WITA/GWU TRADE SEMINAR
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RICHARD KJELDGAARD

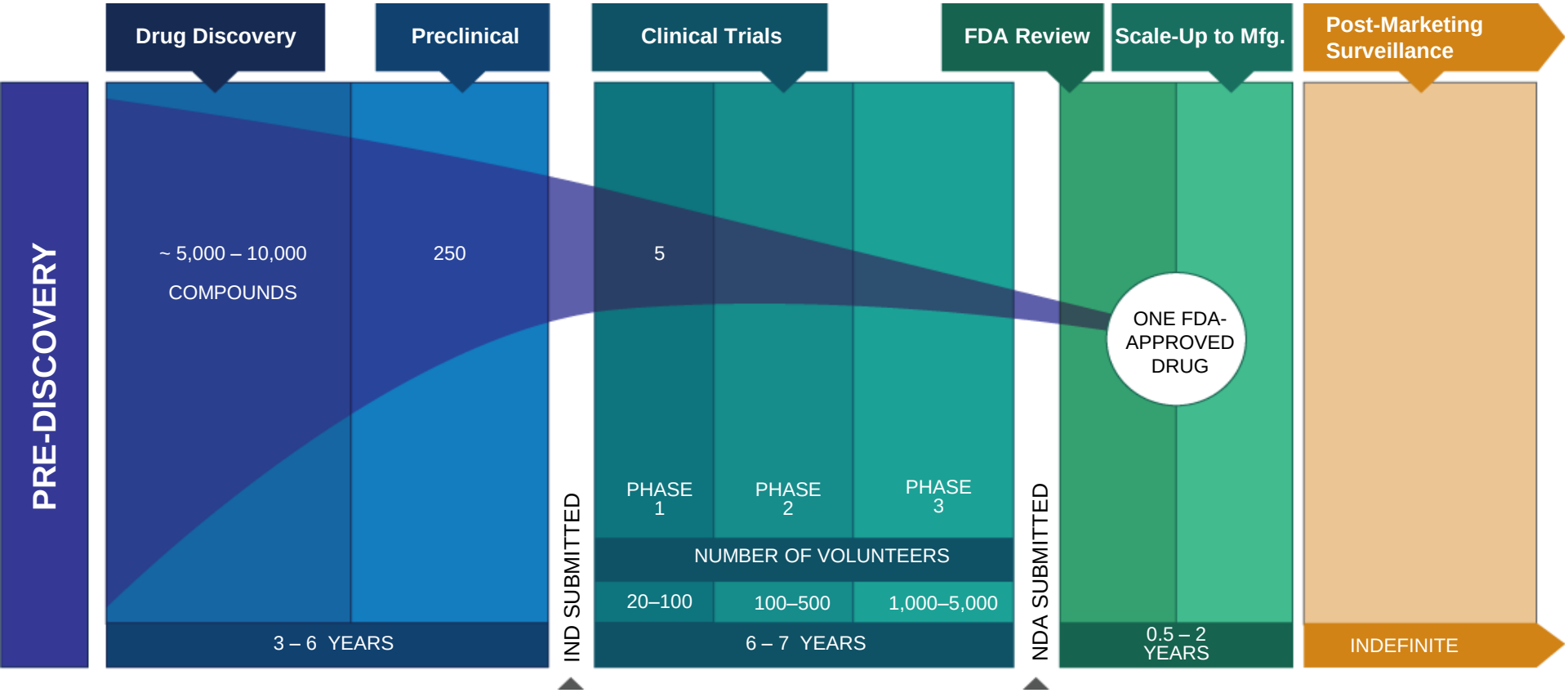
INTELLECTUAL PROPERTY AND TRADE CONSULTANT

Pharmaceutical IP Policy Issues

- Economics - Business Model – IP
- TPP
- Global Challenges
- Access

Valuable But Vulnerable: Limitless Possibilities, Growing Challenges

Developing a new medicine is lengthy, risky, and costly.
New drug development takes an average of 10–15 years, and costs approx. US $1.3 billion.

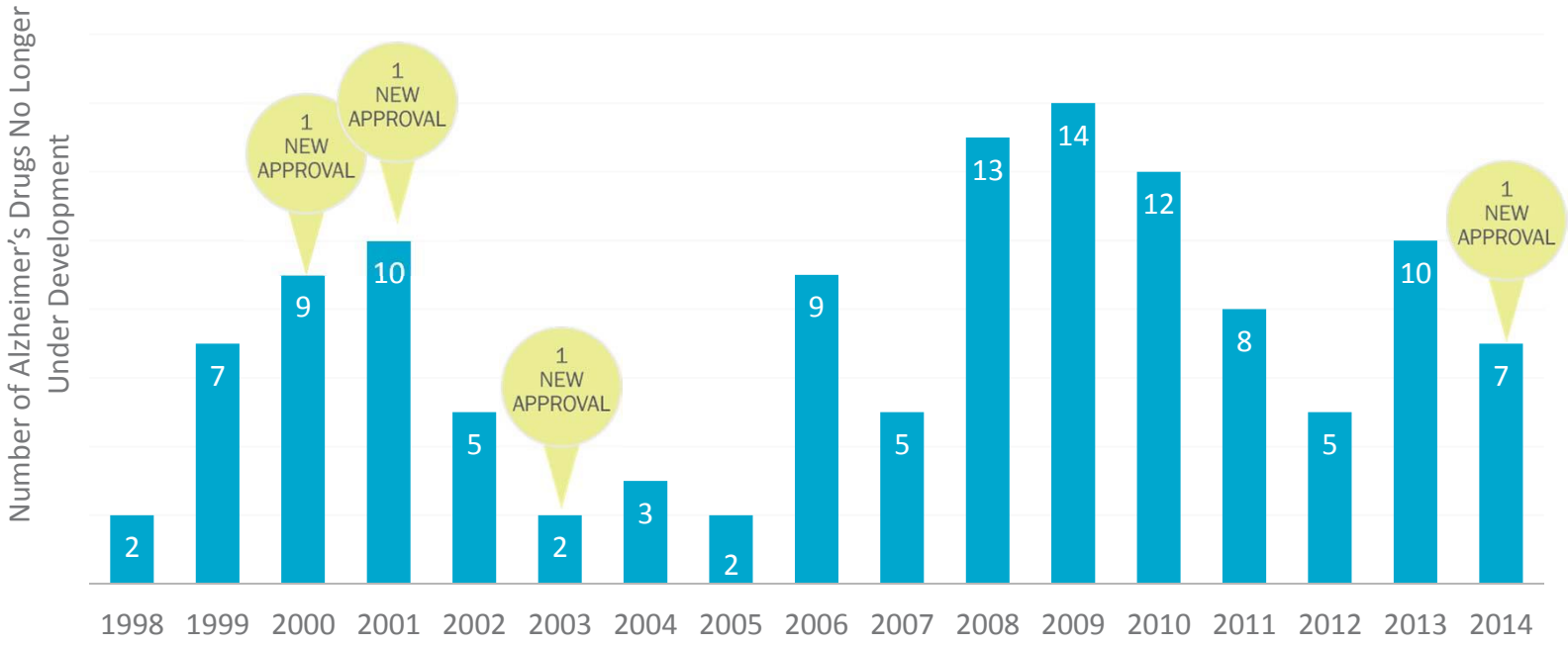


Sources: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org

Setbacks in Alzheimer's Disease Research Provide Stepping Stones for Future Innovation

Since 1998, 123 medicines in development for the treatment of Alzheimer's disease have not made it through clinical trials, with only 4 gaining FDA approval. These setbacks highlight the complexity of the R&D process. Though disappointing, they provide important knowledge to fuel future research.

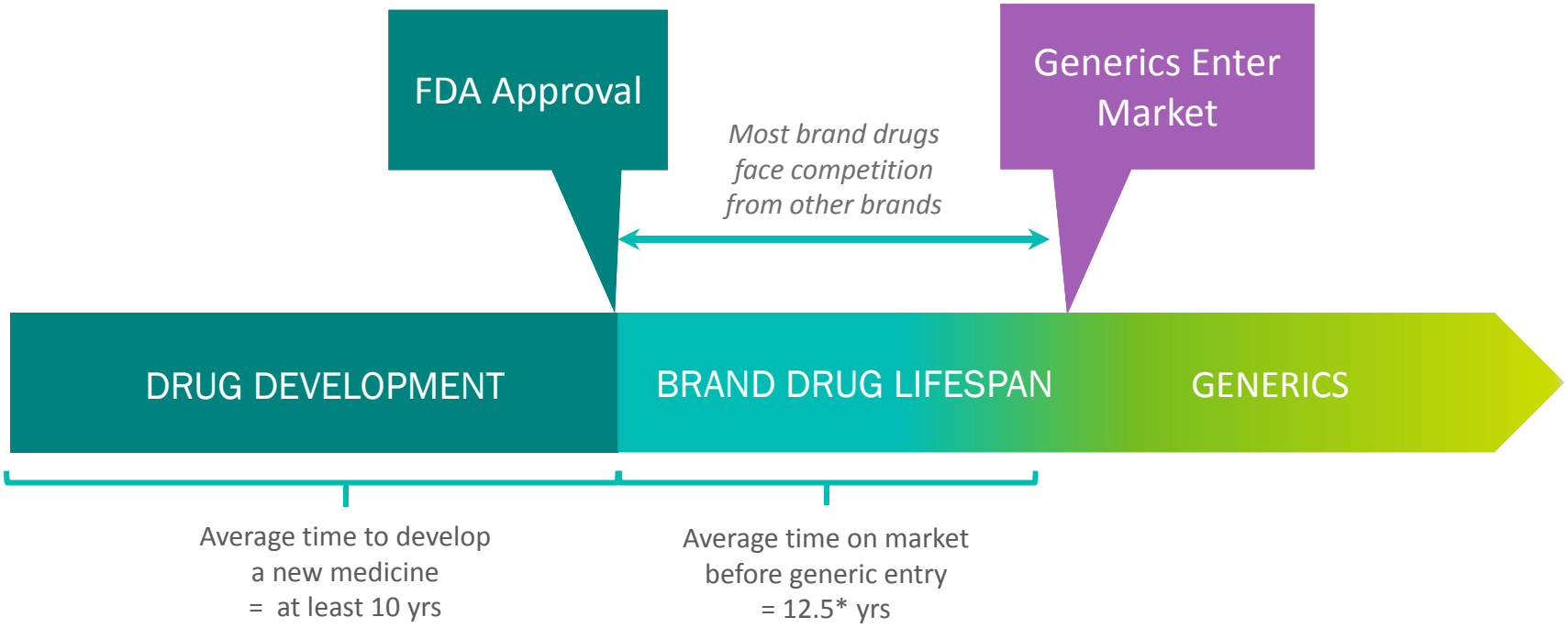
Unsuccessful Alzheimer's Drugs in Development, 1998-2014



Source: PhRMA[22]

Illustrative Pharmaceutical Lifecycle

New pharmaceutical medicines face competition after a relatively short period on the market.



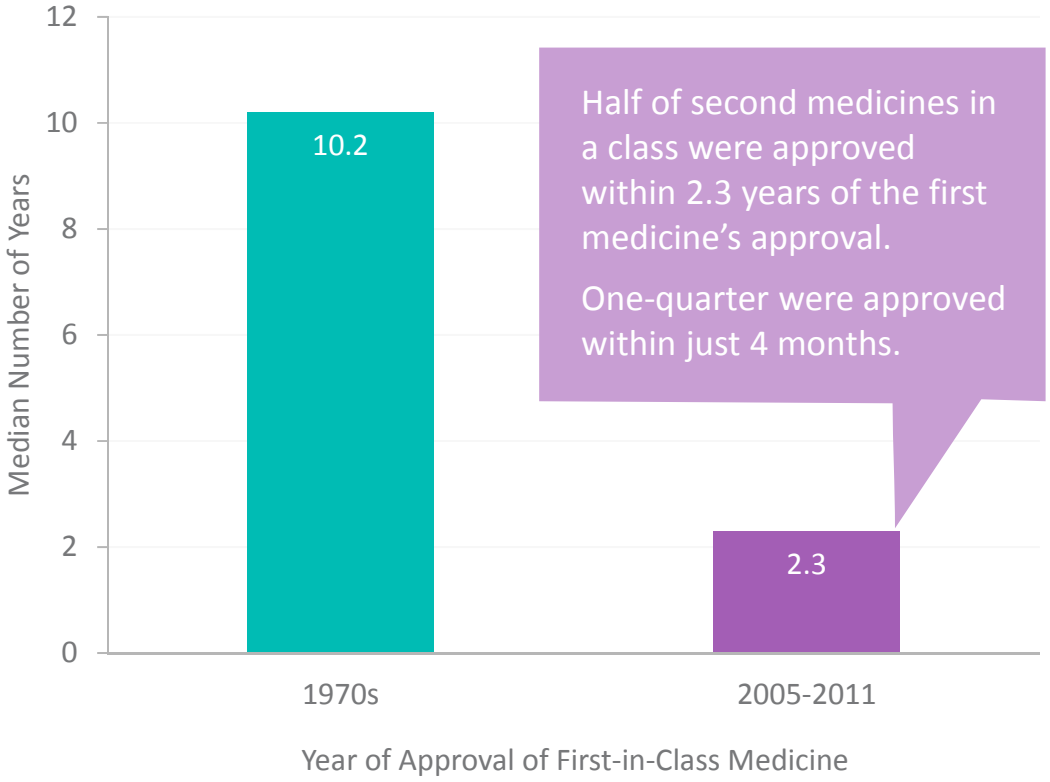
*For brand medicines with more than $250 million in annual sales in 2008 dollars, which account for 92% of sales of the brand medicines analyzed

Sources: PhRMA[1]; Grabowski H, et al.[2]; Tufts CSDD[3]

Increasing Competition Within Therapeutic Categories

The time a medicine is the only drug available in its pharmacologic class declined from a median of more than 10 years in the 1970s to close to 2 years in the 2000s.

Time Between Approval of First and Second Medicines in a Pharmacologic Class

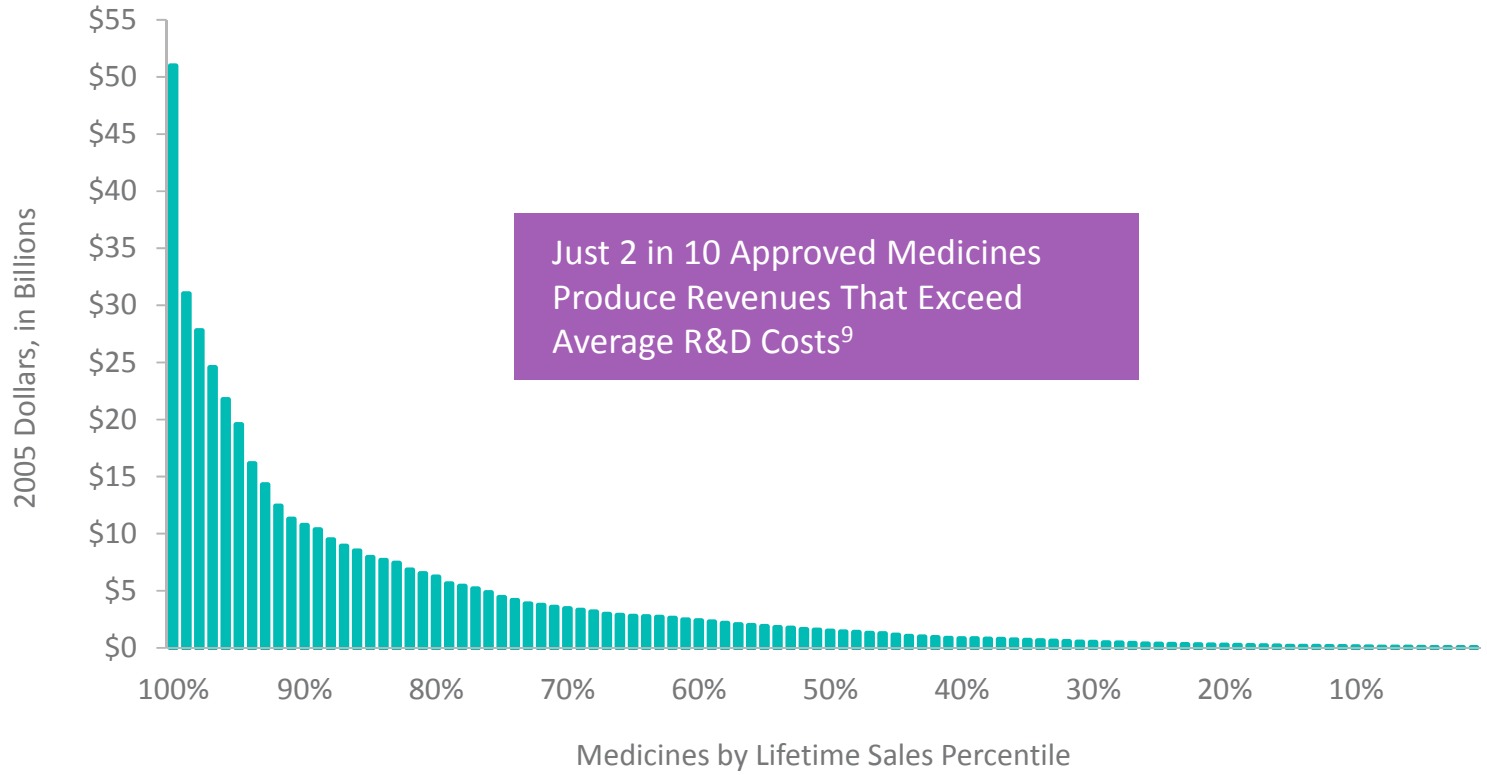


Source: Tufts CSDD[4]

Few Approved Medicines Are Commercially Successful

Ongoing investment in R&D depends on the commercial success of a few products that must make up for all the rest, including those that never reach the market.

Present Value of Lifetime Sales of Medicines Introduced 1991-2009[7]



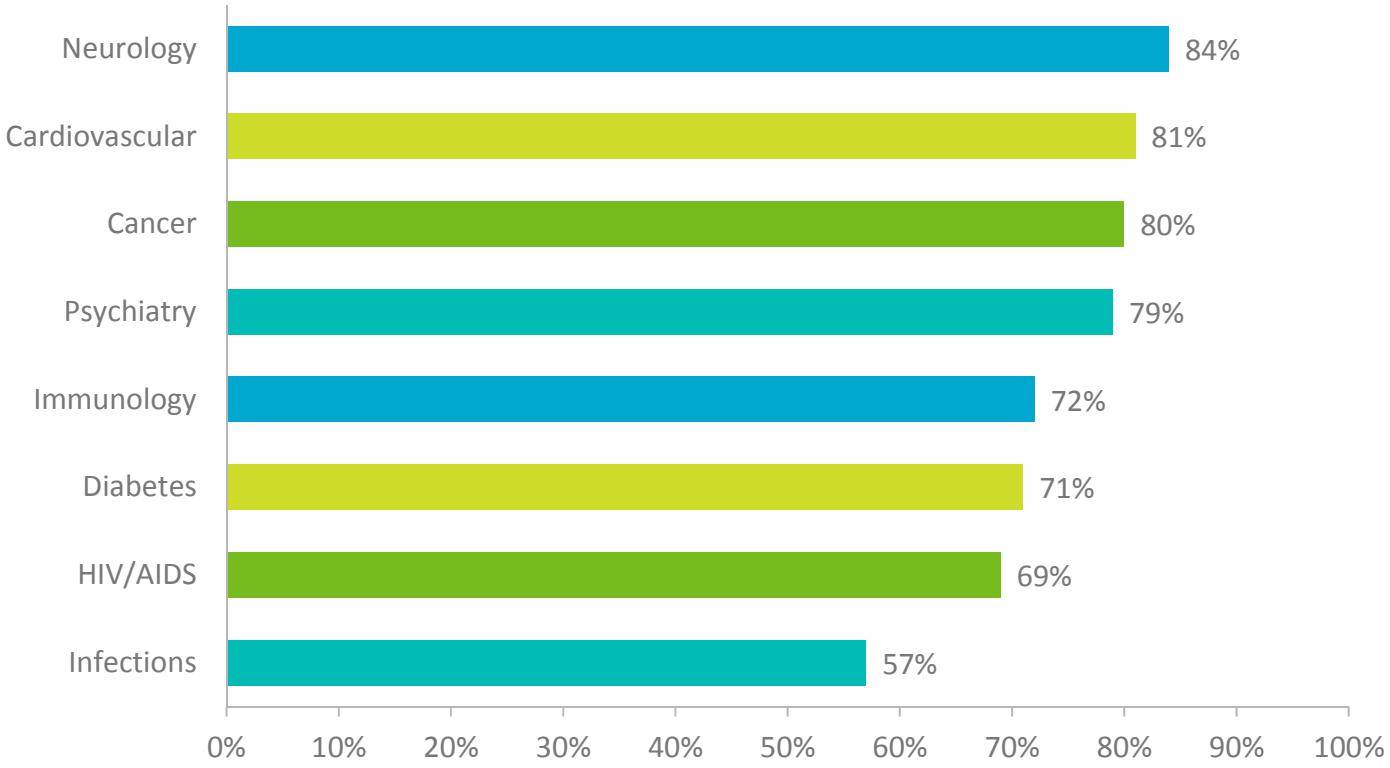
A "medicine" is defined as a novel active substance (ie, a molecular or biologic entity or combination product in which at least one element had not been previously approved by the FDA). Sales are global sales net of rebates and discounts.

Sources: Berndt ER, et al.[8]; Vernon JA, et al.[9]

Potential First-in-Class Medicines in the Pipeline

An average of 70% of drugs across the pipeline are potential first-in-class medicines.

Percentage of Projects in Development That Are Potentially First-in-Class Medicines in Selected Therapeutic Areas, 2011

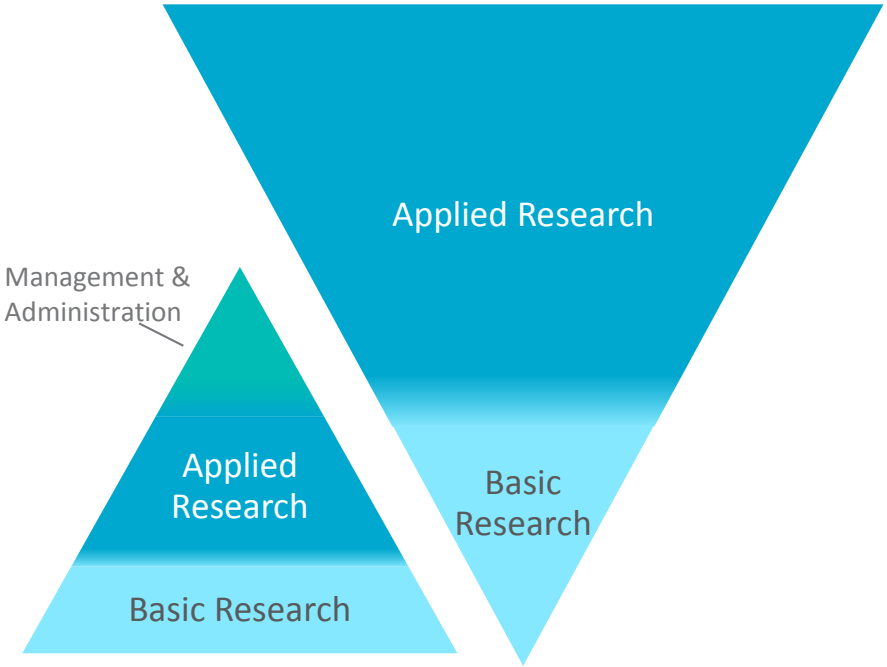


Source: Analysis Group[2]

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

While basic science is often initiated in government and academia, it is biopharmaceutical firms that provide the necessary critical mass, expertise, and experience needed to develop new medicines.[12]

2015 PhRMA Member Companies
Biopharmaceutical R&D Investment: $58.8 Billion (est.)[11,13]



2015 TOTAL NIH Budget: $30.3 Billion[11,14]

In addition to biopharmaceutical R&D, the NIH budget includes funding in support of medical devices, diagnostics, prevention, training, and other activities.

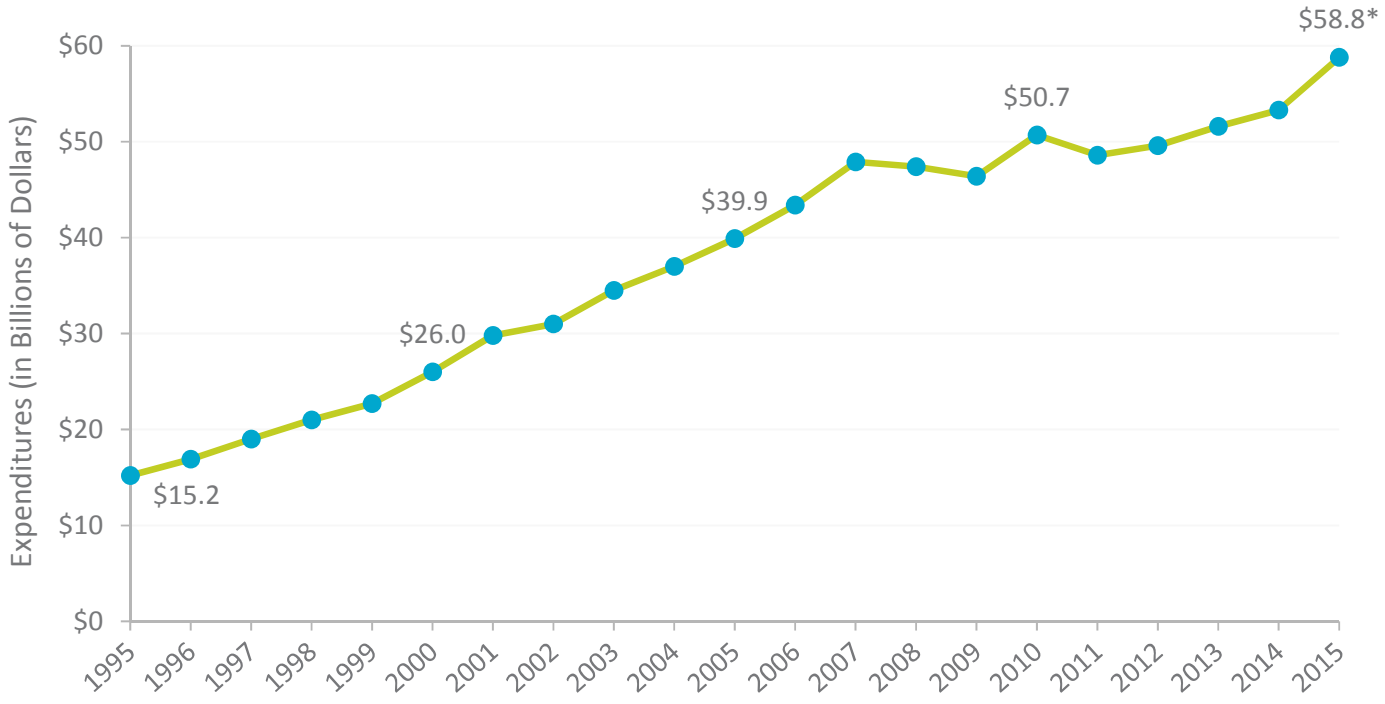
Sources: Tufts CSDD[12]; PhRMA[13]; NIH[14]

PhRMA Member Company R&D Investment

The pharmaceutical industry is one of the most research-intensive industries in the United States. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm.

— Congressional Budget Office (CBO)[19]

PhRMA Member Company R&D Expenditures, 1995-2015



*Estimated fiscal year 2015

Sources: CBO[19]; PhRMA[20]

TPP – IP PERSPECTIVES

It is the opinion of ITAC-15[1] that to a reasonable extent and with consideration of the broader impact of this agreement, the TPP promotes the economic interests of the United States and advances the overall and principal negotiating objectives with respect to intellectual property set forth in section 102 of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015.

- [1]ITAC Members representing BIO and PhRMA and those representing companies that are members of PhRMA or BIO reserve their position on this statement.

https://ustr.gov/sites/default/files/ITAC-15-Intellectual-Property.pdf.

Extending Data Protection - Budget Impact

- Canada
  - 2006 RDP went from 0 to 8 years
  - 2006 medicines spend = 17.2% total health spend
  - 2011 medicines spend = 16.6% total health spend

ILLUSTATIVE GLOBAL CHALLENGES

- BRAZIL
  - ANVISA
- CHINA
  - Regulatory Data Protection
- CANADA
  - Utility requirement
- INDIA
  - New formulations and other follow-on innovations

COMPULSORY LICENSING - COLOMBIA

- Glivec introduced into Colombia at government determined price
- 100% Access
- 2 generic versions marketed in Colombia
- March 4, 2016 Minister of Health recommended complusory license
- September 2016 Government said it would impose severe price reduction

“Ever-greening”

CONTENTION:

- Patent protection on original product extended by grant of follow-on patents on new formulations - prevents generics from commercializing the original product, even after expiration of the original product patent.

REALITY:

- The secondary patent protects only the improved product, not the original product. Generic applicants are free to market the original product if its patent is expired.

"Ever-greening" is a False Premise: A Real-World Example

- PROZAC®, a first-in-class therapy for major depressive disorder, launched in 1987
  - Daily dosage regimen, generally 20mg/day
  - Patent protection expired August 2001
- PROZAC® Weekly™ approved February 2001
  - Separate patent protection for weekly dosing regimen
  - Launched only months before expiration of PROZAC compound patent
- Generic applicants were free to launch Prozac for daily use after expiration of the compound patent
- Patients & Doctors decide whether the secondary patent has value

R&D ON NEGLECTED DISEASES OF DEVELOPING WORLD

THREE LARGEST FUNDING SOURCES IN ORDER:

- UNITED STATES (71% OF GOVERNMENT CONTRIBUTIONS)
- GATES FOUNDATION (78% OF PHILANTHROPIC)
- PHARMACEUTICAL INDUSTRY (68% OF PRIVATE SECTOR)
  - LARGER THAN EC AND EU MEMBER STATE CONTRIBUTIONS
  - CHEMICAL LIBRARY CONTRIBUTIONS VALUED AT 0

2015 G-FINDER REPORT

Committed to Sustainable Access Solutions

- Support over 340 initiatives with more than 600 partners to improve health

- $94.8 billion contributed since 2000 towards achieving UN Millennium Development Goals on Health
  - Product donations and wide array of capacity building interventions to strengthen local health care institutions and improve access

Source: Norris, Jeremiah et. al., *The Pharmaceutical Industry's Contributions to the United Nations Millennium Development Goals*, Hudson Institute Center for Science in Public Policy Economic Policy/Briefing Paper, 16 (2013). Available at: http://www.hudson.org/files/documents/ThePharmaceuticalIndustry_sContributionstotheUNMillenniumDevelopmentGoals.pdf.

Barriers to Access

- Insufficient infrastructure - lack of:
  - trained health care workers;
  - health care systems;
  - transportation
- Inadequate Government investment
- Significant mark ups in distribution chain
- High government taxes and tariffs

Sources: *See, e.g.*, Wilsdon, Tim et. al., *Evidence on Access to Essential Medicines for the Treatment of HIV/AIDS* (2011).

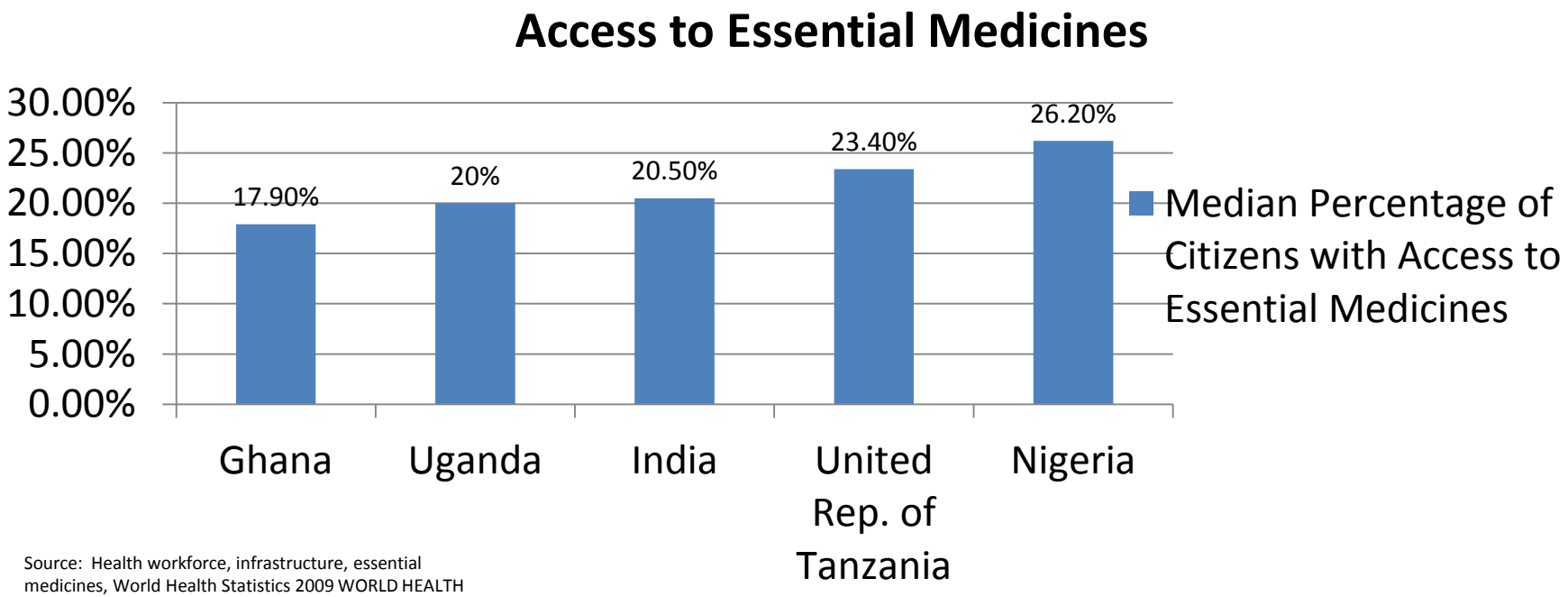
Eliminating IP Does not Solve Access Problems for the Poor

India - Between 1970 and 2005

- no patents on medicines
- large generic industry developed

WHO - Between 2000 and 2007 in India

- Access to medicines among worst in world



Source: Health workforce, infrastructure, essential medicines, World Health Statistics 2009 WORLD HEALTH ORGANIZATION.

THANK YOU