Pharmaceutical Patents

The Value of Pharmaceutical Patents & Strong Intellectual Property Protection

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Overview

- Abraham Lincoln said that patents "added the fuel of interest to the fire of genius." But, it was not genius alone that Lincoln and our founding fathers desired from a patent system. Rather, their objective was *innovation*. Innovation is why we protect intellectual property.

- The founding fathers felt so strongly about the importance of innovation that patent and copyright protection is the only right expressly mentioned in the original articles of the Constitution.

- Patent protection in the United States gives inventors the exclusive right to sell an invention for up to 20 years before others may copy and sell it. However, the effective patent life, which only begins to run when the patent is granted and the invention can be marketed, is closer to 18 ½ years. For pharmaceuticals, the effective patent life is actually closer to 11 or 12 years since federal law requires a company to test its product for safety and efficacy and secure regulatory approval before marketing it, a process that can take years.

- Patents are a kind of agreement in which an inventor is given a limited period of time of exclusivity to make and sell a product incorporating an invention in exchange for agreeing to make his or her invention public, thus enabling and encouraging the continuation of scientific discovery.

Patent Protection for Pharmaceuticals is Different From Protection in Other Industries

- Unlike patents in other industries, pharmaceutical patents cover products that take a very long time to develop. It takes 10–15 years on average to develop a new medicine from the earliest stages of compound discovery through FDA approval. As a result, significant portions of the patent term for a new drug are lost before a product enters the market. In fact, the average effective patent life for medicines is 11.5 years.

- Since initial investment in pharmaceutical R&D is so costly, strong patent protection is an important step to provide the opportunity to recoup investments in new products. The average cost to develop a new medicine has been estimated at upwards of $800 million according to an analysis conducted by the Tufts Center for the Study of Drug Development.

- In discovering and developing a new medicine, the pharmaceutical industry faces significantly increasing complexity in required clinical trials.

Patents Provide Incentive to Innovate

- Patents are the legal protection for inventions, including new medicines discovered by research-based pharmaceutical companies. This protection allows a company time to recoup their significant investment in research and development.

- In return for such protection, a patent-holder discloses to the world patented research and science underlying the invention. Thus, important scientific information behind a new cancer drug becomes available immediately to researchers worldwide.

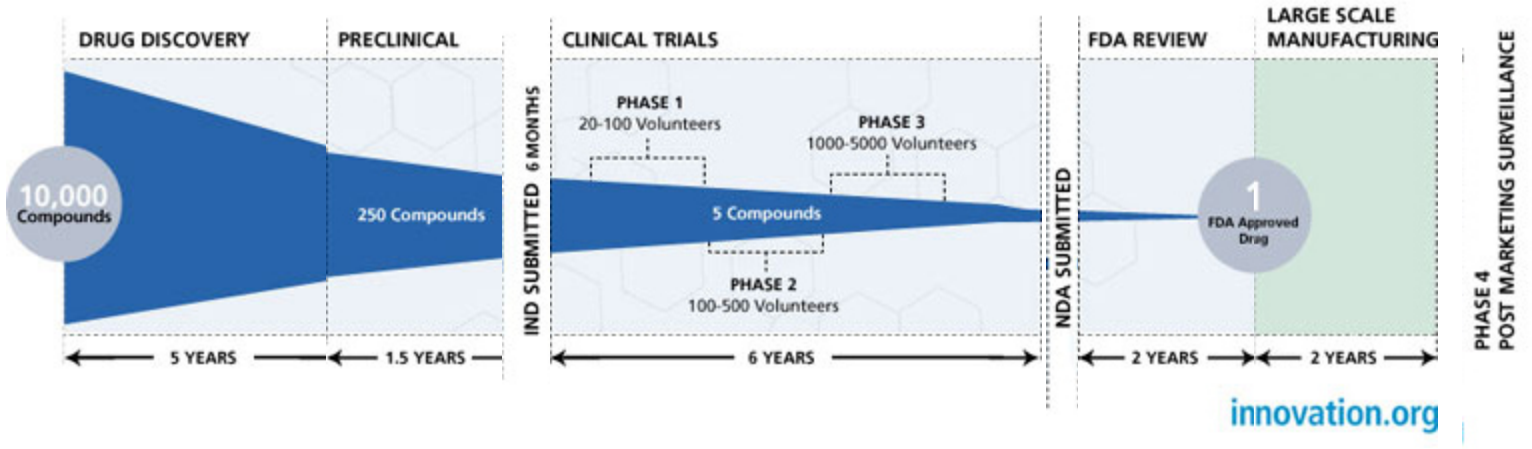
- "It is widely acknowledged that patents are a fundamental incentive to innovative activities in pharmaceuticals and biotechnology." (Source: F. Pammoli, et al., "Global Competitiveness in Pharmaceuticals: A European Perspective," prepared for the Directorate General Enterprise of the European Commission, November 2000.)

The Process of Innovation is Complex, Risky and Expensive

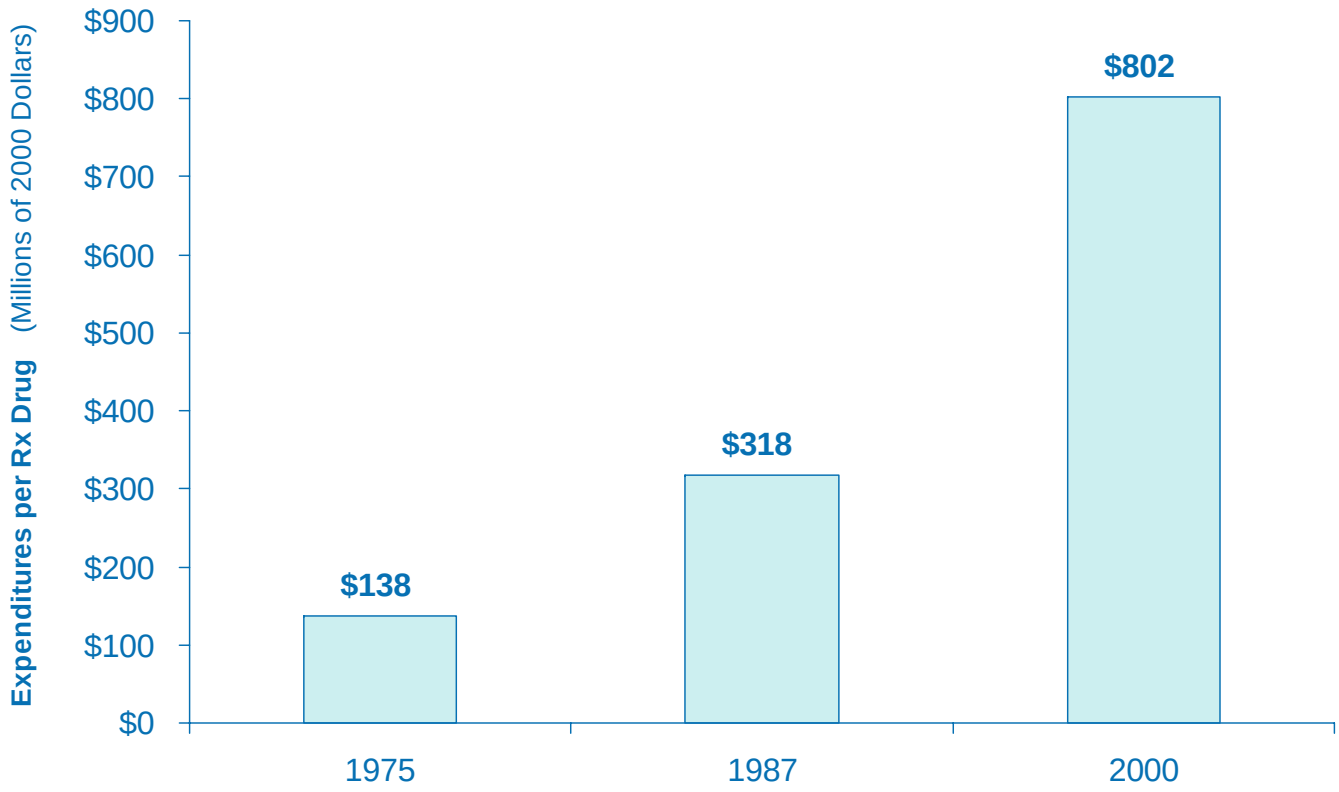
Odds are almost overwhelmingly against bringing a new medicine to patients

- The process of innovation is a very complex, lengthy and expensive endeavor. Consider these odds:
  - Only one in 5,000-10,000 compounds tested eventually reach consumers.
  - Only two out of every ten compounds that enter clinical testing reach the market.
  - Once on the market, new drugs on average have only 11 to 12 years of useful or effective patent life remaining.
  - Only three out of ten drugs that reach the market ever earn back enough money to match or exceed the average R&D cost of getting them to the marketplace.

Drug Discovery

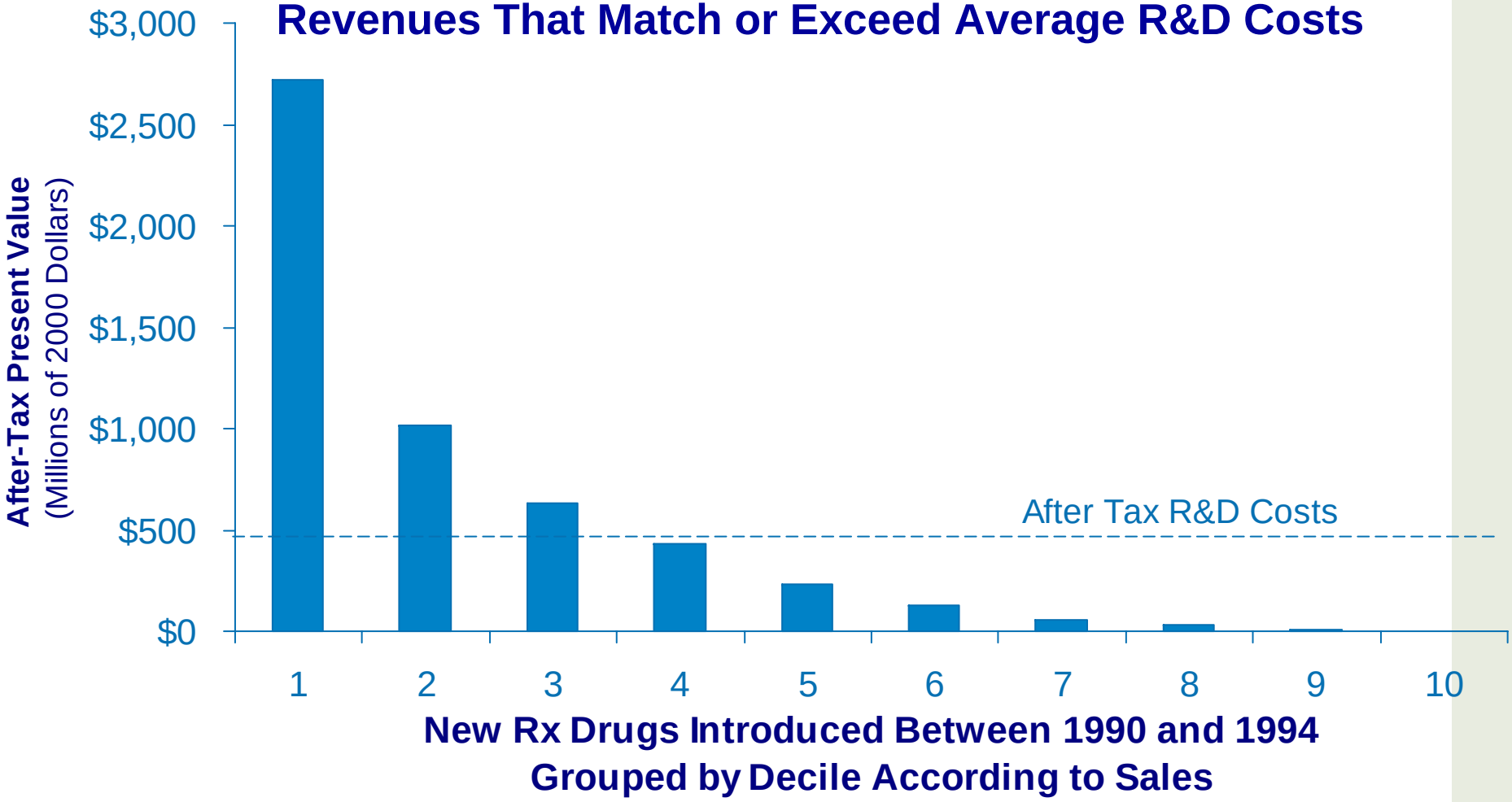


The Cost of Developing a New Drug Has Greatly Increased



Source: J. A. DiMasi, R. W. Hansen, and H. G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22 (2003):151-185.

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



Note: The drug development costs cited in this chart are out-of-pocket after-tax in 2000 dollars for drugs introduced 1990-1994. 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.

Strong IP Protection Makes Risk Palatable

- A strong patent system is critical…. "Ideas drive today's economy," Alan Murray wrote in the *Wall Street Journal*.
- Even with patent protection, market success depends on many factors beyond a manufacturer's control, including, for example, consumer demand for the drug therapy and competition from other brand-name drugs.
- The strength of patent protections is a factor in decisions to invest in new technologies or products.

Incentives for Innovation are Particularly Important as the Market Becomes More Competitive

TODAY:

– Brand name companies face vigorous competition from other brand name drugs in the same therapeutic class long before a generic drug ever enters the market.

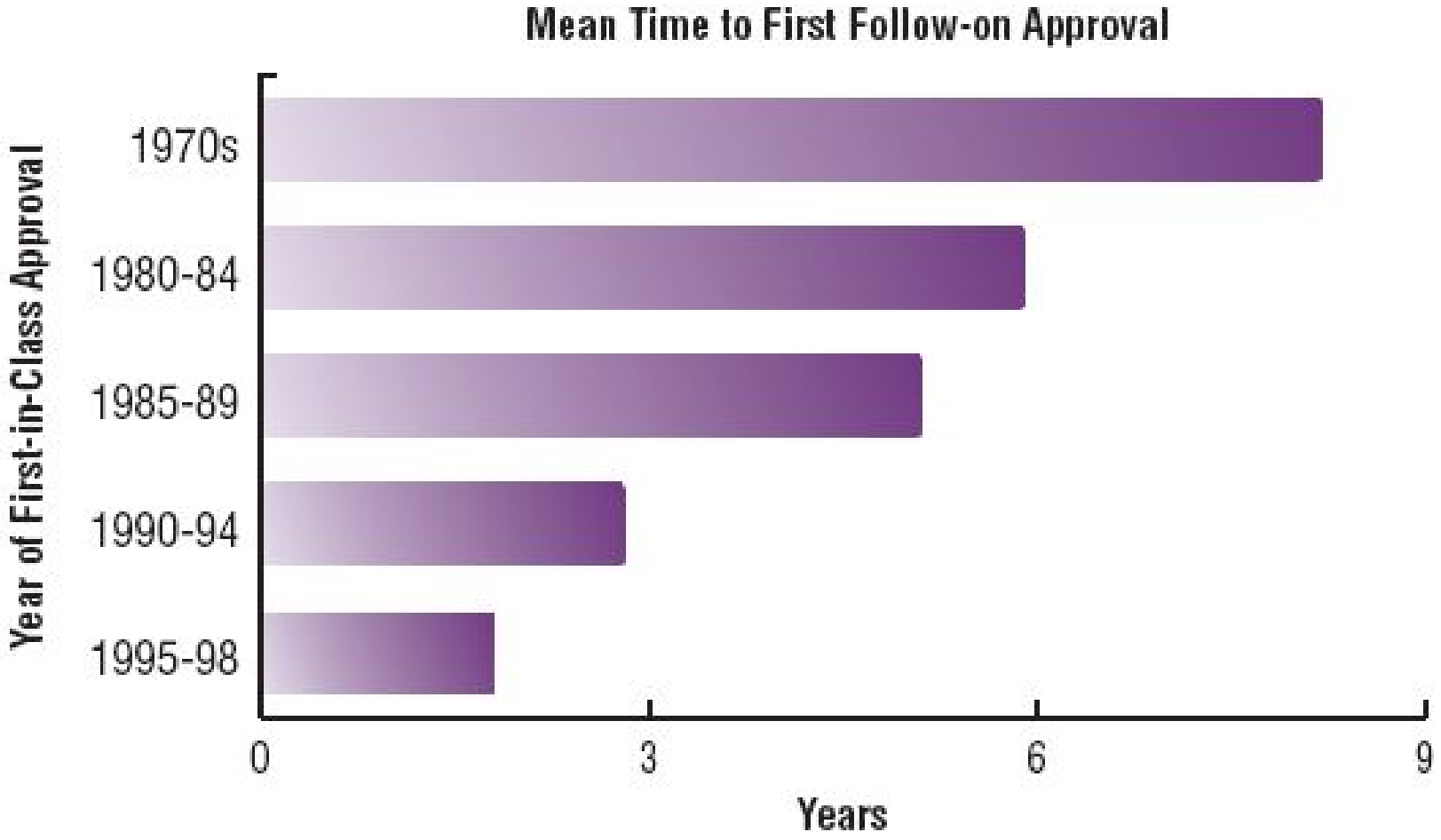
– Innovator companies face fierce competition with generic copiers immediately following patent expiration.

Brand Drugs Face Vigorous Competition Long Before Generic Copies Arrive on the Market

- Notwithstanding patents, brand drugs face vigorous competition long before generic copies arrive on the market. A recent study from Tufts University researchers showed that the amount of time between the entry of the first and second drug in a class has fallen by about 78 percent since 1970. In fact, the average length of time before a first-in-class drug got its first direct competitor dropped from 8.2 years in the 1970s to 1.8 years in 1995.

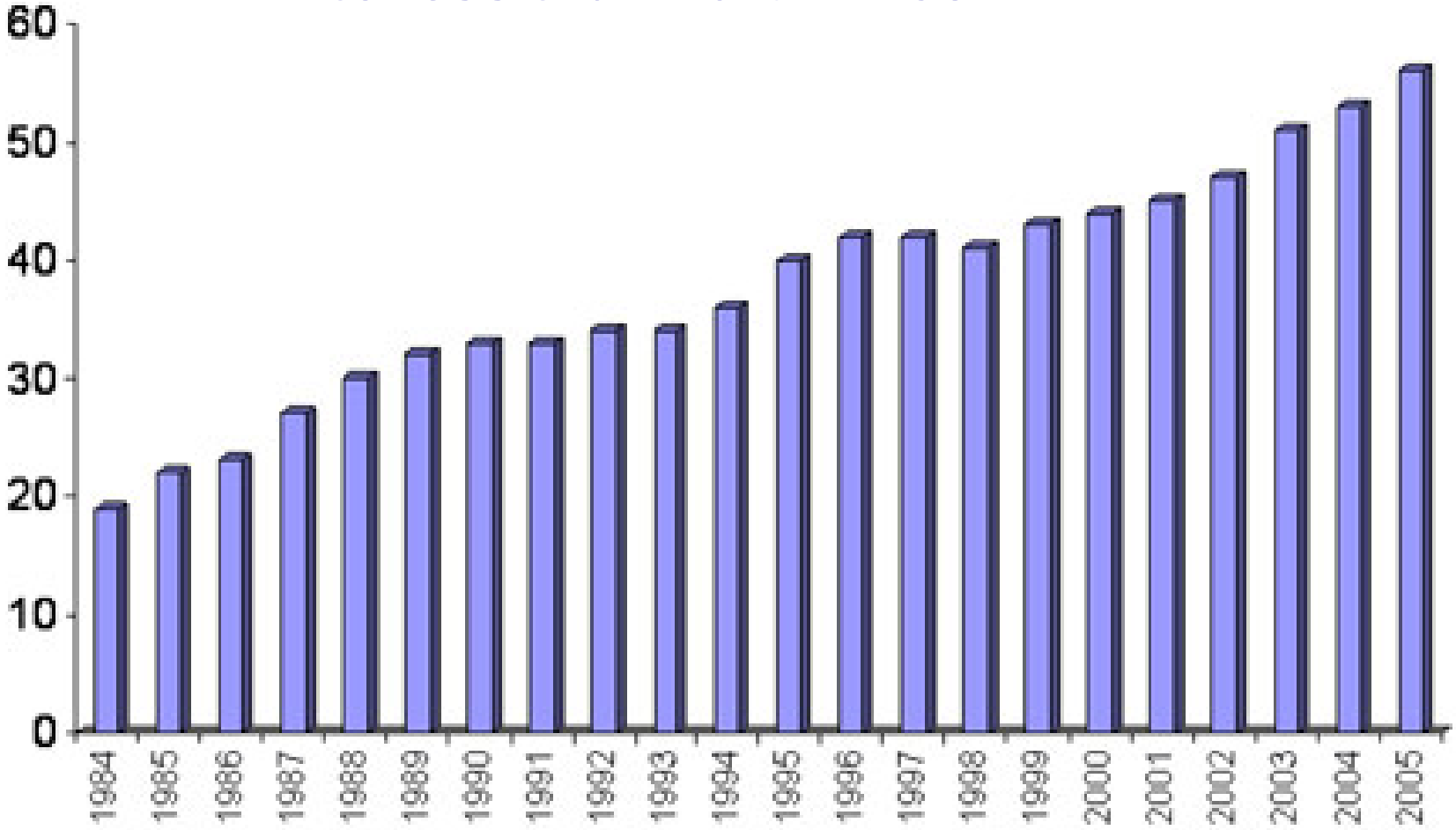
- Since 1984, there has been a significant increase in the number of prescriptions dispensed for generic medicines compared to branded medicines, 18% in 1984 compared to nearly 60% in 2005.

Effective Market Exclusivity for First-in-Class Has Declined During Last 30 Years



Source: DiMasi, Paquette, Pharmacoeconomics *2004; 22 Suppl. 2:1-14*

In 2005 generic medicines account for 56% of all prescriptions dispensed in the United States, compared to less than 20% in 1984



Source: GPhA

Patents Help Save Lives, Enhance Life

- Of all the advances of the 20th and 21st centuries, from aviation to the Internet, few have been as important and valuable to the preservation and enhancement of life as pharmaceutical and biotech innovations. In fact, according to University of Chicago economists, "Over the last half century, improvements in health have been as valuable as all other sources of economic growth combined."

- Prescription drugs, biologics and vaccines have revolutionized public health worldwide:
  - Tuberculosis was no longer a threat after the Bacille Calmette-Guerin vaccine was discovered in the 1920's. By 1944, new antibiotics were being used to treat it.
  - Polio was eliminated in 1952 when Jonas Salk discovered his vaccine.
  - Thanks to new medicines introduced in the 1990s, people living with schizophrenia can now manage their condition more effectively than ever, and with fewer side effects. These medicines - dubbed "atypical antipsychotics" also help people whose schizophrenia had not previously responded to treatment, making it possible for them to leave institutionalized care, return to work, and lead normal lives.
  - In 1995, InviraseTM became the first protease inhibitor approved by the FDA for the treatment of AIDS. Since then, these drugs have become a key ingredient in "drug cocktails" that have reduced AIDS deaths in the U.S. by 70 percent.
  - In 2001, the first targeted cancer treatment was approved. Since then more have been approved and they are proving to be a powerful new tool, with far fewer side effects than older therapies.

New Medicines Help Extend Life, and the Quality of Life for Millions of Patients

- Patients benefit extraordinarily from new medicines – keeping them out of the hospital, off the surgery table, on the job and in the home.
- Without new medicines, the already staggering costs of uncured diseases will explode with the aging of baby boomers.

Antihypertensive Medicines Have Prevented Deaths and Hospitalizations

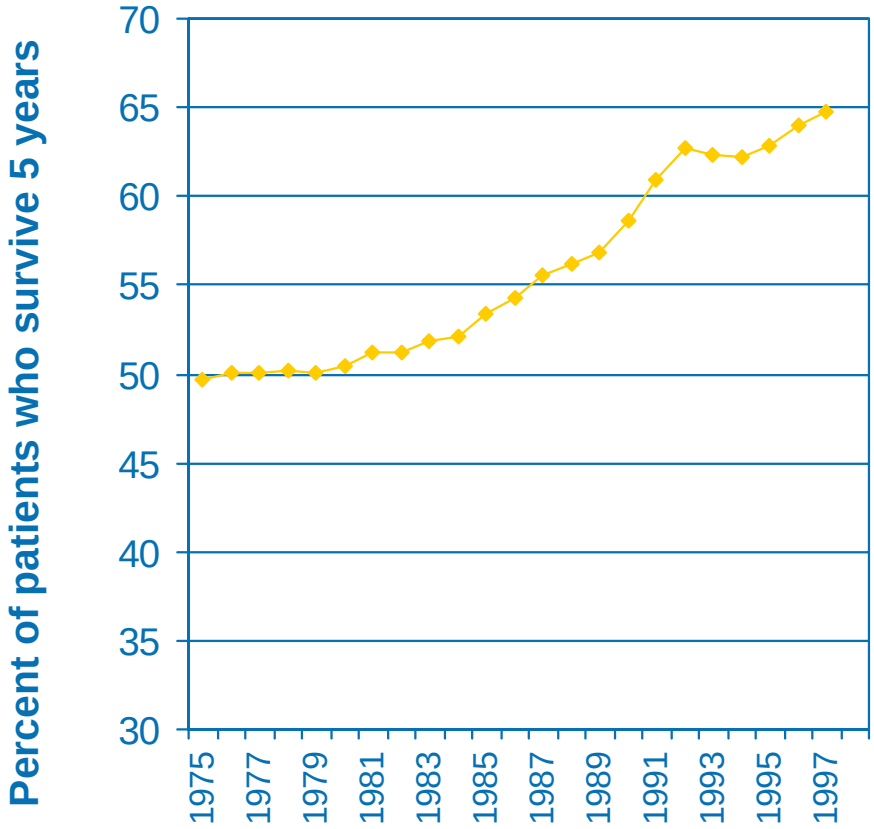
Study Quantified Impact of High Blood Pressure Drugs on the U.S. Population 1999–2000

WITHOUT antihypertensives we would have seen:

Life Expectancy—MEN	**0.5 years lower**
Life Expectancy—WOMEN	**0.4 years lower**
Blood Pressure	**10%–13% higher**
Deaths	**86,000 additional**
Hospitalizations	**833,000 additional**

Data source: G. Long et al., *The Impact of Antihypertensive Drugs on the Number and Risk of Death, Stroke, and Myocardial Infarction in the United States,* National Bureau of Economic Research Working Paper No. 12096 (Cambridge, MA: NBER, March 2006).

Cancer Survival Increasing



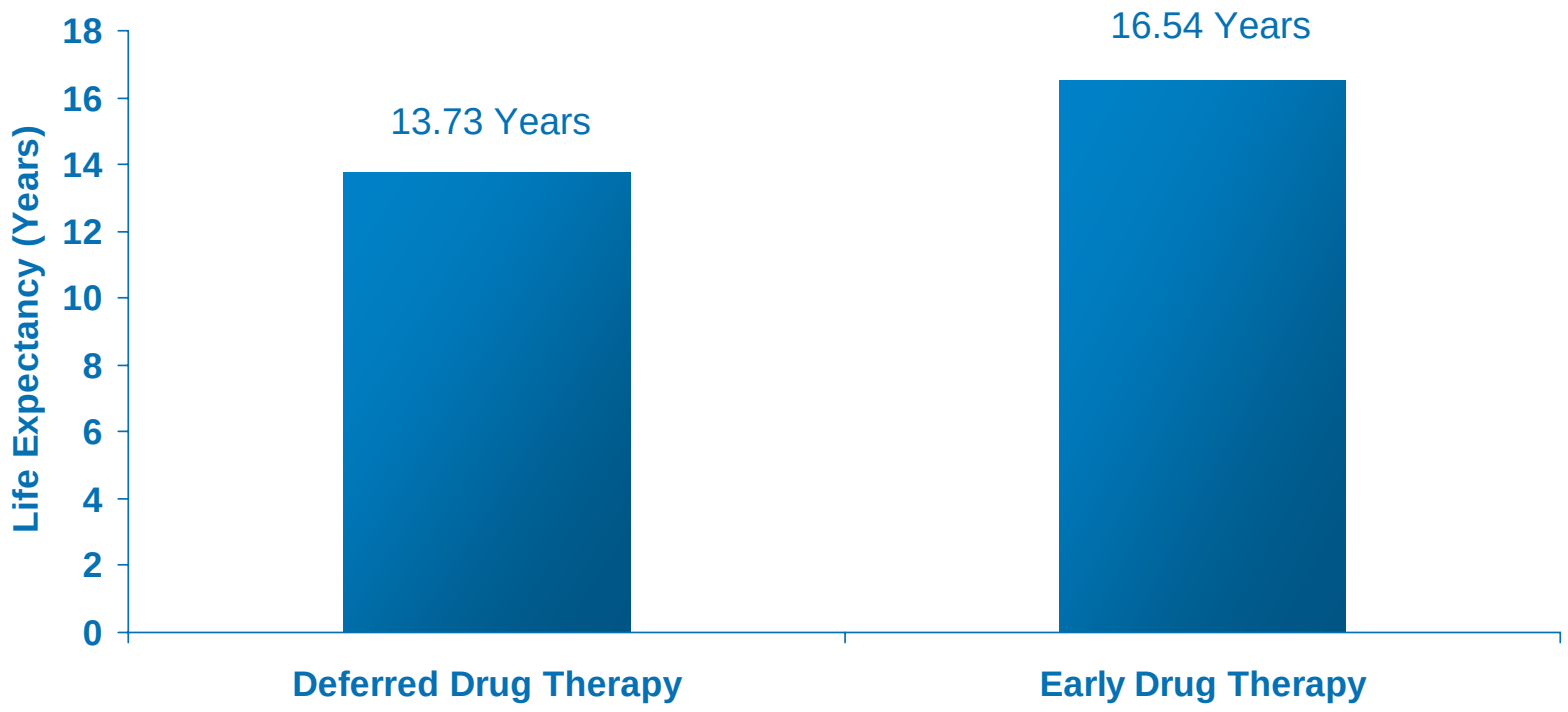
Recent study found that new drugs account for **50-60%** of the increase in six-year cancer survival rates since 1975.*

*F.R. Lichtenberg, "The Expanding Pharmaceutical Arsenal in the War on Cancer," National Bureau of Economic Research Working Paper No. 10328 (Cambridge, MA: NBER, February 2004).

National Cancer Institute, National Institutes of Health, Department of Health and Human Services, "Cancer Trends Progress Report – 2005 Update," (Bethesda, MD: NCI, December 2005), http://progressreport.cancer.gov/ (Accessed 26 January 2006).

Medicines Prolong Life

Early HIV Drug Therapy Prolongs Life

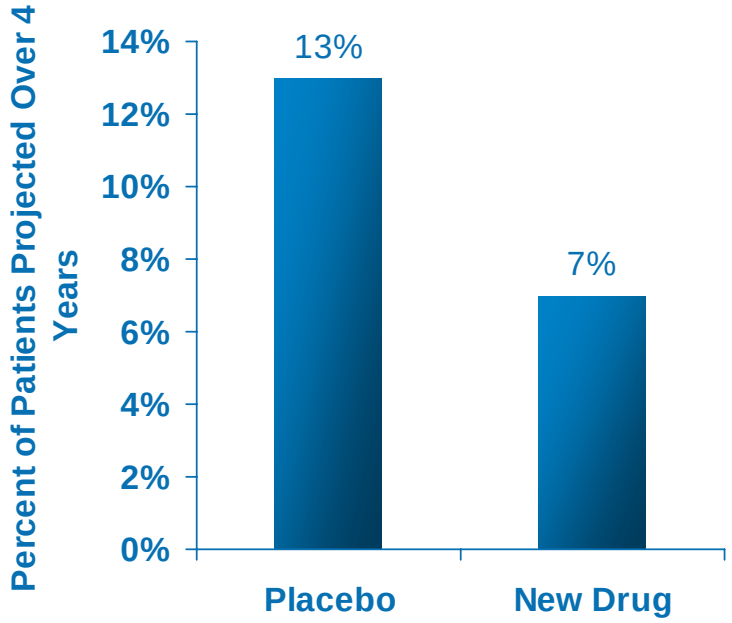


Source: B.R. Schackman, *et al*; "Cost-effectiveness Implications of the Timing of Antiretroviral Therapy in HIV-infected Adults," *Archives of Internal Medicine*, 162 (2002): 21, 2478-2486.

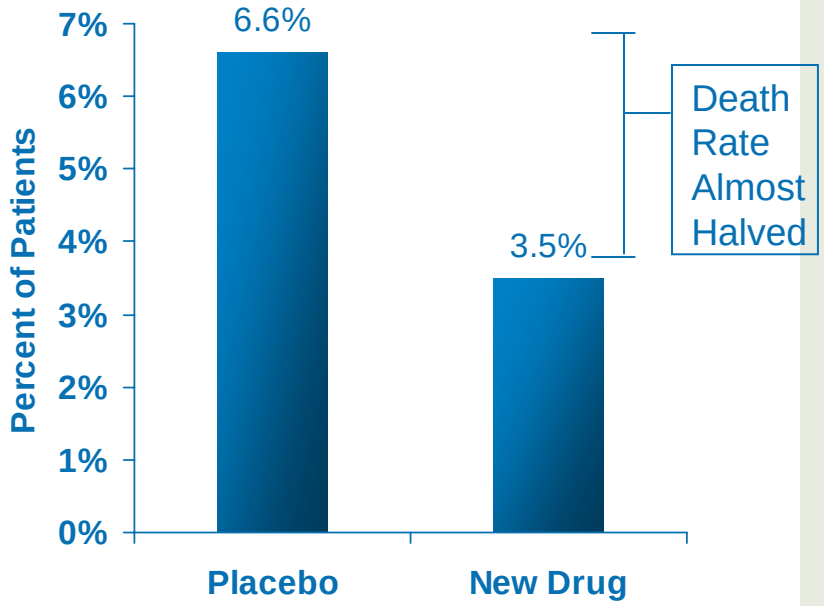
Medicines Prevent Cancer Recurrence

New Breast Cancer Drug Greatly Reduces Recurrence and Death
(Five to Ten Years After Diagnosis in Postmenopausal Women)

Breast Cancer Recurrence or Death



Deaths Due to Breast Cancer

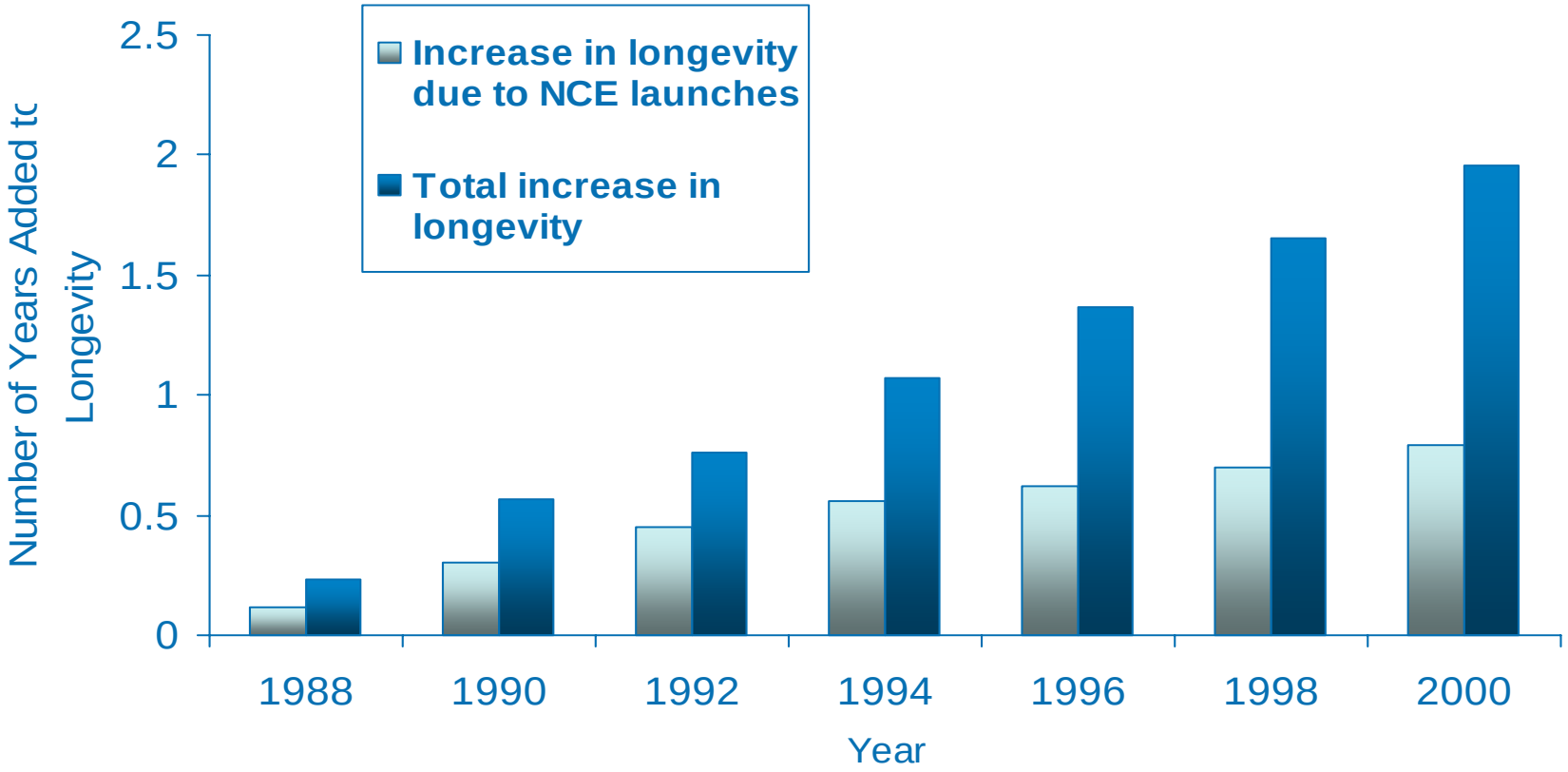


Note: Study halted early in order to provide the drug to all participants.

Source: P.E. Goss, *et al*., "A Randomized Trial of Letrozole in Postmenopausal Women After Five Years of Tamoxifen Therapy for Early-stage Breast Cancer," *The New England Journal of Medicine*, 349 (2003): 19, 1793-1802.

New Medicines

Account for 40% of Increase in Life Expectancy

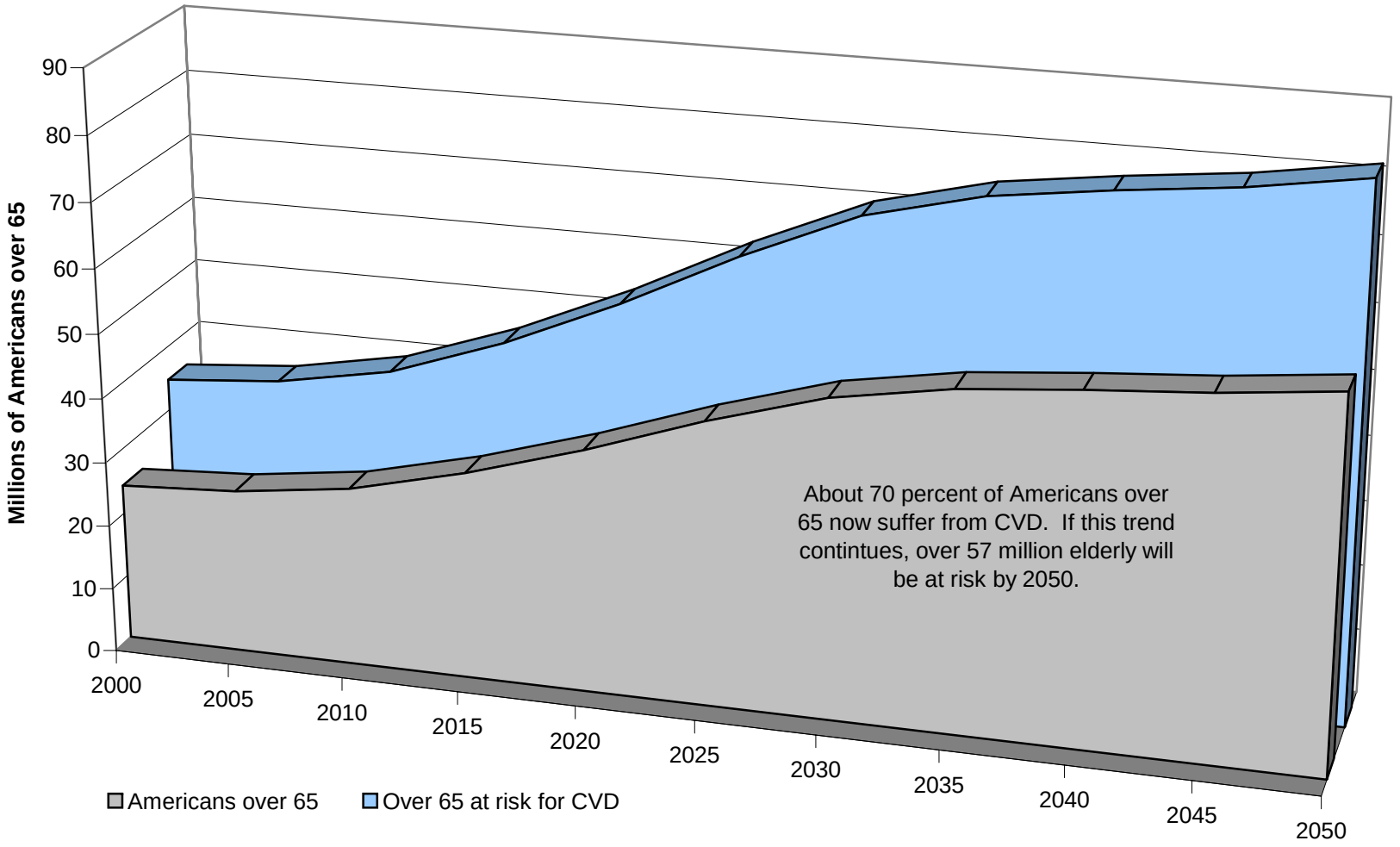


Source: FR Lichtenberg, "The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-Level Data from 52 Countries, 1982-2001," (Cambridge MA, National Bureau of Economic Research: June 2003).

Strong Patent Protection is Needed to Ensure Innovation in Pharmaceuticals Continues
Especially Given the Future Economic Costs of Disease

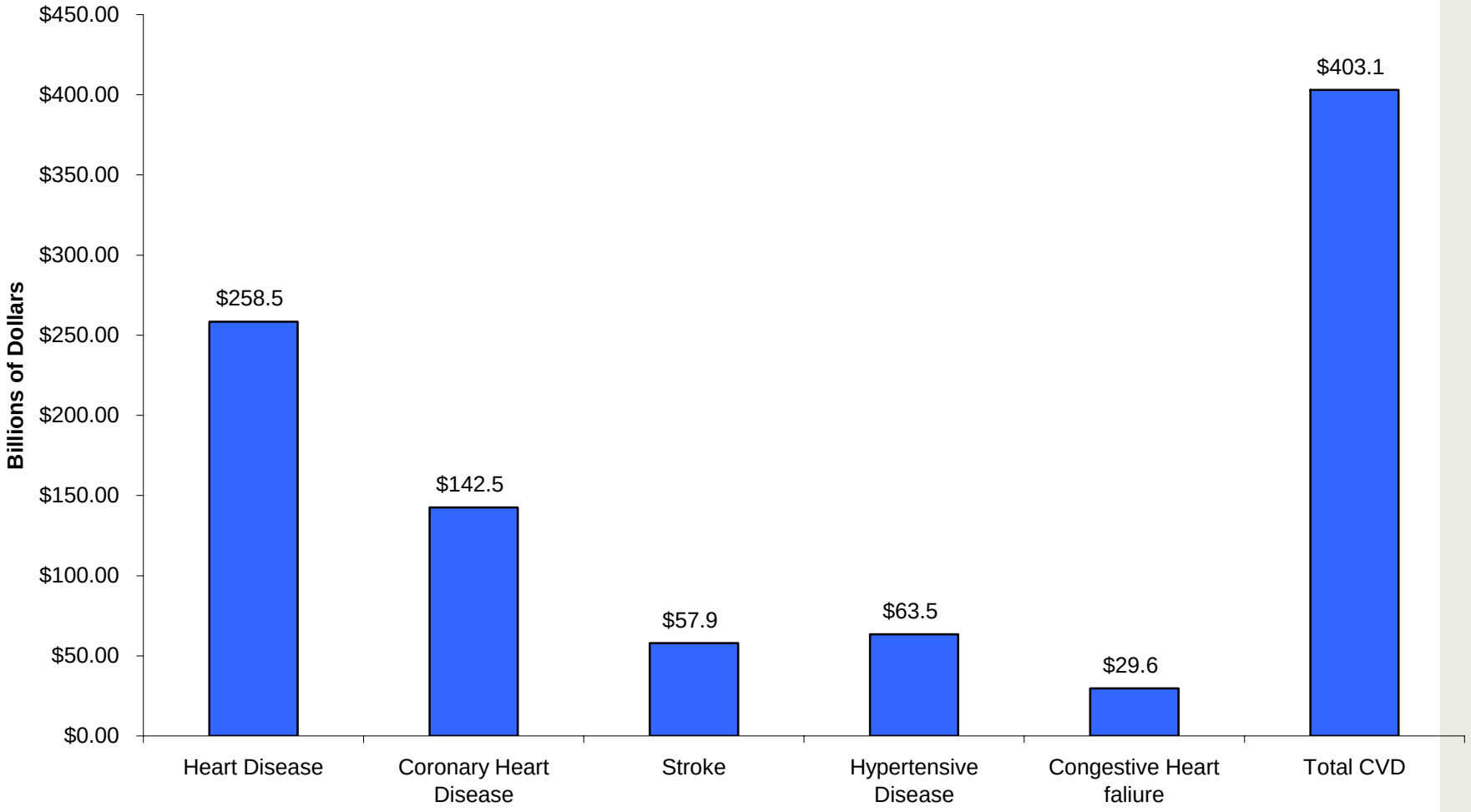
- Already, new medicines and biotechnology help extend life, and the quality of life, for millions of patients. There is more in the pipeline.
- The revolution of genomics, computer science and other technology promises to help even more patients tomorrow.
- "Screening" tools, which help researchers sort through millions of compounds in a short period, have drastically reduced the time and cost associated with discovering compounds that might have use as medicines. Other technologies are enabling more efficient delivery of drugs to the patient.
- And greater knowledge of how diseases work at the genetic and molecular level has allowed researchers to pursue new targets for therapy and better predict how certain biopharmaceuticals will affect specific groups of people.

Aging of Baby Boomers Will Dramatically Increase Population Potentially at Risk for Cardiovascular Disease (CVD)



Source: PhRMA, 2006 based on data supplied by National Heart, Lung, Blood Institute (1998); U.S. Census Bureau, Tables np-t3-a through np-t3-h, *Projections of the Total Resident Population by 5-Year AgeGroups, and Sex with Special Age Categories (Washington,DC: U.S. Census Bureau, 2002), http://www.census.gov/population/projections/nation/summary.*

Leading Cause of Death - Cardiovascular Disease - Imposes Huge Economic Cost



Source: American Heart Association, Heart Disease and Stroke Statistics—2006 Update

Research Breakthroughs Could Result in 45 Percent Decrease in Alzheimer's Cases and $149 Billion in Annual Medicare and Medicaid Savings by 2025

Recent Alzheimer's Association Report Finds:

- Significant savings in Medicare spending on people with Alzheimer's. If the projected research breakthroughs occur by 2010, taxpayers would begin to see savings as early as 2015, when Medicare spending would decline by $51 billion to $138 billion.
- By 2050, Medicare would save $444 billion in annual spending for beneficiaries with Alzheimer's – from $1,049 billion to $605 billion. In addition, 5.3 million fewer Americans would have Alzheimer's disease in 2050 because of the advances.
- Dramatic savings in Medicaid spending for nursing home care for people with Alzheimer's disease. Medicaid would have savings of up to 60 percent by 2025 because of improvements in prevention and treatment. Without medical advances, Medicaid spending is projected to increase from $27 billion in 2015 to $38 billion in 2025 and $118 billion by 2050. With improvements in prevention and treatment, the 2015 cost is projected to be $17 billion, the 2025 cost is $15 billion, and the 2050 cost is $48 billion.

Source : Lewin Group, "Saving Lives, Saving Money: Dividends for Americans from Investing in Alzheimer Research," 2004

Strong Intellectual Property Protections Stimulate Economic Development and Investment in the Discovery of New Medicines

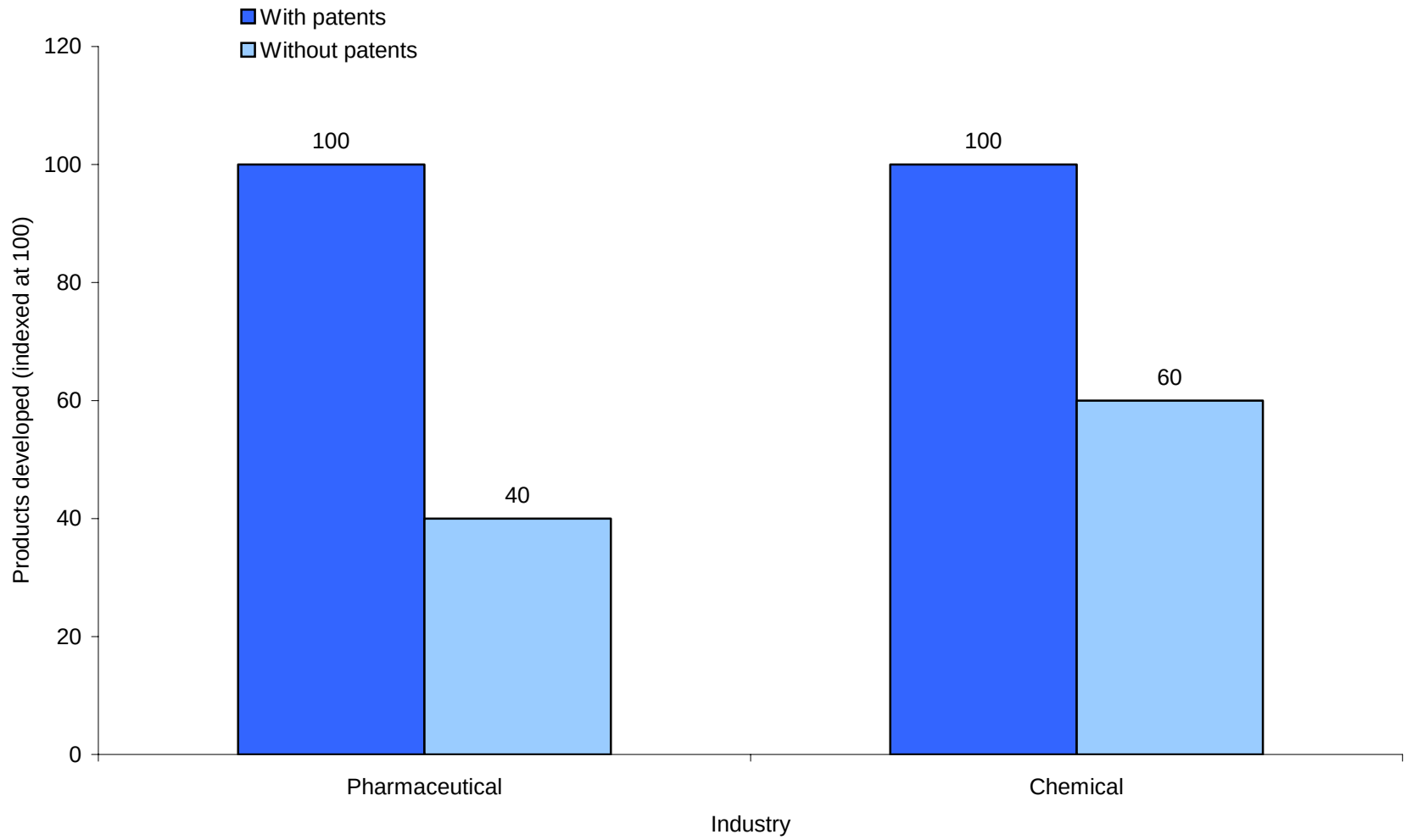
- According to the 2006 Economic Report of the President, "Well-defined and enforced intellectual property rights are an important element of the American economy and can contribute to the economic growth of all countries."

- While IP protection does not directly lead to growth, according to the same report, "it helps create an incentive structure that encourages research and development, which in turn leads to increased innovation. Increased innovation generates greater rates of economic growth."

- According to a 2005 report entitled, *The Economic Value of intellectual Property*, "Virtually all of the inventions which ultimately hastened economic development and lifted living standards – especially new technologies and manufacturing processes – were developed in societies with strong intellectual-property protections."

Sources: The Economic Report of the President, February 2006; Robert Shapiro and Kevin Hassett, "The Economic Value of Intellectual Property," October 2005.

Relative Product Development with and without Patent Protection



Source: The Economic Report of The President, February 2006

IP: The Key to Innovation and Growth

- Since the founding of our country, legal protection for innovation and creativity has been the key to critical advances in science, technology and arts that have generated economic growth, benefited society and improved the quality of life for all Americans.

- Without strong IP laws, including patent protection, the huge costs and economic risks of modern research, manufacturing and distribution would hobble innovation and creativity.

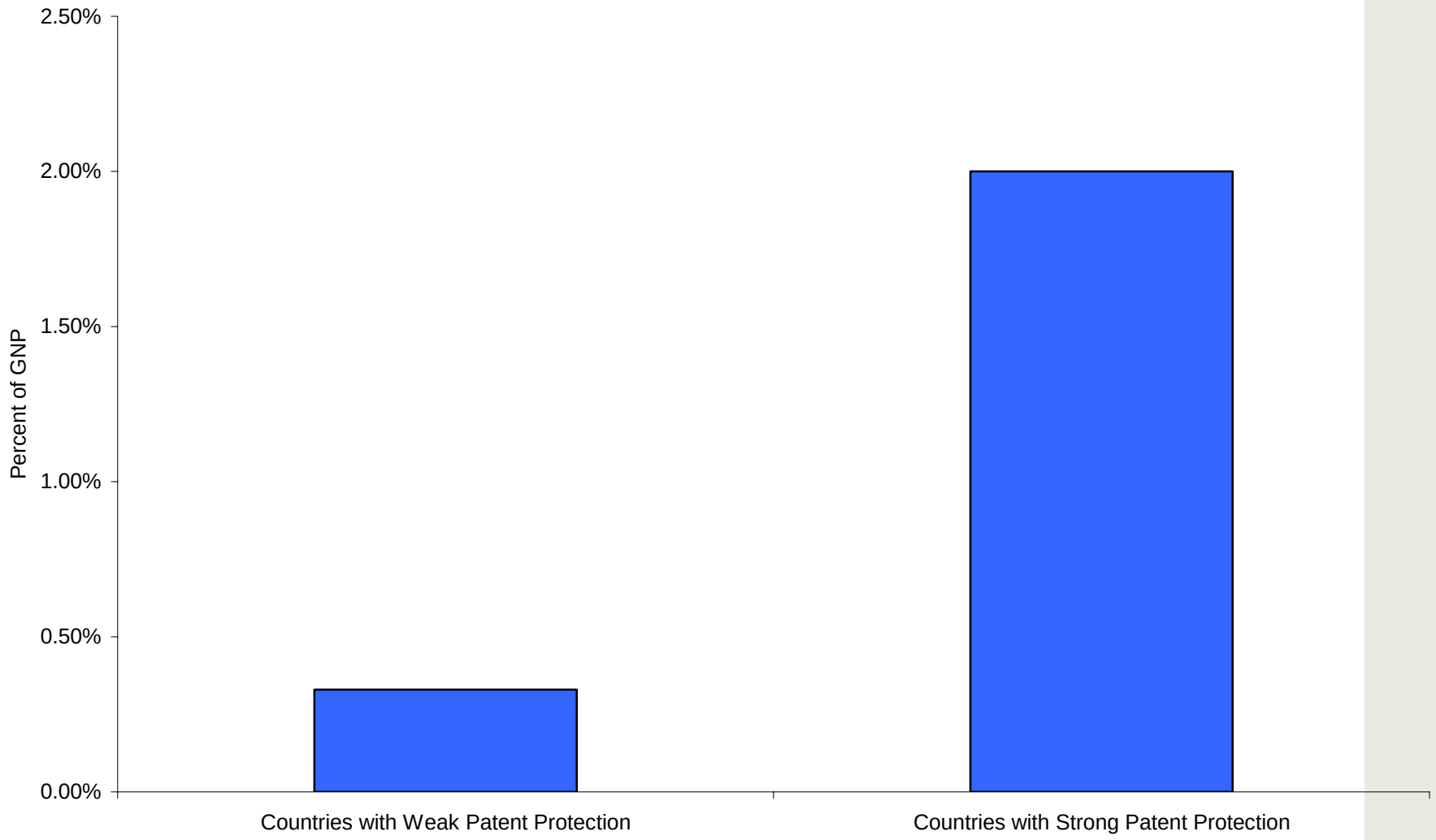
IP is a Driver of Economic Growth

- The power of IP protection is evident.
  - In 1980, Congress allowed universities for the first time to obtain patents for innovations resulting from their federally funded research. The number of patents awarded to universities boomed, from fewer than 250 a year prior to that time to almost 2,700 a year by 1998, creating in the process not only huge economic benefits for public and private universities, but also far-reaching health care and other benefits for millions of Americans.

IP is a Driver of Economic Growth

- Power of IP as a driver of economic growth extends beyond U.S.:
  - R&D investment in Mexico tripled after the nation adopted full IP protection in 1991.
  - South Korea, Japan and Italy all have experienced similar growth in sectors reliant upon strong IP protection.
  - The World Bank reported that since 1980, the world's greatest economic gains have been achieved by developing nations that aggressively opened their economies to foreign technologies and business methods and protected the IP rights of their developers.
  - Countries with weak IP protections receive less direct foreign investment; and the investment they receive is less technologically sophisticated. (Source: R. Shapiro and K. Hassett, "The Economic Value of Intellectual Property," October 2005.)

Percent of GNP Invested in R&D by Country Type



Source: The Economic Report of The President, February 2006

Strong IP Protection Helps Deter Counterfeiting & Piracy

- Strong IP protections safeguard against counterfeit, illegitimate and fake pharmaceutical products.
- Counterfeit medicines not only infringe intellectual property rights, they are very dangerous to human health. They can be: not strong enough, too strong or potentially toxic.
- Counterfeit medicines are most prevalent in countries with weak regulatory regimes and little or no Intellectual Property Rights (IPR).
  - For example, India is a major supplier of the world's counterfeit medicines because medicines made before 2005 have no patent protection there, so there is an abundant supply of knockoffs.
- The U.S., in contrast, has strong patents, tough penalties for trademark infringement (10 years) and laws against trafficking in counterfeits.

Ensuring Strong IP Protections Can Improve Patients' Health Worldwide

- Patents are a crucial factor in innovation, ensuring that companies have the possibility of being rewarded for the major investments needed to develop new medicines and cures that are vitally important to patient health worldwide.

- Patents provide a degree of assurance for investors to risk the capital necessary in the long development process and to fund new R&D initiatives.

- Legislative changes that diminish the value of patents could have a detrimental impact on decision makers considering investing in R&D-based ventures, and could negatively affect needed long-term innovation.

Differences between Industries Should be Considered in Context of Patent Reform

- The long development cycle for and heavy regulation of patented pharmaceuticals distinguishes such products from short development cycle, unregulated products.
- Reform proposals should consider the impact on pharmaceutical innovation.