

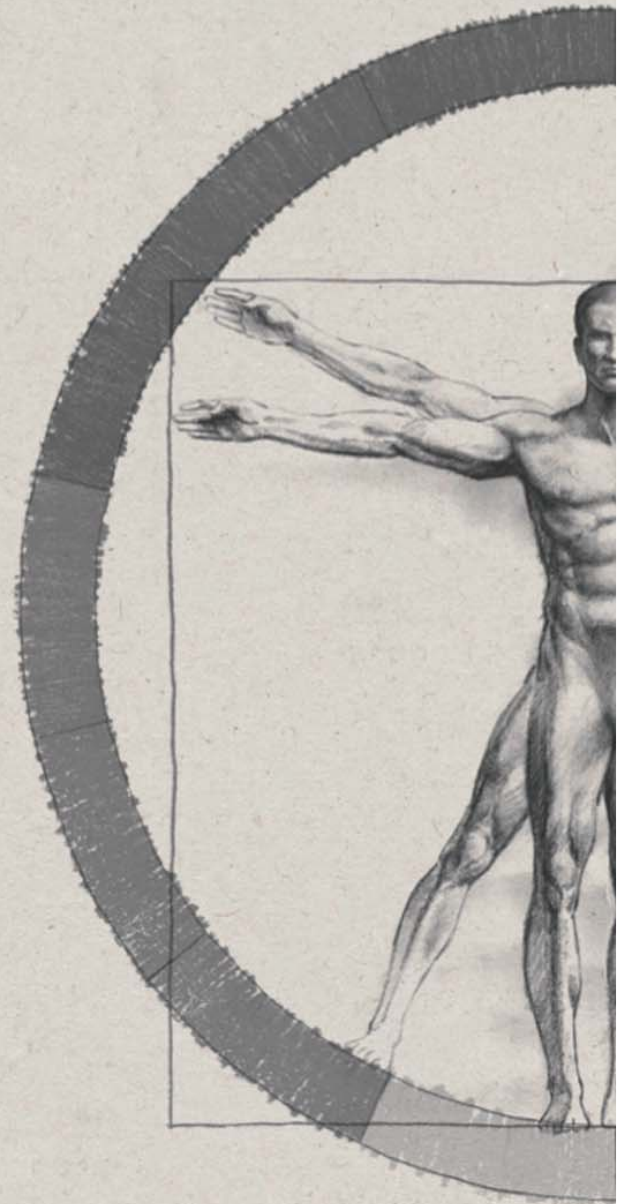
Introduction to the Pharmaceutical Industry

University Joins Industry

March 11, 2015

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Galenicum believe in life



Topics to be covered today..

- ▶ History
- ▶ Drug\$
- ▶ Economics
- ▶ R&D. The core of the Industry
- ▶ RISK Factors
- ▶ Current trends

Introduction

- ▶ Develops, produces, & markets medicinal drugs
- ▶ Deal in generic &/or brand medications
- ▶ They are subject to a variety of laws & regulations regarding the patenting, testing & marketing of drugs

History

Some Important Events

- **American Civil War**
- **Legislation – UK Cruelty to Animals Act (1876); US Federal Food and Drug Act (1906)**
- **World War 1 - Development of UK regulatory rules**
- **World War 2 – antibiotics**
- **Vaccines – Smallpox: Jenner (1796) – eradicated in 1977**
- **Thalidomide (1960) – report adverse drug reactions**
- **AIDS (1980s) – fast track approval, “buyer power”**
- **Viagra (1998)**
- **Tamiflu – H1N1 (swine flu) pandemic (2009)**
- **NICE (1999) – the affordability factor**
- **Vioxx – anti-inflammatory – 1999-2004 due to litigation**
- **Avandia – Type 2 (non-insulin dependent) diabetes - 1999-2010 also due to litigation**

History of the Drugs

- The early days - Egyptians, Greeks, Arabs, China, India
- Plant-derived medicines
 - morphine (1805), quinine (1819), colchicine (1820), pilocarpine (1875)
- Hormones
 - insulin (1921), estradiol (1929), testosterone (1931), “the pill” (1960)
- Antibiotics, Psychoactive drugs (post-1945 to 1960's)
 - penicillin (1944), streptomycin (1944), valium (1963)
- Treatment of metabolic disorders (1960's to current day)
 - Ventolin (1969), Lipitor (1997), Viagra (1998), Avandia (1999), Vioxx (1999), Gleevec (2001)
 - Search for gene therapies (1990), stem cell-based therapies
 - Stem-cell replacement of a trachea (2008)

DRUG\$

Health expenditure as % of govt budget

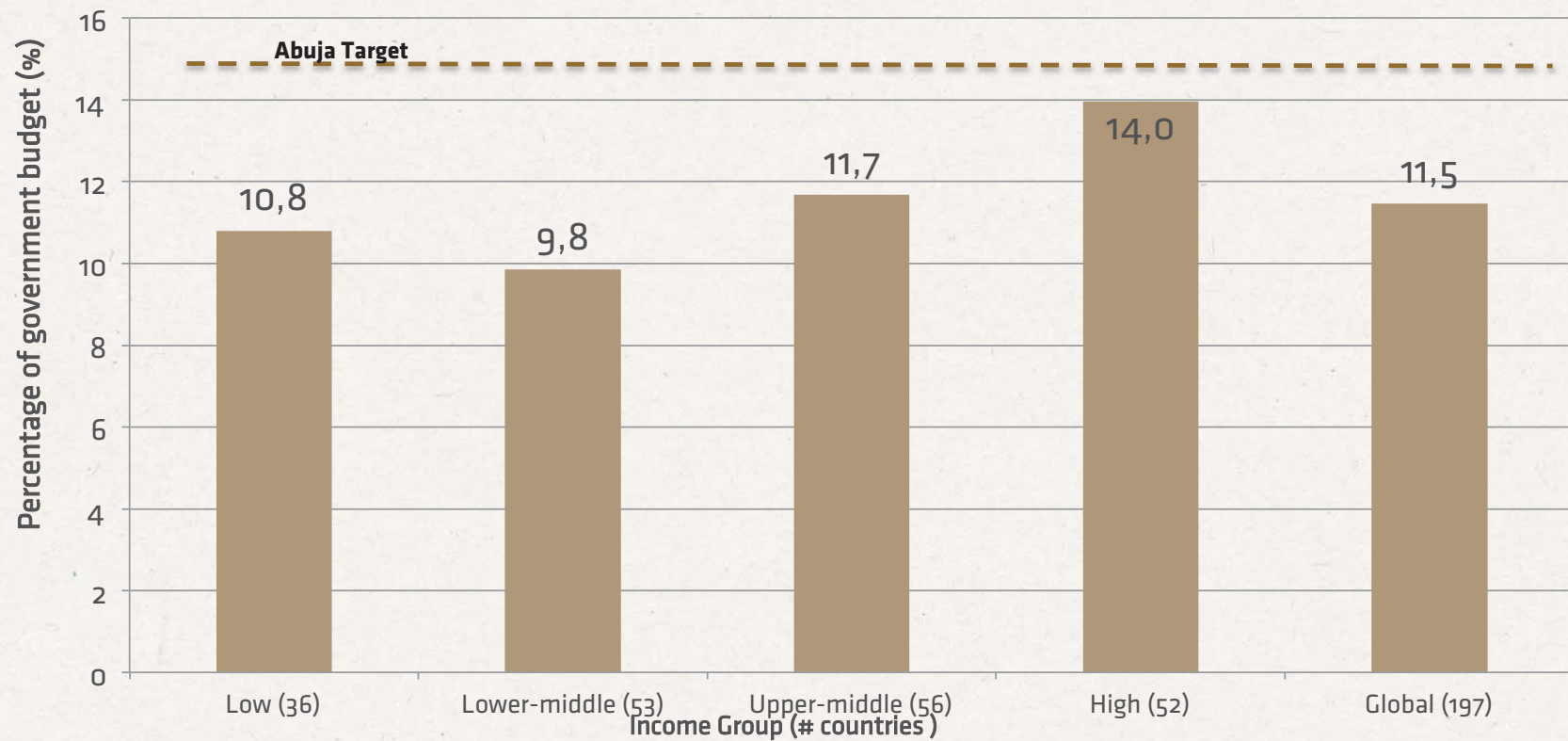


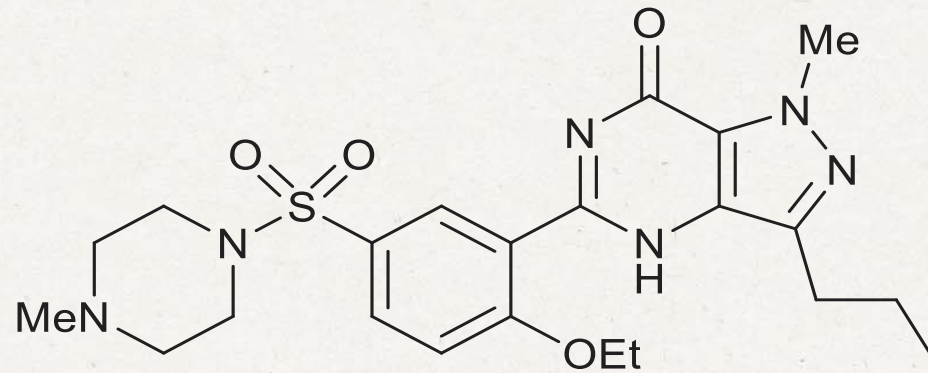
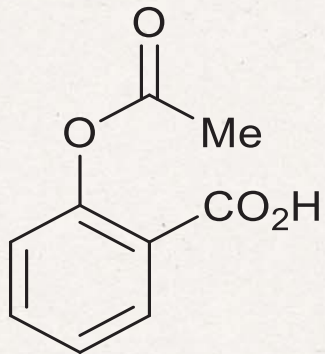
Table 4.1.5: Total Pharmaceutical Expenditures (2010)

Country group (number of countries)	Population		Total Pharmaceutical Expenditure				Per capita (US\$)
	Millions	%	Million US\$	%	%THE	%GDP	
WHO region							
Africa (43)	819	12.1%	\$19,464	1.7%	23.0%	1.3%	\$10.59
Americas (35)	923	13.6%	\$436,004	38.7%	19.8%	1.3%	\$87.30
Eastern Mediterranean (19)	573	8.4%	\$20,763	1.8%	20.1%	1.2%	\$50.31
Europe (52)	896	13.2%	\$331,683	29.5%	21.5%	1.6%	\$308.48
South-East Asia (10)	1,783	26.2%	\$41,157	3.5%	33.2%	1.3%	\$13.05
Western Pacific (27)	1,800	26.5%	\$276,362	24.6%	18.7%	1.2%	\$37.90
World Bank income group							
High-income (49)	1,092	16.1%	\$775,305	68.9%	18.5%	1.4%	\$463.59
Upper-middle- income (55)	2,474	36.4%	\$283,864	25.2%	21.2%	1.3%	\$96.78
Lower-middle- income (50)	2,480	36.5%	\$59,580	5.3%	23.6%	1.3%	\$26.28
Low-income (32)	749	11.0%	\$6,683	0.6%	27.7%	1.6%	\$8.01
Global Global (186)	6,795		\$1,125,433		20.8%	1.4%	\$68.78

Source: World Health Organization Global Health Observatory Database, 2013
National Health Accounts, 2013

What is a drug\$?

“A Chemical Substance that Interacts with a Living System and Produces a Biological Response”



What criteria **MUST** new drugs meet?

- Drugs must address a **new need** or provide a significant “**added benefit**” over an existing medicine
- Drugs must also meet five criteria:
 - **Must be safe, effective, of high quality**
 - ...cost effective (1980s)
 -affordable (1990s)
 -**REALLY** affordable (2000+)

Classification of Drug Types

- Ethical drugs
- Generic drugs (no longer under patent)
- “Prescription Only” vs “Over the Counter”
- “Off Label” applications
- Orphan drugs
- Biotechnology products
- Counterfeit drugs
- Street drugs!



Economics

Economics of the Pharmaceutical Industry

- ▶ Worldwide revenues > \$980 billion/year
- ▶ Sales for the 10 largest drug companies: \$297 billion in 2013
- ▶ Greater than 5000 companies worldwide
- ▶ Top 5 companies have market shares about 4 - 5 %
- ▶ US = Largest markets (40 % of worldwide sales)

The companies in 2013

Company	\$Billions
Pfizer	48
Novartis	47
Roche	39
MSD	37
Sanofi	37
GSK	33
Johnson & Johnson	28
AstraZeneca	25
Lilly	21
AbbVie	18

Economics

- ▶ 18.6% profit margin in 2013
- ▶ 16.4% in 2000 (\$24 billion)



Largest of any industry

4 times greater than average return of all fortune 500 companies

8 out of 25 most profitable U.S. companies are pharmaceutical companies

Mergers and Acquisitions

▶ Drug company mergers

- Pfizer-Warner-Lambert, Upjohn-Pharmacia, Glaxo-Wellcome-SmithKline Beecham, etc.

Pfizer acquired Pharmacia in 7/02 for \$60 billion to become the world's most powerful drug conglomerate. In 2015, Pfizer acquires Hospira

Who pays the party?

- ▶ 55% out-of-pocket
- ▶ 25% private insurance
- ▶ 17% medicaid
- ▶ 3% Other (VA, Workman' s Comp, IHS, etc..)

Where Prescription Money Go

- ▶ Research and development - 12%
 - preclinical testing - 6%
 - clinical testing - 6%
- ▶ Manufacturing and distribution - 24%
- ▶ Sales and marketing - 26%
- ▶ Administrative / miscellaneous expenses - 12%
- ▶ Taxes - 9%
- ▶ Net profit - 17%

R&D. The core of the
Industry

The "Pay Off"to the companies

- R&D = 15 to 25 % of sales turnover
- Patent protection – 20 years from filing
- On average, 11yrs. of *productive* market life
 - **Losec** – \$2.7Bn in 1998; **Nexium** (single enantiomer)
 \$7.7Bn in 2008
 - **Lipitor** - \$1Bn in 1998; **\$13.8Bn in 2008**

Cost of launching an NCE continues to rise

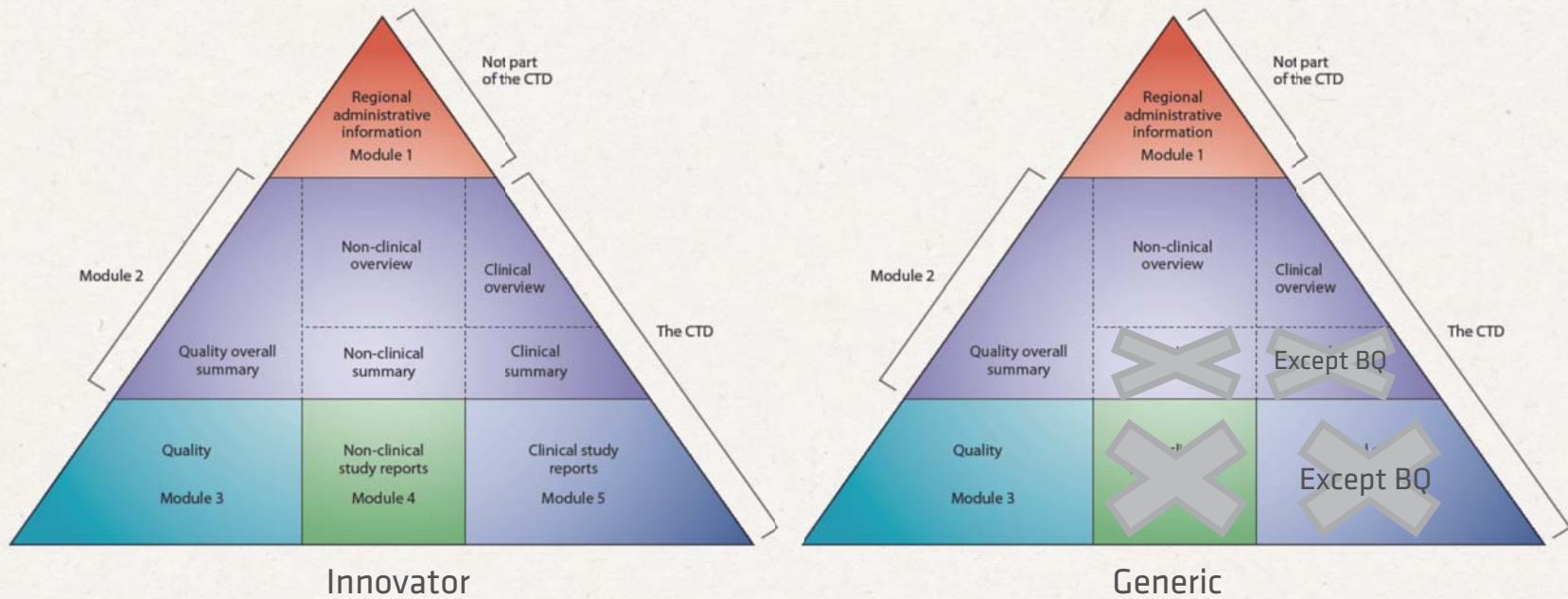
	25th percentile	75th percentile	Average	Standard deviation	Standard error
Industry (n=20) \$M	782	1235	1064	311	70

Source: CMR International © THOMSON REUTERS

Pharmaceutical Industry Facts

- ▶ Revenues from approved drugs (1 of 5 to 10,000) must cover the “dry holes” of non approved compounds.
- ▶ Average cost of bringing a drug to market is 1000 million dollars.
- ▶ Average approval time is 12 to 15 years.
- ▶ Time to recoup investment is shrinking- generic drugs and limited patent life

Pharma Industry: Innovators vs. Generics

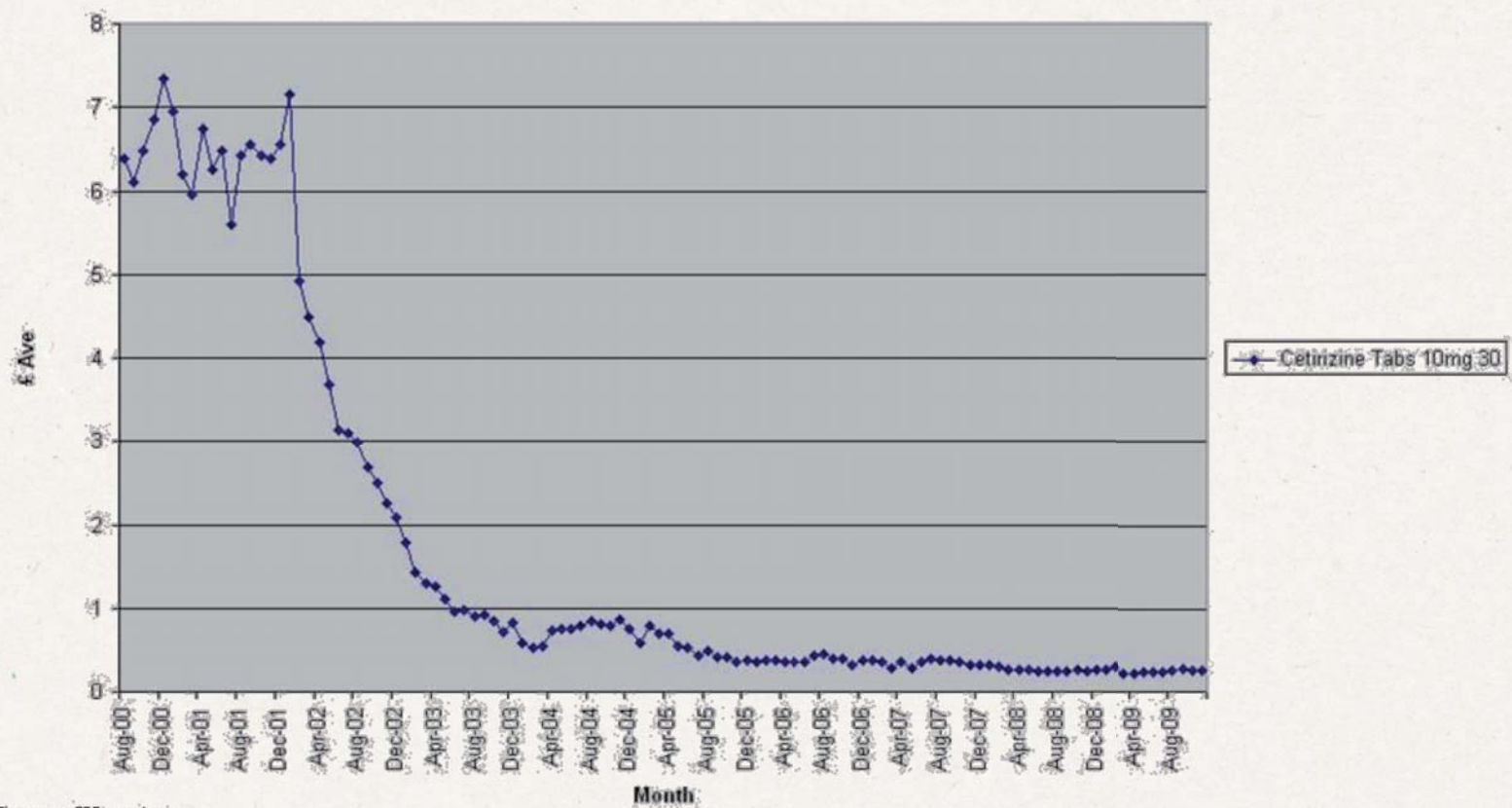


Pharmaceutical Industry Facts Generics

- ▶ High competition
- ▶ Price Pressure
- ▶ Short product lifecycle
- ▶ Same regulatory requirements

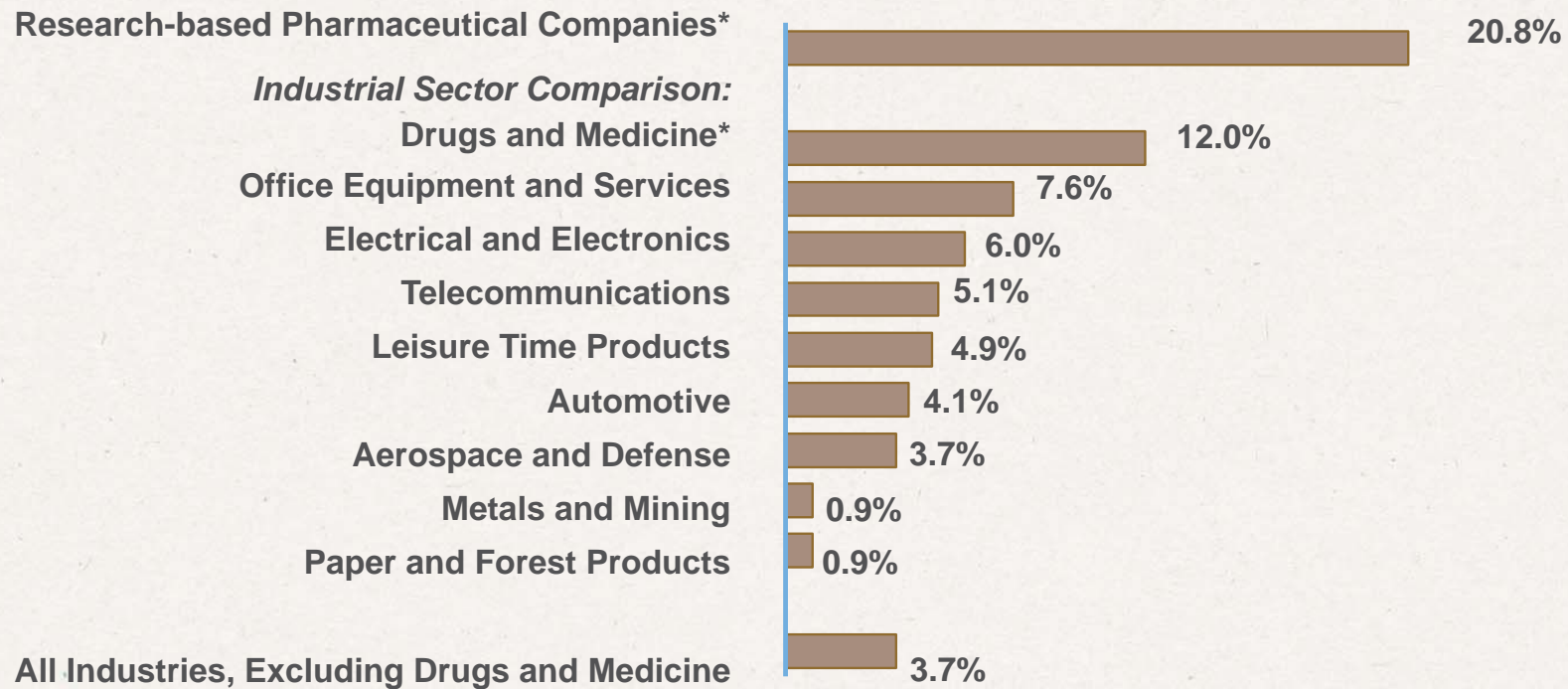
Pharmaceutical Industry Facts Generics

Cetirizine Generic Price Decline



Source: Wavedata

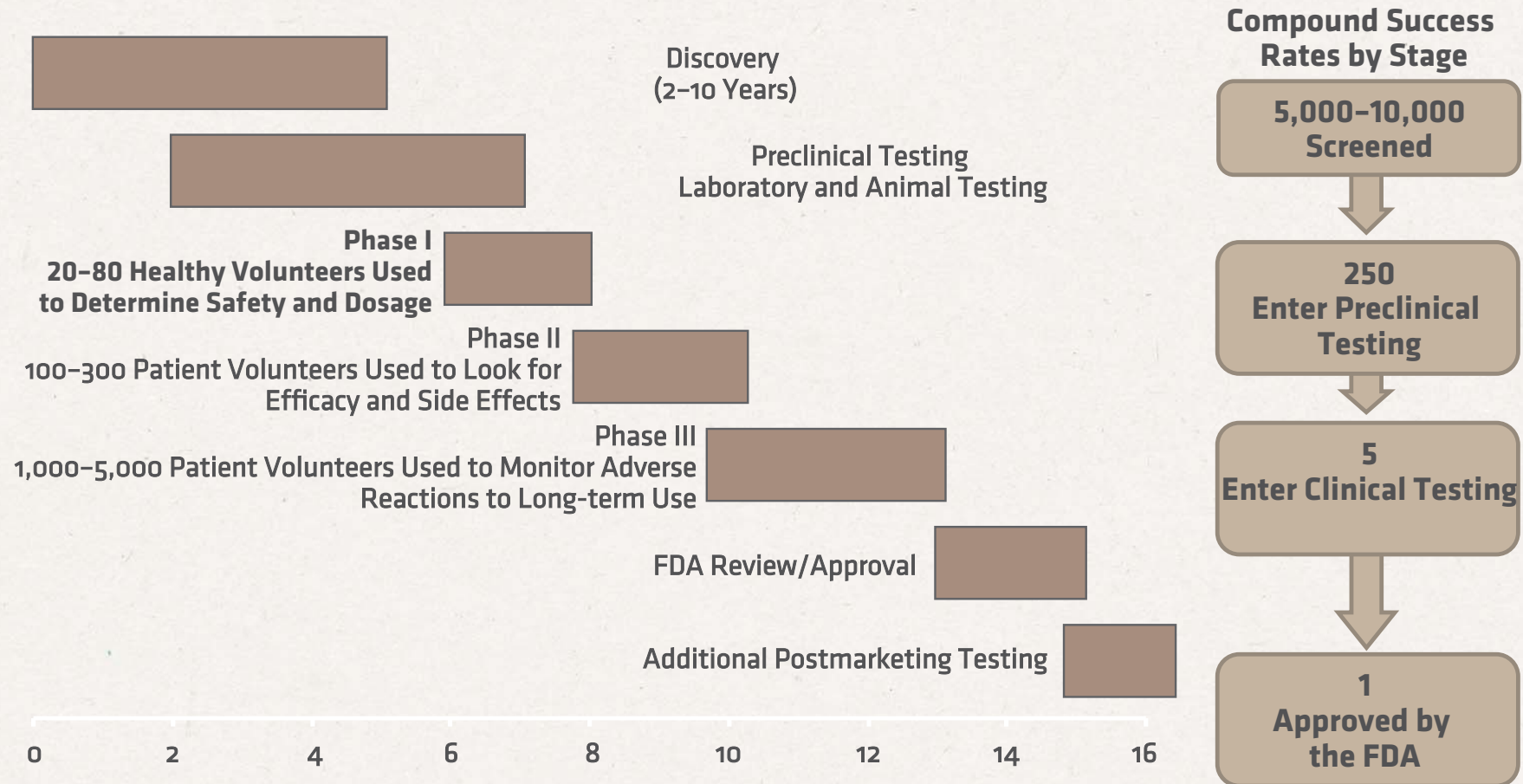
R&D for Pharmaceuticals and Other Industries (% of Sales)



*"Research-based Pharmaceutical Companies" Based on Ethical Pharmaceutical Sales and Ethical Pharmaceuticals R&D Only as Tabulated by PhRMA; "Drugs and Medicine" Sector as Tabulated by Standard & Poor's Compustat, a Division of McGraw-Hill

Source: PhRMA, 1999, Based on Data From PhRMA Annual Survey and Standard & Poor's Compustat, a Division of McGraw-Hill

Compound Success Rates: 1 in 10,000 Reach FDA Approval



Source: PhRMA, Based on Data From the Tufts Center for the Study of Drug Development, 1995

Top 10 Therapies - sales in 2008 (US\$Bn)

	2008 sales	% share
Oncology agents	45.8	6.4
Lipid regulators	34.2	4.8
Respiratory agents	30.7	4.3
Acid pump inhibitors	26.7	3.8
Antidiabetics	26.0	3.7
Antipsychotics	22.4	3.1
Angiotensin antagonists	21.6	3.0
Antidepressants	20.4	2.9
	US\$227.8Bn	32.1%

Decreasing Costs

- ▶ Formularies
- ▶ Generics
- ▶ Volume discounts/mail order prescriptions
- ▶ Patient activism
-e.g., AIDS/ACT UP

Drug Reimbursement Systems

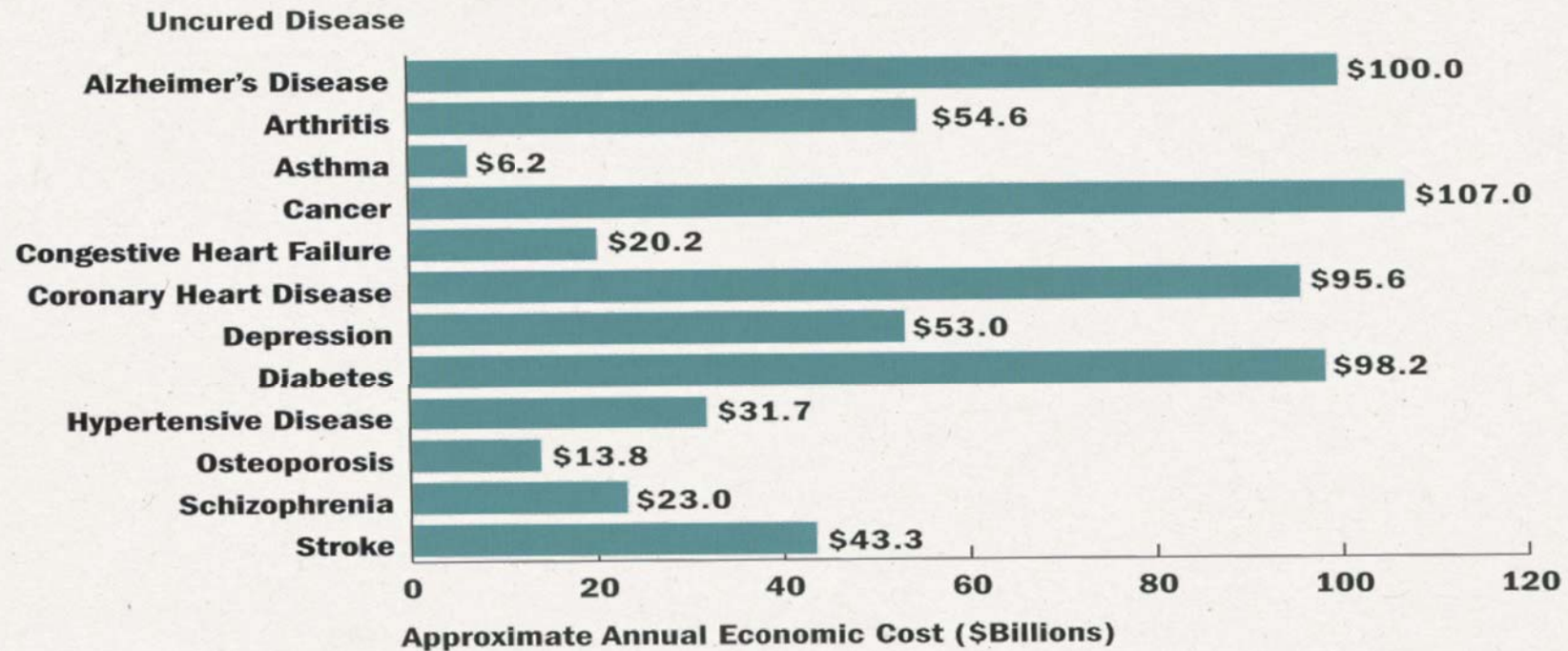
- ▶ Copayments
 - income variation
 - exempted groups
- ▶ Cost-sharing
- ▶ Expenditure limits
- ▶ Positive and negative prescribing lists
- ▶ Therapeutic efficacy categories

COST Perspective

What is the cost if pharmaceutical manufacturers did not create revolutionary drugs.....

COST of Uncured Disease States

Figure 5
Prevalence, Cost, and Medicines in Development
for Selected Major Diseases in the United States



Source: Compiled by PhRMA, 2000.

The "Pay Off"to us

- Massive contributions to health, quality of life, reduced child mortality, life expectancy
- Vaccines have eradicated major disease – smallpox; vaccines for malaria and pneumonia soon.....?
- But costs and accessibility to healthcare are becoming major social and geopolitical issues
- And, is there something seedy about making money out of illness?
- What will happen into the future?

RISK Factors

Vioxx®

- ▶ \$2.5 Billion annual sales in 2003
 - #1 arthritis and acute pain medicine outside the US
 - #2 in the US
- ▶ Use >18months will cause heart attack and stroke
- ▶ Voluntarily withdraw worldwide (Sep 30, 2004)
- ▶ share price dropped from \$45.07 to \$33.00(one day)
- ▶ \$27 billion in market cap was erased

Vioxx®

- ▶ 9,650 Vioxx liability lawsuits has been filed (Dec 31, 2005)
- ▶ 19,100 plaintiffs has involved (Dec 31, 2005)
- ▶ The company spent \$285 Million in legal defense during 2005
- ▶ Increase the reserve amount to \$685 Million for legal fees through 2006 and 2007 (Dec 2005)
- ▶ Unpredictable outcomes in lawsuits, substantial damages, fines, criminal penalties

Other Risk Factors

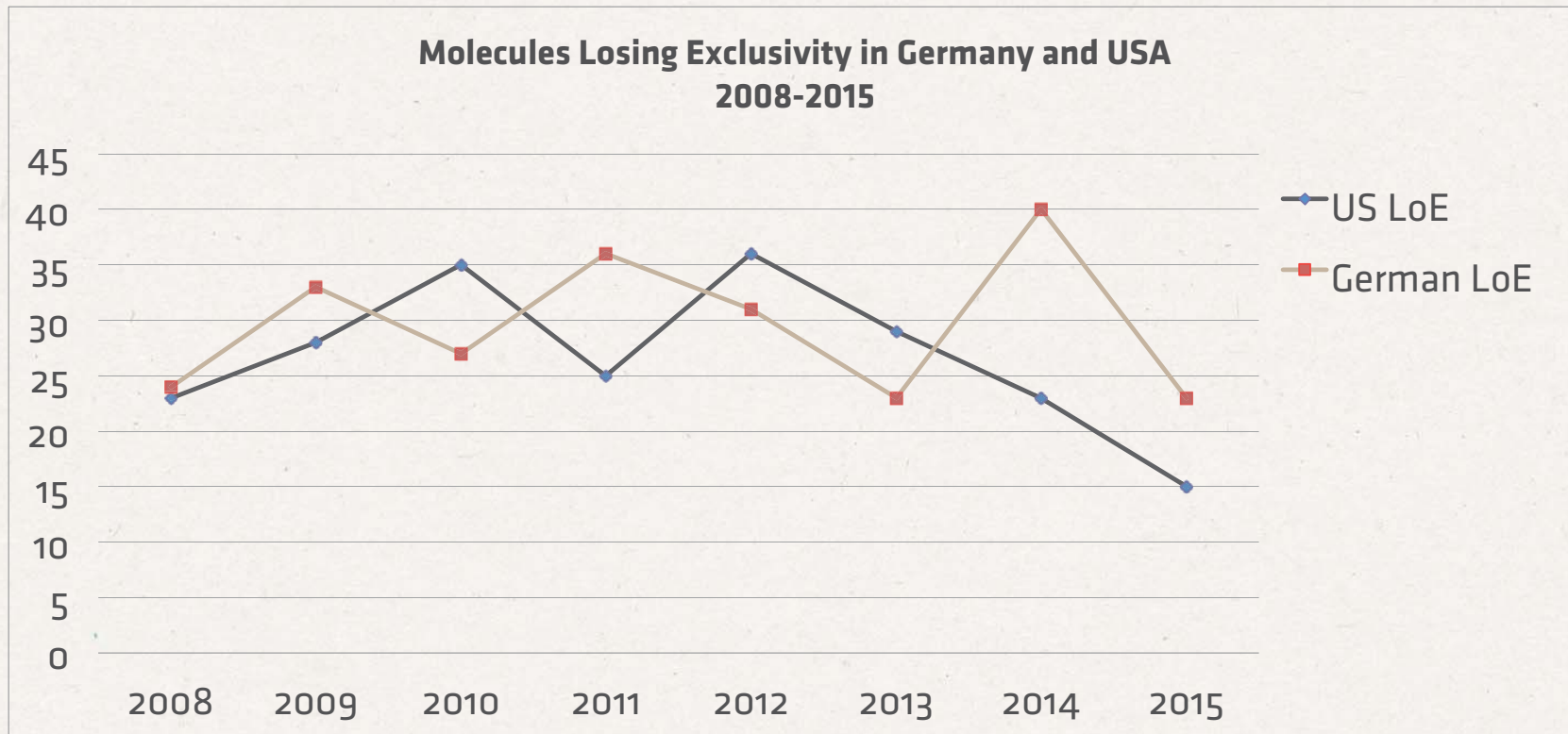
- ▶ Failure in developing and acquiring commercially successful products

- ▶ Failure in regulatory approval

- ▶ Competition from other products
 - 1) More efficiency
 - 2) price pressure

- ▶ Unexpected future changes in government laws and regulations

Too many companies, too few products



Source: Newport Horizon Premium™ © THOMSON REUTERS

Current Trends

Trends of the Market

Ageing World Population

Arthritis

- **46 million adults** (non-institutionalized) in the U.S. (2003)
- 21% of adults (non-institutionalized) in the U.S. (2003)

Cancer

- **23 million** suffering worldwide. Estimated of 1.37 million people in the US were diagnosed with cancer in 2005
- about 1 in 3 lifetime risk; 38% of women and 43% of men
- The average cost of cancer treatment is well over \$100,000 per person.
- Estimated **\$280 billion spent** on treatment drugs for cancer annually. More than \$100 Billions in US

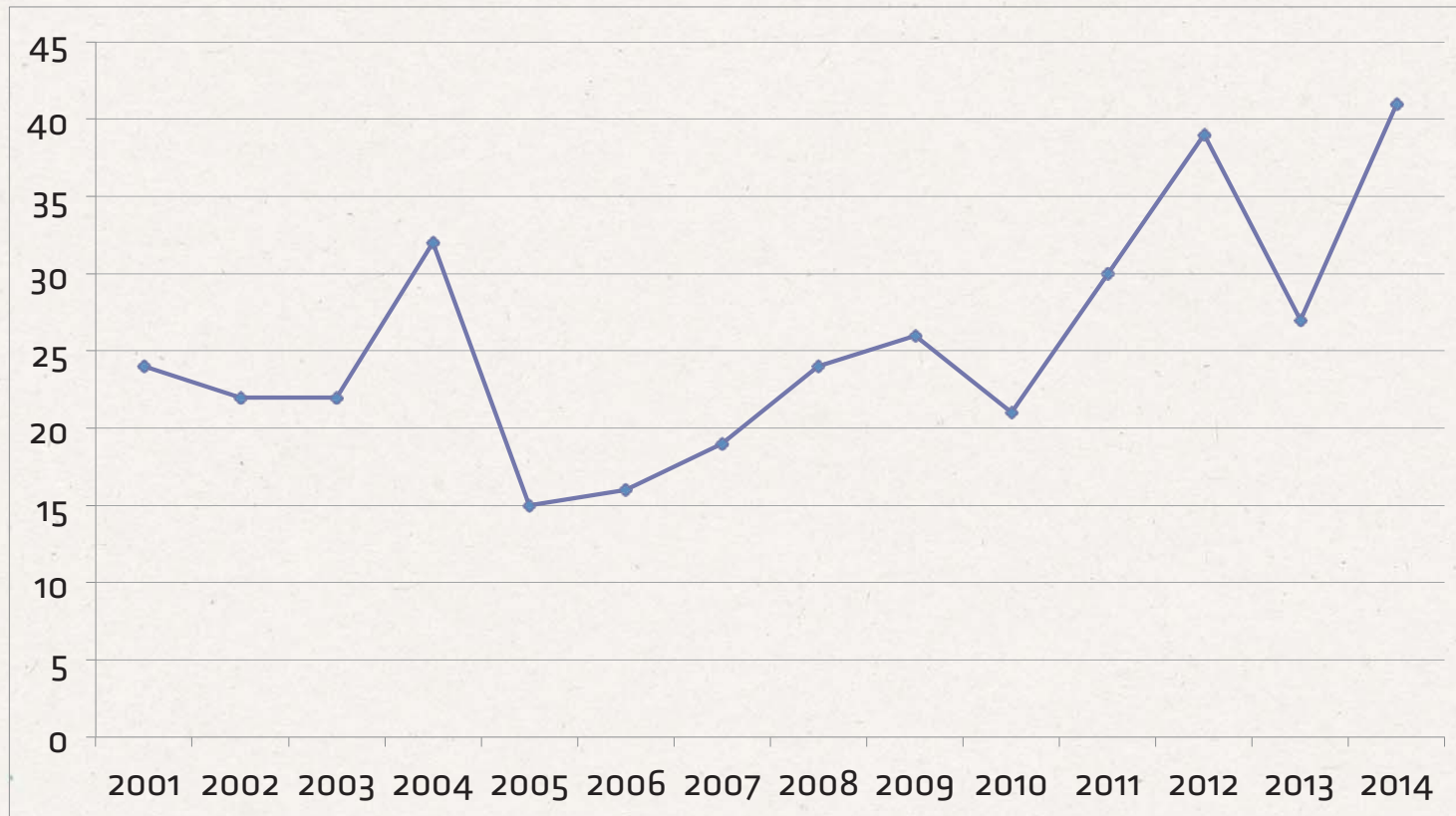
Diabetes

- Estimated **18.2 million** people in the United States, or 6.3% of the population (2005)
- 165 million cases worldwide (2003)
- **\$132 billion spent** in direct and indirect costs in America (2002)

Heart Disease

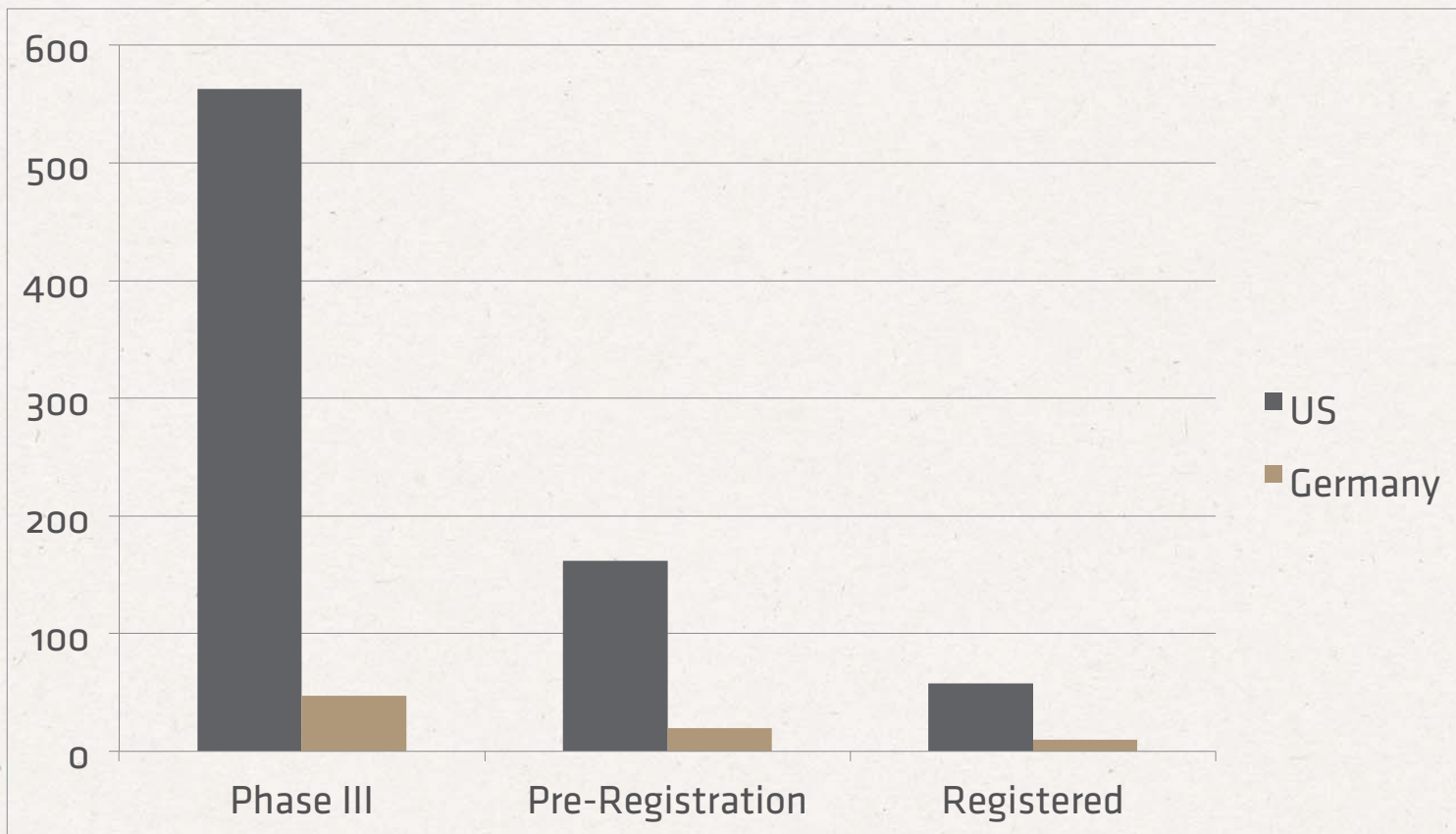
- **25 million** adults in the US
- Heart disease and stroke cost US around **\$214 billion annually**. (\$115 billion direct) (2002)

US NCE Approvals 2001-2007



Source: Newport Horizon Premium™ © THOMSON REUTERS

Current pipeline activity looks to continue the trend



Source: Thomson Pharma © THOMSON REUTERS

Jobs Opportunities in Pharmaceutical Industry

It includes many job opportunities of pharmacists:

- ▶ Drug discovery
- ▶ Manufacturing
- ▶ Marketing
- ▶ Medical information
- ▶ Product development
- ▶ Quality assurance
- ▶ Training & development
- ▶ Sales
- ▶ Regulatory
- ▶ Project management
- ▶ Health outcomes research
- ▶ Legal (e.g. IP)
- ▶ Information technology
- ▶ Scientific communications

thank you!