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Access to Essential Medicines: An Introduction

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Overview

- 1) What is access to essential medicines?
- 2) Unaffordable drug prices
- 3) Globalization of patents
- 4) Research & Development
- 5) Conclusions

Essential Medicines

- “...are those that satisfy the **priority health care** needs of the **population**.”
- “...are selected with due regard to **disease prevalence**, evidence on **efficacy and safety**, and **comparative cost-effectiveness**.”
- “...are intended to be **available** within the context of functioning health systems **at all times** in adequate amounts, in the appropriate dosage forms, with assured quality, and **at a price the individual and the community can afford**.”

--World Health Organisation (WHO)

The Problem

- 1/3 of the world's population lacks access to essential medicines
- 1/2 in the poorest parts of Africa & Asia
- Developing countries facing major public health problems:
 - Infectious diseases (HIV/AIDS, malaria, TB, diarrheal, etc)
 - Non-infectious (heart disease, diabetes, mental illness, cancers, etc.)

What affects access?

- Quality of diagnosis;
- Accurate prescribing,
- Selection, Distribution and Dispensing of medicines;
- Drug quality;
- Capacities of health systems and budgets;
- **Price**
- **Research and development (R&D);**

Health is a human right

“recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”

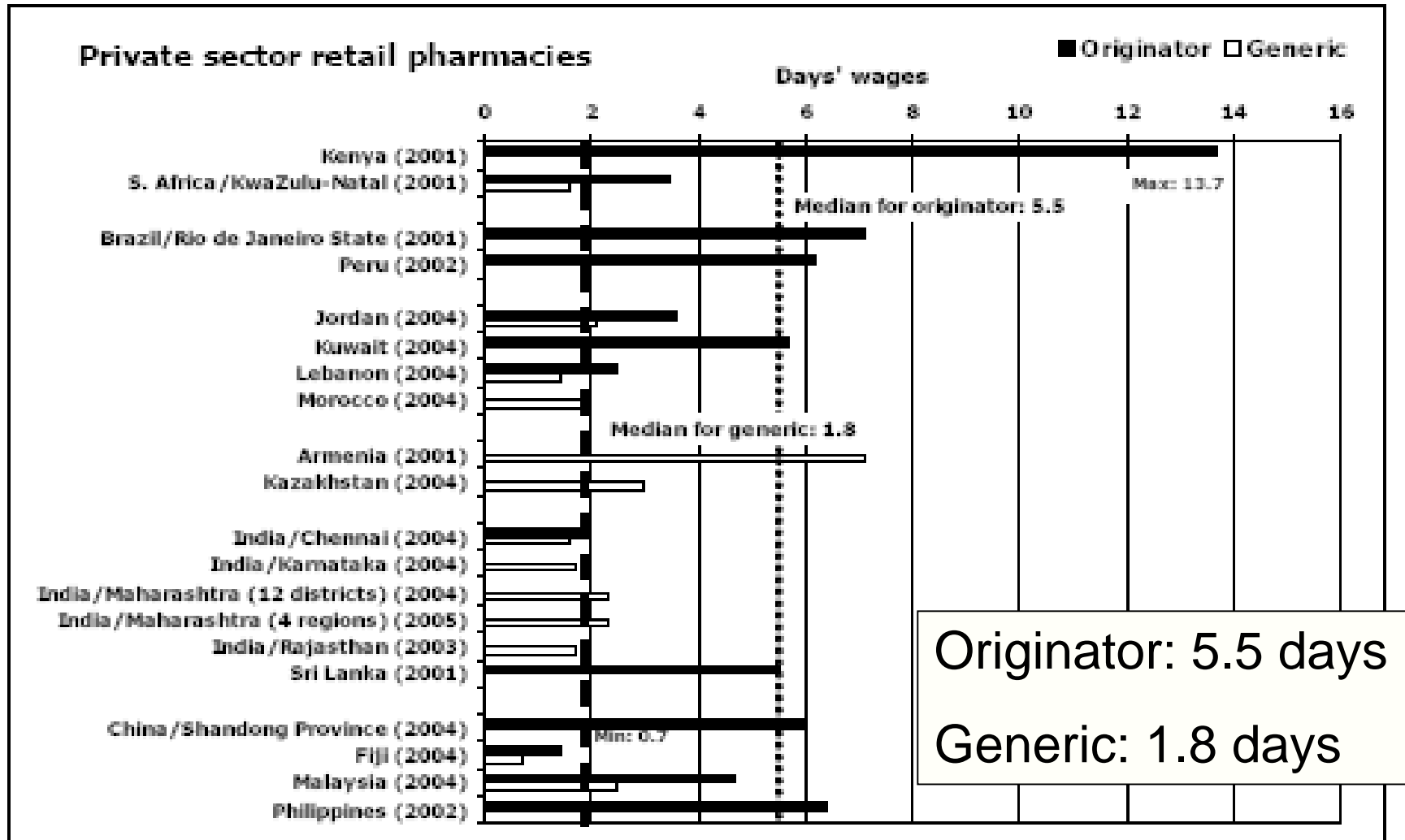
--International Covenant on
Economic, Social and Cultural Rights, Art.12

Access to essential medicines
increasingly recognized as a
component of the human right to health.



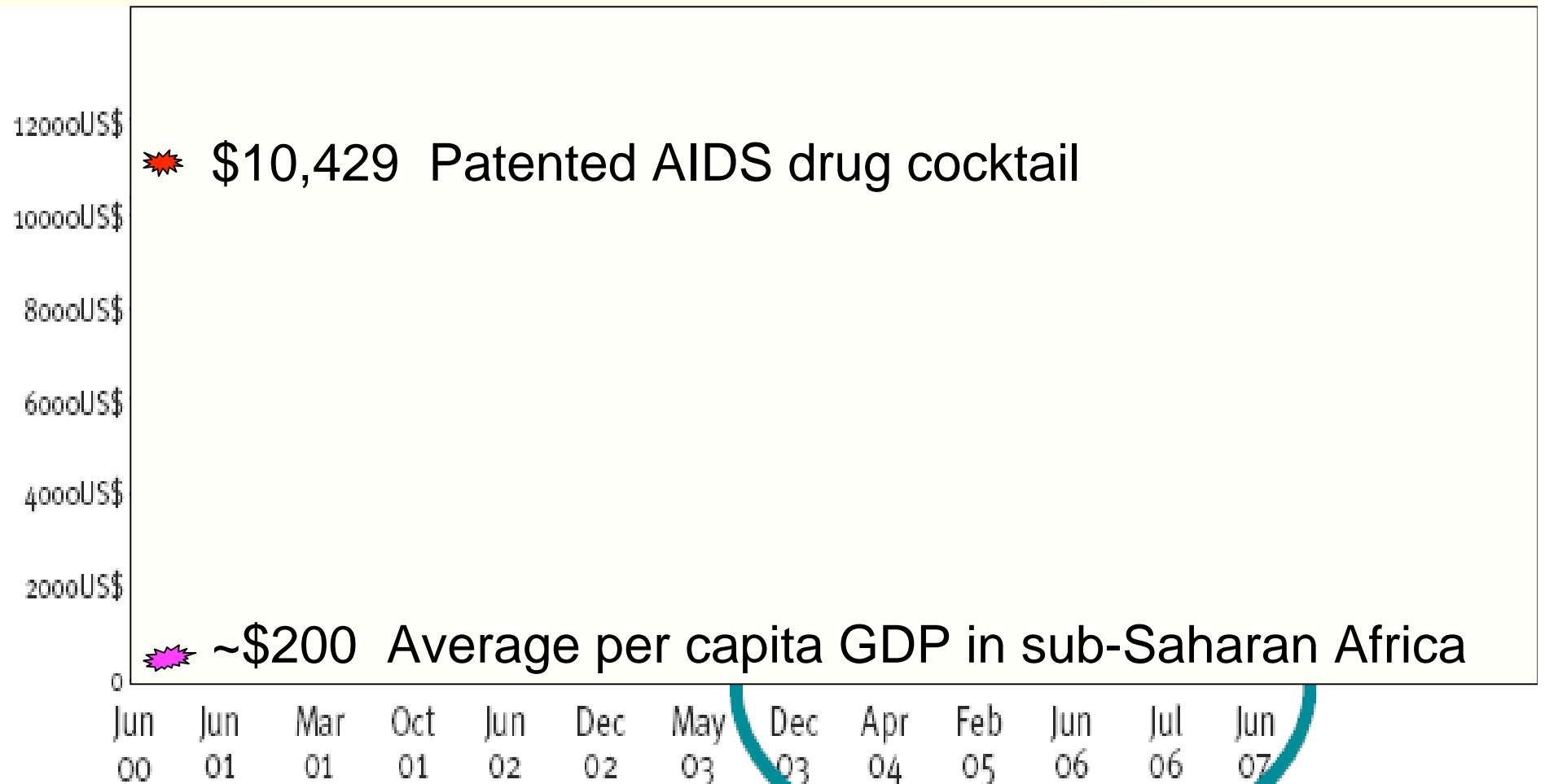
Unaffordable Drug Prices

Figure 5.1: Affordability of asthma treatment in private retail pharmacies
 Affordability of beclometasone inhaler 50 mcg/dose (200 doses or 1 inhaler per month) +
 salbutamol inhaler 0.1 mg/dose (200 doses or 1 inhaler per month)

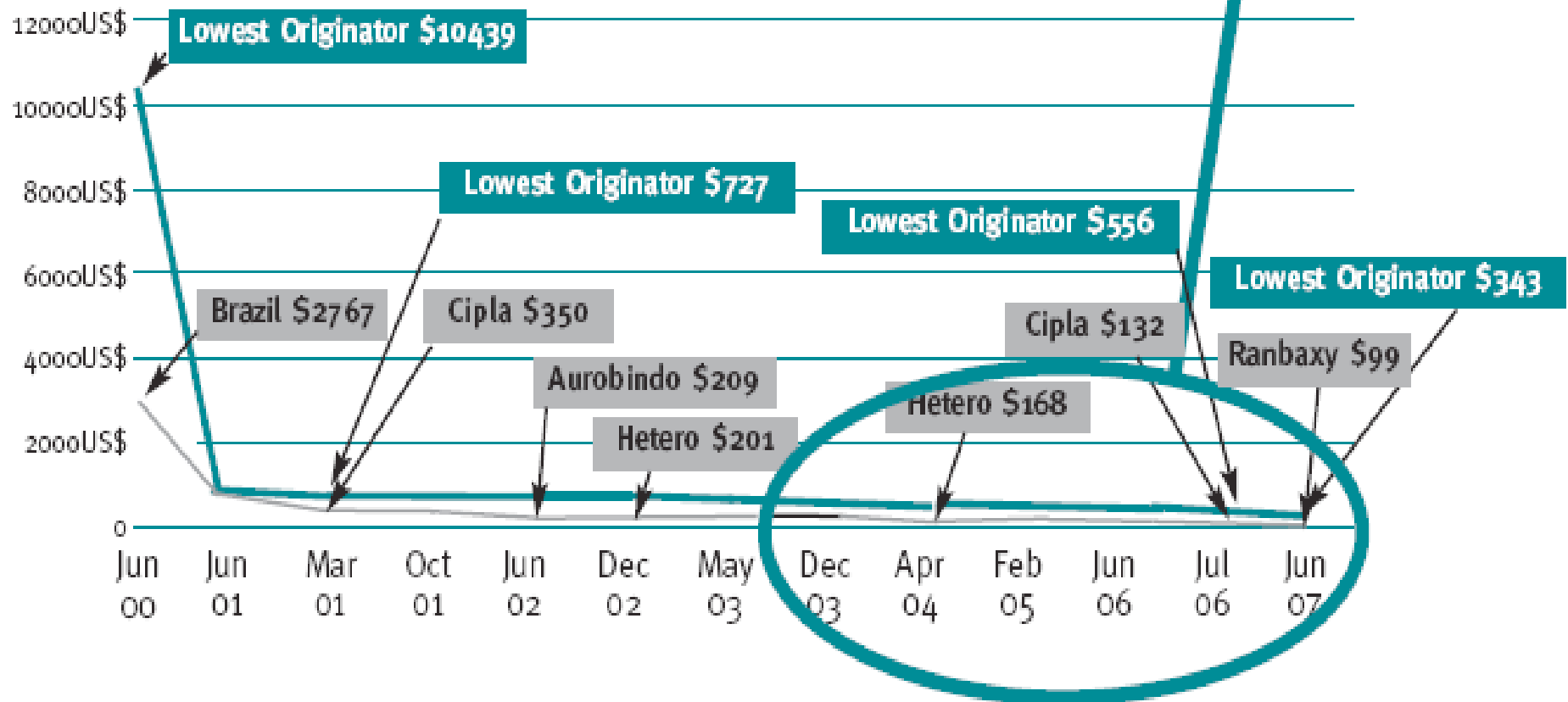
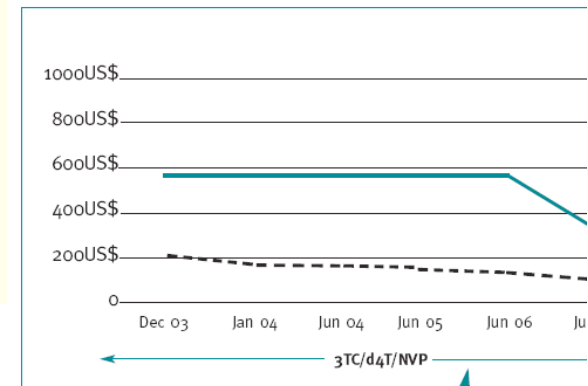


Source: WHO/HAI. "Price, availability and affordability: An international comparison of chronic disease medicines." December 2005.

AIDS Drug Prices: June 2000



AIDS Drug Prices After Generic Competition

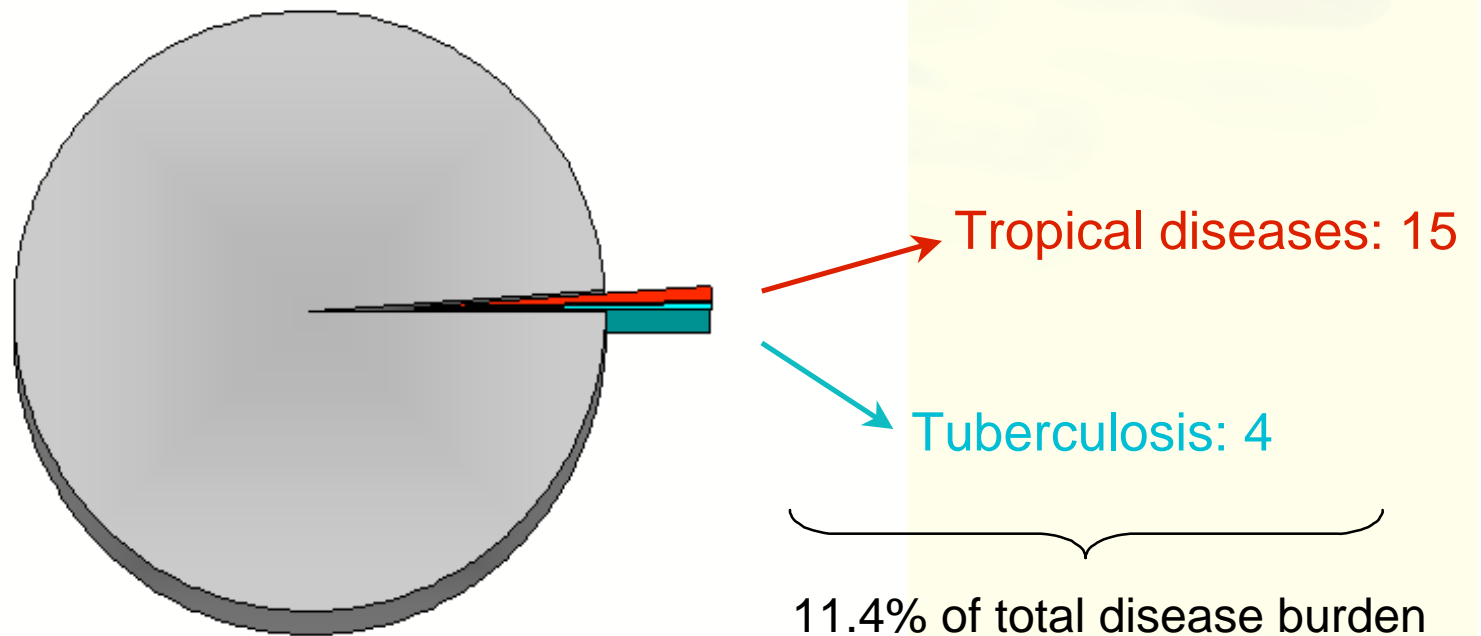


Globalization of Patents

- Patents:
 - Time-limited monopolies,
 - Intended to provide incentive for R&D
- Pre-1990s: ~ 50 developing countries excluded or shortened patents on medicines
- 1994 WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)
 - Minimum standards for IP protection in all WTO members
 - 20 year patents on pharmaceutical products
 - Lifesaving medicines = trivial goods
 - One size fits all
- Pharmaceutical products became patentable in
 - West Germany, 1967; France 1967; Italy 1979; Spain 1992
- Negotiating history: Developing country tradeoff for agriculture, promised R&D into developing country health conditions

Neglected Drug Development

- 1975-2004: **1,556** new chemical entities marketed
- Only 1% of new drugs developed are for neglected diseases



Failures of existing system

WTO TRIPS: is it an R&D treaty?

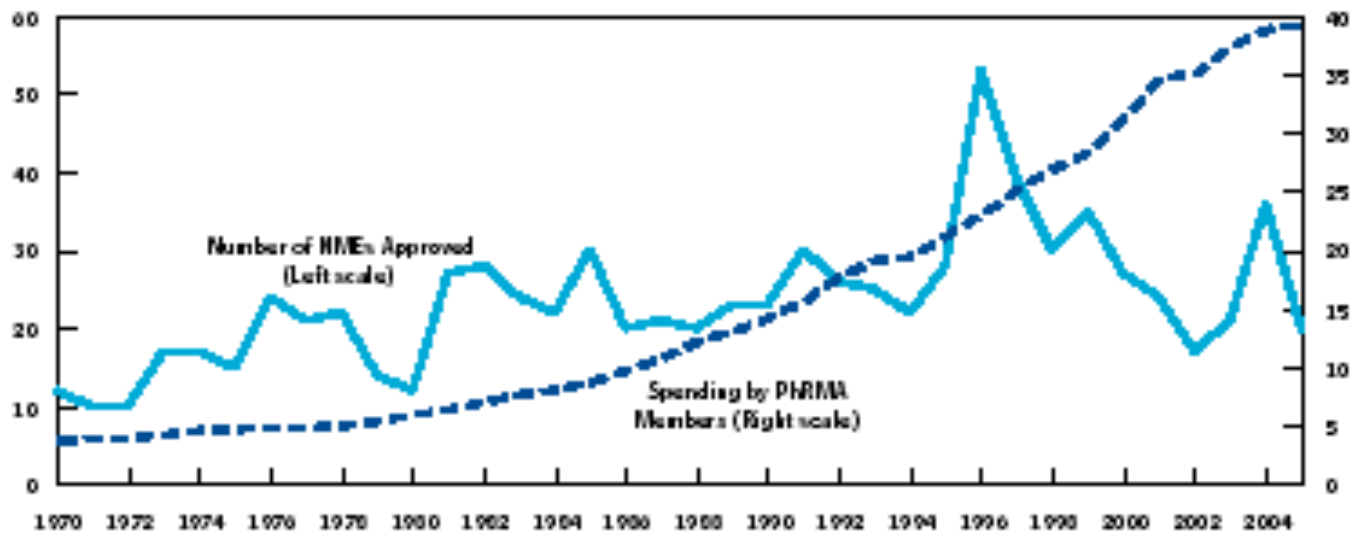
20 year patents on medicines

- Patents → Monopoly → High prices
(example: 2nd line AIDS medicines)
- Patents → Market-driven research
 - Little R&D for diseases of the poor
(ex: TB drugs & diagnostics)
 - Drugs for the wealthy countries → Tools poorly adapted
(ex: viral load testing)

US spending on R&D 50% increase (39 bill US\$)

NME Approvals and Drug Companies' Spending on Research and Development

(Billions of 2005 dollars)



Source: Congressional Budget Office based on Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2006* (Washington, D.C.: PHRMA, March 2006); and Food and Drug Administration, Center for Drugs and Biologics, *New Drug Evaluation Statistical Report* (1985), Table III-1, Graph III-2, and Appendix B, and *New Drug Evaluation Statistical Report* (March 1986 and April 1987), Table II-1 and Graph II-2; Food and Drug Administration, Center for Drug Evaluation and Research, Office of Management, *Office of Drug Evaluation Statistical Report* (1987-1989), Table II-1, Graph II-1, and Graph II-2; Food and Drug Administration, "CDER NDAs Approved in Calendar Years 1990-2004 by Therapeutic Potential and Chemical Type" (March 22, 2005), available at www.fda.gov/cder/rdmt/pstable.htm; and Food and Drug Administration, "FDA Facts: The Center for Drug Evaluation and Research," available at www.fda.gov/bbs/topics/news/2006/NEW01342/Fact_Sheet_CDER.pdf.

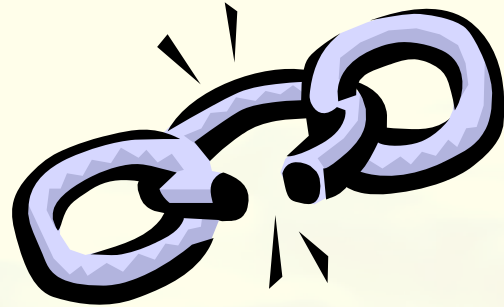
Note: Spending was adjusted for inflation using the biomedical research and development price index from the Bureau of Economic Analysis.

Tuberculosis R&D failures

- No new diagnostic for 100 years
- No new drug for nearly 50 years
- Pipeline of new drugs is thin
- New problems:
 - MDR-TB: 500,000 new cases/year
 - XDR-TB: increasing # cases
 - TB/HIV: joint epidemic

Alternative Approaches

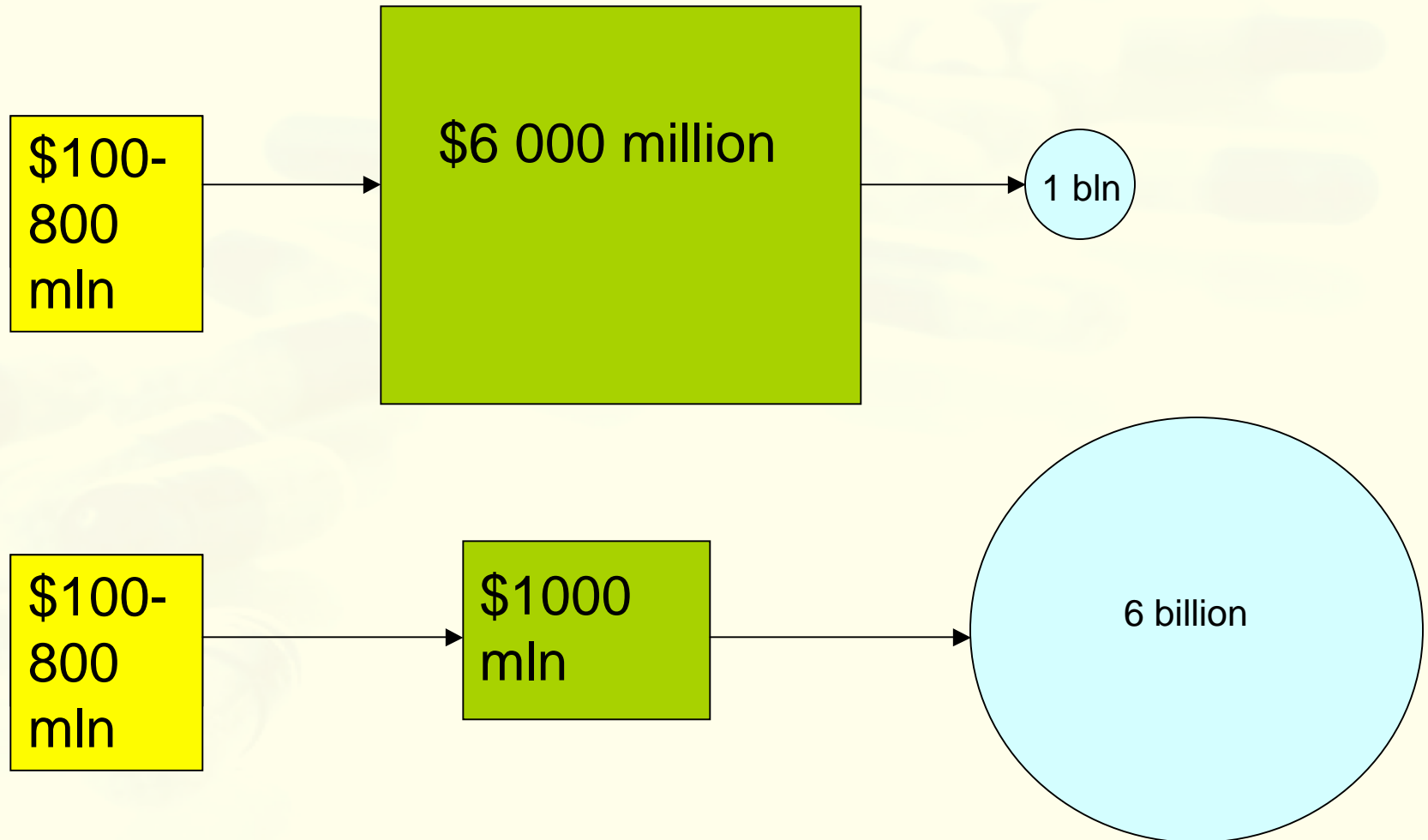
R&D funding



Medicines Prices

- R&D treaty: alternative to TRIPS?
- Open university licensing practices
- Sustainable funding for needs-driven R&D
- Access to compound libraries
- Prize funds
- Patent pools
- Advanced Purchase Commitments

Implications of R&D system



Cervical Cancer:

Prevalence: 2,274,000 women have cervical cancer¹

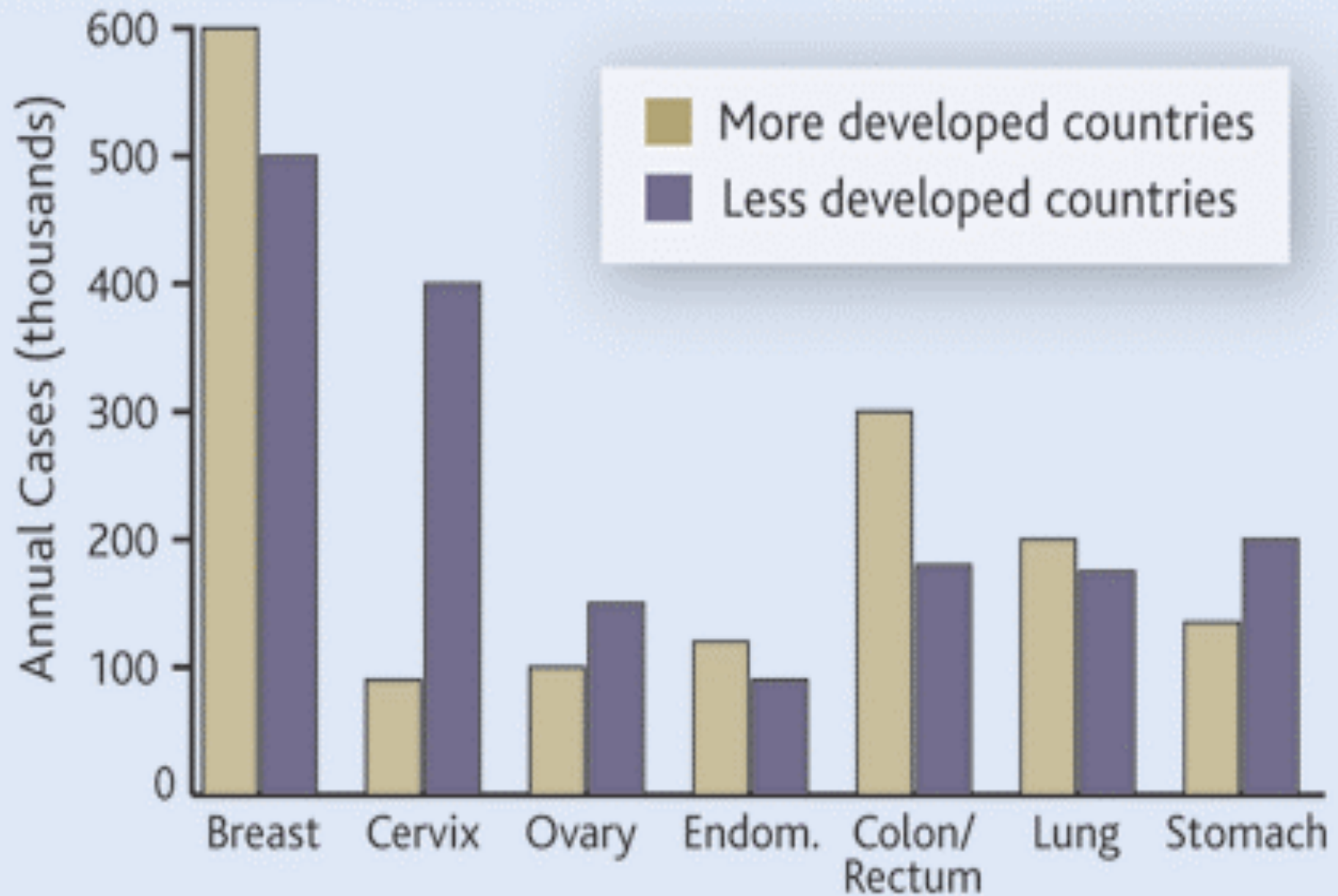
Incidence: 510,000 new cases each year¹

Mortality: Second leading cause of female cancer-related deaths (288,000 annually)¹



1. World Health Organization. Geneva, Switzerland: World Health Organization; 2003:1–74. 2. Bosch FX, de Sanjosé S. *J Natl Cancer Inst Monogr.* 2003;31:3–13.

Most Common Cancers in Women



HPV Vaccine- Access?

- 80% cervical cancer deaths in the developing world
- HPV Vaccine (Merck) Price:
 - Gardasil ~500 USD
- Limited production capacity
- No global system to ensure affordability, availability
- Access: not just an AIDS drug issue

Ongoing issues...

- Thailand compulsory license on three drugs (lopinavir, efavirenz, clopidogrel)
- Brazil compulsory license (efavirenz)
- India new patent law, Novartis court case
- WHO-based Intergovernmental Working Group process on new R&D models (IGWG)

Conclusions

1. Access to medicines is an ongoing crisis
2. High drug prices need to be addressed
3. Manage IP for public health:
 - Open university licensing practices
 - Compulsory license, voluntary license, patent pools, etc.
4. Alternative R&D systems needed (IGWG)



“We have no model which would meet the need for new drugs in a sustainable way” ...

*“You can’t expect for-profit organisations to do this in a large scale. If you want to establish a system where companies systematically invest in this kind of area you need a **different system**”*

Daniel Vasella, CEO Novartis

Financial Times 30 Sept. 2006

Thank You

Find out more at:

www.accessmed-msf.org

www.essentialmedicine.org

www.keionline.org

www.oxfamamerica.org

www.twinside.org

www.who.int/medicines