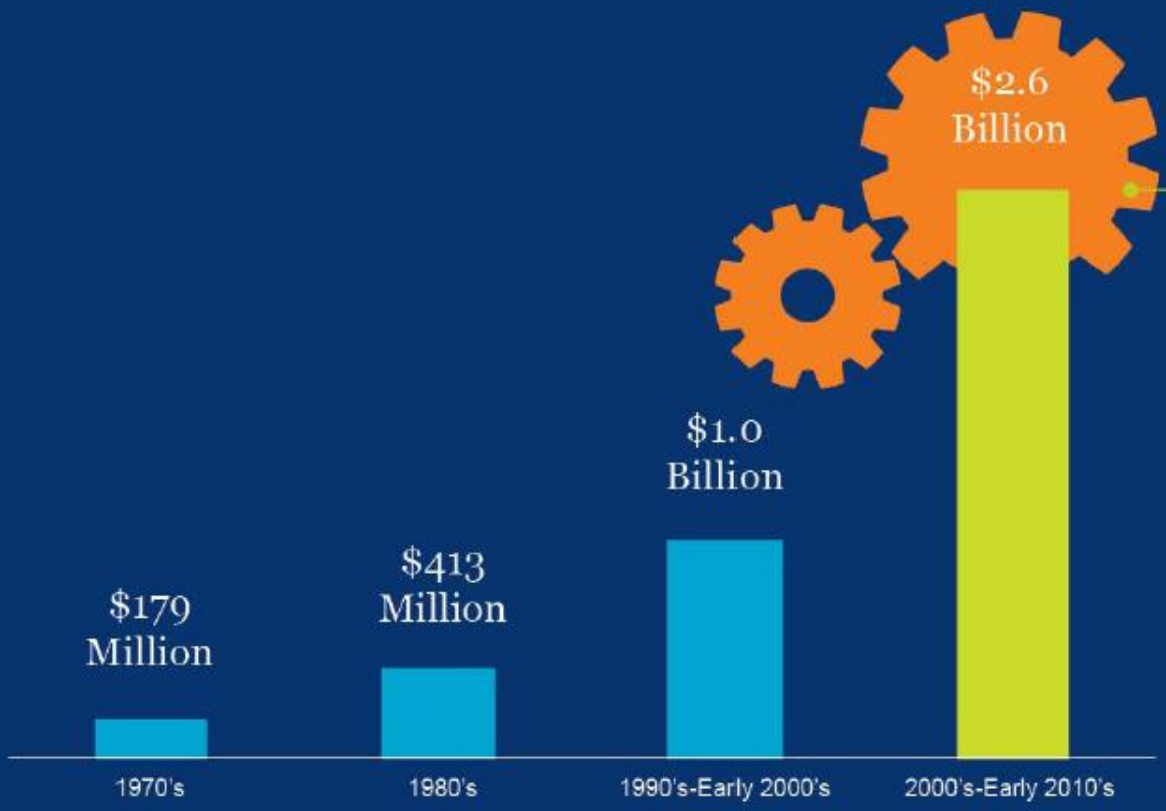
From drug discovery to regulatory approval, developing a new medicine on average takes 10 to 15 years and costs $2.6 billion



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, NDA = 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



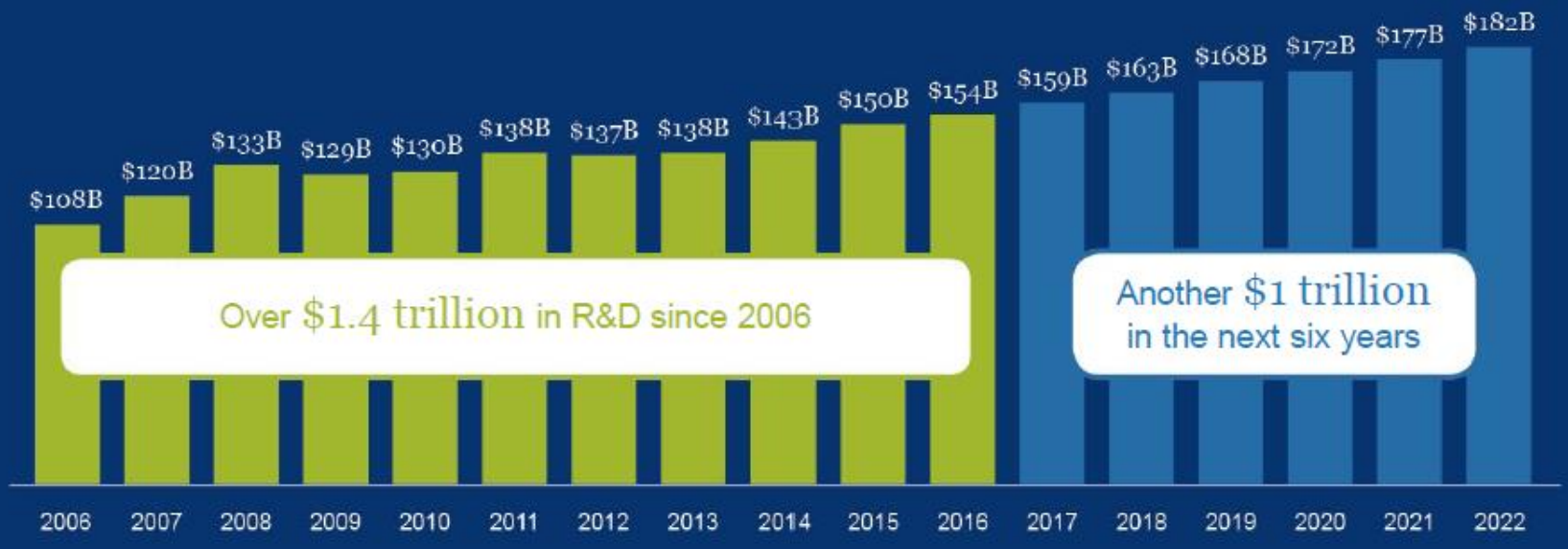
KEY DRIVERS INCLUDE:

- 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.

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 use today's revenues to invest in tomorrow's treatments and cures.

Invested about

$75 Billion

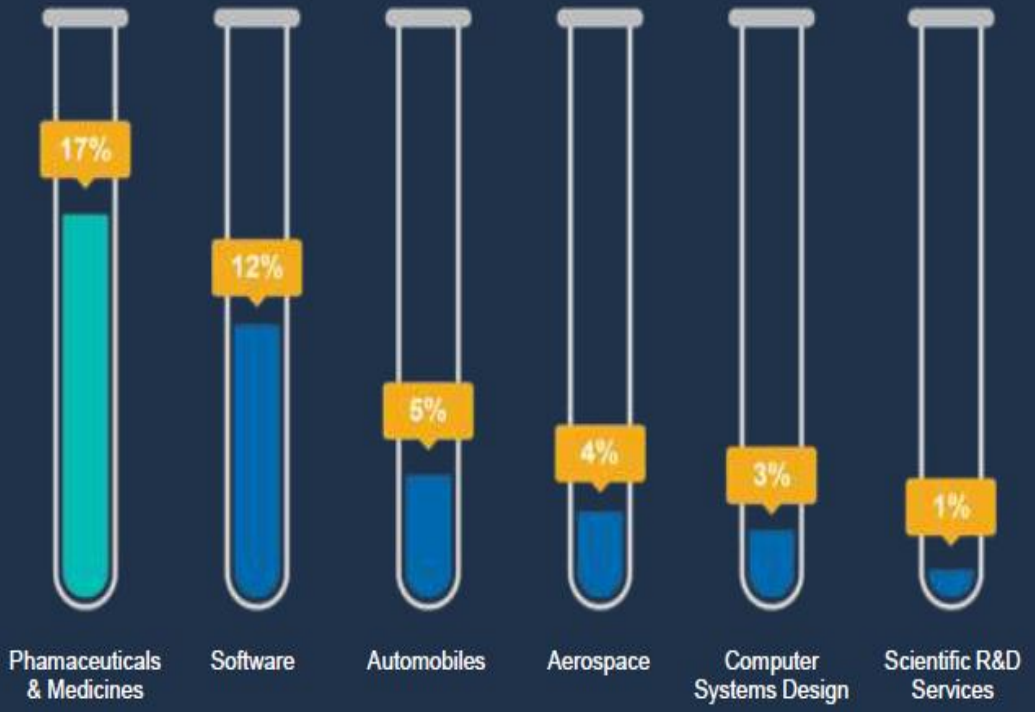
in R&D in 2015

And

20%

of revenues are reinvested into R&D

Industry invests **17%** of all domestic research and development funded by U.S. businesses



We need a public policy environment that recognizes and rewards risk taking.

On average, it takes more than

10 years and $2.6B to research and develop a new medicine.

BETWEEN 1998 AND 2014

Unsuccessful Attempts

123
Alzheimer's Disease

96
Melanoma

167
Lung Cancer

Just

12%

of drug candidates that enter clinical testing are approved for use by patients

Successful Attempts

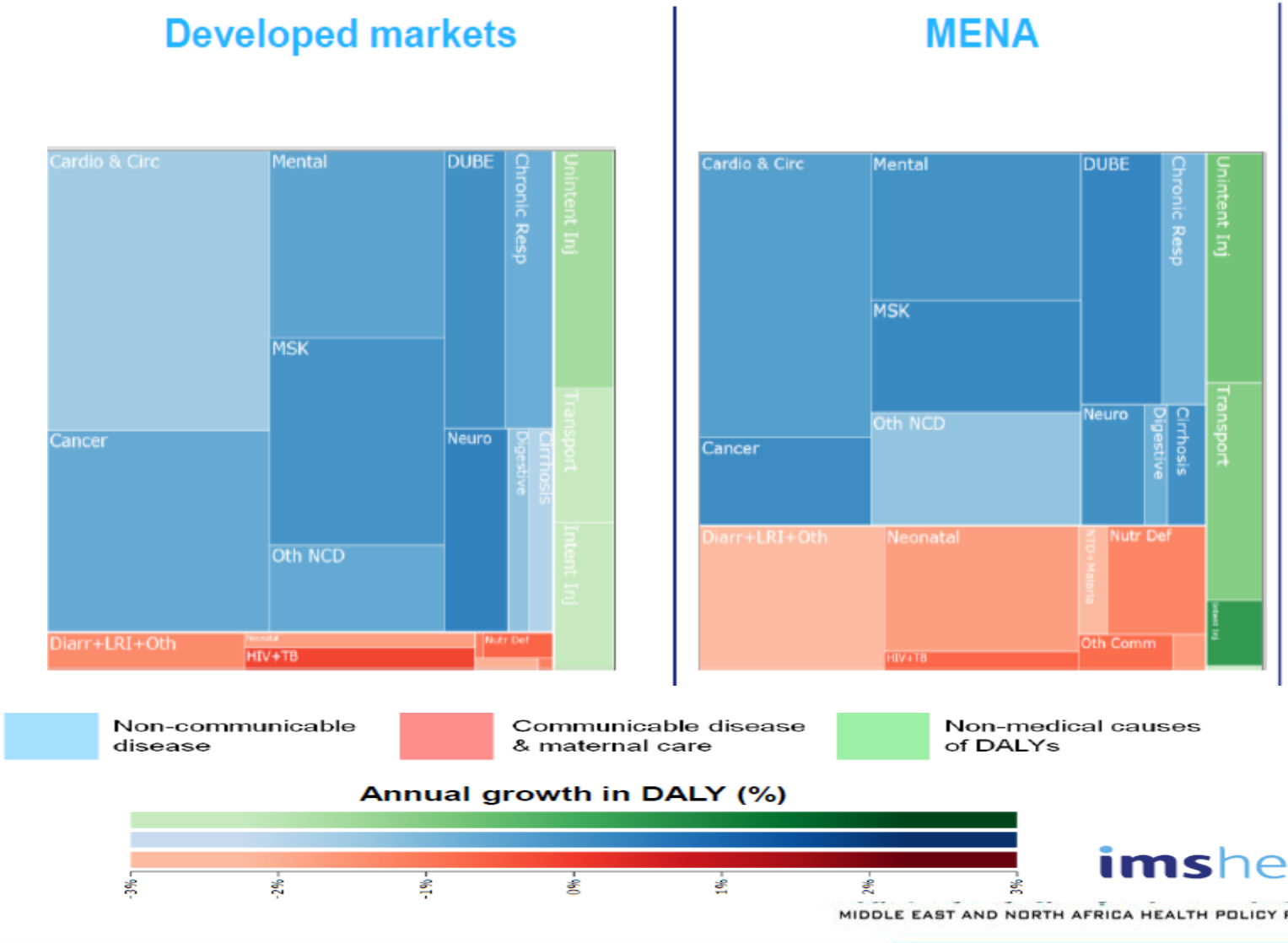
4
Alzheimer's Disease

7
Melanoma

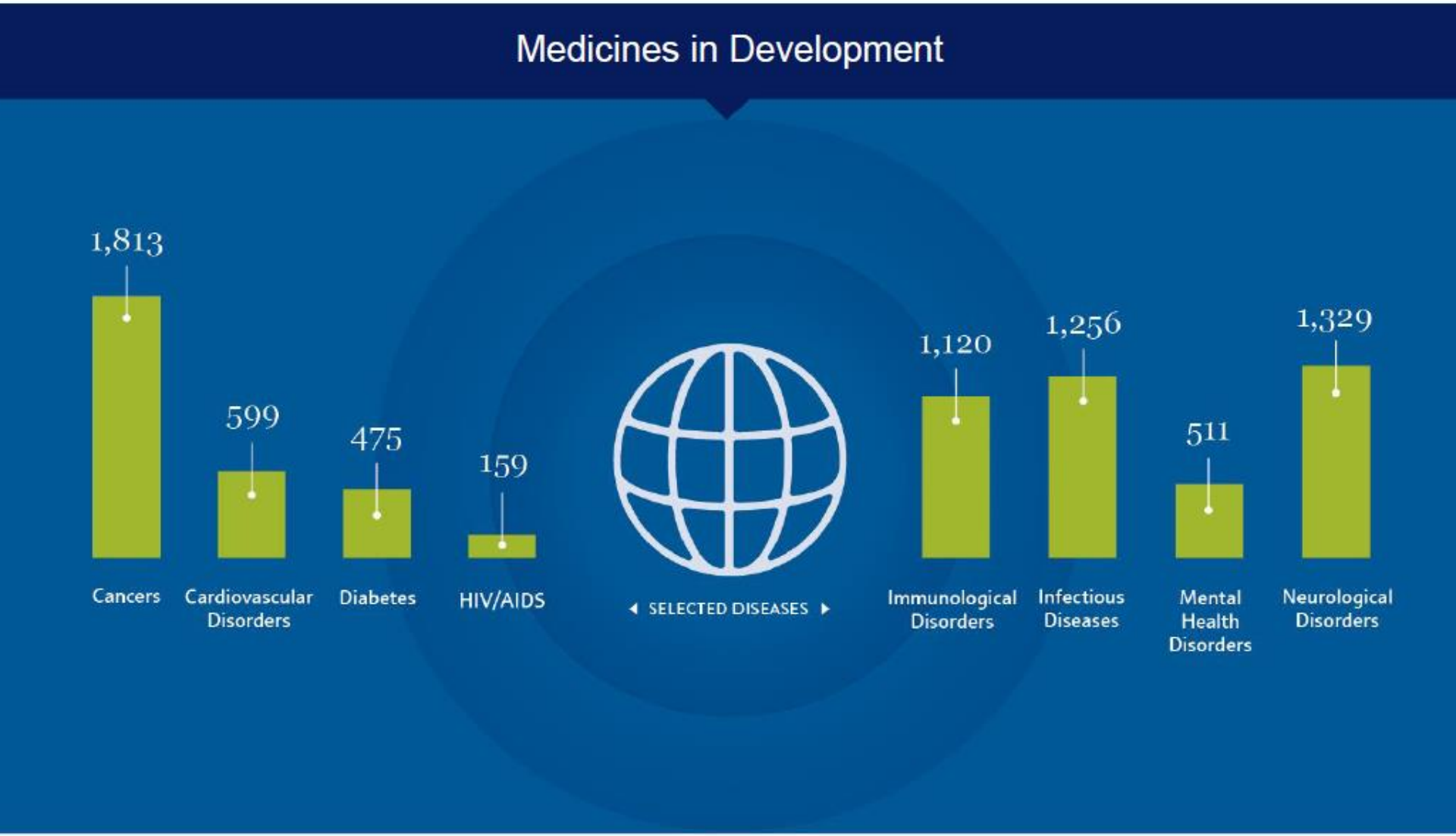
10
Lung Cancer

Communicable disease burden in MENA

DALY: Disability-Adjusted Life Year



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.

We are in a new era of medicine where breakthrough science is transforming care with innovative treatment approaches...

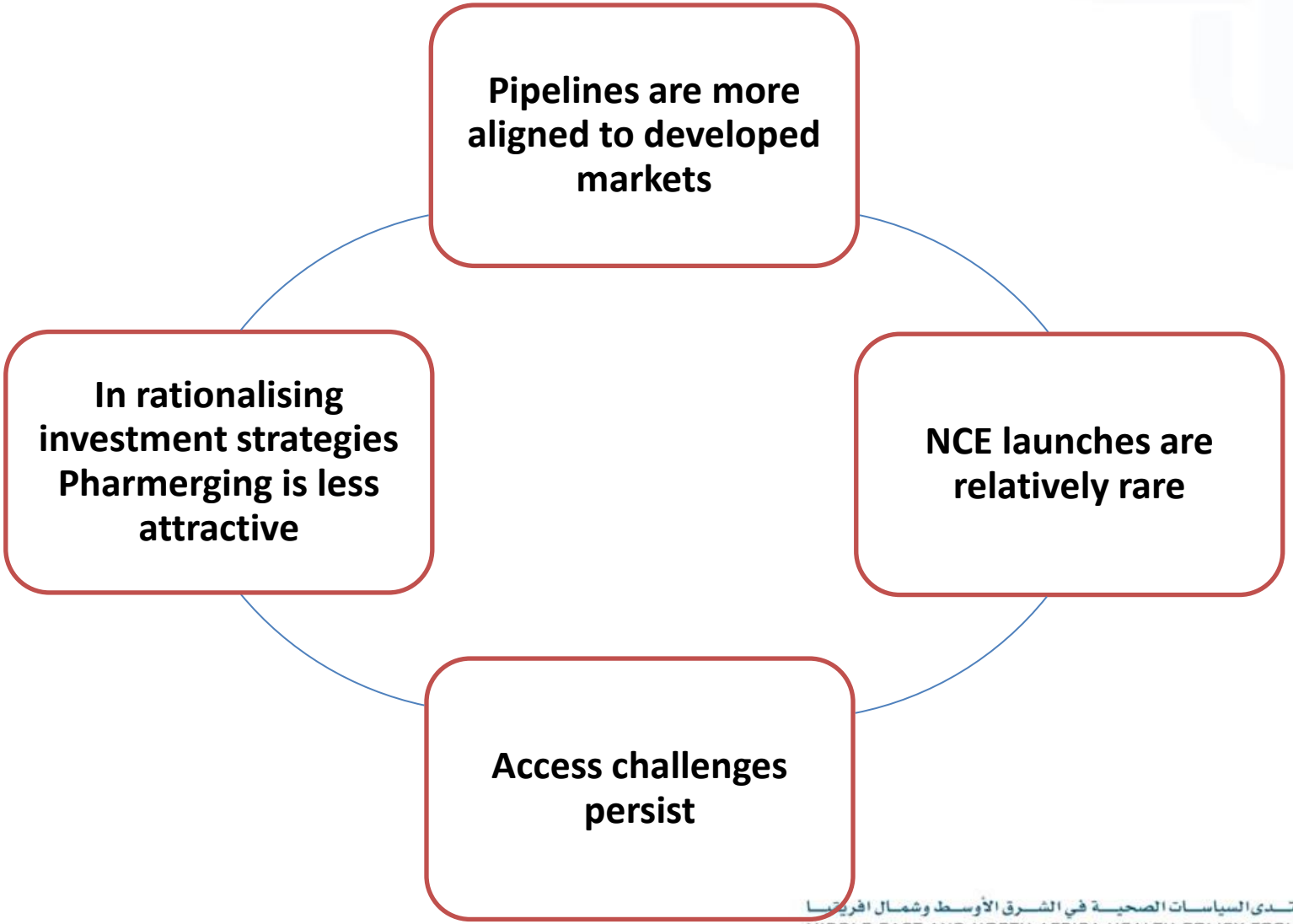
Then

- Medicines made of chemical compounds
- Medicines treat broad diseases
- Radiation and chemotherapy to treat cancer

Now

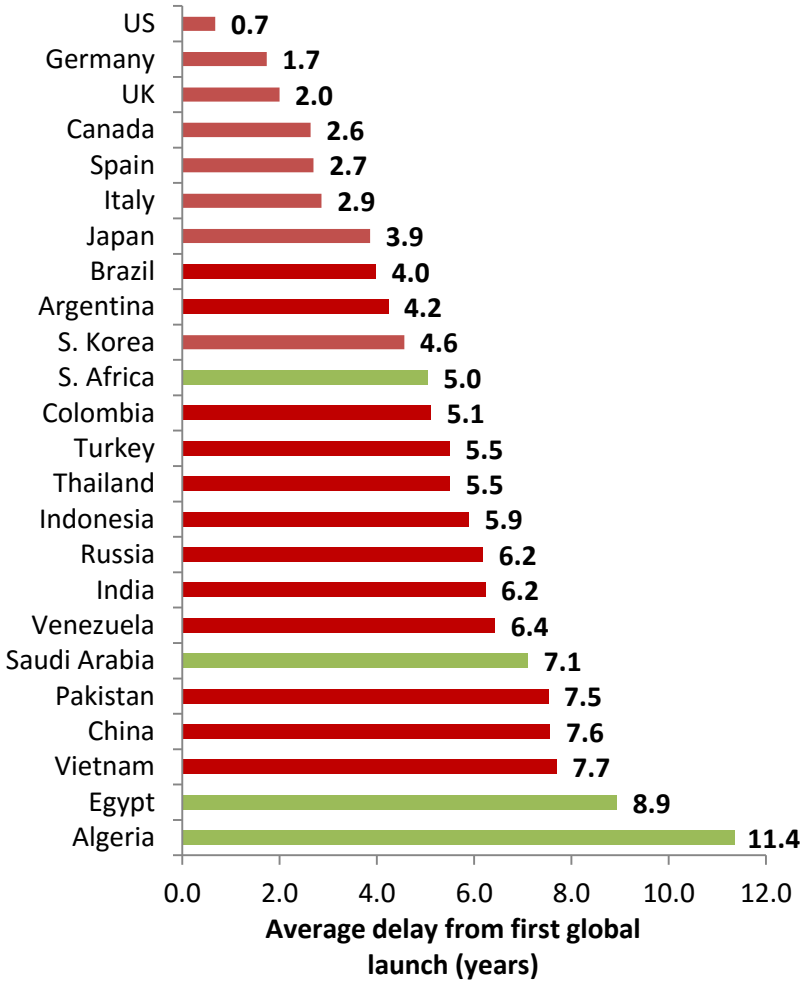
- Medicines made from living cells
- Medicines targeted to specific patient based on genetic makeup
- Immunotherapy that harnesses body's own immune system to fight disease
- CAR T-cell therapy
- CRISPR

Pharmerging risks being marginalised as Pharma shifts strategic focus



Key MEA markets starved of innovation (NCEs)

Delay between NCE global launch and local launch (Years)



Top MEA markets NCE Launch

MEA	NCE's launched 2006-2010	NCE's launched 2011-2015
US	**90**	**144**
SAUDI ARABIA	13	13
EGYPT	6	9
ALGERIA	2	0
SOUTH AFRICA	18	5
UAE	19	30
MOROCCO	6	2

Increase in NCE launches

Decrease in NCE launches

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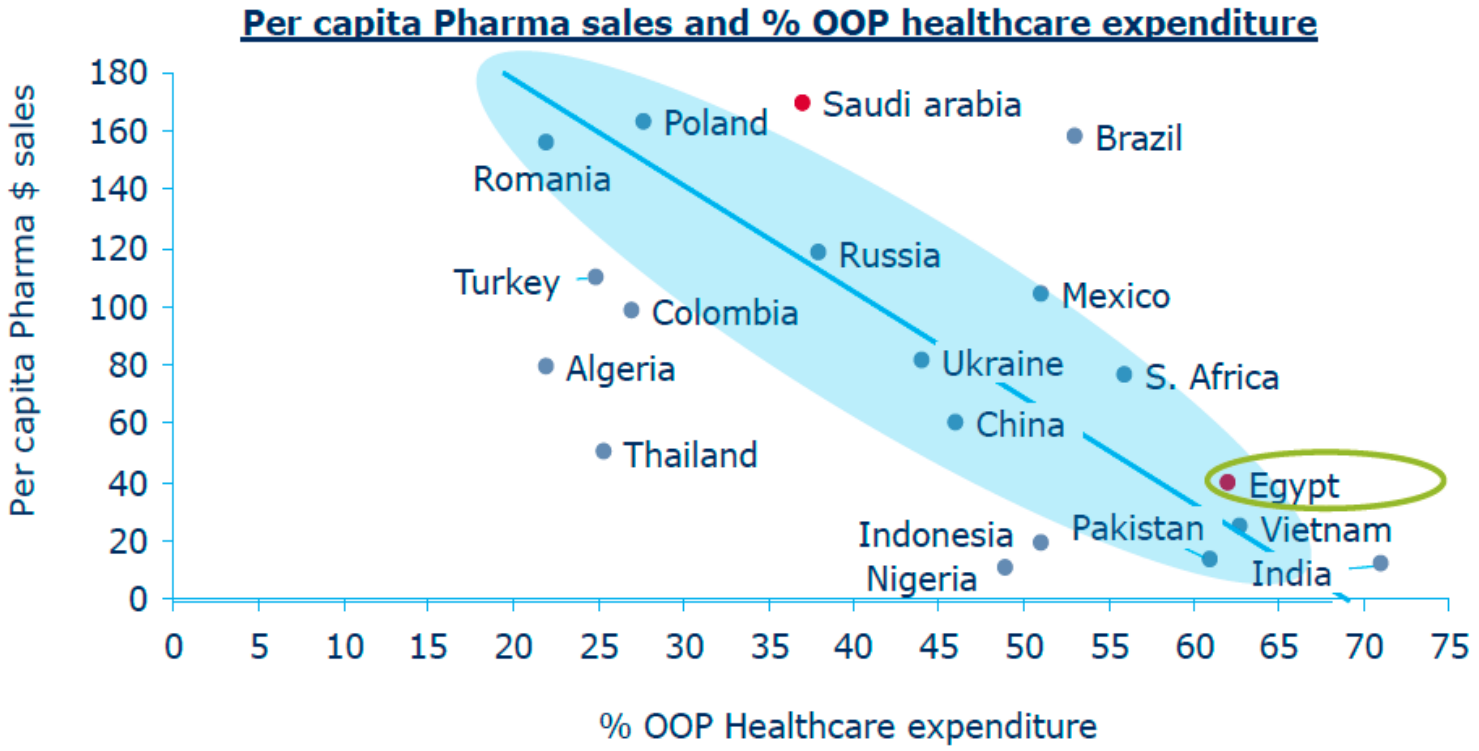
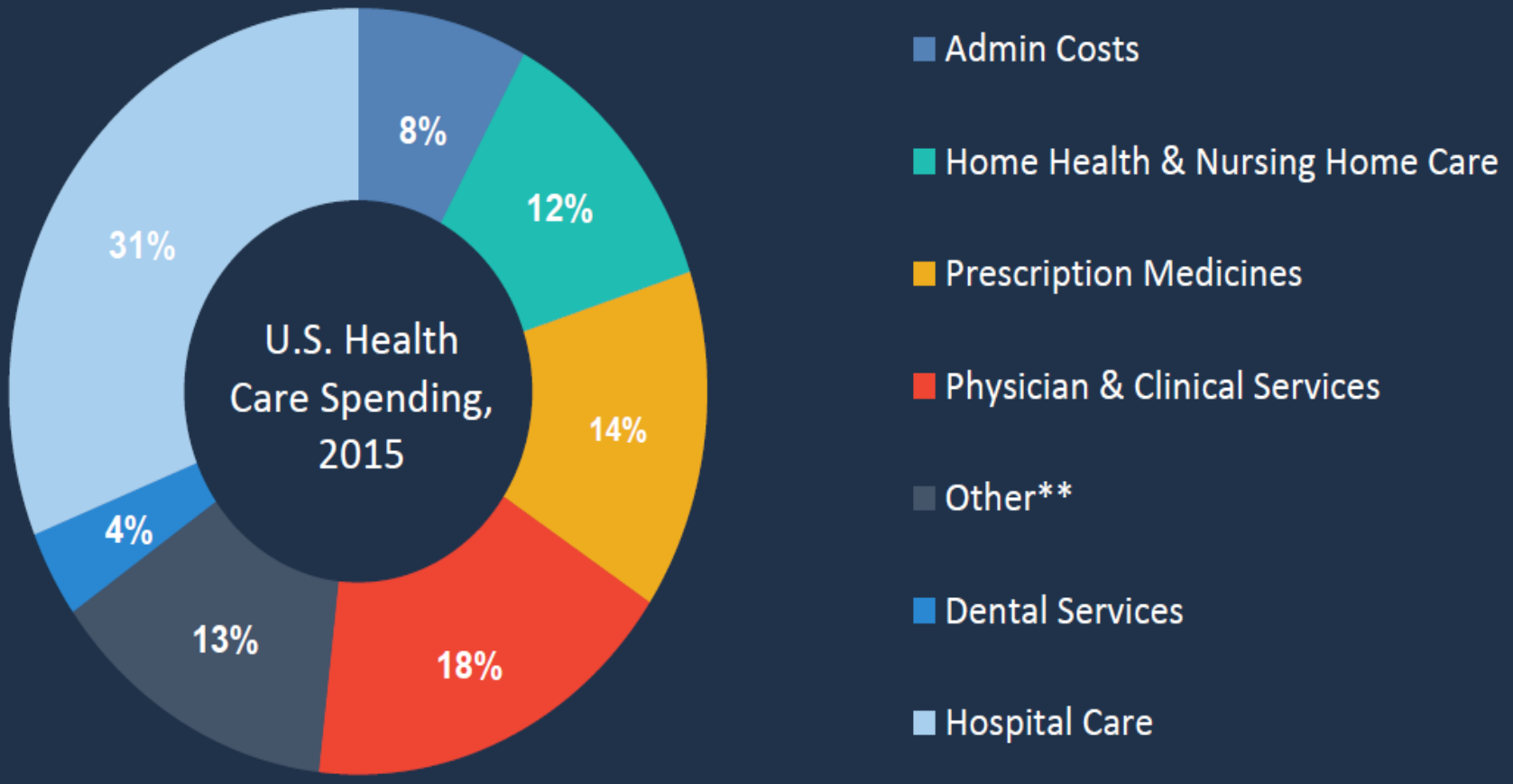
Notes: NCE launches between 2006-2015 considered; an NCE is counted for a country if the local launch falls within the same time period as the global launch; KSA, Egypt, Algeria, UAE & Colombia retail only; Brazil & Mexico retail included
Source: QuintilesIMS MIDAS 2015

Lower relative income and higher OOP contributions translates into lower pharma sales in most cases



Source: World Health Organization WHOSIS database; IMS analysis, IMS Global market prognosis 2012-2016

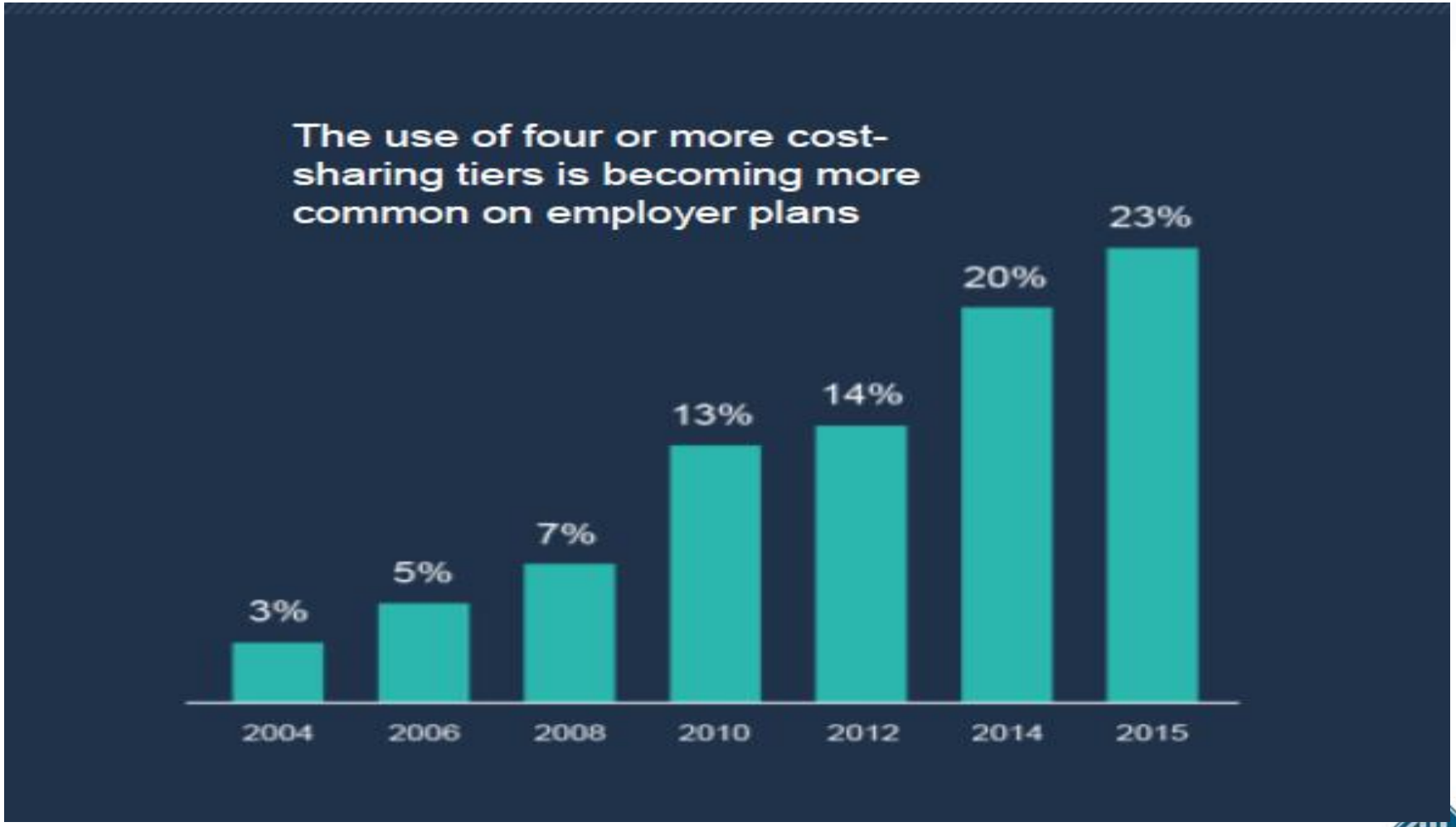
Spending on retail and physician-administered medicines continues to represent just 14% of spending…



Spending on prescription medicines is a small percentage of total health care spending around the world.

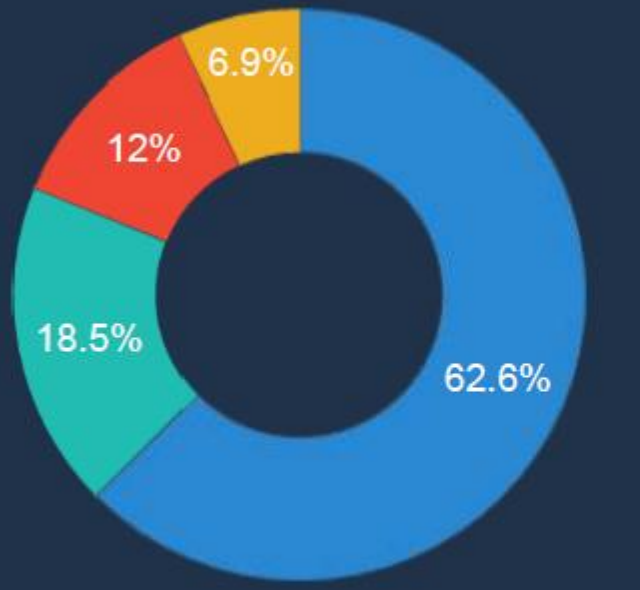
Prescription Medicines as a Percentage of Total Health Care Spending

Patients in the United States are facing rising out-of-pocket costs and other barriers to care.



More than 1/3 of the list price is rebated back to payers in US

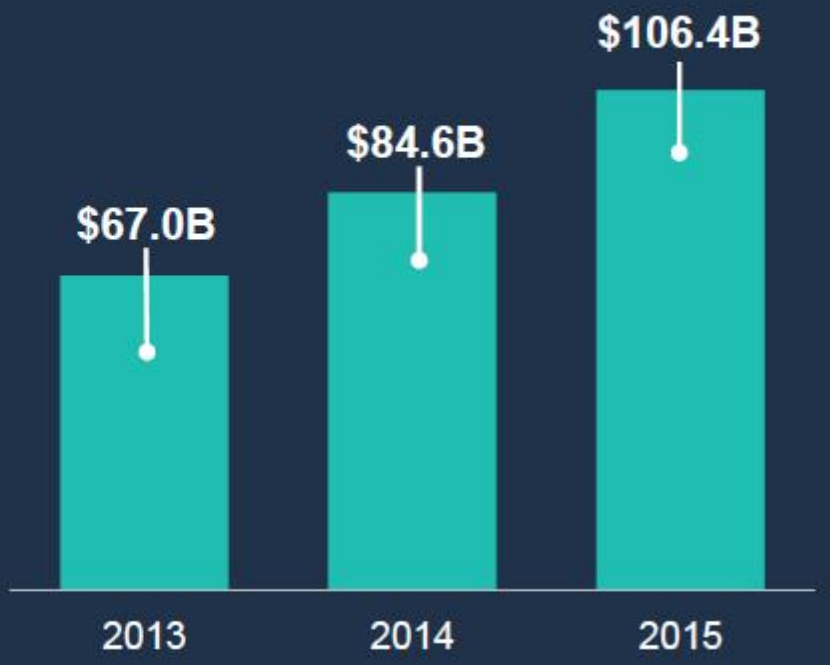
Brand companies retain just 63% of list price spending on medicines



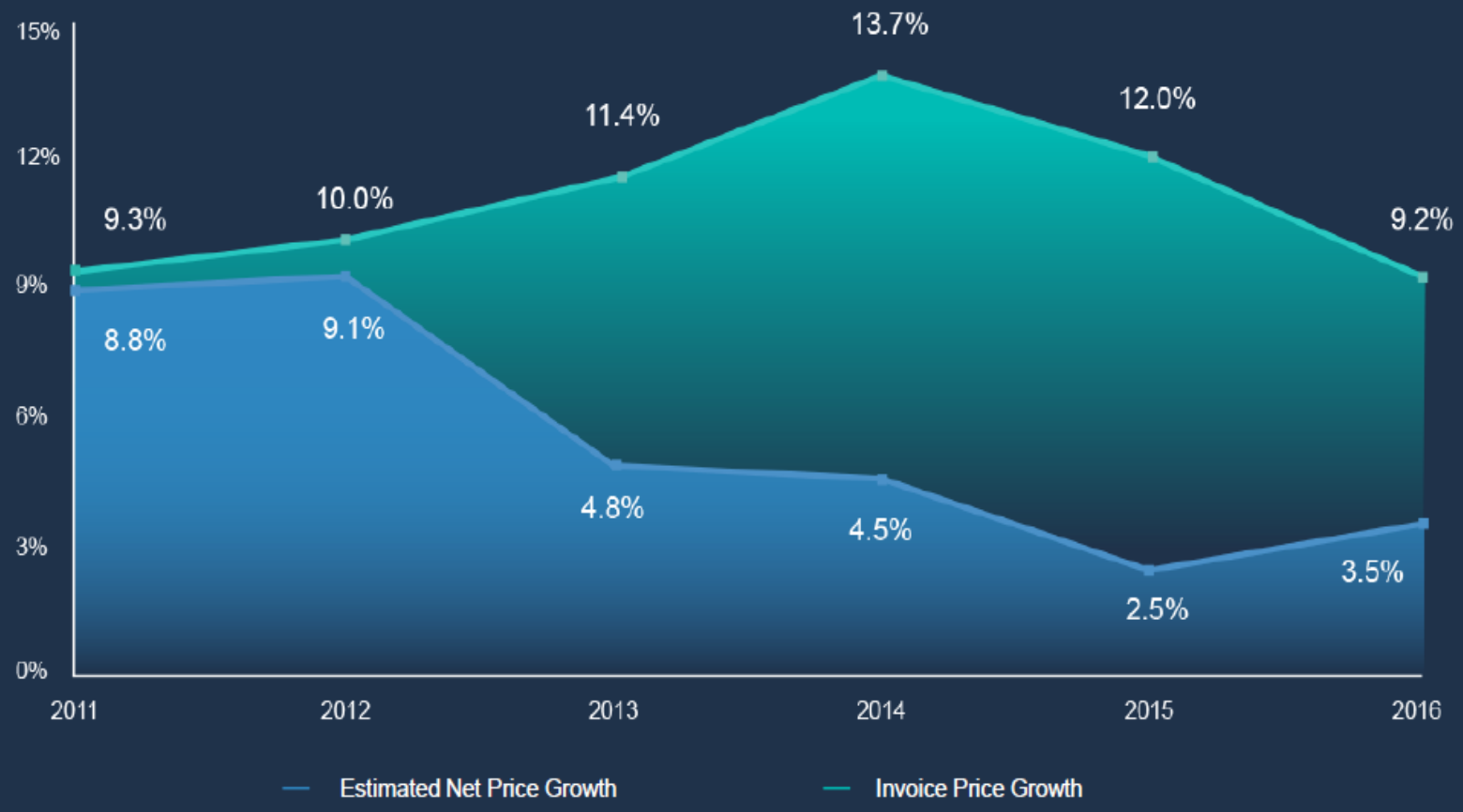
- Brand Companies
- Market Access Rebates and Discounts
- Statutory Rebates and Fees
- Supply Chain Entities

Source: Berkeley Research Group.

Rebates, discounts and fees keep increasing



In fact, after discounts and rebates, brand medicine prices grew just 3.5% in 2016.



Patients share the costs for their medicines. They should share the savings, too

- **Negotiated discounts for medicines are not shared with patients with high deductibles or coinsurance.** A new analysis from Amundsen Consulting found more than half of commercially insured patients' out-of-pocket spending for brand medicines is based on the full list price.

- **Insurers should share more of these rebates with patients.** Providing access to discounted prices at the point-of-sale could dramatically lower patients' out-of-pocket costs.

Your insurer doesn't pay full price for medicines.

So why do you?

Patients share

Reforms can make medicines more affordable and accessible.

MODERNIZE THE DRUG DISCOVERY AND DEVELOPMENT PROCESS

- Modernize the authorities to keep pace with scientific discovery and increase efficiency of generic approvals
- Promote and incentivize generic competition.

EMPOWER CONSUMERS AND LOWER OUT-OF-POCKET COSTS

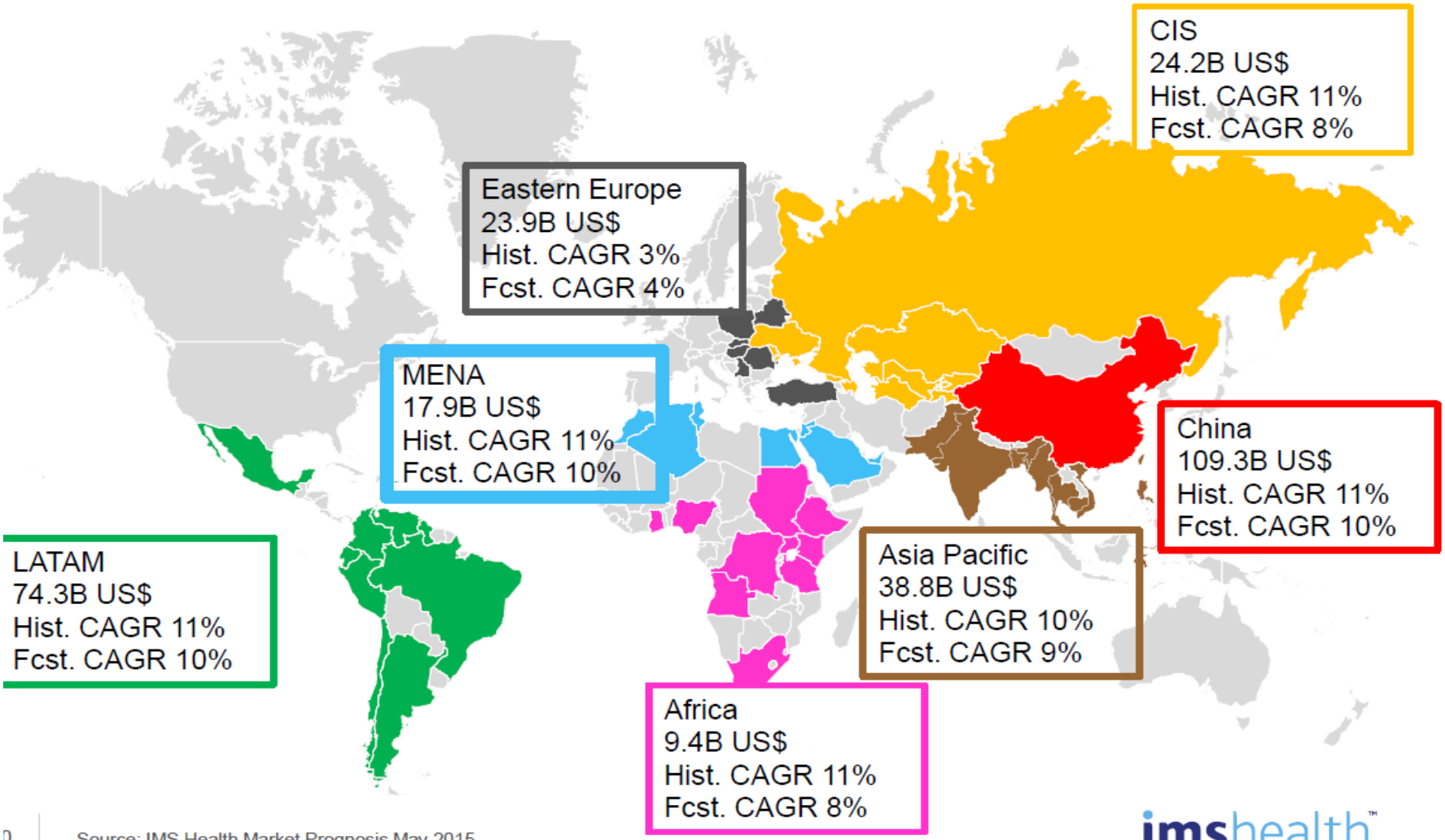
- Provide patients with access to negotiated rebates.
- Address affordability challenges in the deductible.
- Make more information on health care out-of-pocket costs and quality available to patients.

PROMOTE VALUE-DRIVEN HEALTH CARE

- Remove barriers restricting information companies can share with insurers.
- Reform regulations discouraging companies from offering discounts tied to outcomes.

END

At a macro level MENA is not the largest but it has attractive growth rates



Source: IMS Health Market Prognosis May 2015