

Patient Workshop on Innovation and Global Health

Innovation & Access: The importance for patients

19 February 2008

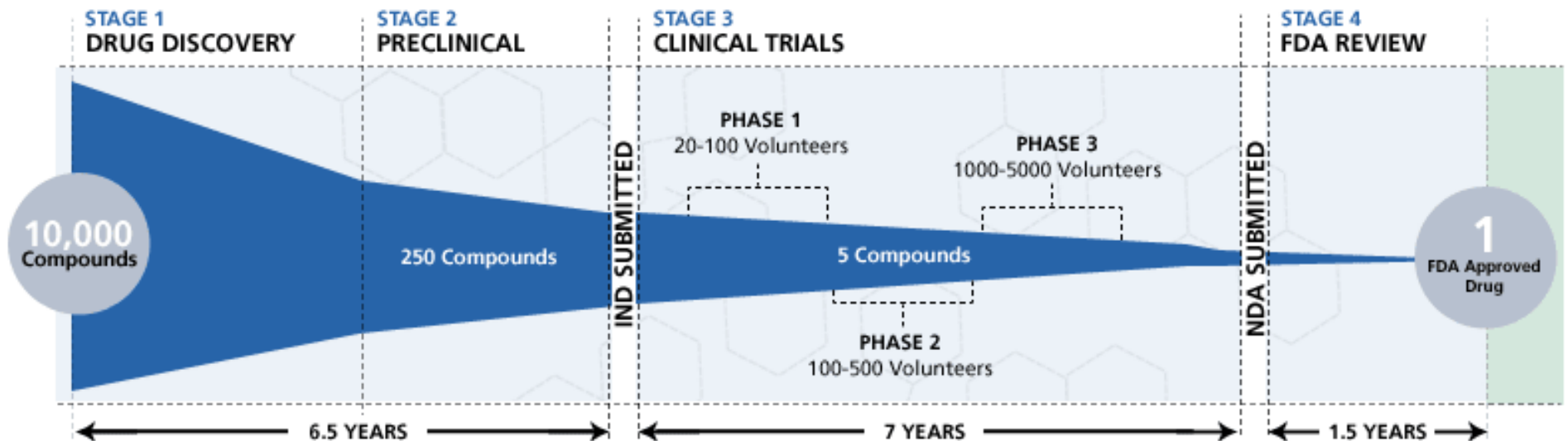
Budapest

Paul T. Antony, MD, MPH

Chief Medical Officer

**Pharmaceutical Research & Manufacturers of America
(PhRMA)**

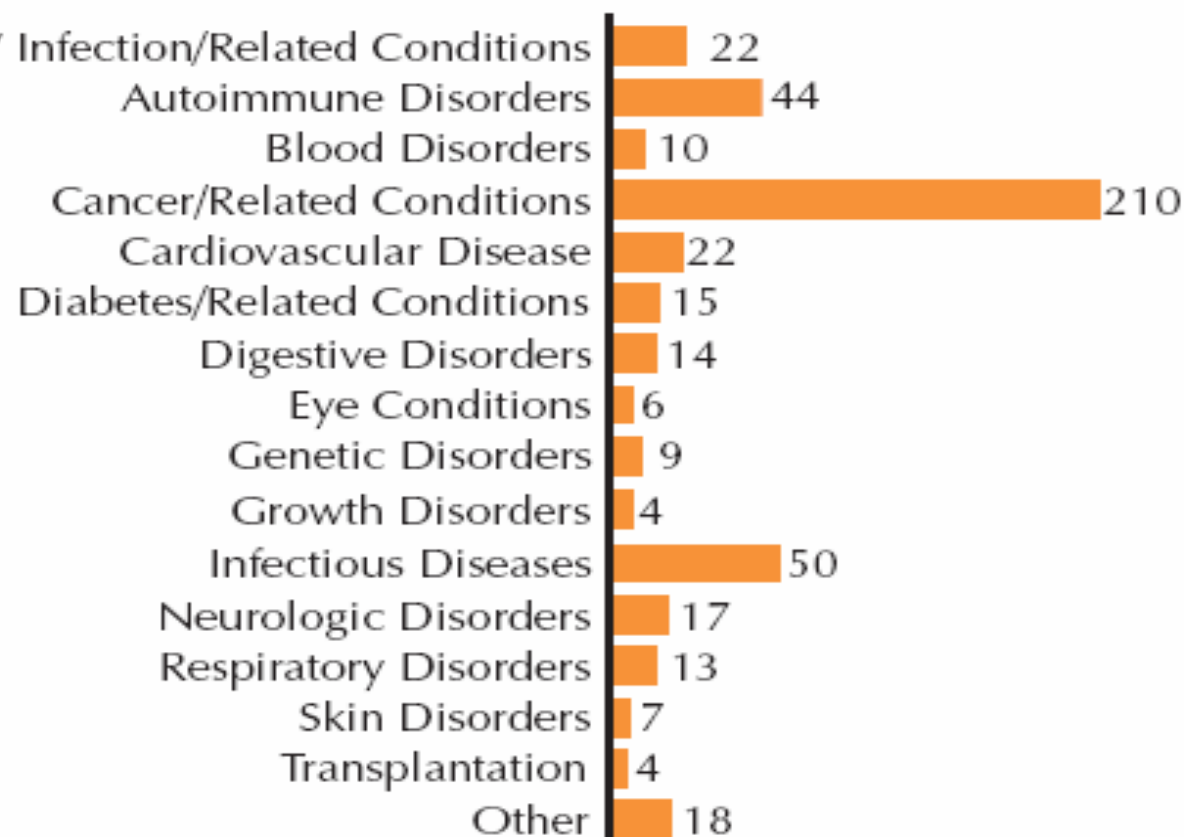
Developing New Medicines: Difficult, Risky, and Expensive



Hundreds of new medicines being developed: Over \$50 billion/year industry R&D spending

PhRMA

BIOTECHNOLOGY MEDICINES IN DEVELOPMENT— BY THERAPEUTIC CATEGORY*



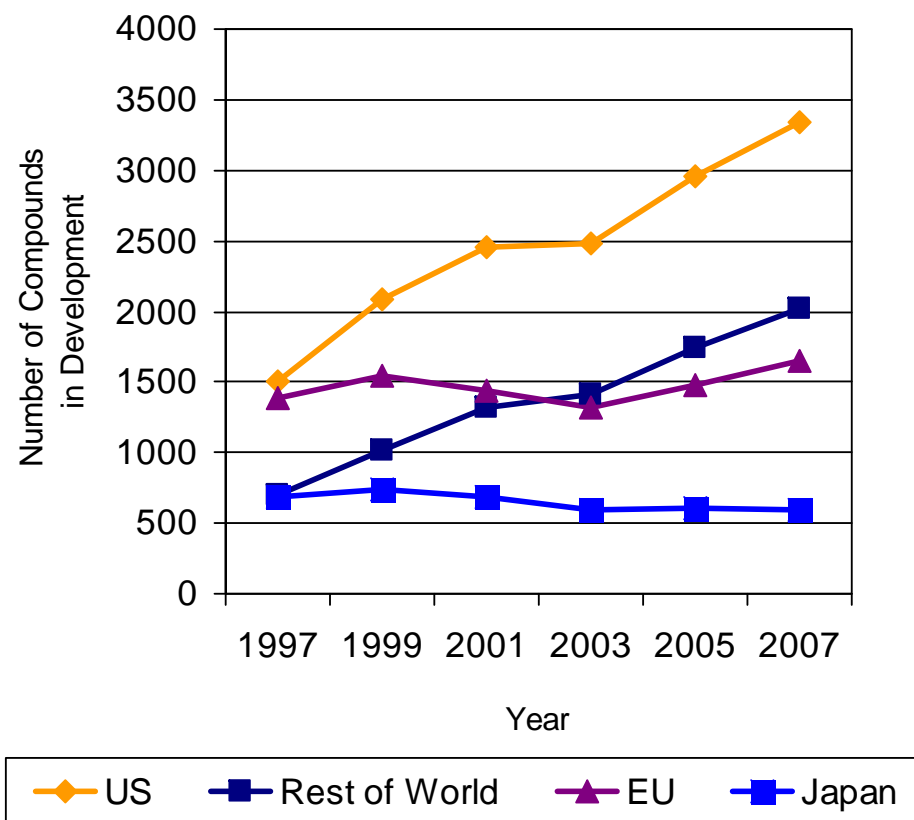
*Some medicines are listed in more than one category.

Source: PhRMA 2006 report – Medicines in Development: Biotechnology

Europe no longer leads in development of new medicines



In 2007, U.S. companies had more medicines in development than the rest of the world of the world



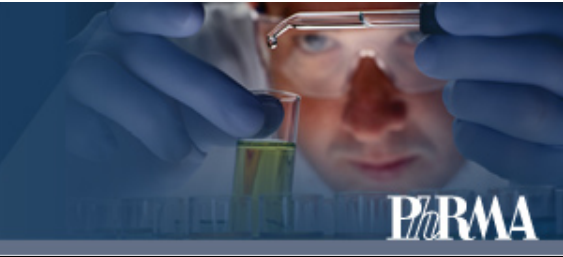
"...in the late 1980s only 41% of the top 50 innovative drugs were of American origin, in the late 1990s...[it had] climbed to 62%.

"In 1990, the pharmaceutical industry spent 50% more on research in Europe than in the U.S. In 2001, the situation was reversed with 40% spent more in the U.S.

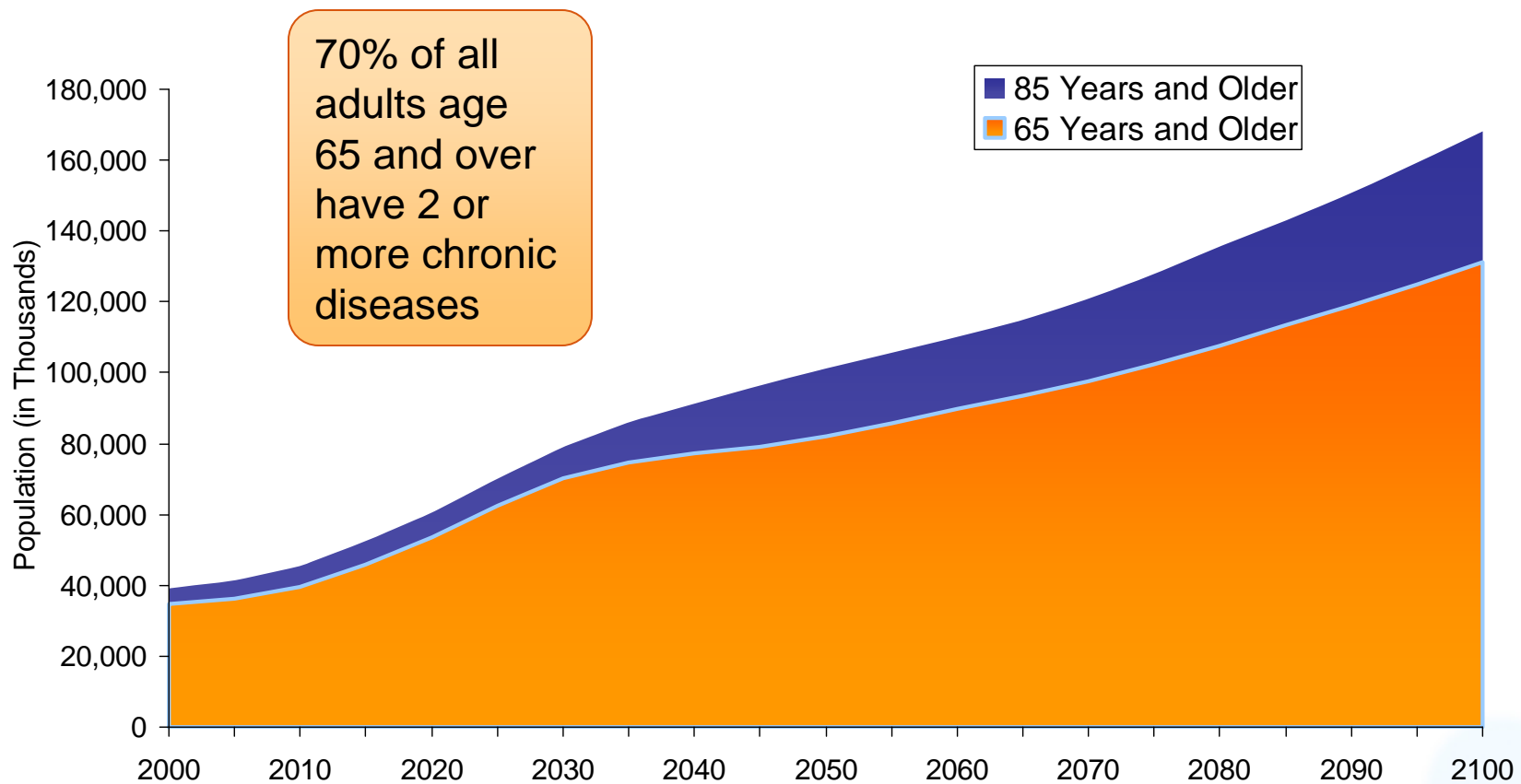
--Gunter Verheugen, Vice-President of the European Commission for Enterprise and Industry

Source: Adis R&D Insight Database, customized run, December 2005 and Verheugen, G., "Address to the Concluding Session of the European Track", Lyon, April 14, 2005. Notes: Comparisons were completed for June of each year. Some compounds are at different phases for different indications.

As population ages innovation is important to combat chronic disease

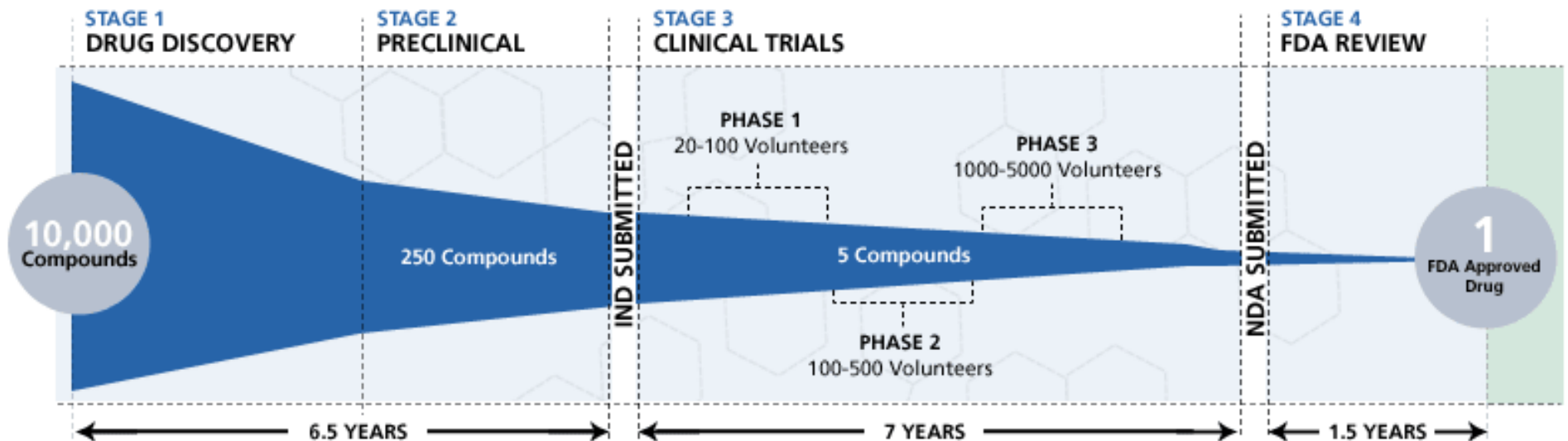


Costly chronic diseases are much more prevalent among older age groups



Data source: U.S. Census Bureau

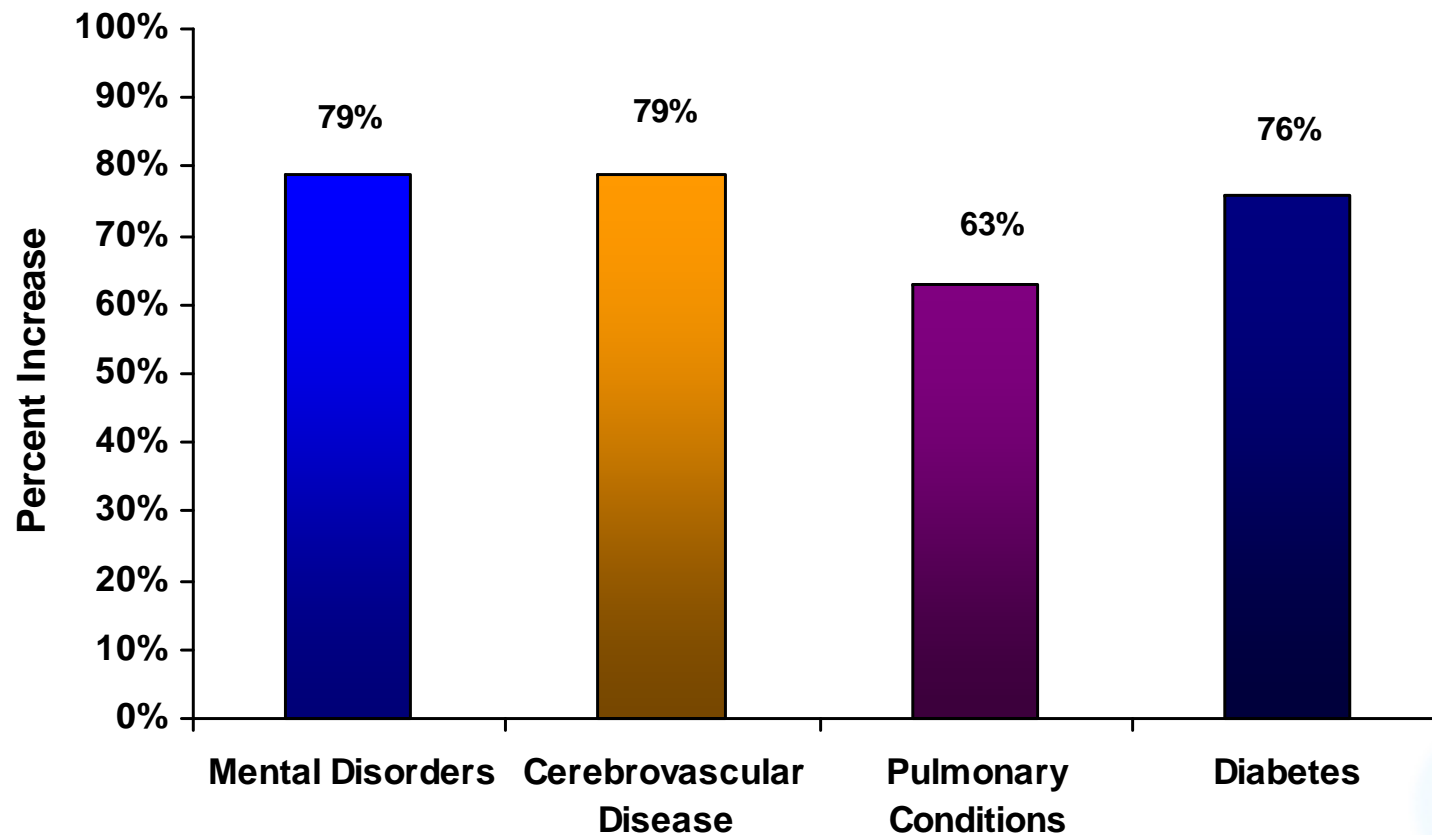
Developing New Medicines: Difficult, Risky, and Expensive



Four chronic conditions contribute up to 79% of increased health care costs

P/RMA

Percent Change in Health Spending Due to Rise in Treated Prevalence and Increased Population, 1987-2000

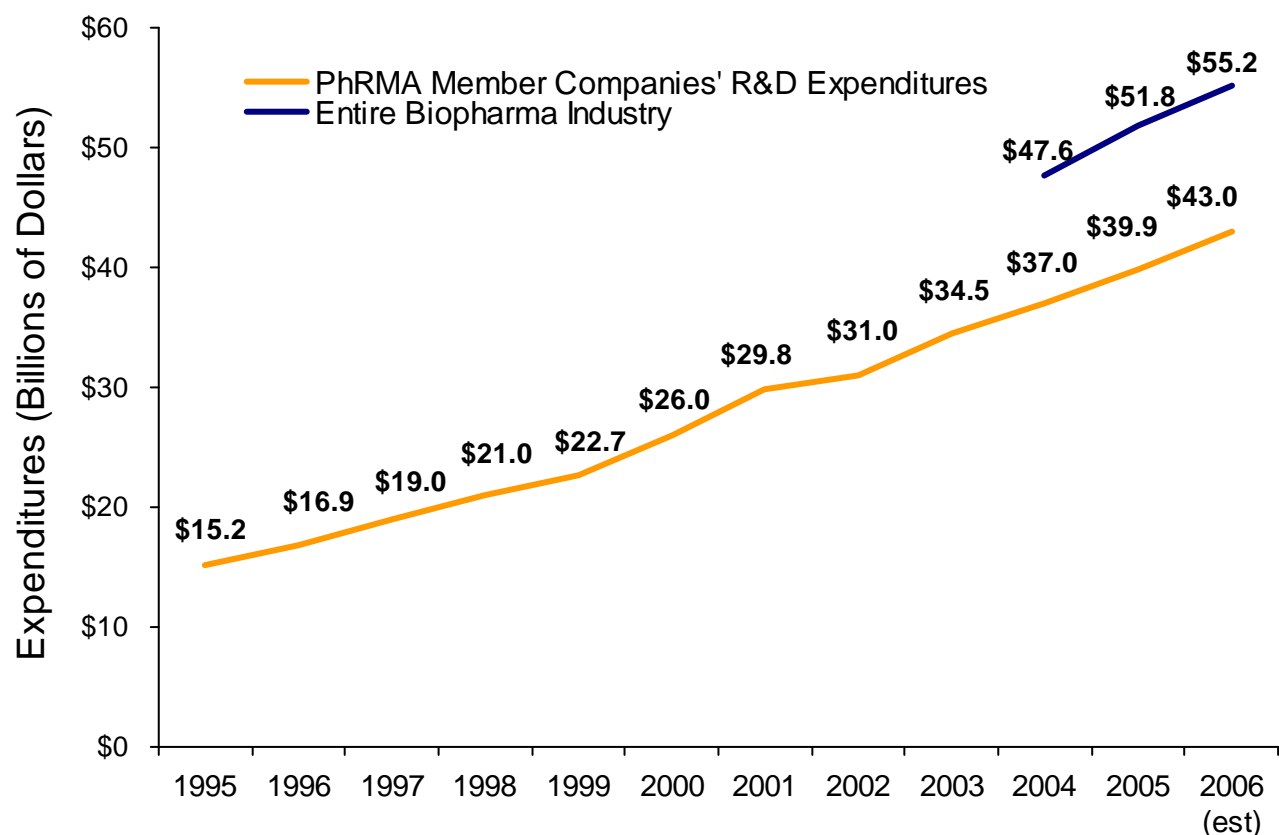


Source: K. Thorpe et. al., "Which Medical Conditions Account for the Rise in Health Care Spending," *Health Affairs*, 25 August 2004.

Industry investment in R&D increasing steadily



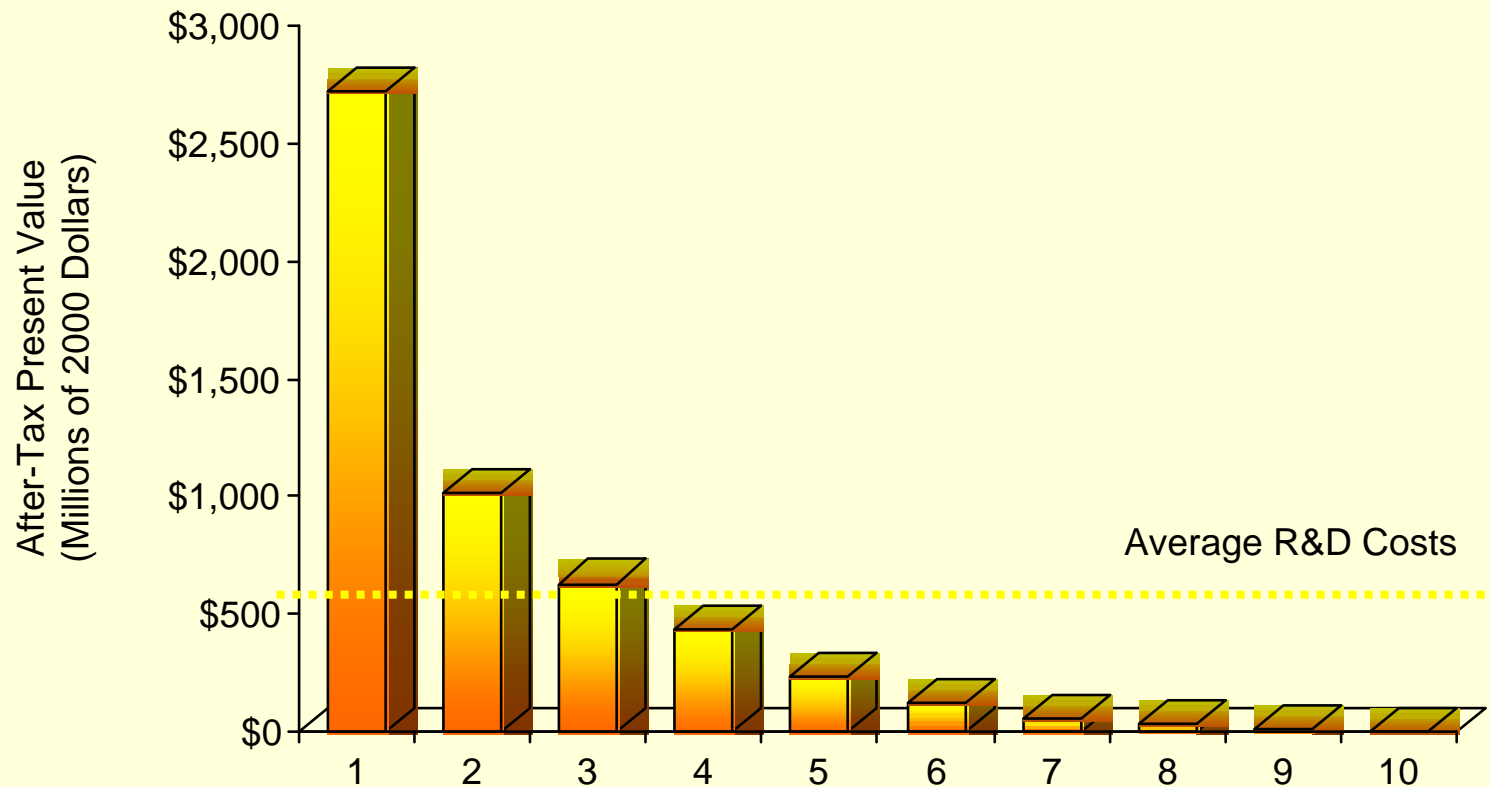
In 2006, total industry spending on R&D exceeded \$55 billion



“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

Only 3 Out of Every 10 Marketed Rx Drugs Produce Revenues That Match or Exceed Average R&D Costs

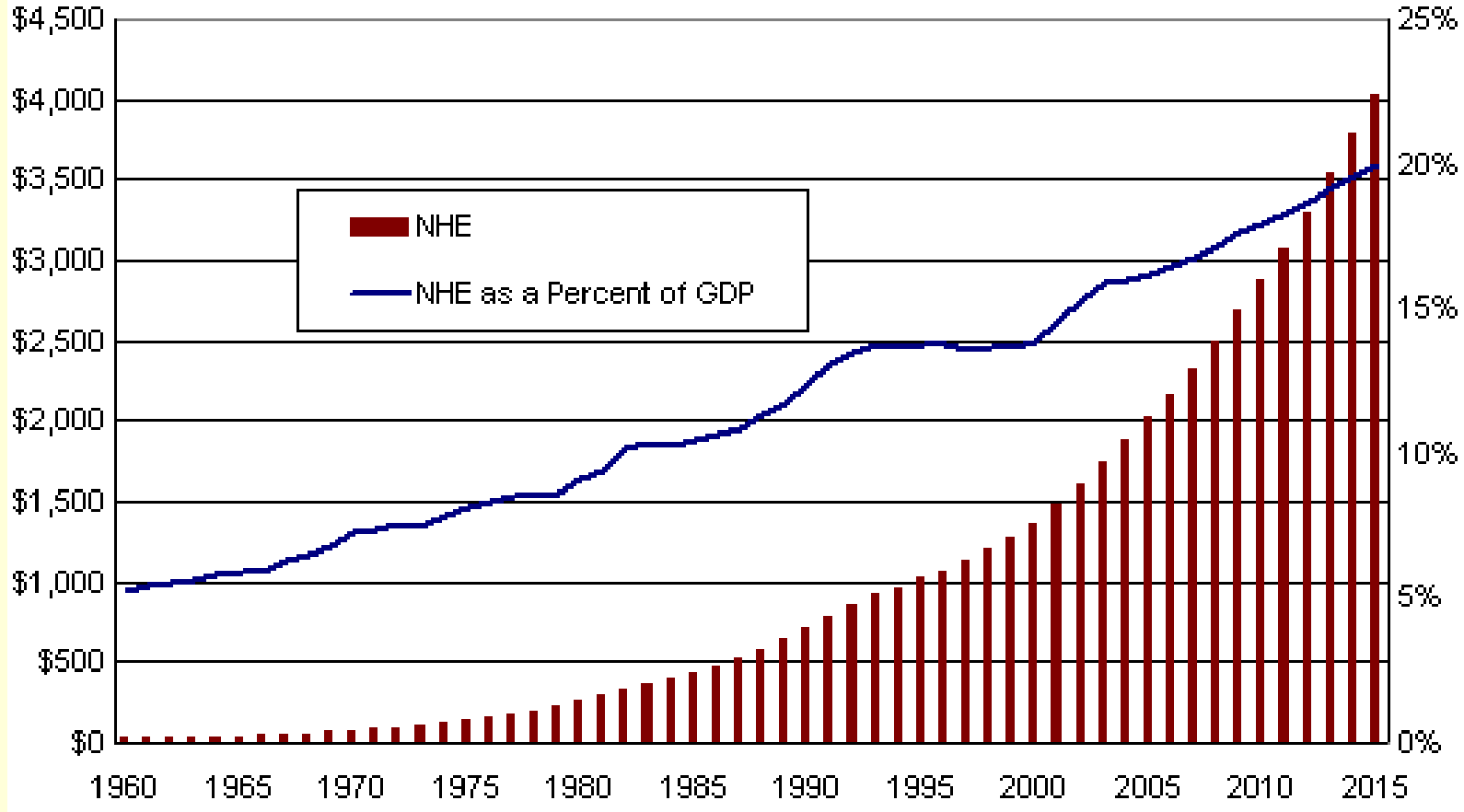


New Rx Drugs Introduced Between 1990 and 1994 Grouped by Decile According to Sales

Note: The drug development costs cited in this chart are out-of-pocket after-tax in 2000 dollars for drugs introduced 1990 and 1994. The same analysis found that the total cost of developing a new drug was \$802 million.

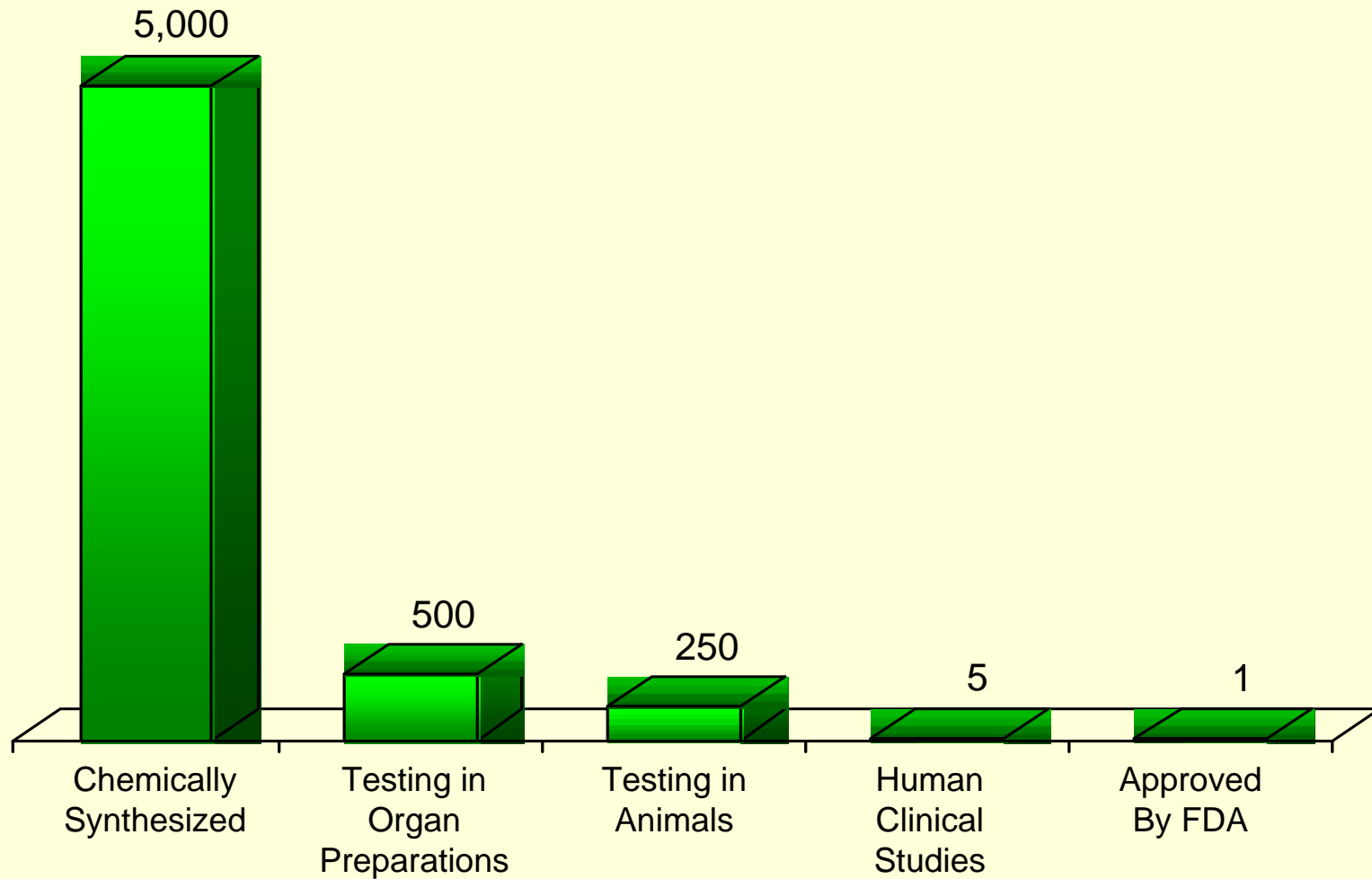
Source: H. Grabowski, J. Vernon, and J. DiMasi, "Returns on Research and Development for 1990s New Drug Introductions," *Pharmacoeconomics* 20 (December 2002): suppl. 3, 11-29.

US National Health Expenditures (1960-2015)



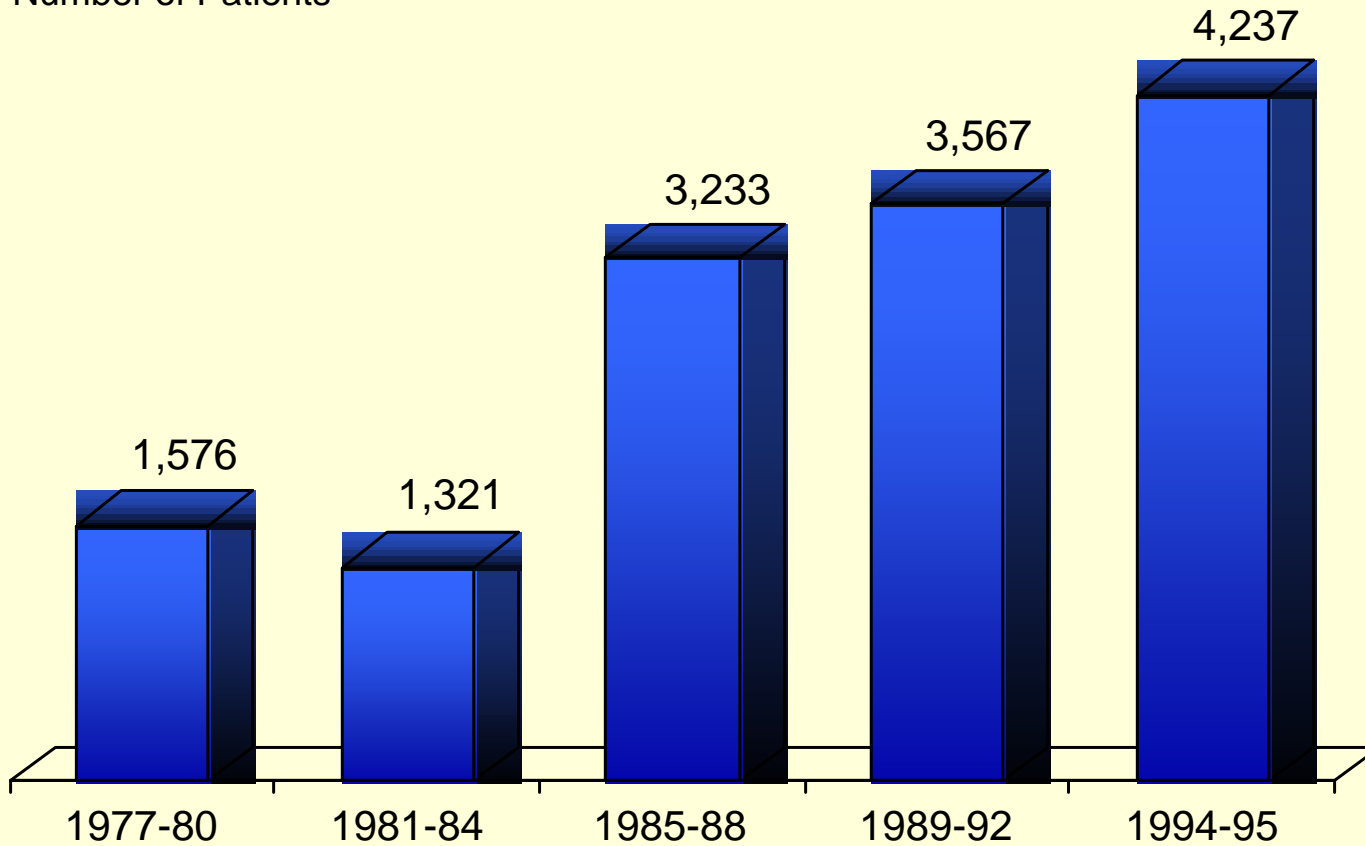
Source: CMS, \$millions

Profile of High-Risk Research

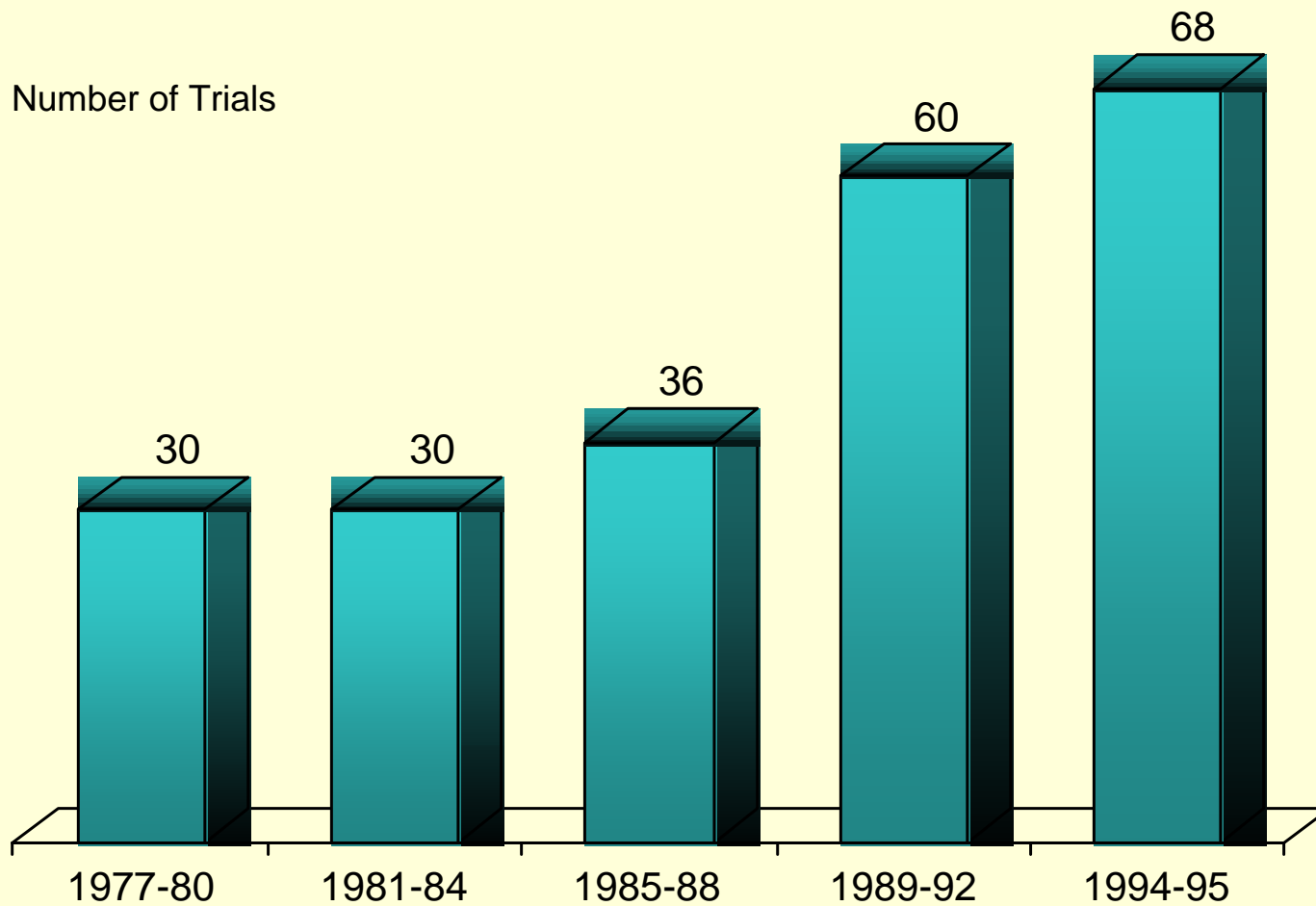


Each New Drug Application Requires More Patients

Number of Patients



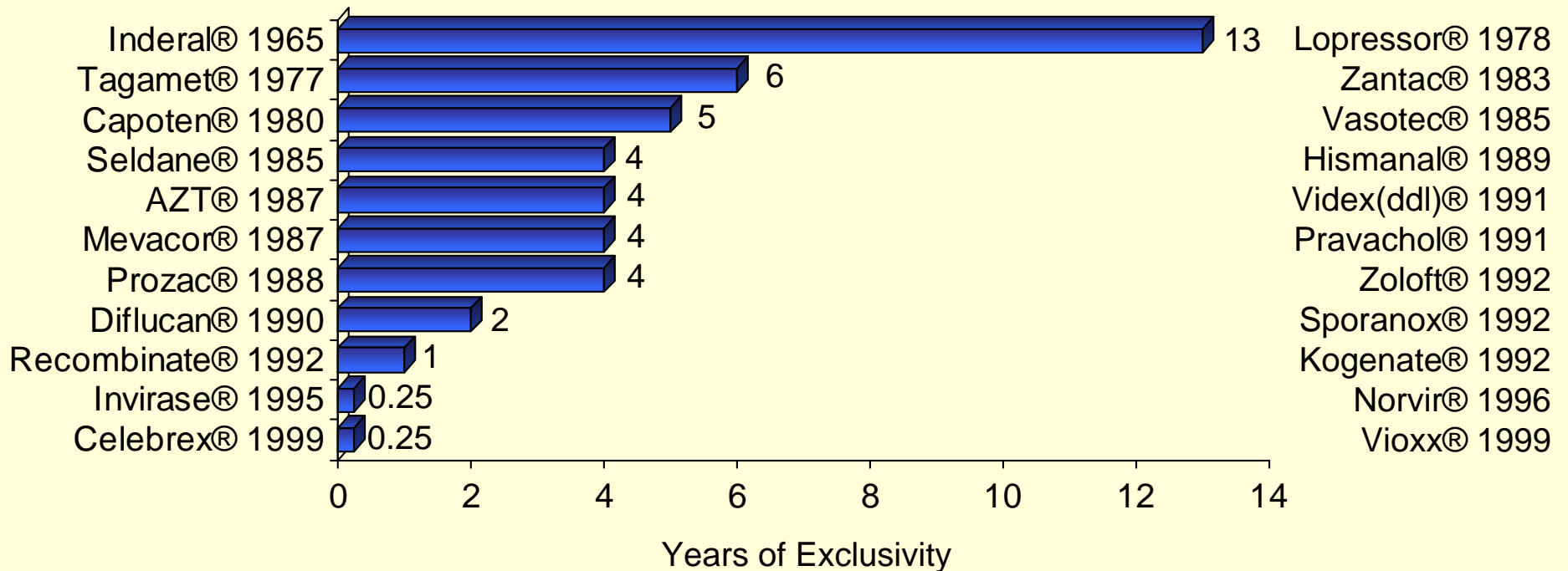
Average Number of Clinical Trials per New Drug Application



Shrinking Period of Market Exclusivity Between Introduction of Breakthrough Medicine and Competing Innovators

Innovative Drug–Year of Introduction

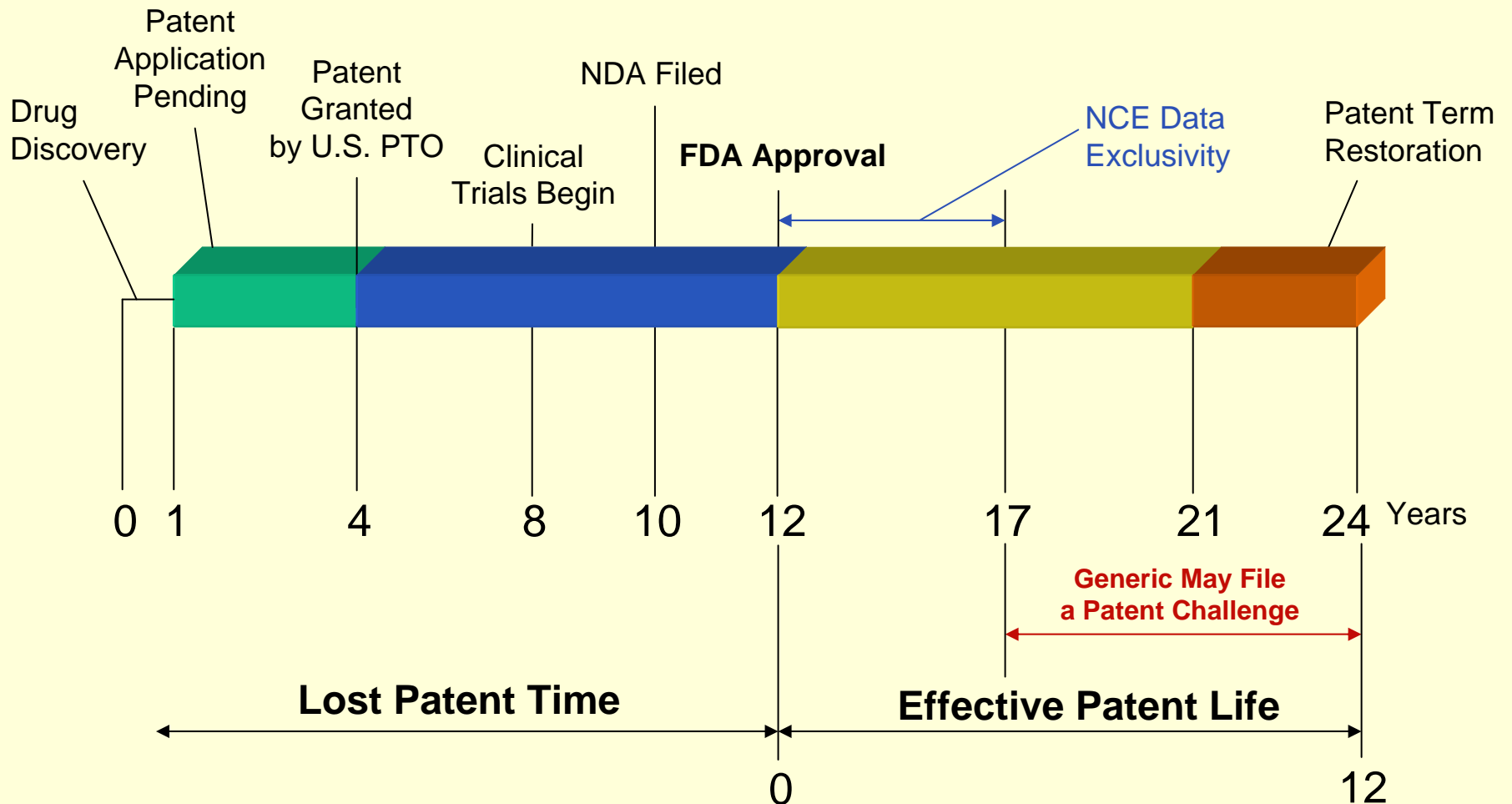
Follower Drug



Inderal® (beta blocker for cardiovascular disease); Tagamet® (H₂ antagonist for ulcers); Capoten® (ACE inhibitor for cardiovascular disease); Seldane® (antihistamine for allergies); AZT® (antiviral for HIV/AIDS); Mevacor® (HMG-CoA reductase inhibitor for high cholesterol); Prozac® (serotonin reuptake inhibitor for depression); Diflucan® (antifungal); Recombinate® (antihemophilic blood factor); Invirase® (protease inhibitor for HIV/AIDS); Celebrex® (cox 2 inhibitor for arthritis).

Sources: Pharmaceutical Research and Manufacturers of America, 2000; The Wilkerson Group, 1995.

Patent Timeline



Source: Gregory J. Glover and Bruce N. Kuhik, "Patents and Hatch-Waxman: Understanding the Debate Between Innovative Drugs and Generic Copies," presentation to The National Governors Association (Washington, DC), 19 April 2002.