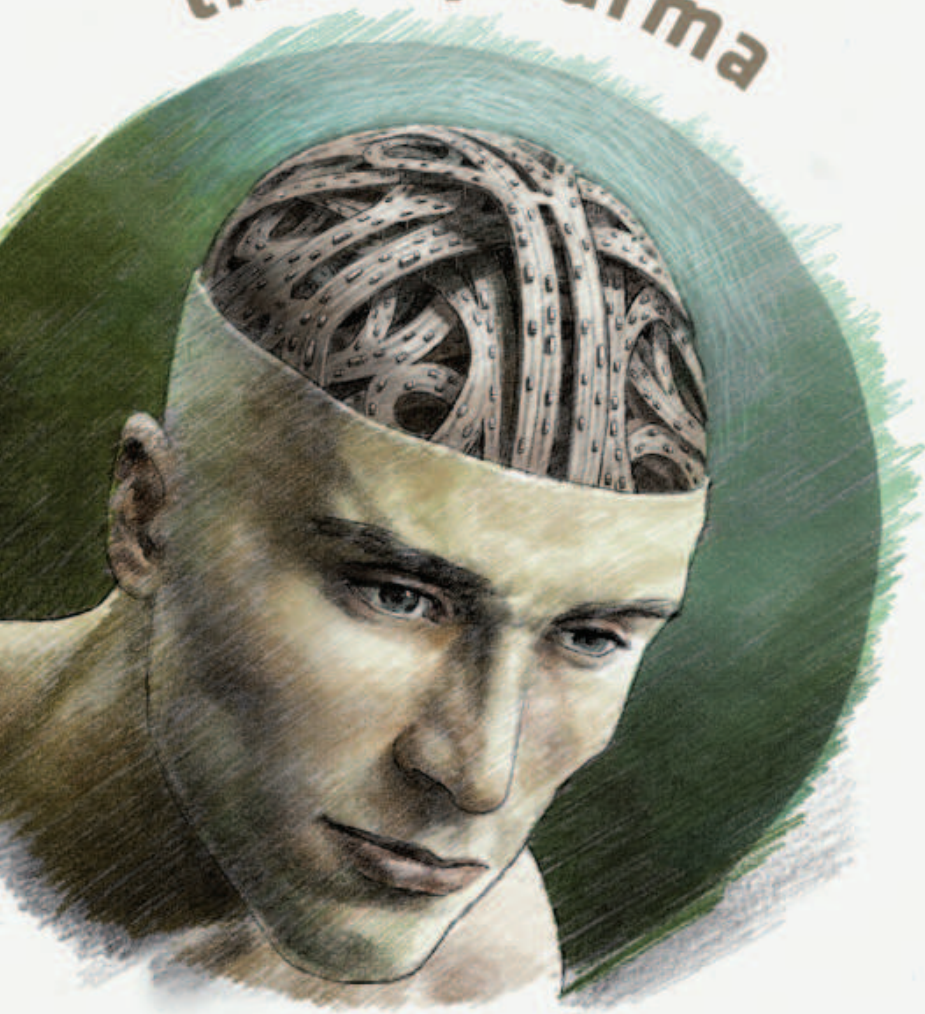


Think forward,
think pharma



Pharma Industry

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BARCELONA - MARCH 2019

■ believe in life
Galenicum
PHARMACEUTICAL COMPANY

Topics to be covered today..

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

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)
- NICE (1999) – the affordability factor
- Vioxx – anti-inflammatory – 1999-2004 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

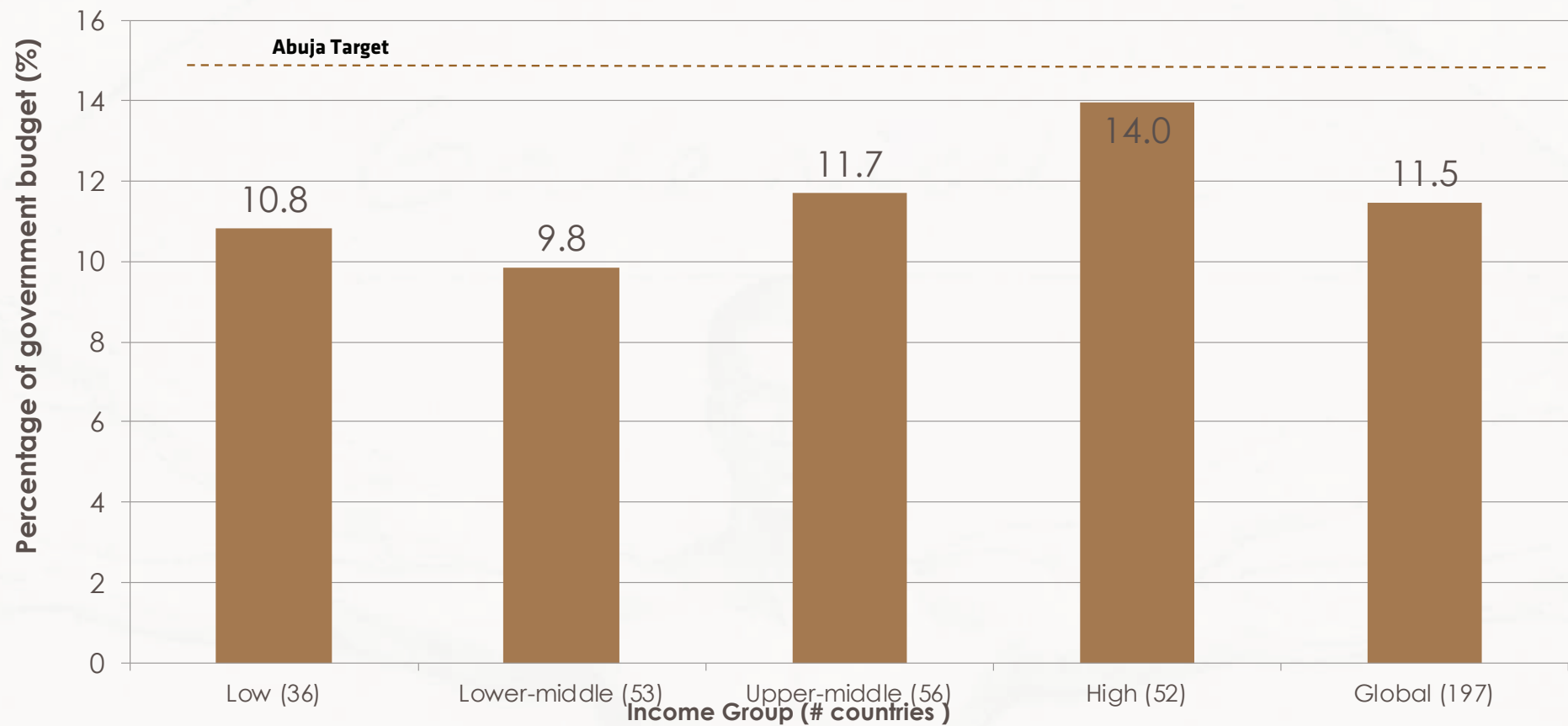


Table 4.1.5: Total Pharmaceutical Expenditures (2010)

| Country group (number of countries) | Population | | Total Pharmaceutical Expenditure | | | | |
|---|--------------|-------|----------------------------------|-------|--------------|-------------|-------------------------|
| | Millions | % | Million US\$ | % | %THE | %GDP | Per capita (US\$) |
| 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 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+)

Economics

Economics of the Pharmaceutical Industry

- Worldwide revenues > \$1,143.3 billion/year
- Sales for the 10 largest drug companies: \$437 billion in 2017
- Greater than 5000 companies worldwide
- Top 5 companies have market shares about 4 - 5 %
- US = Largest markets (40 % of worldwide sales)

The companies in 2017

| Company | \$Billions |
|-------------------|------------|
| Pfizer | 53 |
| Roche | 44 |
| Sanofi | 37 |
| Johnson & Johnson | 36 |
| MSD | 35 |
| Novartis | 33 |
| AbbVie | 28 |
| Gilead | 26 |
| GSK | 24 |
| Amgen | 23 |

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

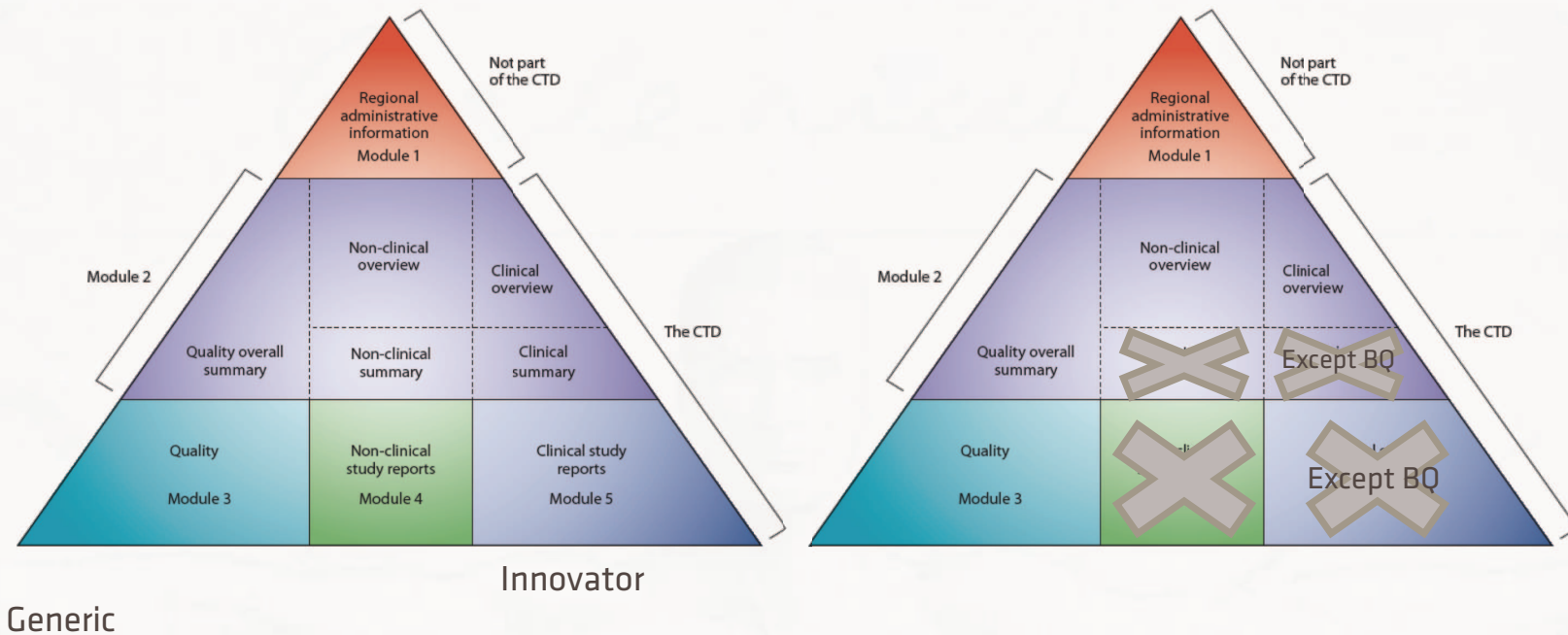
| | 25th percentile | 75th percentile | Average | Standard deviation | Standard error |
|---------------------|-----------------|-----------------|-------------|--------------------|----------------|
| Industry (n=20) \$M | 782 | 1235 | 1064 | 311 | 70 |

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

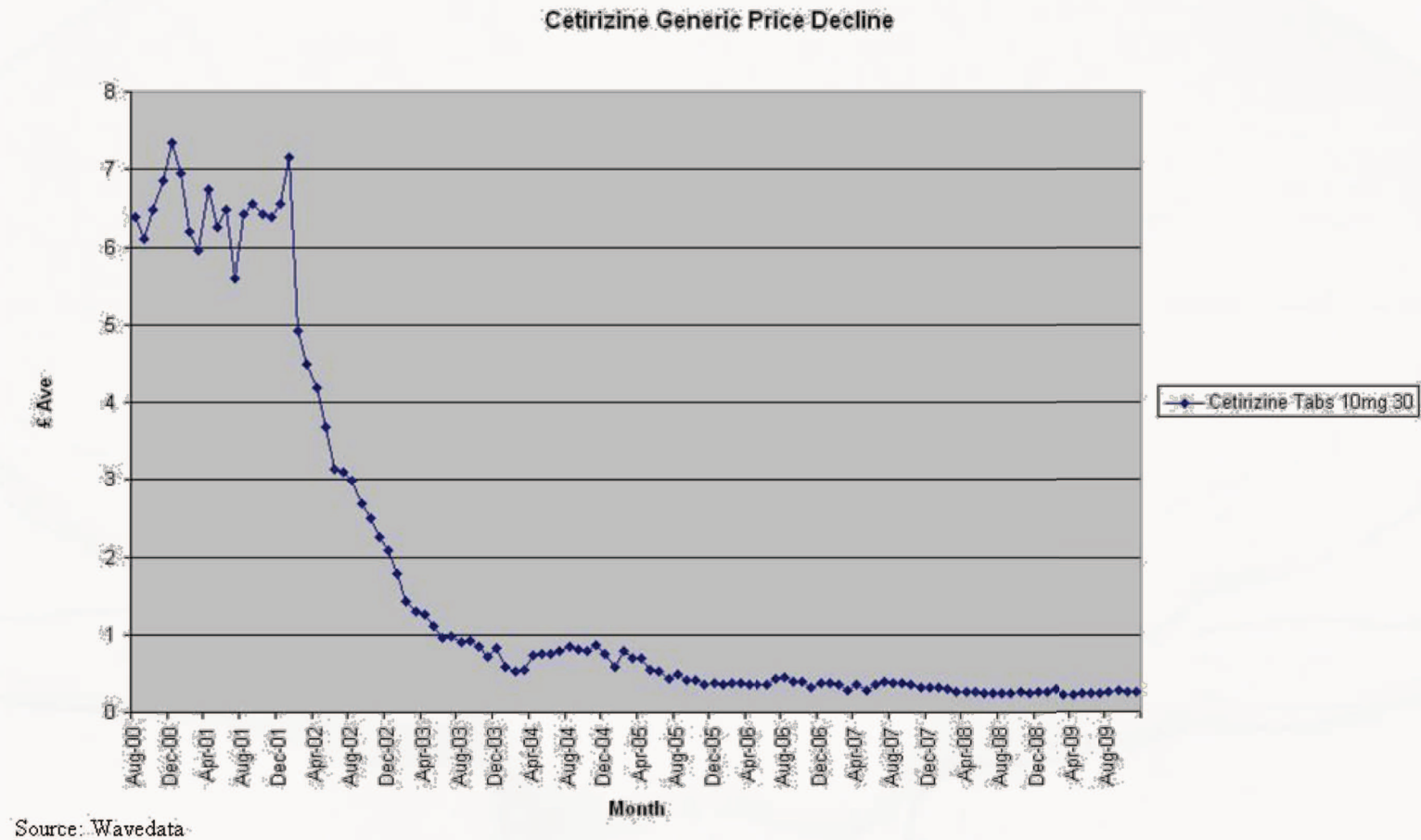
Pharma Industry: Innovators vs. Generics



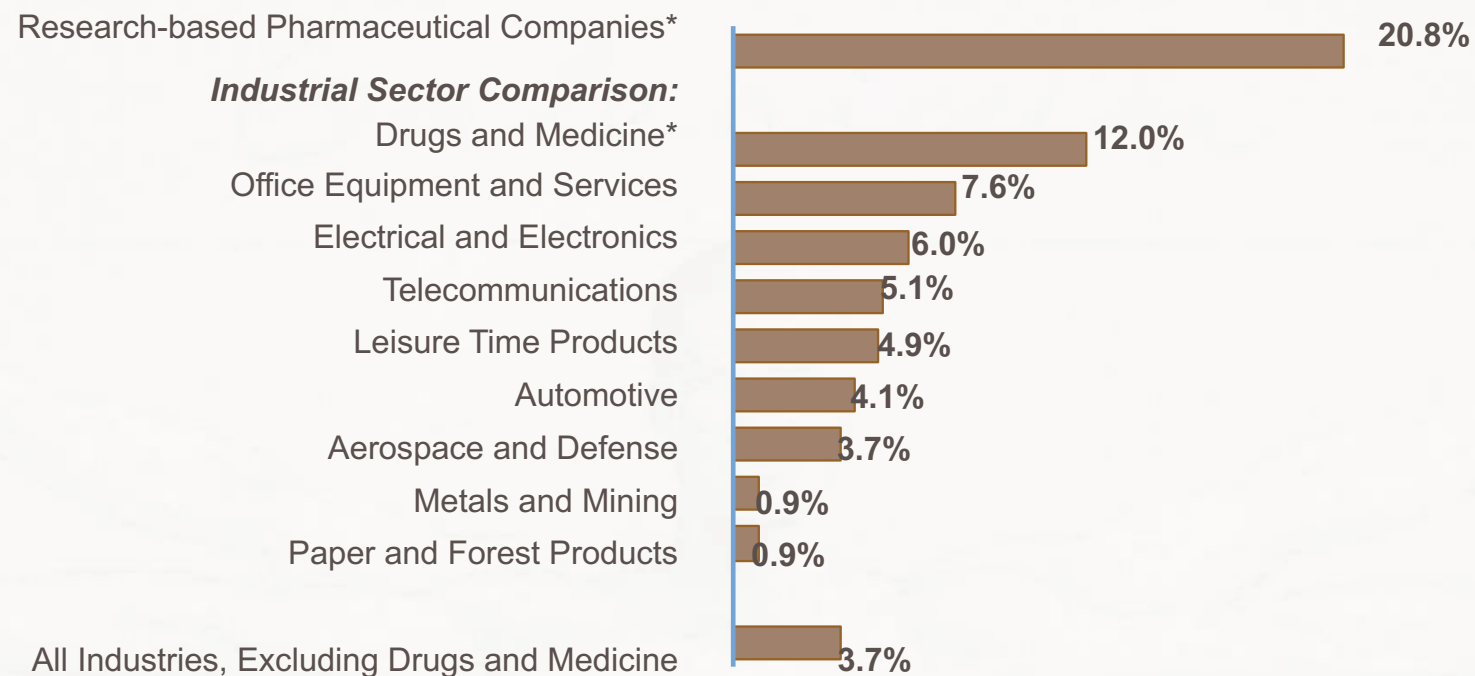
Pharmaceutical Industry Facts Generics

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

Pharmaceutical Industry Facts Generics



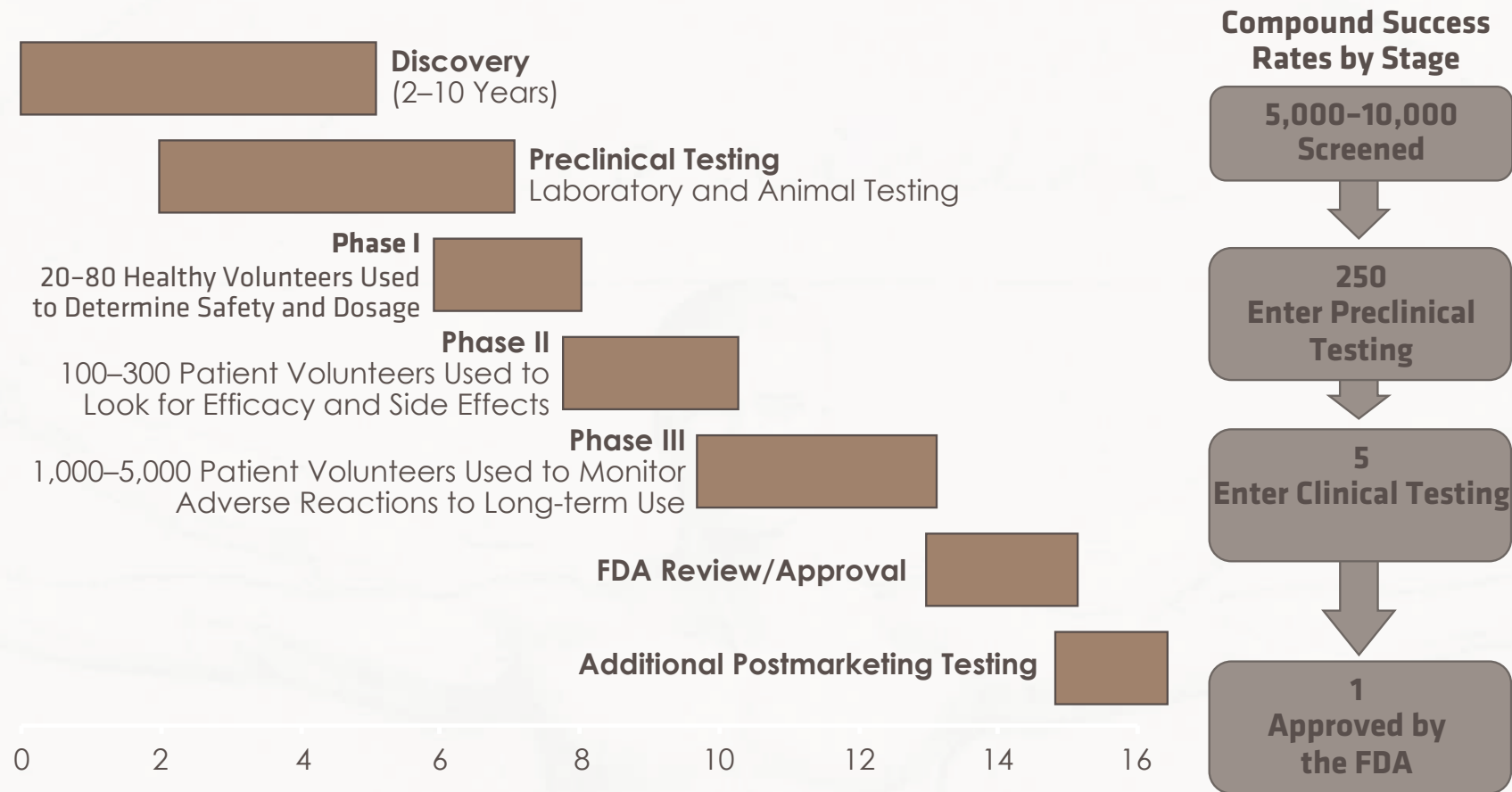
R&D for Pharmaceuticals and Other Industries (% of Sales)



*“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% |

Drug Reimbursement Systems

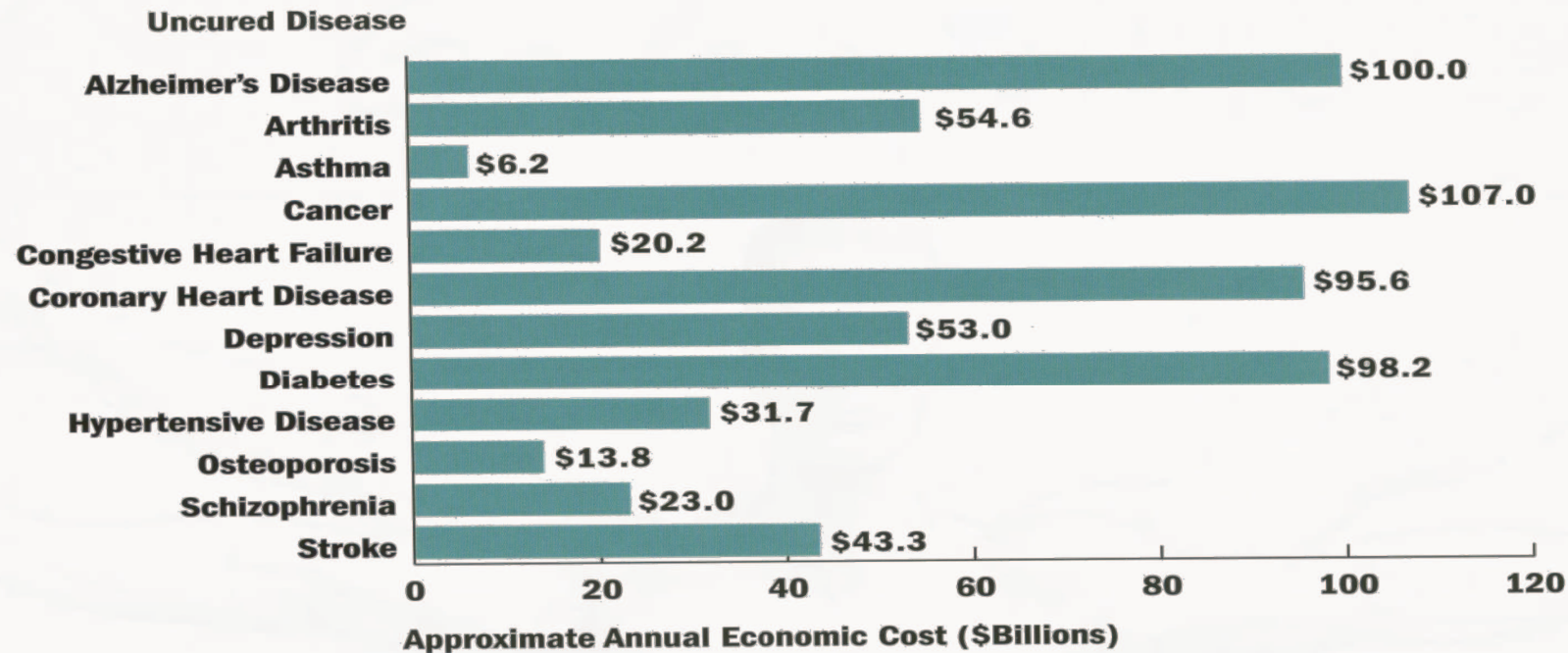
- Copayments
income variation
exempted groups
- Cost-sharing
- Expenditure limits
- Positive and negative prescribing lists
- Therapeutic efficacy categories

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

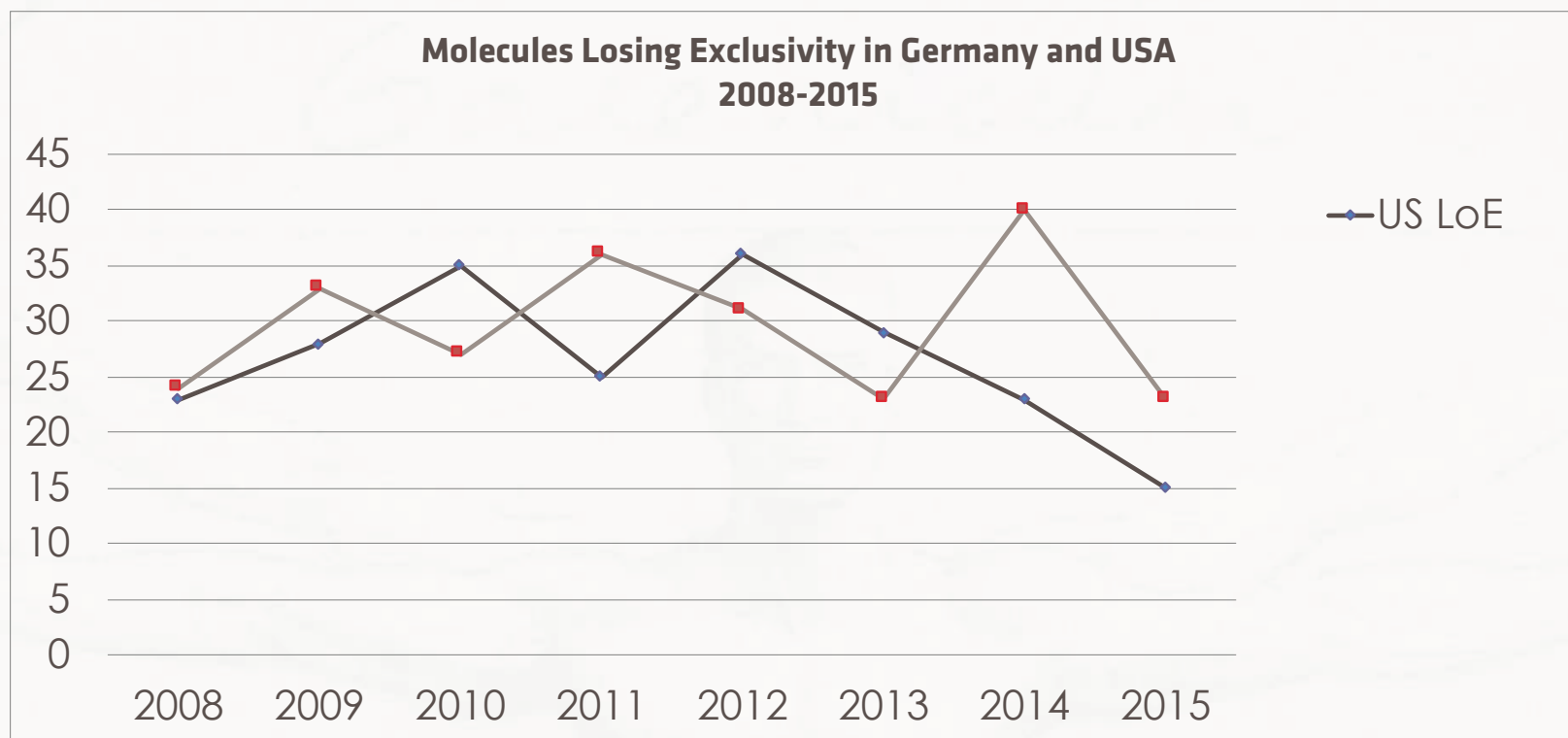
Vioxx®

- 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

Aging 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

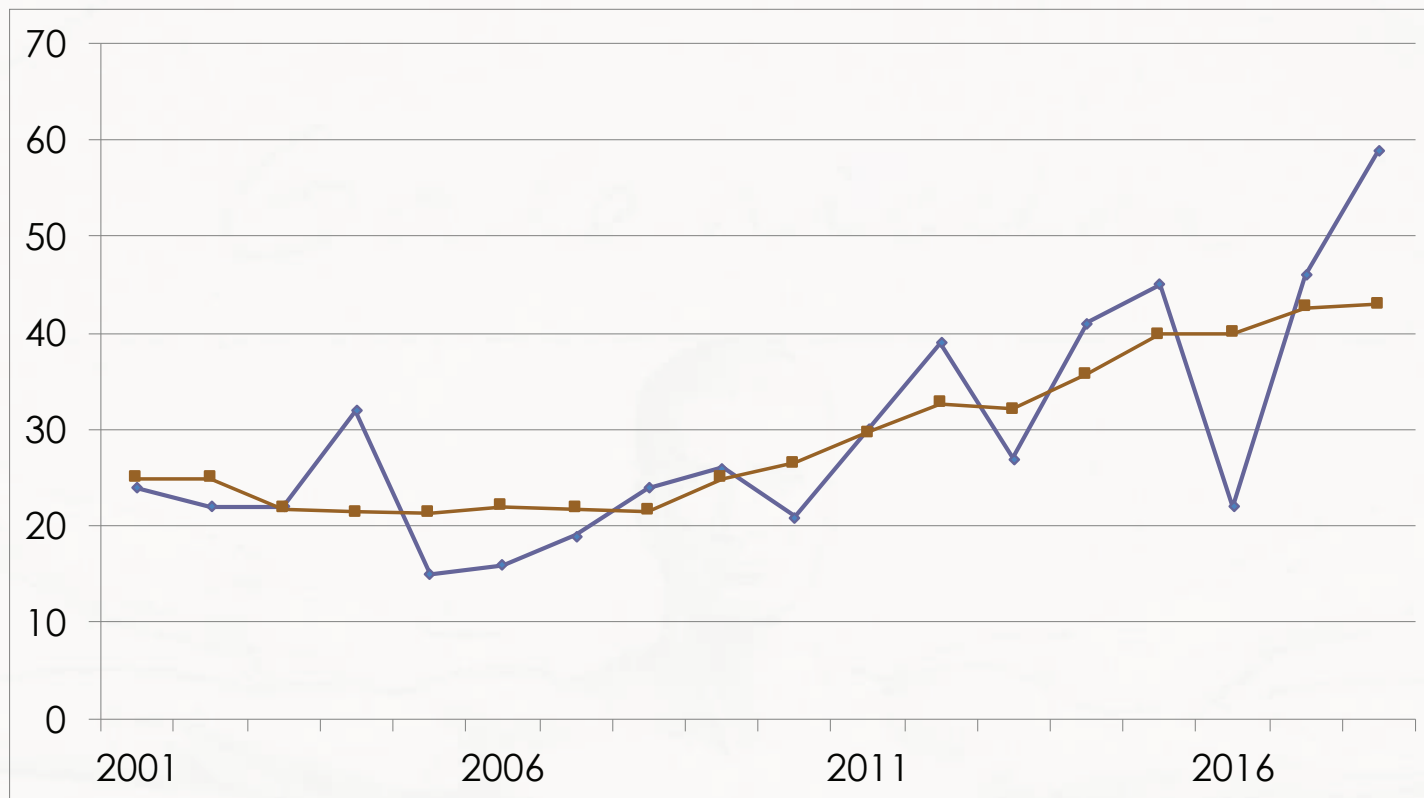
Diabetes

- 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

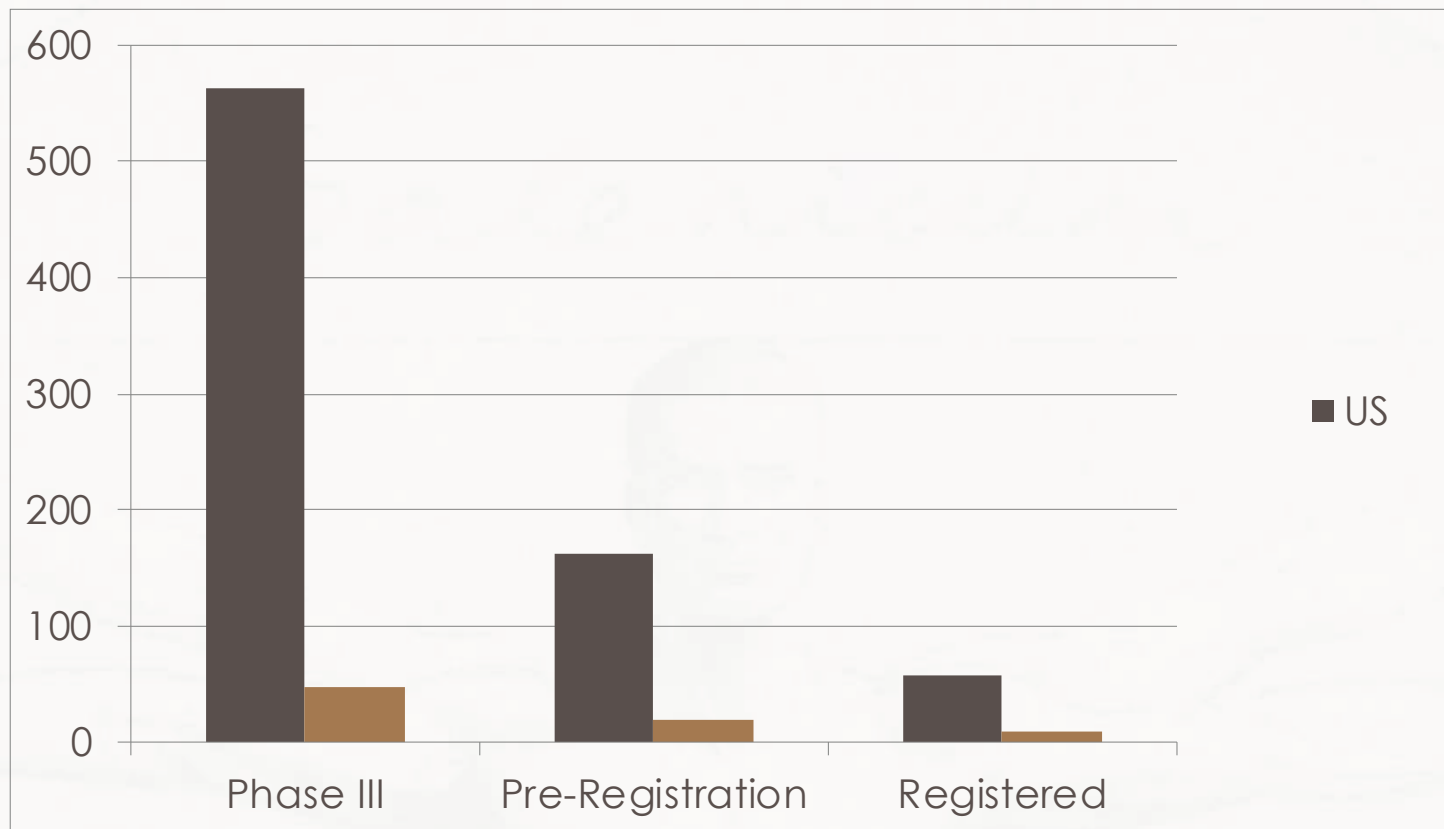
- **25 million** adults in the US
- Heart disease and stroke cost US around **\$214 billion annually**. (\$115 billion direct) (2002)

US NCE Approvals 2001-2018



Source: Newport Horizon Premium™ © THOMSON REUTERS

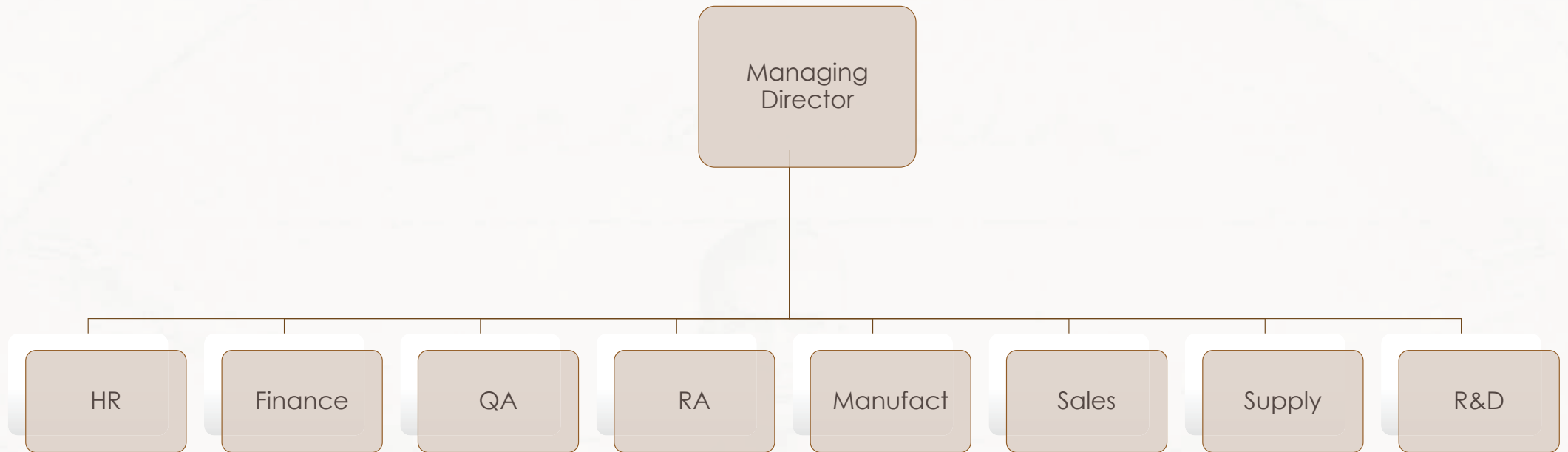
Current pipeline activity looks to continue the trend



Source: Thomson Pharma © THOMSON REUTERS

Your future

Typical Organogram



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

Jobs Opportunities in Pharmaceutical Industry

It includes many job opportunities of pharmacists:

- Patience
- Attention to detail
- Decisiveness
- Independence
- Excellent IT skills
- Numerical skills
- Analytical skills
- Teamworking skills
- Languages

Jobs Opportunities in Pharmaceutical Industry

The interview

- Decide what you want
- Excellent CV
- Be Prepared (from beginning to end)
- Do not lie. Be honest.
- Ask questions.
 - Show interest in the position
 - The company
 - The team
 - The expectations
 - Understand the position offered

Jobs Opportunities in Pharmaceutical Industry

Solution selling

- Focus on other party problems
- Be solution to the problems
- No problems by yourself

thank you!