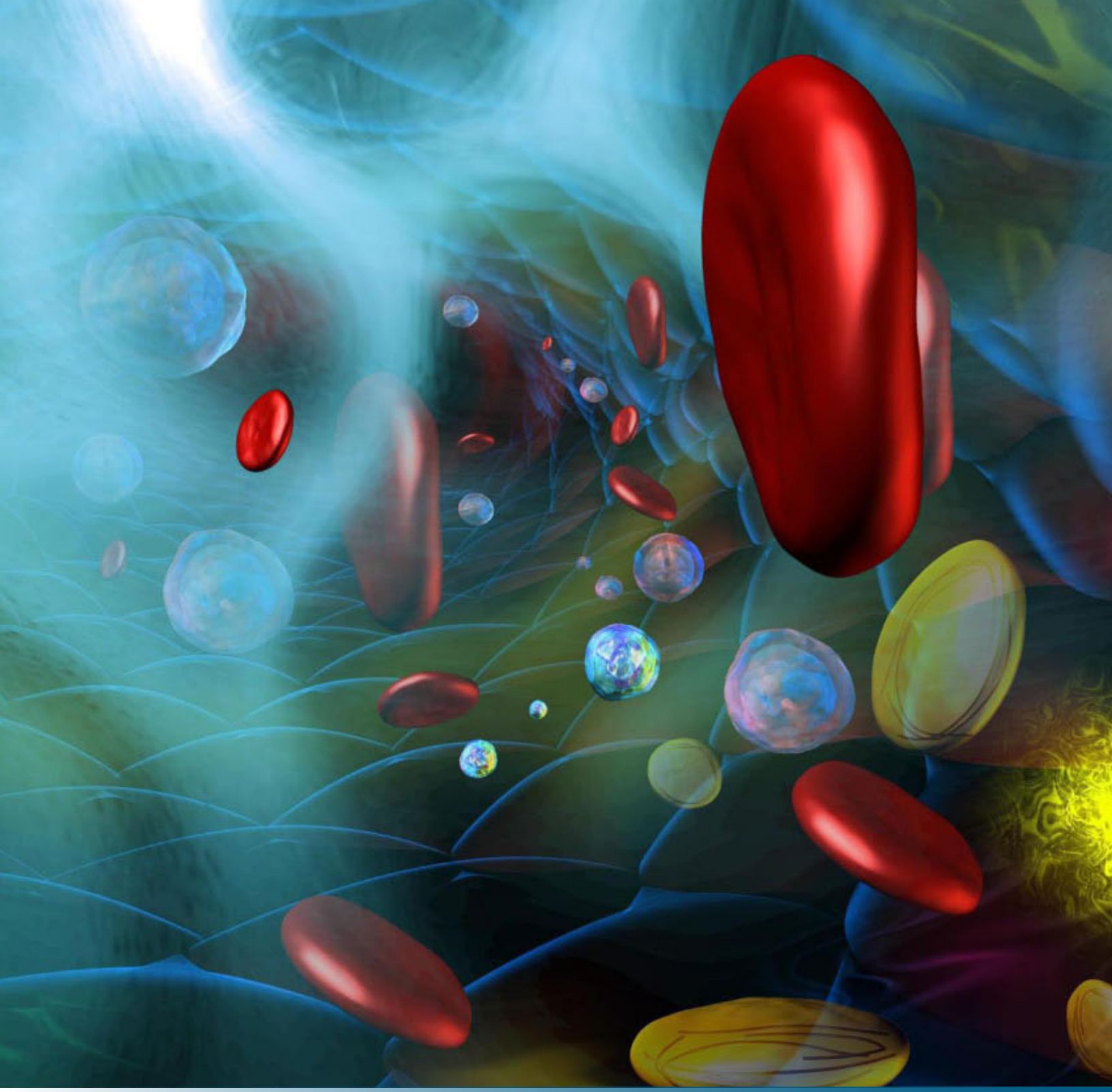


PHARMACEUTICAL INDUSTRY

# profile 2009

PhRMA

# Key Facts

## Research and Development (R&D)

- Time to develop a drug = 10 to 15 years[1]

## Development Costs

- Cost to develop a drug
  2006 = $1.318 billion[2]
  2001 = $802 million[3]
  1987 = $318 million[3]
  1975 = $138 million[3]
- Cost to develop a biologic
  2006 = $1.2 billion[4]

## R&D Spending

| Year | PhRMA members[5] | Total industry[6] |
|---|---|---|
| 2008 | $50.3 billion *(est.)* | $65.2 billion *(est.)* |
| 2007 | $47.9 billion | $63.2 billion |
| 2006 | $43.4 billion | $56.1 billion |
| 2005 | $39.9 billion | $51.8 billion |
| 2004 | $37.0 billion | $47.6 billion |
| 2000 | $26.0 billion | not available |
| 1990 | $8.4 billion | not available |
| 1980 | $2.0 billion | not available |

## Percentage of Sales That Went to R&D in 2008[7]

Domestic R&D
As a percentage of domestic sales = 20.3%

Total R&D
As a percentage of total sales = 17.4%

## Economic Impact of the Biopharmaceutical Sector[8]

Direct jobs =
686,422 in 2006 *(most recent data)*

Total jobs, including indirect and induced jobs =
3.2 million in 2006 *(most recent data)*

## Approvals

- Drugs and biologics approved in 2008 = 31[9]
- In the 25 years since the *Orphan Drug Act* was established, more than 300 orphan drugs have been approved.[10]

## Medicines in Development

2009 = 2,900 compounds[11]

1999 = 1,800 compounds[12]

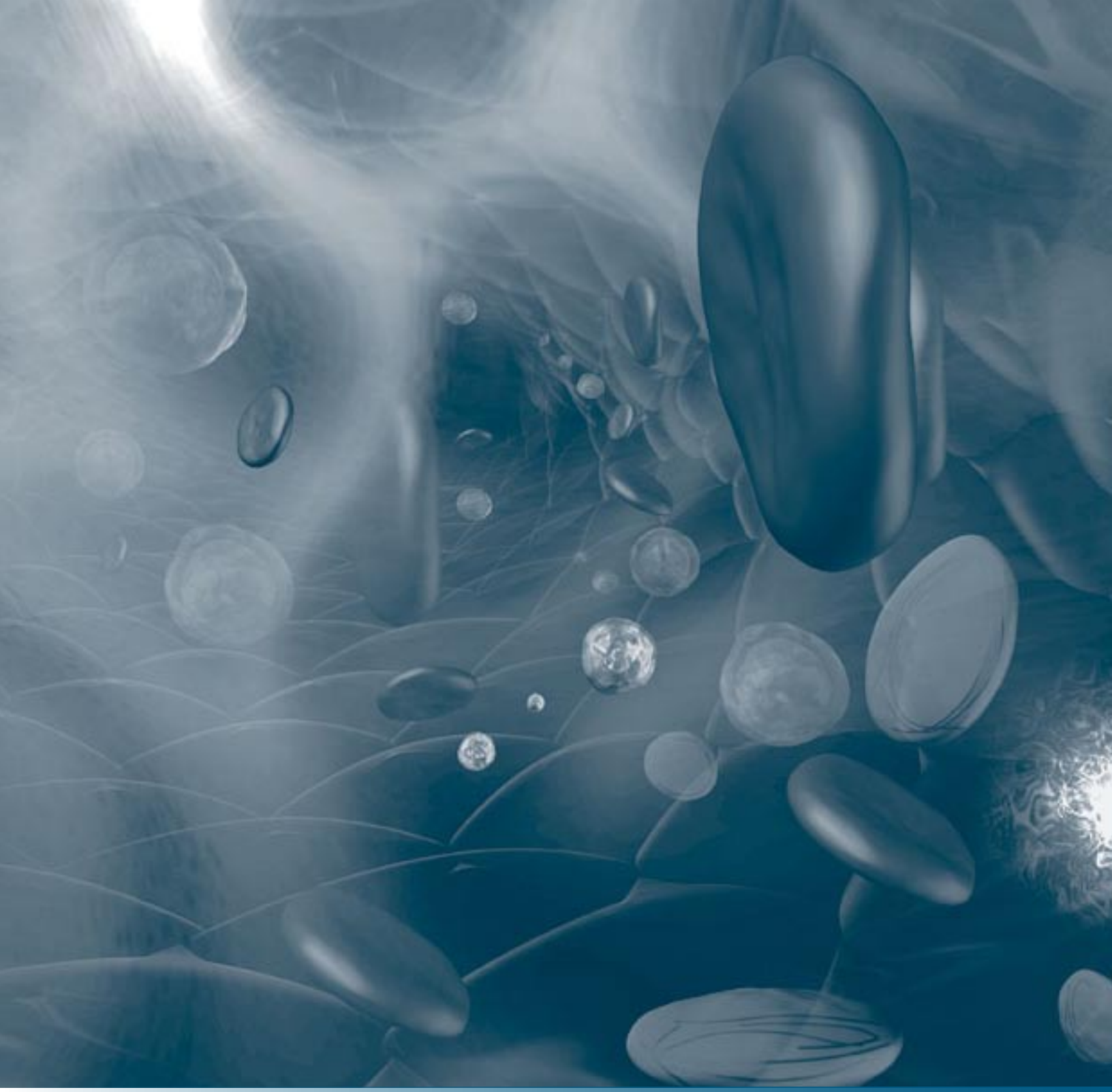
## Value of Medicines

- **Cancer:** Since 1980, life expectancy for cancer patients has increased about three years, and 83% of those gains are attributable to new treatments, including medicines.[13] Another study found that medicines specifically account for 50% to 60% of increases in survival rates since 1975.[14]
- **Cardiovascular Disease:** According to a 2009 statistics update by the American Heart Association (AHA), death rates for cardiovascular disease fell a dramatic 26.4% between 1999 and 2005.[15] The AHA lists better control of high blood pressure and high cholesterol, and reduced tobacco use as factors in the improvement.[16]
- **HIV/AIDS:** Since the approval of the highly active anti-retroviral treatments (HAART) in 1995, the annual number of AIDS deaths has dropped by more than 70%.[17]

## Sales

- Generic share of market[18]
  2003 = 54%
  2008 = 72%
- Only 2 of 10 marketed drugs ever return revenues that match or exceed R&D costs.[19]

*See inside back cover for endnotes.*



PHARMACEUTICAL INDUSTRY

# profile 2009

PhRMA

Permission to reproduce is granted if proper credit is given.

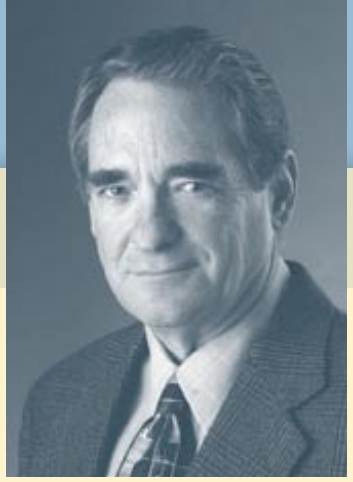
**SUGGESTED CITATION:**
Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 2009 (Washington, DC: PhRMA, April 2009).

Copyright © 2009 by the Pharmaceutical Research and Manufacturers of America.

Pharmaceutical Research and Manufacturers of America, Washington, DC
www.phrma.org

2009

FSC Mixed Sources
Product group from well-managed forests, controlled sources and recycled wood or fiber
www.fsc.org Cert no. SW-COC-001635
© 1996 Forest Stewardship Council
25%



# Letter from PhRMA's President and CEO

Over the past year, economic reports have been filled with almost nothing but bad news, and the biopharmaceutical sector has not been immune to the current recession. But PhRMA's member companies continue to give us reasons for hope at a time when such promise is hard to come by.

Despite the economic downturn, America's biopharmaceutical sector maintained the scale of its commitment to discovering new medicines in 2008. As a whole, the sector invested a record $65.2 billion in research and development, with PhRMA's member companies alone investing $50.3 billion.

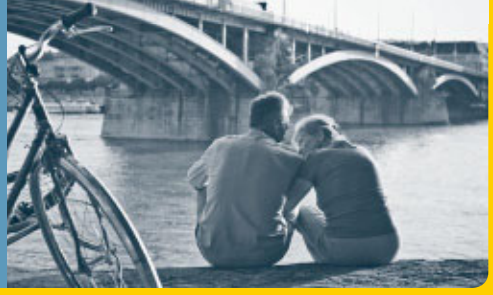
Scientifically, research has never held more promise for patients in need of new treatments. Today there are more than 2,900 medicines in the development pipeline. Researchers are armed with vast amounts of new information on the genetic and molecular underpinnings of disease, and they are working to translate this knowledge into treatments that can ease symptoms, slow progression and, ultimately, prevent or halt disease.

Economically, the biopharmaceutical sector has faced challenges along with the rest of the economy, but our innovative companies stand tall as valuable contributors to the American economy. The latest data show that the industry directly provides nearly 700,000 jobs in the United States, and that another 2.5 million jobs in other sectors are also supported by the industry.

I am pleased to present PhRMA's 2009 *Pharmaceutical Industry Profile.* This year, the *Profile* highlights the scientific and economic hope that the biopharmaceutical sector brings to patients and to all Americans.

Billy Tauzin
*President and CEO*
*Pharmaceutical Research and Manufacturers of America*

# TABLE OF CONTENTS



# BIOPHARMACEUTICAL RESEARCH COMPANIES' IMPACT: VALUE FOR AMERICANS

This year's *Profile* spotlights the significant value the biopharmaceutical research sector and its products represent for Americans and the American economy. Even in challenging times, this sector is a source of:

- **Value for Patients.** In the last 10 years, more than 300 new medicines have contributed to increases in life expectancy. New medicines have also helped in many cases to transform diseases – such as HIV/AIDS and some cancers – into treatable chronic conditions. As a result, Americans have greater potential than ever to live long, active and productive lives.
- **Value for the Economy.** While facing the challenges of a struggling economy, the biopharmaceutical sector is an important source of strength for the U.S. economy today and into the future. This industry provides thousands of high-quality jobs, contributes substantially to federal, state and local tax bases, and creates economic ripple effects that strengthen other economic sectors.
- **Value for Health Care.** Americans can realize the full value of biopharmaceuticals only when they have adequate access to them. Biopharmaceutical research companies support policies and programs that both improve patients' access to health insurance, and offer free or low-cost medicines for people facing financial challenges. These efforts are

particularly important in today's struggling economy.

- **Value in Preventing Disease.** Chronic diseases represent a growing burden for public health, health care costs, and the productivity of our economy. Yet many chronic diseases can be prevented and treated through lifestyle changes and new medicines, both of which can improve outcomes and reduce costs. The biopharmaceutical research sector supports making chronic disease prevention a health care priority and is a partner in this effort.

## Innovation Drives Value

Innovation — and the growing research and development (R&D) investment that enables it — is the underlying source of the biopharmaceutical industry's multifaceted value for Americans. In fact, the biopharmaceutical sector is one of the most R&D-intensive industries in the United States,[1] and pharmaceutical researchers have helped to create the scientific potential to offer even greater value for health and the economy in the future.

Our growing understanding of genetics and the molecular basis of disease means that science holds greater promise than ever before to tackle diseases such as cancer, Alzheimer's disease, diabetes and many others. Researchers are exploring new targeted approaches to prevent and treat disease, and tailoring treatments to subpopulations of patients.

Despite the great potential, today's R&D environment also presents many challenges to maintaining the pace of innovation. First, biopharmaceutical R&D is inherently risky, and the success rate is low in moving a medicine through development to approval. Second, while the R&D process has become increasingly complex and expensive, companies face increased competition from other medicines within a class[2] and from generic drugs.[3]

While today's science base makes it possible to envision endless research directions and medical advances, policy choices can either invigorate or limit the potential of R&D. Smart policies that foster medical research will create additional value for Americans: better options for health, continued economic growth, and sustained world leadership in biopharmaceutical progress.

[1] Congressional Budget Office, Research and Development in the Pharmaceutical Industry (Washington, DC: CBO, October 2006).

[2] J. A. DiMasi and C. Paquette, "The Economics of Follow-on Drug Research and Development: Trends in Entry Rates and the Timing of Development," *Journal of PharmacoEconomics* 22, suppl. 22 (2004): 1–14.

[3] National Prescription Audit PLUS. Norwalk, CT: IMS Health.

# 1

# VALUE FOR PATIENTS:
Longer Lives, Better Health

# 1

# VALUE FOR PATIENTS:
## Longer Lives, Better Health

**"Reduced disability associated with cardiovascular disease accounts for a significant part of the total reduction in disability – between 19 and 22 percent. The evidence suggests that improvements in medical care, including both increased use of relevant procedures and pharmaceuticals, led to a significant part of this decline."[1]**

*– David Cutler*
*Harvard University*

American patients have seen enormous progress in fighting disease over the past 10 years, and new medicines have played a central role. During this time, the Food and Drug Administration (FDA) approved more than 300 new medicines, which have helped enhance treatment options and transform the health landscape, while improving patients' lives by:

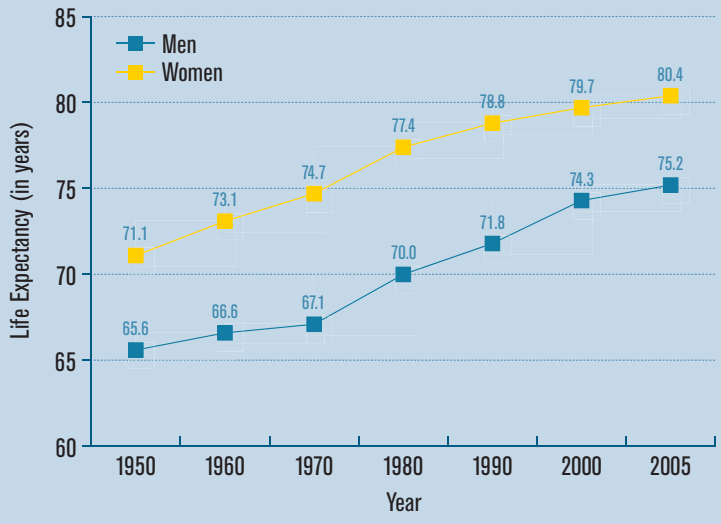
- Increasing life expectancy;
- Decreasing disability; and,
- Reducing the need for expensive health services, such as hospital and nursing care.

### Increasing Life Expectancy

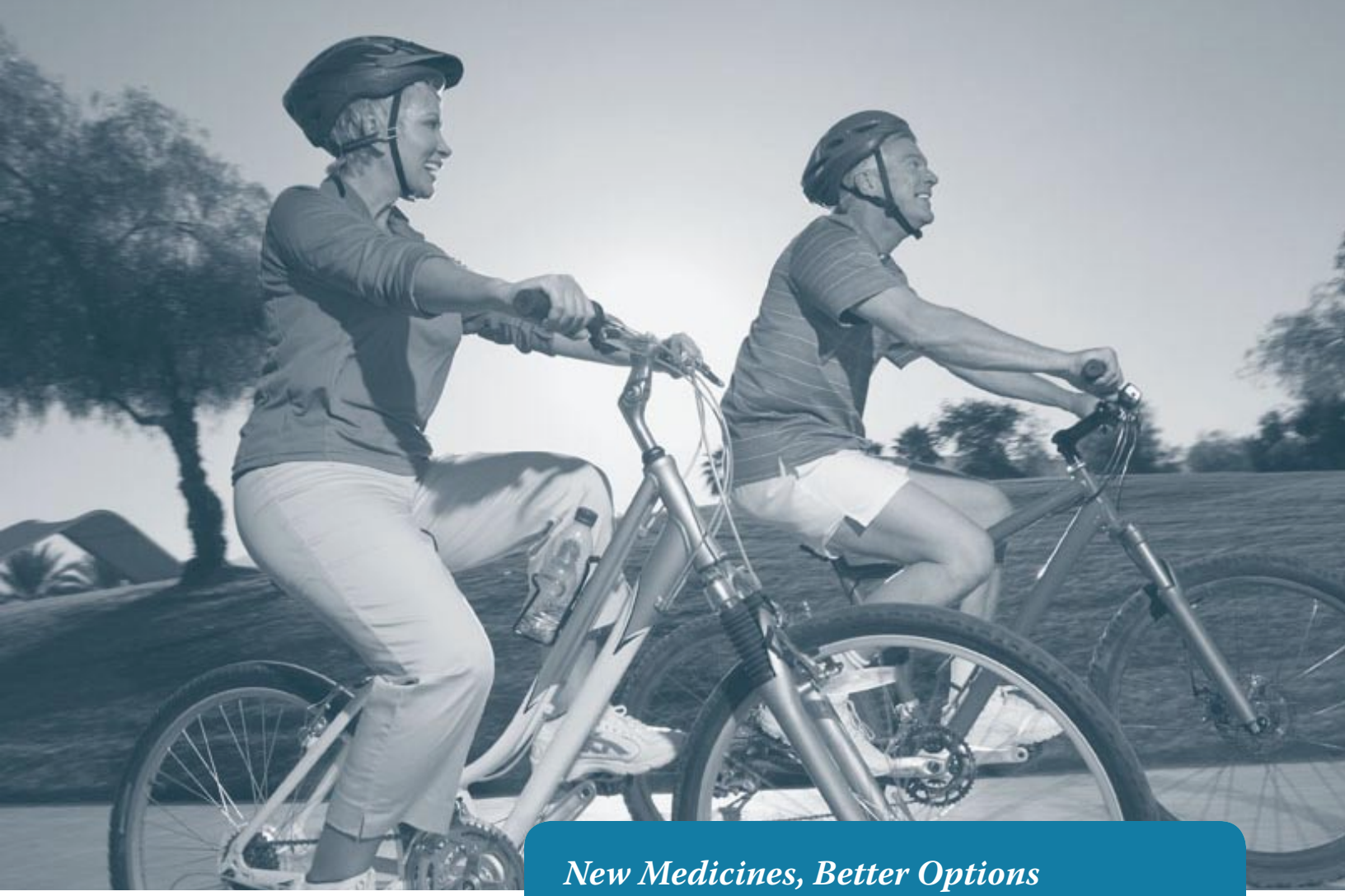
Over the last 55 years, life expectancy for men and women in the United States has increased by nearly a decade, and it is continuing to rise.[2] (See Figure 1.) Medicines have helped make this possible.

In addition to overall increases in longevity, patients with serious diseases are living longer with the help of new medicines:

FIGURE 1: **U.S. Life Expectancy, 1950–2005**




SOURCE: U.S. Department of Health and Human Services, U.S. Centers for Disease Control and Prevention, National Center for Health Statistics, Health, United States, 2008 with Chartbook on Trends in the Health of Americans, Table 26 (Hyattsville, MD: HHS, 2009).



**Cancer.** Since 1980, life expectancy for cancer patients has increased by about three years, and a recent study found that 83% of those gains are attributable to new treatments, including medicines.[3] Another study found that medicines have accounted for 50% to 60% of increases in survival rates since 1975.[4]

> **"Reducing cancer death rates by 10% would be worth roughly $4.4 trillion in economic value to current and future generations."[5]**
>
> – *Kevin Murphy, Ph.D.*
> *Robert Topel, Ph.D.*
> *University of Chicago*

## *New Medicines, Better Options*

In 2008, new approvals included:

- The first new drug in several years to treat prostate cancer. The drug slows tumor growth and progression by suppressing testosterone, which plays an important role in the continued growth of prostate cancer[6];
- The first treatment for chorea (jerky, involuntary movement) caused by Huntington's disease, a rare inherited neurological disorder[7];
- A drug that helps increase the number of blood stem cells for bone marrow transplantation in patients with certain forms of blood cancer[8]; and,
- An orphan drug that is the first treatment for two forms of an extremely rare condition called Cryopyrin-Associated Periodic Syndrome. The two disorders affect only about 300 patients combined in the United States.[9]

**"Factors contributing to the decline in heart disease and stroke mortality include better control of risk factors, improved access to early detection, and better treatment and care, including new drugs and expanded uses for existing drugs."[10]**

*– U.S. Centers for Disease Control and Prevention*

**Cardiovascular Disease.** Death rates for cardiovascular disease fell a dramatic 26.4% between 1999 and 2005, according to a recent report by the American Heart Association.[11] According to the lead researcher, Dr. Donald Lloyd-Jones, there would have been an additional 190,000 deaths in 2006 if death rates had remained at 1999 levels.[12]

**HIV/AIDS.** Since the approval of highly active antiretroviral treatments in 1995, death rates from HIV/AIDS have dropped by more than 70%.[13] Today, patients have a range of treatment options, including different combinations of drugs that often keep them symptom-free for years.

## Decreasing Disability

Overall, disability among seniors has sharply decreased. For example, a study by Harvard University researchers found that between 1984 and 2005, disability in the elderly population fell by 20%.[14]

In addition, disability due to specific diseases has also declined with the

## *To Maximize Value, Reduce Health Disparities*

While life expectancy and better health have increased overall, not all Americans benefit equally. To maximize the value of health advances, it is critical to improve health care access for all and ensure access to treatments that are right for each individual. Examples of current disparities include[15]:

- For African-Americans, heart disease death rates are more than 40% higher than for whites, and the death rate for all cancers is 30% higher.
- Hispanics living in the United States are almost twice as likely as non-Hispanic whites to die from diabetes.
- For American Indians and Alaska Natives, the infant mortality rate is almost double that for whites, and this population is more than twice as likely as whites to develop diabetes.

use of new medicines. For example, a study recently published in *The Lancet* found that patients taking a combination of a new and older medicines for rheumatoid arthritis had a 50% chance of complete clinical remission after 52 weeks of treatment, compared to just 28% of those taking the older medicine alone.[16] An editorial accompanying the study commented on the impact of new biological agents, saying that clinical remission is "a primary endpoint that would have been unthinkable in the 20th century."[17]

Recent research found that elderly patients taking new medicines and other treatments had a 50% greater likelihood of surviving a cardiovascular event without disability than those who didn't have this care.[18] The rate of heart failure, which can produce severe disability, fell by about 45% between 1999 and 2005. Researchers attributed the decline to the increased use of cholesterol drugs, blood thinners, and angioplasty.[19]

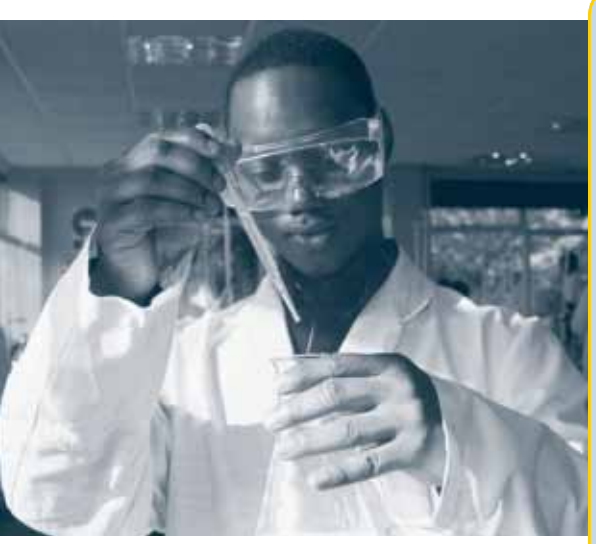
## Reducing the Need for Health Services

New medicines also add value for patients by helping them avoid the need for costly health services that disrupt their lives. Positive effects of increased medicine use include:

### ↓ *Fewer hospitalizations*

*HIV/AIDS* – With increased use of antiretroviral medicines, hospitalizations decreased between 1996 and 2000, despite an increase in the number of people infected with HIV/AIDS.[20]

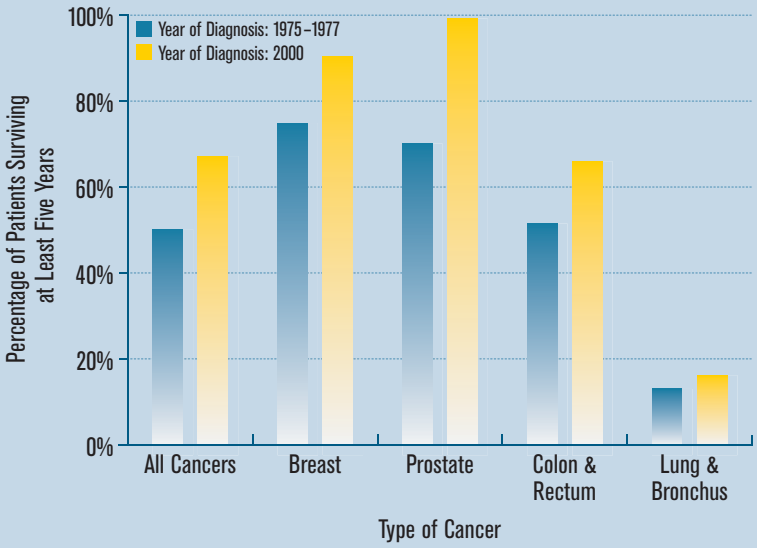
*Diabetes* – Patients who are less than 80% adherent to their diabetes medicines are two to three times more likely to be hospitalized in the next year than more adherent patients.[21]



**"I think we really are in the midst of a revolution in the treatment of cancer."[22]**

*– Dr. Len Lichtenfeld*
*American Cancer Society, 2006*

FIGURE 2: **Five-Year Relative Survival Rates for Cancers in the United States**




Note: Survival rates are adjusted for normal life expectancy and are based on cases diagnosed from 1975 to 1979, and cases diagnosed in 2000 and followed for at least five years.

SOURCE: L. A. G. Ries, *et al.*, eds., SEER Cancer Statistics Review, 1975–2005, National Cancer Institute (Bethesda, MD: 2008), Tables IV-11, XXIII-6, VI-12, XV-12, http://seer.cancer.gov/csr/1975_2005/index.html (accessed 2 March 2009).

## *Advances in Cancer Treatment Increase Survival*

- Between 1975 and 1979, the five-year survival rate for cancer was just 50%. By 2000, survival rose to 67%.[23]
- Survival is increasing dramatically for many forms of cancer. The rate of five-year survival went up 21% for breast cancer, 42% for prostate cancer, 28% for colon and rectum cancer, and 25% for lung and bronchus cancer.[24] (See Figure 2.)
- Improvements in treatment helped accelerate reductions in cancer death rates between 1993 and 2004; rates fell an average of 2.1% per year between 2002 and 2004, twice the decline of the previous five years.[25]
- Gains in cancer survival have been largely driven by improvements in earlier detection and treatment, including new medicines.[26]
- A report by the American Society of Clinical Oncology identified 12 major cancer advances in 2008, nine of which were related to medicines.[27]

**"I often tell cancer patients the idea is to stay here and be as comfortable as possible and wait for the next advance to come along. The advances are coming along faster."[28]**

*– Vincent T. DeVita, Jr.*
*Yale Cancer Center, 2003;*
*Former Director, National Cancer Institute*

*Chronic diseases, generally* – Medicare patients with a capped drug benefit are less likely than other Medicare patients to adhere to their hypertension, diabetes, and cholesterol medicines, and are 13% more likely to visit emergency rooms.[29]

### ↓ *Fewer nursing home admissions*

*Alzheimer's disease* – Patients taking cholinesterase inhibitors were 2.5 times more likely than untreated patients to progress slowly after two years, and after five years, they were only one-fifth as likely to be placed in a nursing home.[30]

### ↓ *Fewer complications*

*Osteoporosis* – Patients who are more than 80% adherent to their osteoporosis medicines have a 25% lower rate of fractures than those who are less adherent.[31]

[1] D. M. Cutler, M. B. Landrum, and K. A. Stewart, "Intensive Medical Care and Cardiovascular Disease Disability Reductions," in D. M. Cutler and D. A. Wise, eds., Health at Older Ages: The Causes and Consequences of Declining Disability Among the Elderly (Chicago, IL: University of Chicago Press, 2008): 191–222.

[2] U.S. Department of Health and Human Services, U.S. Centers for Disease Control and Prevention, National Center for Health Statistics, Health, United States, 2008 with Chartbook on Trends in the Health of Americans, Table 26 (Hyattsville, MD: HHS, 2009).

[3] E. Sun, *et al.,* "The Determinants of Recent Gains in Cancer Survival: an Analysis of the Surveillance, Epidemiology, and End Results (SEER) Database," *Journal of Clinical Oncology* 26, suppl. 15 (2008): Abstract 6616.

[4] F. Lichtenberg, "The Expanding Pharmaceutical Arsenal in the War on Cancer," National Bureau of Economic Research Working Paper 10328, February 2004.

[5] K. M. Murphy and R. H. Topel, eds., Measuring the Gains for Medical Research: An Economic Approach (Chicago, IL: University of Chicago Press, 2003): 42.

[6] U.S. Food and Drug Administration, "FDA Approves Drug for Patients with Advanced Prostate Cancer," 29 December 2008, www.fda.gov/bbs/topics/NEWS/2008/NEW01935.html (accessed 6 February 2009).

[7] U.S. Food and Drug Administration, "FDA Approves First Drug Treatment of Chorea in Huntington's Disease," 15 August 2008, www.fda.gov/bbs/topics/NEWS/2008/NEW01874.html (accessed 6 February 2009).

[8] U.S. Food and Drug Administration, "FDA Approves Drug that Boosts Stem Cell Yield for Bone Marrow Transplants," 18 December 2008, www.fda.gov/bbs/topics/NEWS/2008/NEW01929.html (accessed 6 February 2009).

[9] U.S. Food and Drug Administration, "FDA Approves New Orphan Drug for Treatment of Rare Inflammatory Syndromes," 27 February 2008, www.fda.gov/bbs/topics/NEWS/2008/NEW01801.html (accessed 6 February 2009).

[10] U.S. Department of Health and Human Services, U.S. Centers for Disease Control and Prevention, National Center for Health Statistics, Health, United States, 2006 with Chartbook on Trends in the Health of Americans, (Hyattsville, MD: HHS, November 2006).

[11] D. Lloyd-Jones, *et al.,* "Heart Disease and Stroke Statistics 2009 Update. A Report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee," *Circulation* 119 (2009): e21–e181.

[12] W. Dunham, "Progress Seen in Heart Disease, Stroke Deaths, However, Obesity Epidemic May Offset Decline in Deaths this Decade," Reuters, 15 December 2008.

[13] U.S. Department of Health and Human Services, U.S. Centers for Disease Control and Prevention, National Center for Health Statistics, Health, United States, 2008 with Chartbook on Trends in the Health of Americans, Table 41 (Hyattsville, MD: HHS, 2009).

[14] D. M. Cutler, M. B. Landrum, and K. A. Stewart, *op. cit.*

[15] U.S. Centers for Disease Control and Prevention, Office of Minority Health & Disparities, "About Minority Health," 6 June 2007, www.cdc.gov/omhd/AMH/AMH.htm (accessed 6 February 2009).

[16] P. Emery, *et al.,* "Comparison of Methotrexate Monotherapy with a Combination of Methotrexate and Etanercept in Active, Early, Moderate to Severe Rheumatoid Arthritis (COMET): A Randomized, Double-Blind, Parallel Treatment Trial," *The Lancet* 372, no. 9636 (August 2008): 375–382.

[17] J. M. Kremer, "COMET's Path, and the New Biologicals in Rheumatoid Arthritis," *The Lancet* 372, no. 9636 (August 2008): 347–348.

[18] D. M. Cutler, M. B. Landrum, and K. A. Stewart, *op. cit.*

[19] K. Fox, *et al.,* "Decline in Rates of Death and Heart Failure in Acute Coronary Syndromes, 1999–2006," *Journal of the American Medical Association* 297, no. 17 (2007): 1892–1900.

[20] F. J. Hellinger, "HIV Patients in the HCUP Database: A Study of Hospital Utilization and Costs," *Inquiry* 41, no. 1 (Spring 2004): 95-105; B. Nosyk, *et al.,* "Highly Active Antiretroviral Therapy and Hospital Readmission: Comparison of a Matched Cohort," *BMC Infectious Disease* 6 (2006): 146.

[21] D. T. Lau, "Oral Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes," *Diabetes Care* 27, no. 9 (2004): 2149–2153.

[22] J. L. Lichtenfeld, "Future of Innovation," presentation to PhRMA (Washington, DC) 24 April 2006.

[23] L. A. G. Ries, *et al.,* eds., SEER Cancer Statistics Review, 1975–2005, National Cancer Institute (Bethesda, MD: 2008), Tables IV-11, XXIII-6, VI-12, XV-12, http://seer.cancer.gov/csr/1975_2005/index.html (accessed 2 March 2009).

[24] *Ibid.*

[25] D. Espey, *et al.,* "Annual Report to the Nation on the Status of Cancer, 1975–2004, Featuring Cancer in American Indians and Alaska Natives," *Cancer* 110, no. 10 (2007): 2119–2152.

[26] E. Sun *et al., op. cit.*; F. Lichtenberg, *op. cit.*

[27] American Society of Clinical Oncology, "Clinical Cancer Advances 2008: Major Research Advances in Cancer Treatment, Prevention and Screening," *Journal of Clinical Oncology* 27, no. 5 (10 February 2009): 812–826.

[28] R. Stein, "From Killer to Chronic Disease: Drugs Redefine Cancer for Many," *The Washington Post,* 29 January 2003.

[29] J. Hsu, *et al.,* "Unintended Consequences of Caps on Medicare Drug Benefits," *New England Journal of Medicine* 354, no. 22 (2006): 2349–2359.

[30] O. L. Lopez, *et al.,* "Alteration of a Clinically Meaningful Outcome in the Natural History of Alzheimer's Disease by Cholinesterase Inhibition," *Journal of the American Geriatric Society* 53, no. 1 (2005): 83–87.

[31] J. J. Caro, *et al.,* "The Impact of Compliance with Osteoporosis Therapy on Fracture Rates in Actual Practice," *Osteoporosis International* 15, no. 12 (2004): 1003–1008.

# 2

## VALUE FOR THE ECONOMY:
## A Source of Strength in Difficult Times

# 2 VALUE FOR THE ECONOMY: A Source of Strength in Difficult Times

**"The United States "has held onto its manufacturing lead – particularly in such key sectors as pharmaceuticals and aerospace, in which it produces almost 25 percent of the world's output, according to the World Bank."[1]**

– The Washington Post, *2008*

The biopharmaceutical research sector has long been a positive force that bolsters national, state, and local economies in the United States through its R&D and manufacturing activities. The biopharmaceutical sector is not immune to the recession, but its supportive impact and heavy investment in future innovation is even more important in light of the slowdown.

Although the economic downturn affects all companies and sectors, the biopharmaceutical industry remains a source of many high-quality jobs that boost employment and the tax base. It also has achieved an unusually high rate of annual growth in output and net impact on the economy in recent years. This includes ripple effects that indirectly support jobs and businesses that service the industry and its employees.

Underlying these important contributions is the sector's substantial investment in R&D infrastructure, which has helped the United States lead the global medical research community.

## Employing Americans

**Direct Jobs.** The biopharmaceutical sector comprises an extensive and diverse group of companies that research, develop and manufacture medicines. These companies range in size from small start-ups to large corporations. Together, they provide more than 686,000 Americans[2] jobs that pay well and provide good benefits: jobs for highly educated scientists, as well as positions for technicians in manufacturing, as illustrated in Figure 3 on page 12. The economic crisis has taken a toll on this sector, along with many others, but the biopharmaceutical research industry remains an important source of jobs and investment in innovation.

## *The Sector's Economic Value: Fast Facts*

The biopharmaceutical industry is a foundational piece of the American economy. In 2006, the industry[3]:

- Employed **686,442 people**.
  - ⇨ Each job supported **3.7 additional jobs**.
  - ⇨ The sector supported a total of **3.2 million jobs** (direct, indirect and induced).
  - ⇨ Jobs were in all 50 states, Washington, DC, and Puerto Rico.
- Achieved annual growth rate in direct industry employment at twice the rate of other U.S. economic sectors between 1996 and 2006.
- Contributed $88.5 billion in 2006 to the nation's gross domestic product, which was triple the average contribution of other sectors.

**Indirect and Induced Jobs.** Total sector employment in 2006, including direct, indirect, and induced jobs, was 3.2 million.[4] Many varied jobs are supported as an indirect effect of the biopharmaceutical industry, including these in 2006 (approximate totals)[5]:

- Professional Services (such as employment services, accounting and bookkeeping, management, and legal services): 220,000
- Wholesale Trade Companies (e.g., raw materials): 77,000
- Building Services: 33,000
- Real Estate: 52,000
- Physician Offices, Hospitals, and Nursing Facilities: 165,000
- Food and Beverage Establishments: 135,000
- Retail (e.g., general merchandise and food stores): 79,000

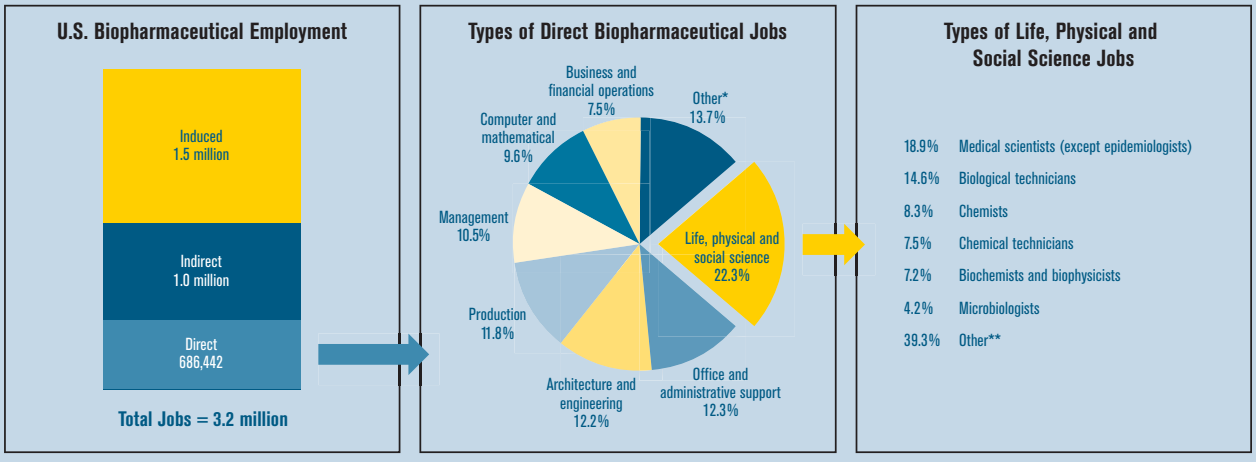
## Bolstering the Economy

The biopharmaceutical sector has had a substantial positive impact on the U.S. economy.

By key measures, the biopharmaceutical sector's contribution to the economy was higher than the average of all other U.S. economic sectors from 1996 to 2006, and it has grown at about twice the pace of other sectors.[6]

State economies also benefit. Overall, the sector is responsible for jobs in all 50 states, and this employment results in substantial tax revenues. The impact of the sector is also evident in state economic output.

FIGURE 3: **American Jobs in the Biopharmaceutical Sector**




*Other includes 15 occupations, each representing less than 3.0% of the total, including installation maintenance and repair occupations (2.9%), transportation and material moving occupations (2.3%), sales and related occupations (2.0%), and health care practitioners and technical occupations (1.6%).

**Other includes 27 occupations, each representing less than 4.0% of the total, including life, physical and social science technicians, all other (3.5%), physicists (2.9%), and market research analysts (2.4%).

Note: Types of direct pharmaceutical jobs are based on company reported data; relationship to direct employment figures is assumed to be directionally accurate.

SOURCE: Adapted from L. R. Burns, The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels (Washington, DC: Archstone Consulting, LLC, March 2009).

## *Economic Impact 2006: Fast Facts*

- Share of Gross Domestic Product: $294.6 billion, or 2.2%[7]

  ***Definition:*** *Value of sales generated, less the value of raw materials used; net effect on the economy.*

- Total Sector Output: $626.6 billion[8]

  ***Definition:*** *The sum of direct, indirect, and induced output.*

  - *Direct output* = Value of goods produced by biopharmaceutical companies
  - *Indirect output* = Value of goods and services that support the sector
  - *Induced output* = Economic activity sustained by the spending of direct and indirect sector employees

- Total federal and Social Security taxes paid by direct sector employees: $15 billion[9]

**"Bioscience is in many ways the key to unlocking our future economic potential as a state. … At the same time it allows us to offer moral leadership as we seek to extend healing and human compassion to our neighbors all around the globe."[10]**

*– Martin O'Malley*
*Governor, Maryland*

[1] J. P. Moore, Jr., "5 Myths About Our Sputtering Economy," *The Washington Post,* 14 December 2008, www.washingtonpost.com/wp-dyn/content/article/2008/12/12/AR2008121203364.html (accessed 6 February 2009).

[2] L. R. Burns, The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels (Washington, DC: Archstone Consulting, LLC, March 2009).

[3] *Ibid.*

[4] *Ibid.*

[5] *Ibid.*

[6] *Ibid.*

[7] *Ibid.*

[8] *Ibid.*

[9] *Ibid.*

[10] L. Smitherman, "MD Joins Sprint to Lead in Biotechnology," *The Baltimore Sun,* 16 June 2008.

3

# VALUE FOR HEALTH CARE:
## Policies That Improve Patient Access

# 3 VALUE FOR HEALTH CARE:
## Policies That Improve Patient Access

**"Researchers are making exciting progress in the search for new cures and treatments. But these efforts are wasted if the medicines we develop aren't accessible to patients who need them."**

*– Billy Tauzin*
*President and CEO, PhRMA*

The value that new medicines offer patients and the economy is directly related to people's ability to access them; when access is maximized, so is the value. The biopharmaceutical research sector supports policies and programs that improve patients' ability to obtain the medicines they need by increasing access to:

- Health insurance, including coverage of new medicines, and
- Extra assistance for people with financial challenges, which is particularly important in today's struggling economy.

### Access to Health Insurance

A lack of good health insurance coverage limits many people's access to needed care, including medicines. Studies show that uninsured Americans[1]:

- Are less likely to receive needed medical care;
- Face serious barriers in obtaining recommended treatment;
- Fail to receive timely preventive care; and,
- Experience lower-quality care and worse health outcomes.

### *Millions of Americans Are Uninsured or Underinsured*

As of 2007:

- More than 45 million Americans had no health insurance.[2]
- About 25 million Americans were underinsured.[3]
- About 14 million insured Americans lacked prescription drug coverage.[4]

Today and tomorrow:

- Over the past year, 4.1 million people lost their employment-based health insurance coverage.[5]
- A 1% rise in unemployment is projected to increase the number of uninsured by 1.1 million.[6]

## *The Biopharmaceutical Research Sector Is a Partner in Helping the Uninsured*

To improve access to health insurance coverage, the biopharmaceutical research sector supports a public-private approach that:

- **Builds on the employer-based system,** which covered about 177 million Americans in 2007.[7]
- **Provides a safety net through public programs,** such as the State Children's Health Insurance Program (SCHIP) and Medicaid. In 2007, more than 80 million Americans received coverage through government programs.[8]

Key strategies for improving access through this approach include:

- Covering those who are eligible but not enrolled in public health insurance or employer plans;

The biopharmaceutical industry has a long history of implementing programs and supporting efforts to improve patients' access to quality health care — particularly those patients who don't have insurance. Our efforts include:

- In 2008, PhRMA — together with America's pharmaceutical research companies — put forward the *Platform for a Healthy America,* a new proposal aimed at assuring that all Americans have access to high-quality, affordable health insurance coverage, as well as a series of initiatives to reduce costs and improve quality and value. The platform is intended as a contribution to a needed national conversation on these essential issues. For more information visit: www.phrma.org/platform_for_a_healthy_america.
- The biopharmaceutical sector worked with a coalition of provider, patient, and consumer advocacy organizations to reauthorize the SCHIP to extend coverage to 4.1 million low-income, previously uninsured children.[9]
- Working through the PhRMA-sponsored Partnership for Prescription Assistance (PPA), companies helped connect uninsured and financially struggling people to government programs, such as Medicaid and Medicare, community health clinics, and more than 40 programs focused on the health needs of children. For more information visit: www.pparx.org.

- Expanding private coverage by providing credits to small, low-wage employers and low/moderate income individuals;
- Assuring comprehensive coverage (including coverage for generic and branded prescription medicines); and,
- Guaranteeing the availability of private health insurance, regardless of health status.

## Access to Medicines

As Chapter 1, "Value for Patients: Longer Lives, Better Health," outlined, new medicines have saved and improved the lives of millions of Americans. To help increase access to medicines needed to treat illness and improve health, biopharmaceutical companies have supported two major successful programs, in addition to SCHIP:

1. Adding prescription drug coverage to Medicare (Part D)
2. Providing free and low-cost medicines to uninsured and financially-challenged Americans through the Partnership for Prescription Assistance (PPA)

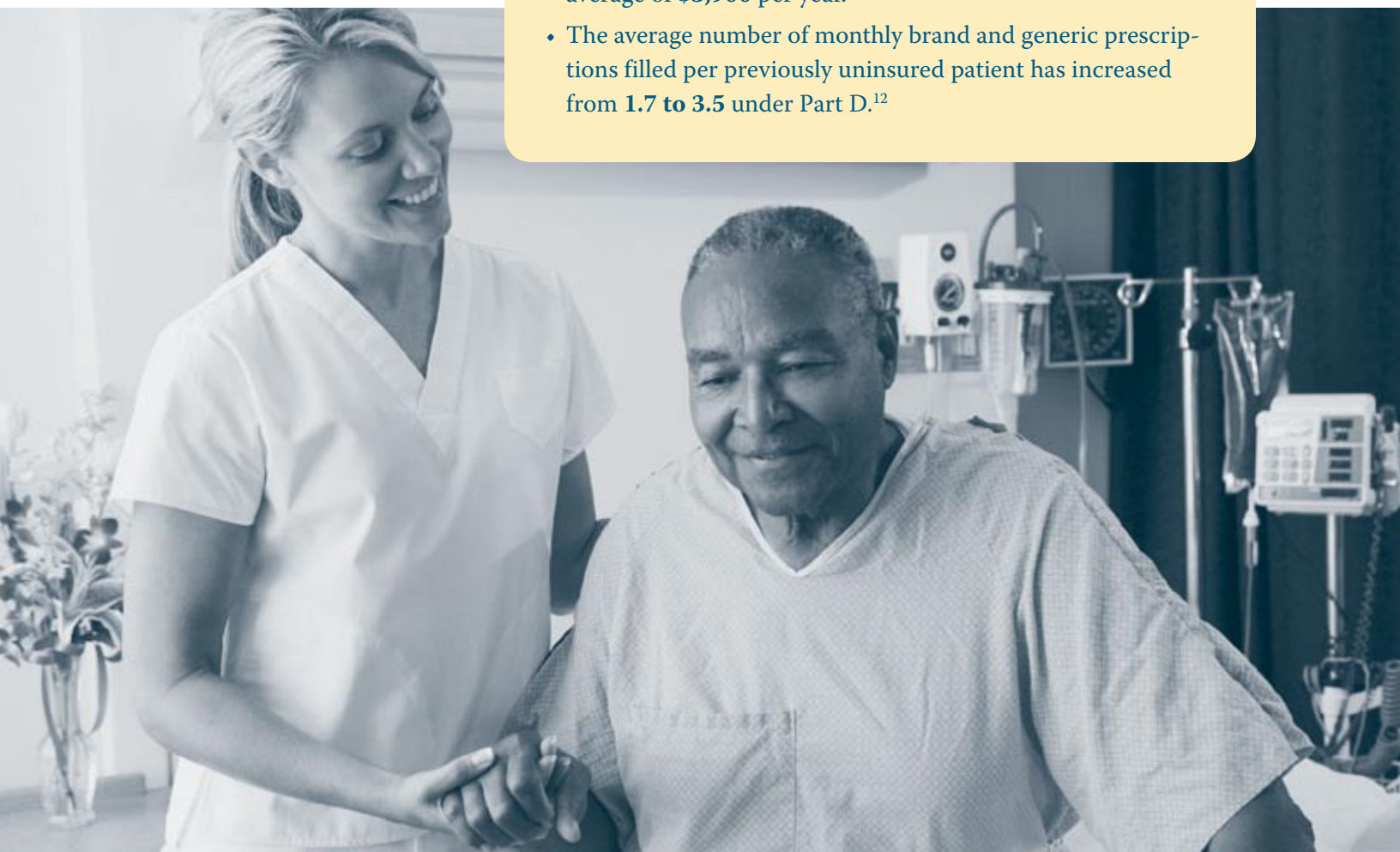
Both of these initiatives have put medicine into the hands of the patients who need it, particularly Americans with lower incomes, as well as seniors and the disabled.

### *Medicare Prescription Drug Coverage: Making a Difference*

Since January 1, 2006, Medicare beneficiaries have had access to comprehensive prescription drug insurance through the Medicare prescription drug benefit. They have a wide range of private plan coverage choices, including prescription drug-only plans and "Medicare Advantage" plans that also cover hospital, physician, and other services.

### *Medicare Drug Coverage: Key Facts*

- Nearly **14 million seniors** and disabled beneficiaries who were uninsured or lacked comprehensive drug insurance gained coverage through the Medicare prescription drug program.[10]
- The average Part D enrollee saves **$1,200** per year under the Medicare drug benefit, while low-income seniors save an average of **$3,900** per year.[11]
- The average number of monthly brand and generic prescriptions filled per previously uninsured patient has increased from **1.7 to 3.5** under Part D.[12]

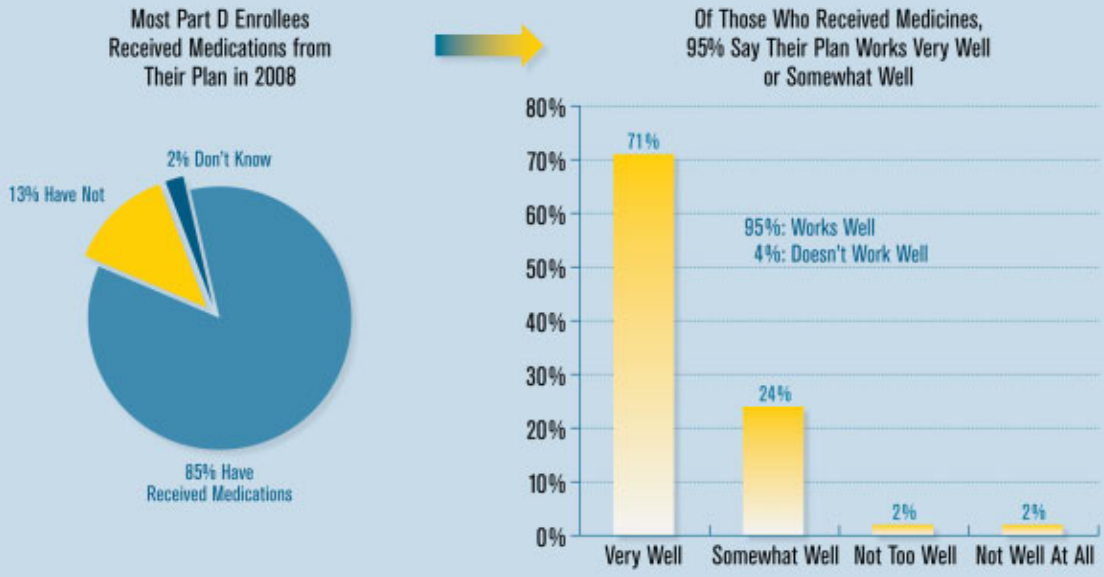


Today, more than 90% of Medicare beneficiaries have comprehensive prescription drug coverage through Medicare or another source.[13] Use of and satisfaction with the program are high. (See Figure 4.)

**"As an easy-to-use doorway to hundreds of existing programs, the PPA is a dramatic improvement to the drug assistance landscape. Patients' caregivers, physicians, and other health care professionals now have ready access to a simplified way of helping themselves and those who can't otherwise afford their medicines."[14]**

*– Bill McLin*
*Executive Director, Asthma & Allergy Foundation of America*

FIGURE 4: **Seniors' Opinions About Medicare Prescriptions**




SOURCE: KRC Survey for *Medicare Today,* "Seniors' Opinions About Medicare Rx: Third Year Update" October 2008, www.medicaretoday.org/pdfs/2008Survey.pdf (accessed 6 February 2009).

**“The program’s been a success. … After the initial confusion at the launch, it started delivering many benefits people need.”[15]**

*– David Certner*
*Legislative Policy Director, AARP*

In addition, results have been even better than expected, both for older Americans and for the health care system:

**Access to medicines has improved, especially for patients with low incomes.** The average number of prescriptions (including brand and generic) has increased from 1.7 to 3.5 filled each month for previously uninsured patients. Patients who received Part D’s Low-Income Subsidy have seen even larger increases.[16]

**The Medicare prescription drug benefit has increased medication access in key chronic diseases for which underuse has been a problem.** For example, Medicare beneficiaries with diabetes who are enrolled in a prescription drug plan filled 11% more prescriptions after the Medicare drug plan began.[17]

**Out-of-pocket medication costs are much lower for patients with Part D.** In 2005, beneficiaries without a Medicare prescription drug plan spent an average of $73 per month on medications; in 2007, those with the Medicare drug benefit spent $42 per month. Low-income beneficiaries’ monthly expenditures dropped even more proportionately, from $41 to $10.[18]

**The Medicare prescription drug benefit has cost less than expected.** The key to the success of Medicare Part D has been the robust competition it fosters among private insurance plans that preserve patient choice for coverage and

**"In 2004, physician assistants in the United States prescribed more than 250 million medications for patients. However, a prescription written does not always translate into a medication taken. Sometimes a patient can't afford the proper medication. That's where the Partnership for Prescription Assistance can help. This program is an invaluable service to patients who may have trouble paying for their medications."[20]**

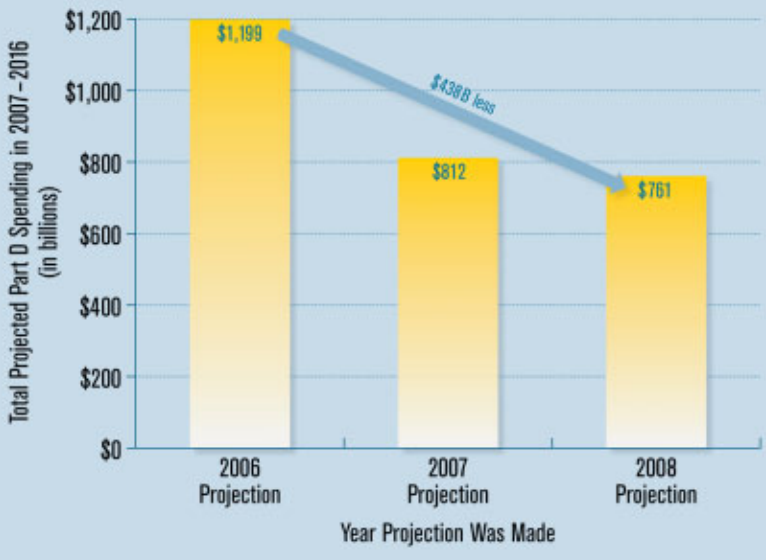
*– Julie A. Theriault, PA-C*
*President, American Academy of Physician Assistants*

medicine options. In fact, competition among plans is credited as a leading factor in the Congressional Budget Office's $438 billion (or 37%) reduction in the 2006 through 2008 projections for the cost of the drug benefit between 2007 and 2016.[19] (See Figure 5.)

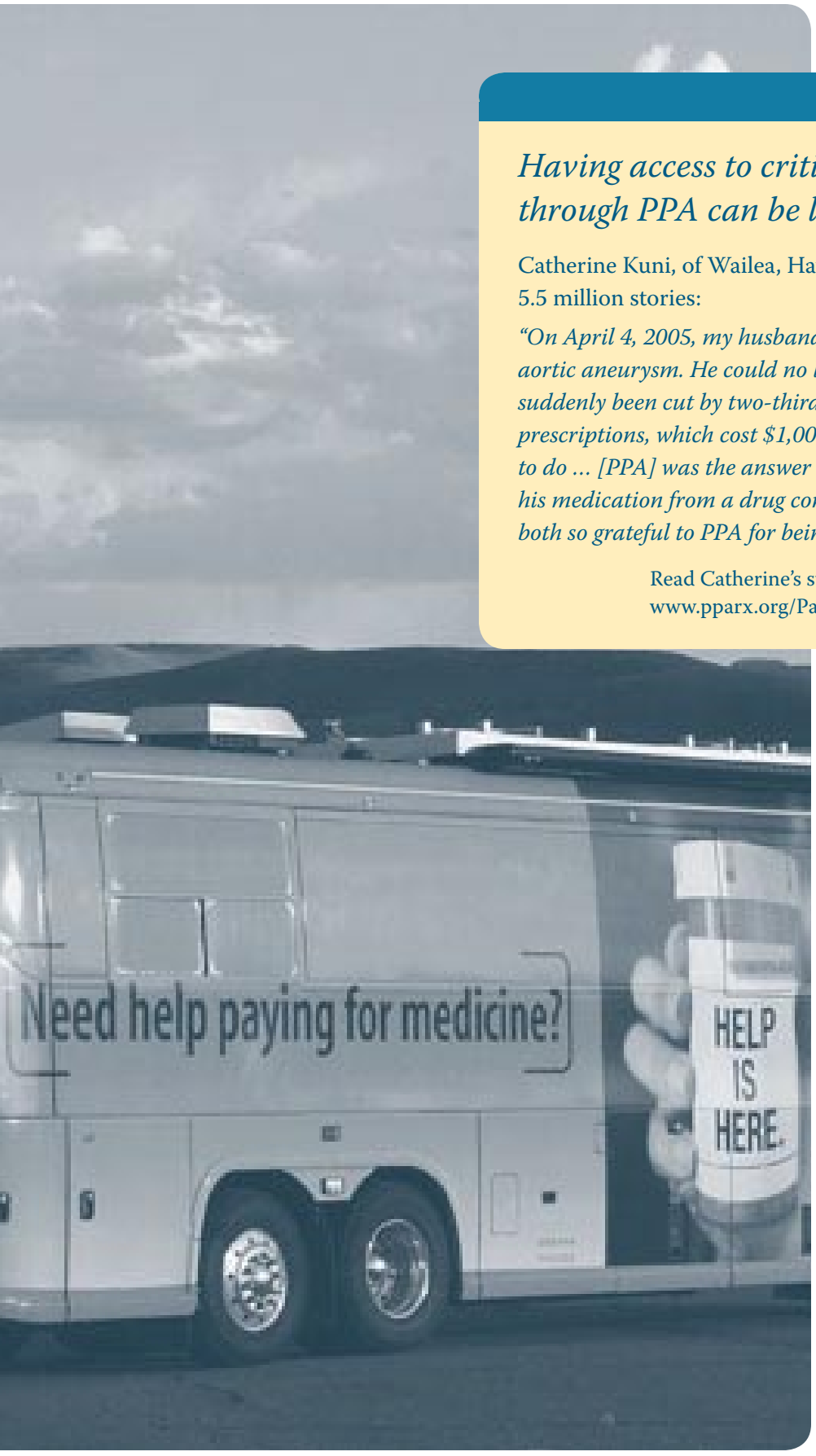
### *The Partnership for Prescription Assistance: More Than 5.5 Million Helped*

Since its inception in April 2005, the Partnership for Prescription Assistance (PPA) has connected more than 5.5 million people to programs that can provide their medicines at little or no cost. Sponsored by America's biopharmaceutical companies, PPA (www.pparx.org) is the world's largest private-sector effort with this purpose. It offers a single

FIGURE 5: **Projections of Total Medicare Part D Spending in FY 2007–2016**




SOURCE: Calculation from Congressional Budget Office March Baselines for 2006, 2007, and 2008.




## *Having access to critical medications through PPA can be life-changing.*

Catherine Kuni, of Wailea, Hawaii, tells one of the more than 5.5 million stories:

*"On April 4, 2005, my husband developed a Type III dissecting aortic aneurysm. He could no longer work … Our income had suddenly been cut by two-thirds and my husband needed five prescriptions, which cost $1,000 a month. We didn't know what to do … [PPA] was the answer to our prayers. My husband got his medication from a drug company program in days … We are both so grateful to PPA for being there."*

Read Catherine's story and many more at www.pparx.org/PatientTestimonials.php.

point of access to more than 475 public and private patient assistance programs, including more than 180 programs offered by pharmaceutical companies. In addition, the PPA has also expanded its efforts to help children get the health care they need through PPA Kids (http://kids.pparx.org).

The PPA advertises its services widely through the media, and it sponsors the "Help Is Here Express," a bus that brings program information to communities around the country.

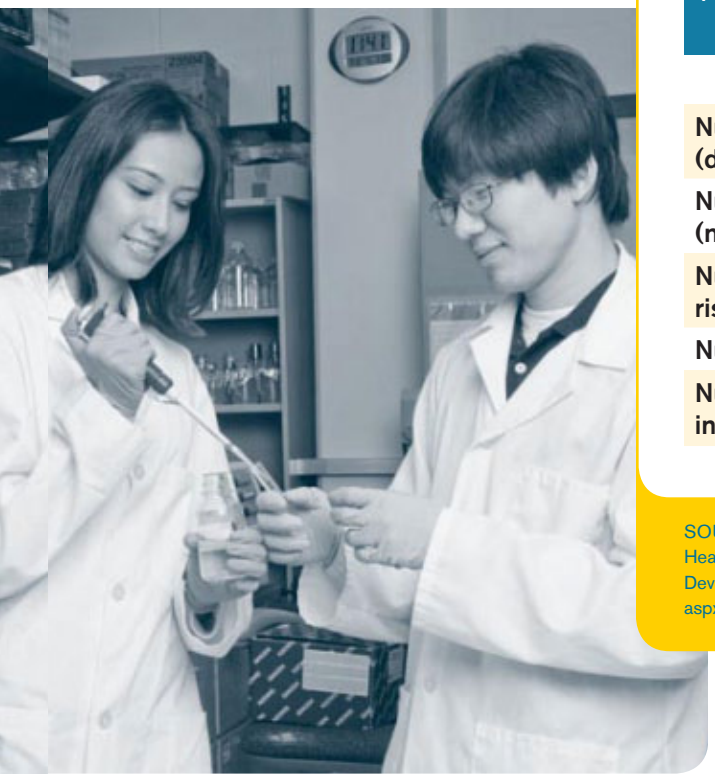


FIGURE 6: **Products and Services Donated 2000 to 2007, Global**

| | |
|---|---|
| Number of courses of Rx therapy (donated) | 1,457,103,151 |
| Number of courses of Rx therapy (no profit) | 281,865,567 |
| Number of patients and people at risk educated | 7,817,428 |
| Number of health workers trained | 298,609 |
| Number of other health care interventions provided | 4,949,734 |

SOURCE: International Federation of Pharmaceutical Manufacturers and Associations, "IFPMA Health Partnerships Survey: Pharmaceutical Industry Contributes a Significant Part of Total Health Development Aid," news release, 19 November 2008, www.ifpma.org/News/NewsReleaseDetail.aspx?nID=10974 (accessed 6 February 2009).

## *Leaders in Philanthropy*

The pharmaceutical research sector gives back to the international community through its substantial and varied philanthropic efforts. (See Figure 6.) Between 2000 and 2007, pharmaceutical companies donated $9.2 billion in medicines, vaccines, diagnostics, equipment and other material and labor to the developing world.[21] Of that total, $2.4 billion was donated in 2007 alone, according to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

**Pharmaceutical companies lead other sectors in philanthropic giving:**

- Recently, the Organisation for Economic Co-operation and Development (OECD) reported that international development assistance in 2005 totaled $13.4 billion.[22] IFPMA data show that pharmaceutical companies donated more than $1.5 billion, or about 11% of the OECD total.
- In the United States in 2006, four of the top five corporate donors (national and international) were pharmaceutical companies. Ten pharmaceutical companies alone gave an average of $232 million — more than 10 times the average corporate donation of $22 million.[23]

*More information on global philanthropy is available at www.globalhealthprogress.org.*

[1] Kaiser Commission on Medicaid and the Unisured, "Five Basic Facts on the Uninsured," issue brief, 16 September 2008, www.kff.org/uninsured/7806.cfm (accessed 6 February 2009); S. R. Collins, *et al*., Gaps in Health Insurance: An All-American Problem (New York, NY: The Commonwealth Fund, April 2006); S. Dorn, Uninsured and Dying Because of It: Updating the Institute of Medicine Analysis of the Impact of Uninsurance on Mortality (Washington, DC: Urban Institute, January 2008).

[2] C. DeNavas-Walt, B. D. Proctor, and J. Smith, U.S. Census Bureau, Current Population Reports, P60-235, Income, Poverty, and Health Insurance Coverage in the United States: 2007 (Washington, DC: GPO, August 2008), www.census.gov/prod/2007pubs/p60-233.pdf (accessed 24 February 2009).

[3] C. Schoen, *et al.,* "How Many Are Underinsured? Trends Among U.S. Adults, 2003 and 2007," *Health Affairs* 27, no. 4 (2008): w298-w309, http://content.healthaffairs.org/cgi/reprint/hlthaff.27.4.w298v1?ijkey=rhRn2Tr4HAKZ.&keytype=ref&siteid=healthaff (accessed 24 February 2009).

[4] C. L. Schur, M. M. Doty, M. L. Berk, Lack of Prescription Coverage Among the Under 65: A Symptom of Underinsurance (New York, NY: Commonwealth Fund, February 2004), www.commonwealthfund.org/Content/Publications/Issue-Briefs/2004/Feb/Lack-of-Prescription-Coverage-Among-the-Under-65--A-Symptom-of-Underinsurance.aspx (accessed 24 February 2009).

[5] Georgetown University Health Policy Institute, Center for Children and Families, Keeping the Promise to Children & Families in Tough Economic Times, November 2008, http://ccf.georgetown.edu/index/cms-filesystem-action?file=ccf%20publications/uninsured/economy%20es.pdf (accessed 6 February 2009).

[6] S. Dorn, *et al*., Medicaid, SCHIP and Economic Downturn: Policy Challenges and Policy Responses (Washington, DC: Kaiser Commission on Medicaid and the Uninsured, April 2008), www.kff.org/charts/042808 (accessed 16 April 2008).

[7] U.S. Census Bureau, Current Population Survey, "Annual Social and Economic (ASEC) Supplement," 28 August 2007, http://pubdb3.census.gov/macro/032007/health/h01_001.htm (accessed 24 February 2009).

[8] *Ibid.*

[9] Congressional Budget Office, Cost Estimate, *H.R. 2: Children's Health Insurance Program Reauthorization Act of 2009*, 13 January 2009, http://cbo.gov/ftpdocs/99xx/doc9963/hr2.pdf (accessed 6 February 2009).

[10] The Lewin Group, "Beneficiary Choices in Medicare Part D and Plan Features in 2006," (Falls Church, VA: The Lewin Group, 13 September 2006), www.lewin.com/content/publications/3849.pdf (accessed 6 February 2009).

[11] Centers for Medicare and Medicaid Services, "Lower Medicare Part D Costs Than Expected In 2009," press release, 14 August 2008, www.cms.hhs.gov/apps/media/press/release.asp?Counter=3240 (accessed 6 February 2009); U.S. Department of Health and Human Services, HHS Budget in Brief for FY2009, "Advancing the Health, Safety, and Well-Being of our People," (Washington, DC: HHS, February 2008).

[12] Amundsen Group, Verispan Longitudinal Data, analysis for PhRMA, May 2008.

[13] Acting CMS Administrator Leslie Norwalk, "Boomers and the Budget: What Does it Mean for America's Seniors," testimony to the Senate Special Committee on Aging (Washington, DC), 15 February 2007, www.hhs.gov/asl/testify/2007/02/t20070215a.html (accessed 6 February 2009).

[14] Partnership for Prescription Assistance, www.pparx.org/partner_quotes.php (accessed 3 March 2009).

[15] D. Cauchon, "Medicare Drug Plan Spending Drops $6B in 2008," *USA Today*, 31 October 2008, www.usatoday.com/news/health/2008-10-30-medicare_N.htm (accessed 11 March 2009).

[16] Amundsen Group, *op. cit.*

[17] Z. Karaca, *et al.,* The Impact of Medicare Part D on Beneficiaries with Type 2 Diabetes, Drug Utilization and Out-of-Pocket Costs, (Washington, DC: Avalere Health, March 2008), www.avalerehealth.net/research/docs/The_Impact_of_Medicare_Part_D_Diabetes_Takeda.pdf (accessed 6 February 2009).

[18] Amundsen Group, *op. cit.*

[19] Calculation from Congressional Budget Office March Baselines for 2006, 2007, and 2008.

[20] Partnership for Prescription Assistance, *op. cit.*

[21] International Federation of Pharmaceutical Manufacturers and Associations, "IFPMA Health Partnerships Survey: Pharmaceutical Industry Contributes a Significant Part of Total Health Development Aid," news release, 19 November 2008, www.ifpma.org/News/NewsReleaseDetail.aspx?nID=10974 (accessed 6 February 2009).

[22] Organisation for Economic Co-operation and Development, 2007 development co-operation report (Paris, France: OECD, 2008).

[23] The Foundation Center, Foundation Growth and Giving Estimates Current Outlook (New York, NY: The Foundation Center, 2008), http://foundationcenter.org/gainknowledge/research/pdf/fgge08.pdf (accessed 6 February 2009).

4

# VALUE FOR PREVENTING DISEASE:
## Lower Burden of Chronic Illness

# 4 VALUE FOR PREVENTING DISEASE: Lower Burden of Chronic Illness

**"As the baby boomers age, the number of people living with chronic conditions will grow dramatically. Forty-six million more Americans are projected to have at least one chronic condition in 2030 than in 2000."[1]**

*– Gerard Anderson*
*Johns Hopkins University*

The growing prevalence and cost of chronic diseases, such as heart disease, cancer, and diabetes, are among the greatest challenges facing America today. Increasing the health care system's emphasis on prevention is critical to lowering the growing burden of disease — a burden that has adverse consequences for public health, health care costs, quality of life for Americans, and the productivity of our economy. The aging of the large baby boomer population makes this emphasis on prevention even more critical, because chronic disease complications often get worse with age. Biopharmaceutical research companies support making prevention a health care policy priority, and they are an active partner in this effort.

## The Problem: Chronic Disease Is Increasing

The number of Americans with at least one chronic condition is increasing every year, and almost half of U.S. health care spending goes toward treating the small subset of patients with three or more chronic conditions.[2] Prevalence rates for common, avoidable chronic diseases are rising much faster than population growth. For example, in just two years between 2005 and 2007, the prevalence of diabetes rose 13.5%.[3]

## The Prevention Gap

Strikingly, many of the costs associated with chronic disease could be avoided, not only because these diseases are often preventable, but also because they are often manageable when they do arise. On the individual level, disease prevention includes self-care steps (such as maintaining a healthy weight, being

physically active, and not smoking), and primary and secondary preventive medical services (such as screening for disease and using medications that help prevent disease and complications). The U.S. Centers for Disease Control and Prevention estimates that better access to health care and a greater emphasis on healthy behaviors could add five to seven healthy years to the lifespan of many people.[4]

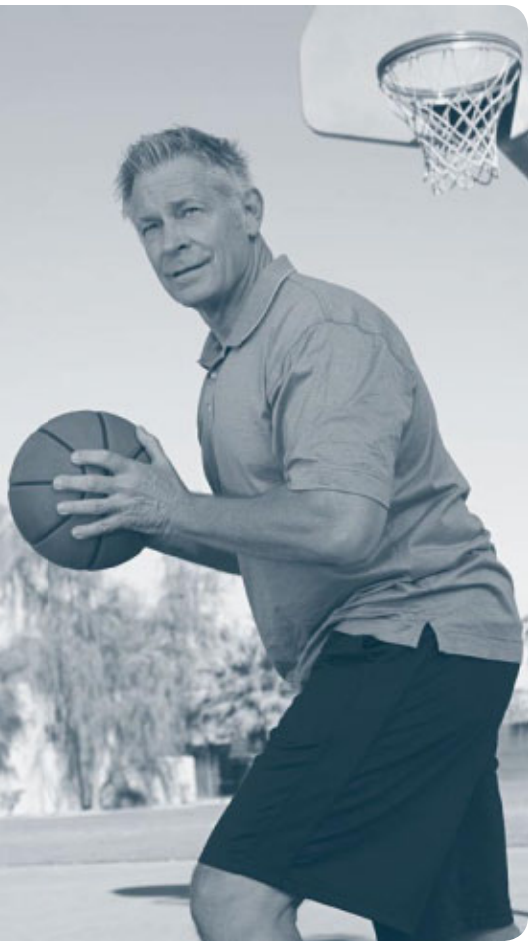
## *The Costs of Chronic Disease in the United States*

Chronic disease accounts for:

- Seven out of 10 deaths in the U.S ⇨ 1.7 million each year[6]
- An estimated 125 million instances of major disability and reduced quality of life[7]
- Treatment expenditures of $277 billion
- Lost productivity estimated at $1.047 trillion

**Total Cost to the Economy: $1.324 trillion**[8]

> **"The "failure to contain the containable is undermining prospects for extending health insurance coverage and for coping with the medical costs of an aging population. The rising rate of chronic disease is a crucial but frequently ignored contributor to growth in medical expenditures."**[5]
>
> – An Unhealthy America: The Economic Burden of Chronic Disease, *Milken Institute*



In particular, studies suggest that greater weight reduction and smoking cessation would substantially reduce chronic disease and its costs. However:

- **Obesity is increasing.** About 65% of American adults are overweight or obese. This compares to 47% of adults who were overweight or obese in 1980.[9]
- **About 45.3 million people still smoke.** About 8.6 million Americans this year will suffer from a disease related to smoking.[10]

Similarly, medications are available for primary prevention (preventing a disease from occurring) of chronic diseases, such as blood cholesterol-reducing drugs to prevent cardiovascular disease. More pharmaceutical options exist for secondary prevention (treating a disease, e.g., hypertension, to avoid disabling and life-threatening complications, such as stroke and kidney failure). Yet common chronic diseases are often untreated or poorly controlled. (See Figure 7.)

## The Value of Prevention

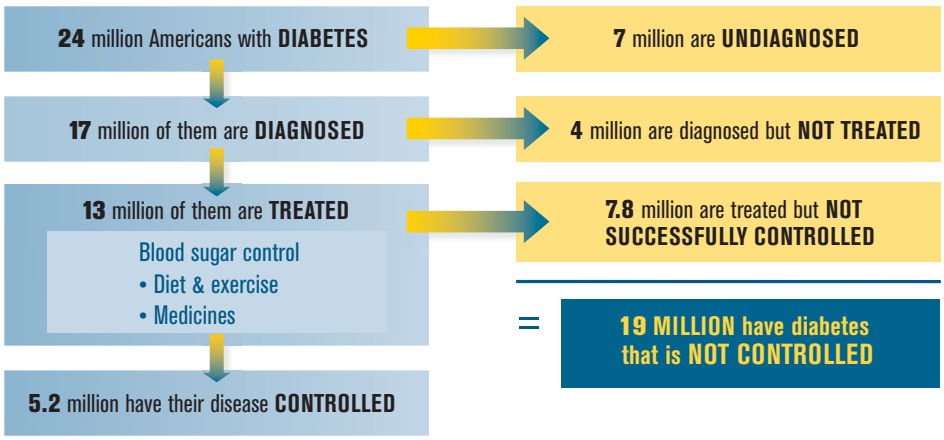
The Milken Institute estimates that by making reasonable improvements in preventing and managing chronic disease, we could avoid 40.2 million cases of chronic conditions in 2023.[11] (See Figure 8.)

In addition to improving and saving lives, strengthened prevention efforts can also provide significant economic benefits, including both increased worker productivity and health care cost-savings:

- Effective prevention efforts for diabetes and obesity, along with effective control of hypertension among the elderly, would create significant annual cost-savings in 2030, compared to taking no preventive action. Prevention of

FIGURE 7: **Common Chronic Diseases Are Often Untreated or Poorly Controlled**

**Diabetes: An Example of the Problems of Underdiagnosis and Undertreatment**




Note: Figures may not sum due to rounding.

SOURCES: PhRMA analysis of data from National Health and Nutrition Examination Survey, 2003–2004; American Diabetes Association, "Diabetes Statistics," www.diabetes.org/diabetes-statistics.jsp (accessed 6 February 2009).

obesity alone could reduce spending by 10%.[12]

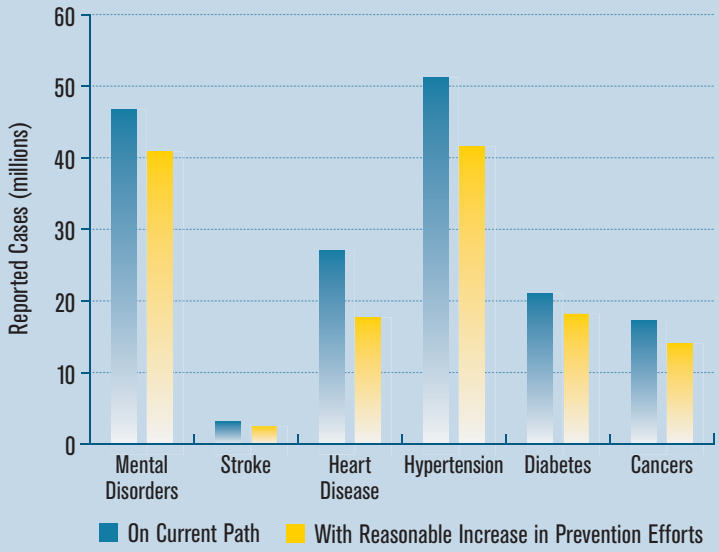
- Improvements in prevention and early detection could reduce costs of chronic disease by $1.1 trillion in 2023: $905 billion from gains in productivity and $218 billion from avoided treatment expenditures.[13]
- By 2050, reasonable disease prevention and management efforts could add $5.7 trillion to the nation's economic output, a boost of 18%.[14]

## Closing the Prevention Gap

An increased emphasis on prevention would both improve the health of Americans and offset some of the costs of an aging population by increasing economic productivity. While closing the prevention gap will not be easy, biopharmaceutical companies support making prevention an individual and a health care system priority. Possible solutions could include:

- Conducting a major public health campaign to reduce obesity, and researching and developing new models addressing obesity
- Promoting wellness programs and healthy lifestyles (e.g., offering tax credits for employer wellness programs)
- Improving care coordination for chronic conditions by:
  - Creating a new public-private commission on chronic care management to identify effective strategies
  - Improving access to prevention, early detection and disease management
  - Implementing effective medication therapy management through Medicare

FIGURE 8: **Preventable Cases of Chronic Diseases**




SOURCE: Adapted from R. DeVol, *et al.*, An Unhealthy America: The Economic Burden of Chronic Disease, (Santa Monica, CA: Milken Institute, October 2007), www.milkeninstitute.org/publications/publications.taf?function=detail&ID=38801018&cat=ResRep (accessed 6 February 2009).

## *The Biopharmaceutical Industry Is a Partner in Prevention*

While Americans confront the challenges of a health care system in need of reform, innovators in communities around the United States are proving the value of addressing chronic disease by building a healthier America. There is much to be learned from these leaders in making the changes needed to achieve not just improvements in health care, but — even more importantly — improvements in health. The Partnership to Fight Chronic Disease has developed tools to help leaders with a vision for change to learn about existing programs that are making a difference, and the essential elements to their success. These "promising practices" are available on the Partnership to Fight Chronic Disease Web site: www.promisingpractices.fightchronicdisease.org.

[1] G. Anderson, *et al.,* Chronic Conditions: Making the Case for Ongoing Care (Baltimore, MD: Johns Hopkins University, 2007).

[2] *Ibid.*

[3] American Diabetes Association, "Diabetes Statistics," www.diabetes.org/diabetes-statistics.jsp (accessed 6 February 2009).

[4] U.S. Department of Health and Human Services, The Power of Prevention (Washington, DC: HHS, 2003), www.healthierus.gov/STEPS/summit/prevportfolio/Power_Of_Prevention.pdf (accessed 6 February 2009).

[5] R. DeVol, *et al.,* An Unhealthy America: The Economic Burden of Chronic Disease (Santa Monica, CA: Milken Institute, October 2007), www.milkeninstitute.org/publications/publications.taf?function=detail&ID=38801018&cat=ResRep (accessed 6 February 2009).

[6] U.S. Department of Health and Human Services, *op. cit.*

[7] S. Wu and A. Green, Projection of Chronic Illness Prevalence and Cost Inflation, Rand Corporation, 2000.

[8] R. DeVol, *et al., op. cit.*

[9] U.S. Centers for Disease Control and Prevention, "Women's Health, Overweight and Obesity," 24 April 2006, www.cdc.gov/women/natstat/overwght.htm (accessed 6 February 2009).

[10] U.S. Centers for Disease Control and Prevention, Targeting Tobacco Use, At A Glance, (Washington, DC: CDC, March 2008), www.cdc.gov/NCCDPHP/publications/aag/pdf/osh.pdf (accessed 6 February 2009).

[11] R. DeVol, *et al., op. cit.*

[12] D. Goldman, *et al.,* "The Value of Elderly Disease Prevention," *Forum for Health Economics & Policy* 9, no. 2 (2006): 1.

[13] R. DeVol, *et al., op. cit.*

[14] R. DeVol, *et al., op. cit.*

# 5

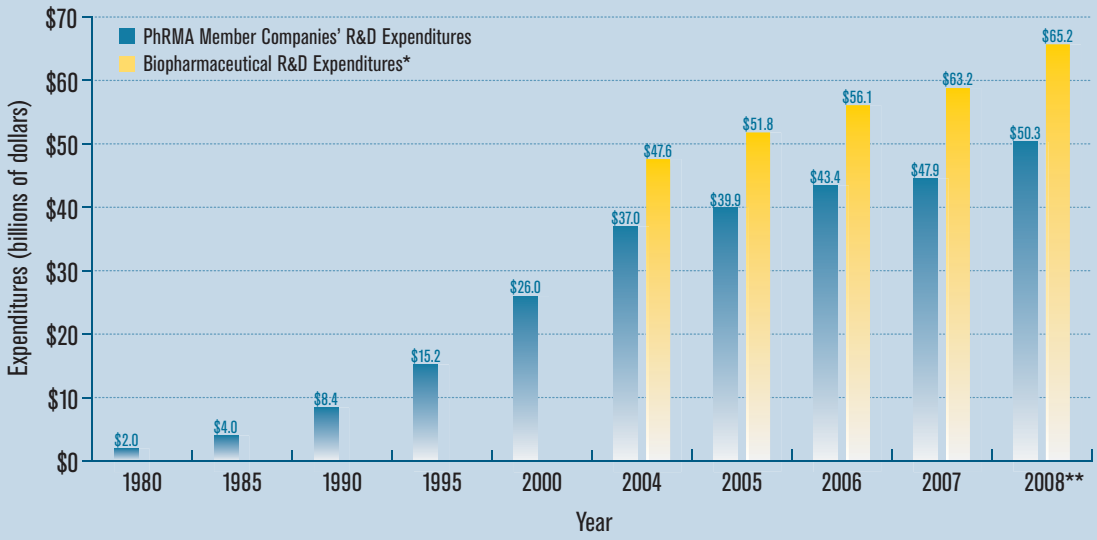
# VALUE FOR THE FUTURE:
## R&D Promise and Challenges

# 5

# VALUE FOR THE FUTURE:
## R&D Promise and Challenges

Research and development — and the life-changing innovation they produce — lie at the heart of the value that the U.S. biopharmaceutical research sector brings to patients, the economy, health care, and chronic disease prevention. Discovering and developing new treatments are the goals of biopharmaceutical research companies, as demonstrated by their disproportionately large R&D investment, even in the face of recession. (See Figure 9.) In 2008, this investment totaled $65.2 billion.[1] PhRMA members alone spent $50.3 billion researching new medicines in 2008.[2]

FIGURE 9: **Biopharmaceutical Companies' Investment in R&D Remains Strong**



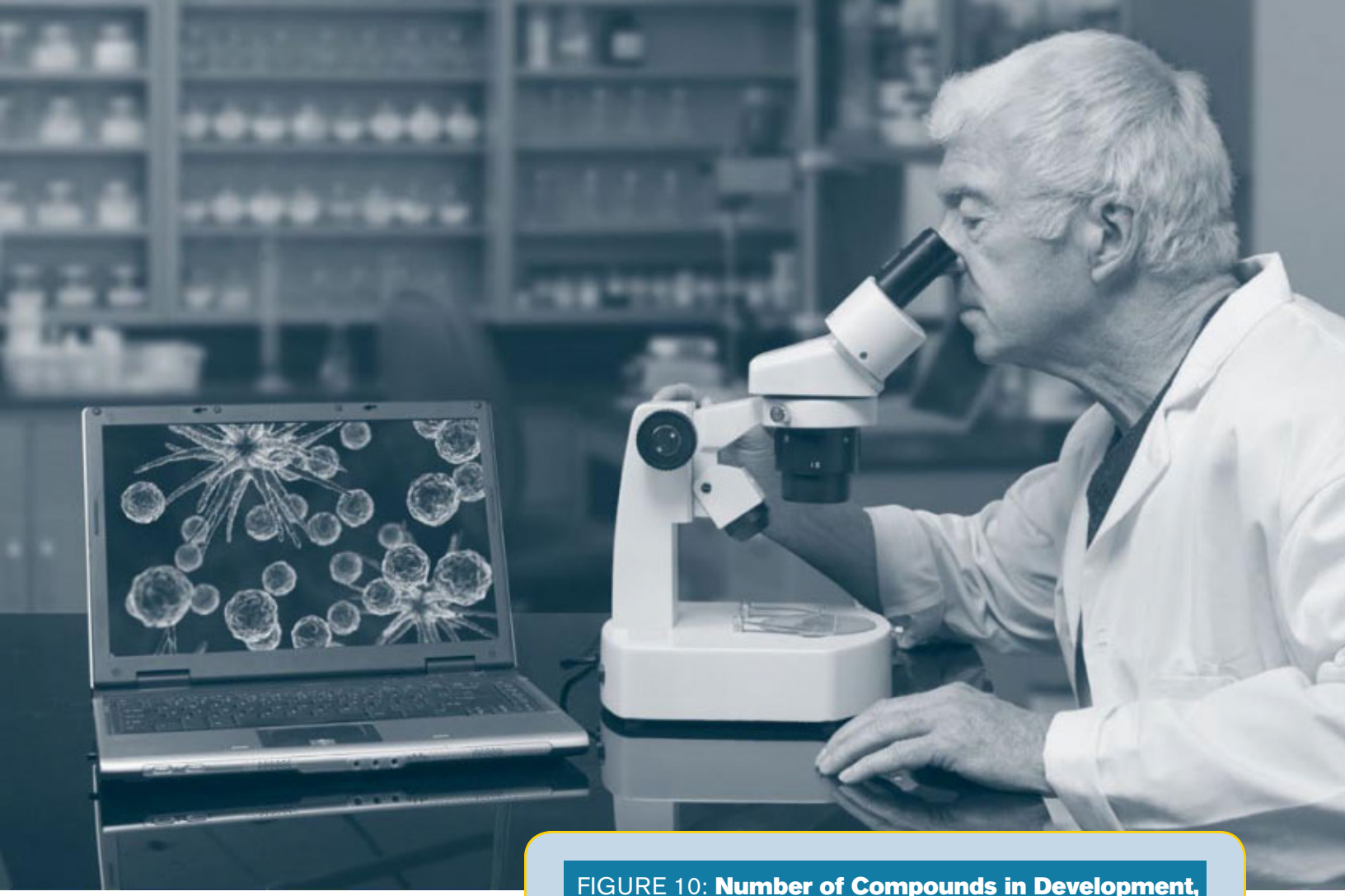

*The "Biopharmaceutical R&D Expenditures" figures include PhRMA research associates and nonmembers; these are not included in "PhRMA Member Companies' R&D Expenditures." PhRMA first reported this data in 2004.

**Estimated.

SOURCES: Burrill & Company, analysis for Pharmaceutical Research and Manufacturers of America, 2005–2009; Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Member Survey* (Washington, DC: PhRMA, 1981–2009).

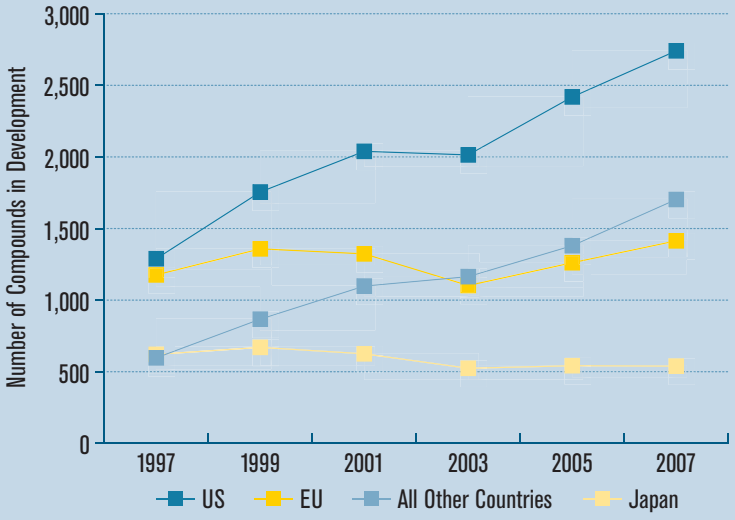
**"The pharmaceutical industry is one of the most research-intensive industries in the United States. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm."[3]**

*– Congressional Budget Office*



Another measure of the biopharmaceutical research sector's commitment to R&D is the number of medicines they are researching: today, the U.S. biopharmaceutical pipeline contains more than 2,900 medicines in clinical trials or awaiting FDA review.[4] In recent years, the American biopharmaceutical sector has consistently had more compounds in development than the rest of the world combined.[5] (See Figure 10.)

FIGURE 10: **Number of Compounds in Development, by Region***




*Note: Reflects the number of compounds in clinical trials or awaiting approval as of June of each year. Compounds in development for multiple regions are counted in each region for which regulatory approval is sought, and multiple indications are counted only once.

SOURCE: Adis R&D Insight Database, Wolters Kluwer Health, Customized Run, December 2007.

## Future Value: Science and Technology Opportunities

Today's scientific opportunities offer enormous potential for patients and society. Scientists are delving deeper into the molecular basis of disease than ever before. They are gaining a better understanding of:

- Genomics — the study of collections of genes and their role in the body and disease;
- Proteomics — the study of the structure and function of proteins; and,
- Biomarkers — molecular, biological or physical characteristics that can help identify risk for disease, make a diagnosis, or guide treatment.

"Personalized medicine" is one particularly promising trend that is emerging from researchers' increasing knowledge of the molecular underpinnings of disease.

## Personalized Medicine

The advent of pharmacogenomics — the application of genomic concepts to the discovery and clinical development of pharmaceuticals — opens the possibility of tailoring diagnostic tests and medication treatments to subpopulations of patients, based on their genetics.

Progress toward the goal of personalized medicine is expected to be steady, but measured, due to the complexity of translating genetic knowledge into viable medical applications. However, potential benefits are compelling, such as enhanced ability to:

- **Find new drug targets.** An estimated 500 drug targets (i.e., molecules that drugs interact with in the body to affect disease) are currently believed to exist. Genomics could increase this number up to 5,000.[6]
- **Streamline the clinical trials process.** It is possible that the size and cost of a clinical trial could be reduced, if patients who were more likely to respond to a drug or less likely to experience an adverse drug reaction could be preferentially enrolled in clinical trials, based on genetic makeup.
- **Target treatment more effectively.** Pharmacogenomic tests have been approved for several drugs already. If such tests proliferate, physicians may be able to use both clinical and genetic information in making treatment decisions.
- **Prevent serious adverse events.** Tests for genetic susceptibility to side effects can prevent patients from taking medicines that may cause unnecessary problems or serious injury.


**"I firmly believe that we stand on the cusp of an unprecedented period of discovery and invention in the life sciences in which our understanding of human differences replaces the pursuit of generalized well-being as the main driver of medical progress … Our goal is to give doctors the ability to prescribe for individual patients – with a high level of confidence – the right dose of the right medicine at the right time."[7]**

*– Sidney Taurel*
*Former Chairman, Eli Lilly, 2008*

## Medicines Currently in Development

The more than 2,900 compounds in clinical trials or undergoing FDA review represent today's "discoveries in waiting."[8] They include:

- 300 potential medicines for rare diseases, such as chronic sarcoidosis, an immune system disorder; Lennox-Gastaut syndrome, a severe form of epilepsy; and cystic fibrosis[9]
- 750 possible treatments for cancer, including many for lung cancer and breast cancer[10]
- 277 new approaches for heart disease and stroke[11]
- 109 new treatments to fight and prevent HIV/AIDS[12]

While these possibilities are exciting, trends to date suggest that only a small percentage of them will receive FDA approval and become new medicines. According to the Tufts Center for the Study of Drug Development, out of every five compounds that enter clinical testing, only one will eventually be approved.[13]

**"Advances in 2008 "reflect a maturation, if you will, of the whole approach of personalized medicine to oncology care."[14]**

*– Dr. Richard L. Schilsky*
*President, ASCO; Professor of Medicine, University of Chicago Medical Center*

## *Incremental Innovation*

In any R&D endeavor, most advances come from an accumulation of small changes, rather than a breakthrough discovery. Incremental innovation in pharmaceutical R&D takes many forms, with important benefits for patients. Key examples include:

**Class development.** Different medicines may work by the same mechanism to fight a disease, offering patients choices between different profiles of efficacy, safety, and pharmacology.

**New delivery methods.** Taking an existing drug and altering its method of delivery can open up new indications, or improve the patient experience for indications already approved.

**New indications for existing medicines.** Drugs approved for one indication may show benefit for another indication, often during post-approval R&D. Such innovation gives new populations of patients more new treatment choices, without the costs and development times associated with *de novo* development.

**Combinations.** Combining two or more drugs together, either separately in a treatment regimen or in a single dose, can enhance the benefit of each drug, while promoting treatment compliance and reducing costs.

## Today's Pharmaceutical R&D Process: Long, Increasingly Complex and Costly

R&D represents enormous value and promise. It is also a long, challenging process requiring enormous skill, persistence and some luck.

As Figure 11 shows, the R&D process includes many steps, numerous disciplines, and an army of people. From the first testing in the lab to FDA approval, the process takes an average of 10 to 15 years. But pharmaceutical R&D doesn't stop there. For the small number of products that achieve FDA approval, post-approval research and post-marketing surveillance can continue for many additional years. Here's a summary of the typical stages of R&D:

**Pre-discovery** – Scientists spend years researching the underpinnings of the disease in question, searching for a potential way to prevent or treat a disease.

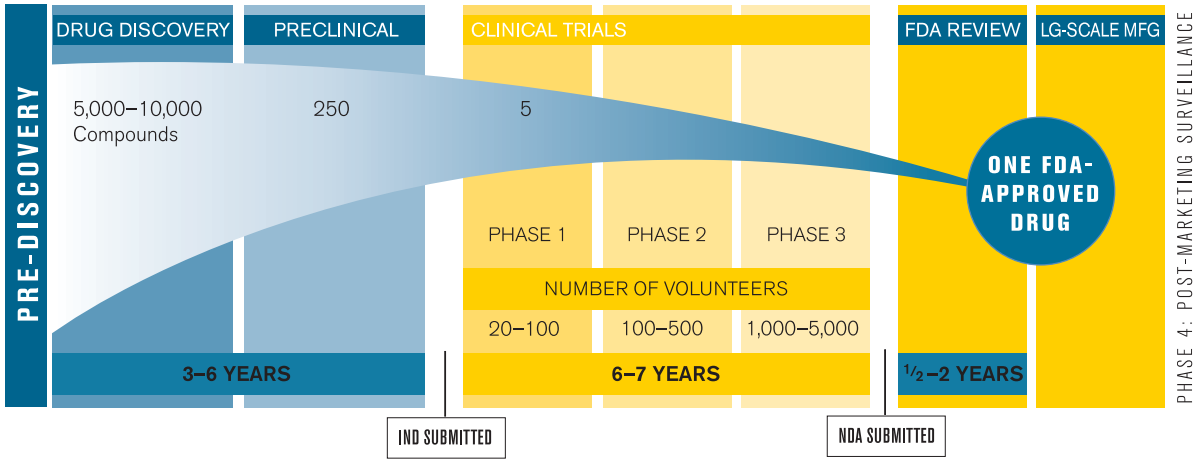
**Discovery** – Researchers search for candidate drugs by screening compound libraries that contain thousands or millions of potential medicines, evaluating molecules found in nature, and developing new molecules from scratch. They test the potential candidates against the disease target (usually a protein or a gene), and modify or optimize the compound to make it more effective.

**Preclinical Studies** – Once a compound has shown some activity against the drug target, it undergoes extensive testing in the lab — both in test tubes and animal models. Years of preclinical testing must establish that the candidate medicine is likely to be safe and effective in humans before clinical testing can begin.

**Clinical Trials** – When a company is ready to begin clinical trials, it submits an Investigational New Drug (IND) Application to the FDA, showing the data it has gathered in preclinical tests, as well as a clinical studies plan or protocol. The FDA has the authority to prevent or delay clinical testing if it is not satisfied with the IND. Clinical trials proceed in three phases:

- Phase 1 – The first phase of studies in humans assesses safety and evaluates how the compound affects the body. These studies are usually done in small groups of healthy volunteers.

FIGURE 11: **The R&D Process: Long, Complex, and Costly**



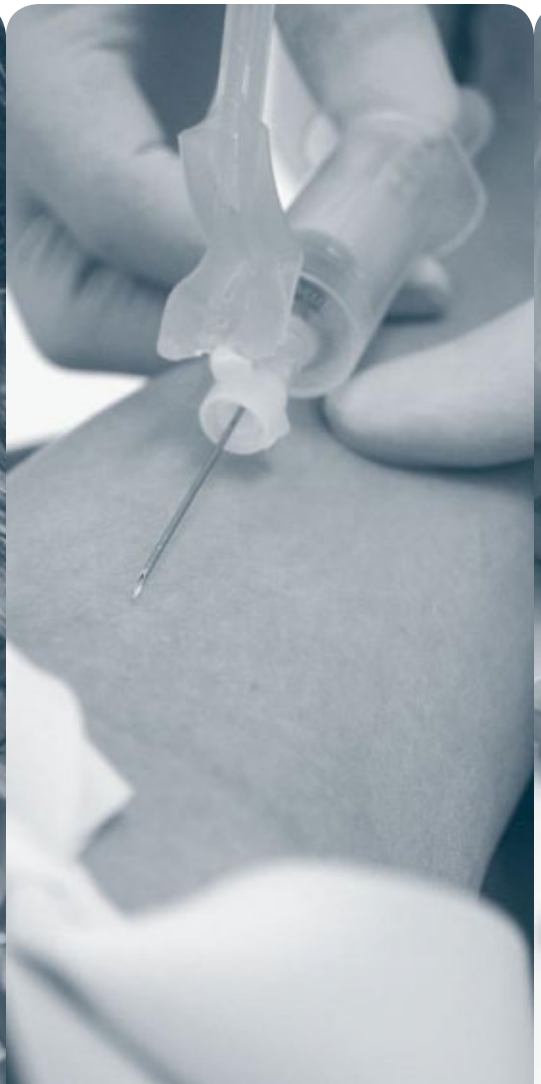
- Phase 2 – In the second phase of clinical trials, researchers test the candidate medicine in patients. They study its safety and begin to examine its efficacy against the disease in question.
- Phase 3 – The final stage involves large-scale trials in hundreds or thousands of patients to test the efficacy of the medicine and to find any rare adverse events.

**FDA Review** – Upon successful completion of clinical trials, the company submits a New Drug Application (NDA) to the FDA. The NDA is an extensive collection of documents, including all results from preclinical and clinical studies, and details of the manufacturing plan. The FDA can choose to approve a new medicine, request more information or studies, or deny approval.

**Manufacturing** – Teams of engineers, biologists, chemists and physicists work to develop ways to produce the medicine at high quality on a large scale. Researchers often begin planning mass production prior to approval in order to be ready if approval is granted. In many cases, they must build a new facility for each new drug. All manufacturing areas must meet strict FDA guidelines for "Good Manufacturing Practices."

**Post-approval Research** – Studies and monitoring continue for the life of the medicine. For example, the FDA may require specific Phase 4 studies to get more information about the medicine; the company may research additional indications (to treat other diseases or to expand the current indication); and, the company must always monitor and report adverse events to the FDA.

Prior to 2007, FDA had strong powers to regulate drug products both before and after they were approved for marketing. In 2007, however, Congress gave the FDA even more resources and authority to enhance drug safety. These include new authorities and funds to require companies to conduct post-market studies and clinical trials, make safety-labeling changes, and develop and implement "Risk Evaluation and Mitigation Strategies." Congress also gave the FDA new resources and authorities to improve post-market risk identification and analyses.



## FIGURE 12: **Increasing Complexity of Clinical Trials**

| | 1999 | 2005 | Percentage change |
|---|---|---|---|
| **Unique Procedures per Trial Protocol (Median)** | 24 | 35 | 46% |
| **Total Procedures per Trial Protocol (Median)** | 96 | 158 | 65% |
| **Clinical Trial Staff Work Burden (Measured in Work-effort Units)** | 21 | 35 | 67% |
| **Length of Clinical Trial (Days)** | 460 | 780 | 70% |
| **Clinical Trial Participant Enrollment Rate** | 75% | 59% | -21% |
| **Clinical Trial Participant Retention Rate** | 69% | 48% | -30% |

***Definitions:***
**Procedures:** Including lab and blood work, routine exams, x-rays and imaging, questionnaires and subjective assessments, invasive procedures, heart assessments, etc.
**Protocol:** The clinical trial design plan
**Enrollment rate:** The percentage of volunteers meeting the increasing number of protocol eligibility criteria (percentage screened who were then enrolled)
**Retention rates:** The percentage of volunteers enrolled who then completed the study; declining retention rates mean firms must enroll more patients initially and/or recruit more patients during the trial

SOURCE: Tufts Center for the Study of Drug Development, "Growing Protocol Design Complexity Stresses Investigators, Volunteers," *Impact Report* 10, no. 1 (January/February 2008).

### *Increasing Complexity*

In recent years, the R&D process has become increasingly complex and costly. Clinical trials in particular have become more complicated for many reasons, including difficulty recruiting and retaining volunteers, increasingly complex diseases being studied, and more testing against comparator drugs.[15] The effects of these changes are summarized in Figure 12.

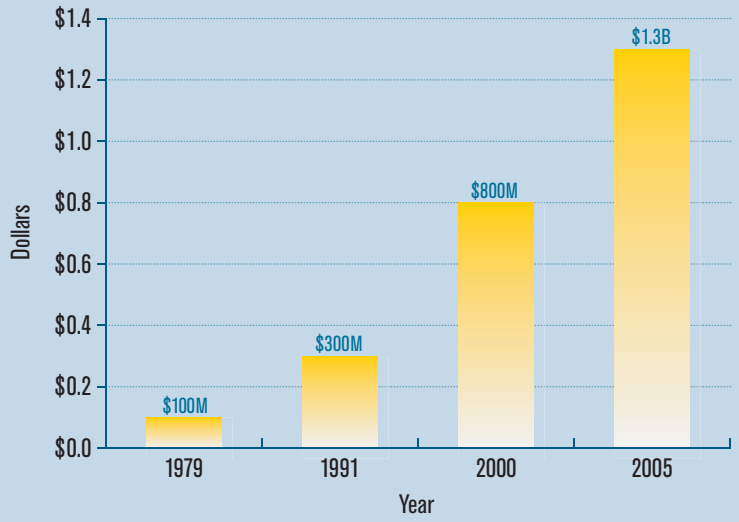
### *Growing Costs*

As the complexity of the process has increased, so have the costs. On average today, companies spend an estimated $1.2 billion to $1.3 billion on R&D for each approved biologic (large molecule) and traditional small

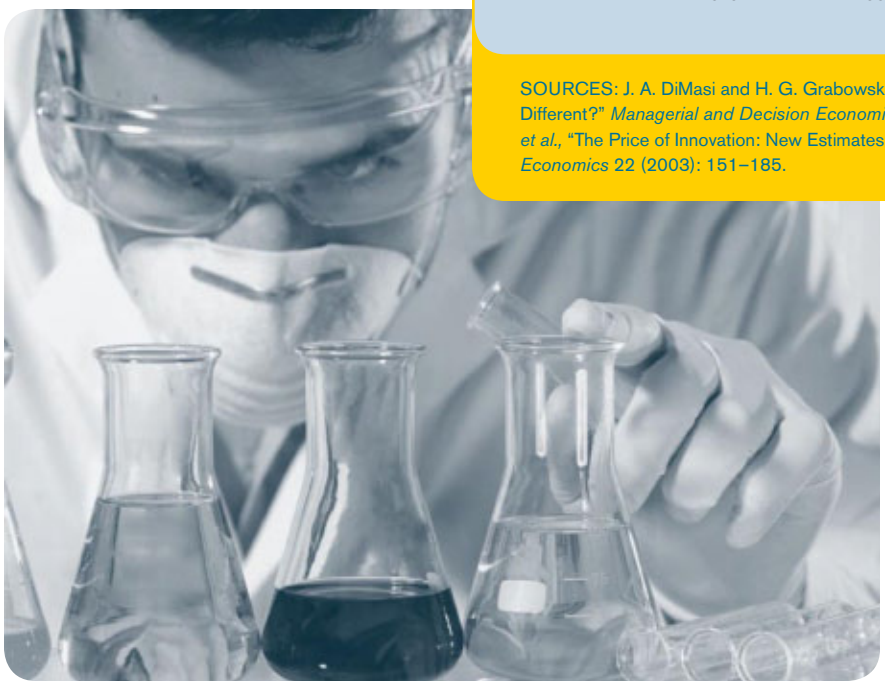
**“Most of the costs involved in developing a new drug come not from the initial discovery research but from clinical testing and regulatory approval – costs that firms tend to bear themselves.”**[16]

*– Congressional Budget Office*

FIGURE 13: **Cost to Develop One New Drug**




SOURCES: J. A. DiMasi and H. G. Grabowski, “The Cost of Biopharmaceutical R&D: Is Biotech Different?” *Managerial and Decision Economics* 28, no. 4–5 (2007): 469–479; J. A. DiMasi, *et al.,* “The Price of Innovation: New Estimates of Drug Development Costs,” *Journal of Health Economics* 22 (2003): 151–185.



molecule drug approved.[17] This represents an increase of $500 million since 2000. (See Figure 13.) These figures include the cost of failures and capital.

On average, $615 million of this investment takes place during the preclinical testing phases, while another $626 million is invested during clinical testing for biologic drugs. For small-molecule/chemical-based drugs, $439 million goes toward preclinical testing, and clinical testing requires an average of $879 million.[18]

### *Investment Risks Are High*

As an investment, pharmaceutical R&D involves substantial risks. First, the nature of scientific research and the translation of new knowledge into a successful new product are inherently uncertain. Then, the rigors of the FDA approval process add to the risk: the Congressional Budget Office reports that “relatively few drugs survive the clinical trial process.”[19]

Once a medication is approved, the commercial success rate of pharmaceuticals is low. In fact, just two in 10 medicines ever produce revenues that match or exceed average R&D costs.[20]

In addition, research-based pharmaceutical companies now face increased competition from other medicines within a class[21] and from generic drugs.[22] For medicines with sales exceeding $100 million, whose generic competitors entered the market between 1995 and 2005, the average time on the market before generic competition was 11.5 years.[23] But generic firms are often able to challenge an innovator company’s patents within a few short years of FDA approval.[24]

[1] Burrill & Company, analysis for PhRMA, 2009. Includes PhRMA research associates and nonmembers; Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 2009).

[2] Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 2009).

[3] Congressional Budget Office, Research and Development in the Pharmaceutical Industry, (Washington, DC: CBO, October 2006).

[4] Adis R&D Insight Database, Wolters Kluwer Health, accessed 13 February 2009.

[5] Adis R&D Insight Database, Wolters Kluwer Health, Customized Run, December 2007.

[6] A. D. Roses, Pharmacogenetics and Drug Development: The Path to Safer and More Effective Drugs, *Nature Reviews Genetics* 5, no. 9 (2004): 645.

[7] S. Taurel, "From the Broad Brush to the Fine Point: How to Enable Personalized Medicine," remarks to the Center for Medical Progress of the Manhattan Institute (New York, NY), 12 December 2008.

[8] Adis R&D Insight Database, Wolters Kluwer Health, accessed 13 February 2009.

[9] Pharmaceutical Research and Manufacturers of America, Orphan Drugs in Development for Rare Diseases, (Washington, DC: PhRMA, January 2007), www.phrma.org/files/Orphan%202007.pdf (accessed 6 February 2009).

[10] Pharmaceutical Research and Manufacturers of America, Medicines in Development for Cancer, (Washington, DC: PhRMA, April 2008), www.phrma.org/files/meds_in_dev/Cancer2008.pdf (accessed 6 February 2009).

[11] Pharmaceutical Research and Manufacturers of America, Medicines in Development for Heart Disease and Stroke, (Washington, DC: PhRMA, May 2007), www.phrma.org/files/Heart%202007.pdf (accessed 6 February 2009).

[12] Pharmaceutical Research and Manufacturers of America, Medicines in Development for HIV/AIDS, (Washington, DC: PhRMA, December 2008), www.phrma.org/files/New%20Meds%20for%20HIV-AIDS%20report.pdf (accessed 6 February 2009).

[13] Tufts Center for the Study of Drug Development, "New Drugs Entering Clinical Testing in Top 10 Firms Jumped 52% in 2003-2005," *Impact Report* 8, no. 3 (May/June 2006).

[14] A. Gardner, "Cancer Medicine Advances on Many Fronts," *HealthDay News,* 23 December 2008.

[15] J. A. DiMasi, "Measuring Trends in the Development of New Drugs: Time, Costs, Risks and Returns," presentation to the SLA Pharmaceutical & Health Technology Division Spring Meeting (Boston, MA), 2007; Tufts Center for the Study of Drug Development, "Growing Protocol Design Complexity Stresses Investigators, Volunteers," *Impact Report* 10, no. 1 (January/February 2008).

[16] Congressional Budget Office, *op. cit.*

[17] J. A. DiMasi, and H. G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics* 28 (2007): 469-479.

[18] Tufts Center for the Study of Drug Development, "Cost to Develop New Biotech Products is Estimated to Average $1.2 Billion," *Impact Report* 8, no. 6 (November/December 2006).

[19] Congressional Budget Office, *op. cit.*

[20] J. Vernon, J. Golec, and J. A. DiMasi, "Drug Development Costs When Financial Risk Is Measured Using the Fama-French Three Factor Model," unpublished working paper, January 2008.

[21] J. A. DiMasi and C. Paquette, "The Economics of Follow-on Drug Research and Development: Trends in Entry Rates and the Timing of Development," *Journal of PharmacoEconomics* 22, no. 2 (2004): 1-14.

[22] National Prescription Audit PLUS. Norwalk, CT: IMS Health.

[23] H. G. Grabowski and M. Kyle, "Generic Competition and Market Exclusivity Periods in Pharmaceuticals," *Managerial and Decision Economics* 28 (2007): 491–502. Note: Average time before generic competition for pharmaceuticals with annual sales in 2005 of more than $100 million (based on sample of 147 NMEs experiencing first generic entry between 1995 and 2005).

[24] E. Berndt, *et al.,* "Do Authorized Generic Drugs Deter Paragraph IV Certifications?" working paper, 17 April 2007, www.analysisgroup/uploadedFiles/Publishing/Articles/PhRMA_Authorized_Generic_Entry.pdf (accessed 17 March 2009).

# CONCLUSION

## POLICIES THAT SUPPORT RESEARCH PROMOTE VALUE FOR AMERICANS

Biopharmaceutical research has never held more potential, as researchers combine knowledge of the human genome with growing molecular understanding of disease to move toward more powerful and precise treatments. In recent years, we have seen great progress in reducing cardiovascular and cancer death rates, managing chronic diseases, and reducing disability in seniors.

Such progress holds enormous promise for patients, as well as the economy. It is a tool for containing health care costs by preventing complications of disease and extending productive years of life.

Yet innovation, even with an expanding knowledge base, is not automatic. Recent pharmaceutical advances — driven by scientific research and creative genius — would have been impossible without a system of laws that provide the structure and stability needed to attract the investment that helps turn an idea into a medical advance.

Realizing the opportunities for medical advances being created by expanding scientific knowledge, it is critical to recognize that innovation requires a supportive public policy environment. This includes intellectual property incentives, market-based valuation of products, and a biopharmaceutical approval process for today's research landscape.

With smart policies that foster medical research and advances, the opportunities to create new value for Americans are endless.

# Appendix

# MEMBER COMPANIES

## MEMBERS

**Abbott**
*Abbott Park, IL*

**Amgen Inc.**
*Thousand Oaks, CA*

**Amylin Pharmaceuticals, Inc.**
*San Diego, CA*

**Astellas Pharma US, Inc.**
*Deerfield, IL*

**AstraZeneca Pharmaceuticals LP**
*Wilmington, DE*

**Bayer HealthCare Pharmaceuticals**
*West Haven, CT*

**Boehringer Ingelheim Pharmaceuticals, Inc.**
*Ridgefield, CT*

**Bristol-Myers Squibb Company**
*New York, NY*
Bristol-Myers Squibb Company Worldwide Medicines Group

**Celgene Corporation**
*Summit, NJ*

**Daiichi Sankyo, Inc.**
*Montvale, NJ*

**Eisai Inc.**
*Woodcliff Lake, NJ*

**EMD Serono**
*Rockland, MA*

**Endo Pharmaceuticals Inc.**
*Chadds Ford, PA*

**Genzyme Corporation**
*Cambridge, MA*

**GlaxoSmithKline**
*Research Triangle Park, NC*

**Hoffmann-La Roche Inc.**
*Nutley, NJ*

**Johnson & Johnson**
*New Brunswick, NJ*

**Eli Lilly and Company**
*Indianapolis, IN*

**Lundbeck, Inc.**
*Deerfield, IL*

**Merck & Co., Inc.**
*Whitehouse Station, NJ*
Merck Human Health Division
Merck Research Laboratories
Merck Vaccine Division

**Novartis Pharmaceuticals Corporation**
*East Hanover, NJ*

**Otsuka America, Inc. (OAI)**
*San Francisco, CA*
Otsuka America Pharmaceutical, Inc. (OAPI)
Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC)
Otsuka Maryland Medicinal Laboratories (OMML)

**Pfizer Inc**
*New York, NY*

**Purdue Pharma L.P.**
*Stamford, CT*
The P.F. Laboratories, Inc.

**sanofi-aventis U.S.**
*Bridgewater, NJ*
sanofi pasteur
sanofi-aventis

**Schering-Plough Corporation**
*Kenilworth, NJ*

**Sigma-Tau Pharmaceuticals, Inc.**
*Gaithersburg, MD*

**Takeda Pharmaceuticals North America, Inc.**
*Deerfield, IL*

**Wyeth**
*Madison, NJ*
Wyeth Pharmaceuticals
Wyeth Research

## PHARMACEUTICAL AFFILIATES

*(none at this time)*

## INTERNATIONAL AFFILIATES

**Novo Nordisk, Inc.**
*Princeton, NJ*

## RESEARCH ASSOCIATES

**Alkermes, Inc.**
*Cambridge, MA*

**Enzon, Inc.**
*Piscataway, NJ*

**Inspire Pharmaceuticals, Inc.**
*Durham, NC*

**Theravance, Inc.**
*South San Francisco, CA*

## CONTRACT RESEARCH ORGANIZATION ASSOCIATE (CRO)

**Quintiles Transnational Corp.**
*Research Triangle Park, NC*

## ADVERTISING & COMMUNICATION SERVICES ASSOCIATES

**HealthSTAR Communications, Inc.**
*Woodbridge, NJ*
- HealthSTAR Advertising
- HealthSTAR Public Relations
- Photosound Communications

**IMS Health**
*Plymouth Meeting, PA*

**PDI, Inc.**
*Upper Saddle River, NJ*

**Publicis Healthcare Communications Group**
*New York, NY*

**Thomson Healthcare**
*Montvale, NJ*

## CONSULTANTS & DRUG DISCOVERY SOFTWARE FIRMS ASSOCIATE

**Accenture LLP**
*Philadelphia, PA*

**Aptuit, Inc.**
*Greenwich, CT*

**Cegedim Dendrite**
*Bedminster, NJ*

**Cytel Inc.**
*Cambridge, MA*

**Ernst & Young**
*New York, NY*

# PhRMA ANNUAL MEMBERSHIP SURVEY DEFINITIONS OF TERMS

## Research and Development Expenditure Definitions

**R&D Expenditures:** Expenditures within PhRMA member companies' U.S. and/or foreign research laboratories plus research and development (R&D) funds contracted or granted to commercial laboratories, private practitioners, consultants, educational and nonprofit research institutions, manufacturing and other companies, or other research-performing organizations. Includes basic and applied research, as well as developmental activities carried on or supported in the pharmaceutical, biological, chemical, medical, and related sciences, including psychology and psychiatry, if the purpose of such activities is concerned ultimately with the utilization of scientific principles in understanding diseases or in improving health. Includes the total cost incurred for all pharmaceutical R&D activities, including salaries, materials, supplies used, and a fair share of overhead, as well as the cost of developing quality control. However, it does not include the cost of routine quality control activities, capital expenditures, or any costs incurred for drug or medical R&D conducted under a grant or contract for other companies or organizations.

**Domestic R&D:** Expenditures within the United States by all PhRMA member companies.

- **Licensed-in:** Products for which a license is held for a compound.
- **Self-originated:** Products for which the company originates the compound.

**R&D Abroad:** Expenditures outside the United States by U.S.-owned PhRMA member companies and R&D conducted abroad by the U.S. divisions of foreign-owned PhRMA member companies. R&D performed abroad by the foreign divisions of foreign-owned PhRMA member companies is excluded.

**Prehuman/Preclinical Testing:** From synthesis to first testing in humans.

**Phase 1/2/3 Clinical Testing:** From first testing in designated phase to first testing in subsequent phase.

**Approval Phase:** From New Drug Application (NDA) submission to NDA approval.

**Phase 4 Clinical Testing:** Any post-marketing testing performed.

**Uncategorized:** Represents data for which detailed classifications were unavailable.

## Sales Definitions

**Sales:** Product sales calculated as billed, free on board (FOB) plant or warehouse less cash discounts, Medicaid rebates, returns, and allowances. These include all marketing expenses except transportation costs. Also included is the sales value of products bought and resold without further processing or repackaging, as well as the dollar value of products made from the firm's own materials for other manufacturers' resale. Excluded are all royalty payments, interest, and other income.

**Domestic Sales:** Sales generated within the United States by all PhRMA member companies.

- **Private Sector:** Sales through regular marketing channels for end-use other than by government agency administration or distribution.
- **Public Sector:** Sales or shipments made directly to federal, state, or local government agencies, hospitals, and clinics.

**Sales Abroad:** Sales generated outside the United States by U.S.-owned PhRMA member companies, and sales generated abroad by the U.S. divisions of foreign-owned PhRMA member companies. Sales generated abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded.

- **Exports to Other Customers:** Sales to third parties only, FOB U.S. port. Excludes all intrafirm transactions, such as sales or shipments to subsidiaries or affiliates.
- **Foreign Sales:** Sales consummated in foreign countries.

## R&D Employment Definitions

**Scientific, Professional, and Technical Staff:** Full-time employees, as well as full-time equivalents for part-time employees, whose work requires the application of R&D knowledge, skills, and scientific techniques in the life, physical, engineering, mathematical, or statistical sciences, as well as persons engaged in technical work at a level that requires knowledge in one of the above-mentioned fields. Does not include persons who have formal training in the sciences but who are not actively engaged in R&D.

**Supported Scientific, Professional, and Technical Nonstaff:** Persons whose work requires the application of R&D knowledge, skills, and scientific techniques in the life, physical, engineering, mathematical, or statistical sciences, as well as persons engaged in technical work at a level that requires knowledge in one of the above-mentioned fields who are supported through contracts or grants to commercial laboratories, private practitioners, consultants, educational and nonprofit research institutions, manufacturing and other companies, or other research-performing organizations located in the United States. Does not include persons who have formal training in the sciences but who are not actively engaged in R&D.

# LIST OF TABLES

## Detailed Results from the PhRMA Annual Membership Survey

### R&D, PhRMA Member Companies



### Sales, PhRMA Member Companies



### R&D Employment, PhRMA Member Companies

## TABLE 1

### Domestic R&D and R&D Abroad,* PhRMA Member Companies: 1970–2008

(dollar figures in millions)

| Year | Domestic R&D | Annual Percentage Change | R&D Abroad* | Annual Percentage Change | Total R&D | Annual Percentage Change |
|---|---|---|---|---|---|---|
| 2008** | $38,427.8 | 5.0% | $11,825.7 | 4.7% | $50,253.6 | 4.9% |
| 2007 | 36,608.4 | 7.8 | 11,294.8 | 25.4 | 47,903.1 | 11.5 |
| 2006 | 33,967.9 | 9.7 | 9,005.6 | 1.3 | 42,973.5 | 7.8 |
| 2005 | 30,969.0 | 4.8 | 8,888.9 | 19.1 | 39,857.9 | 7.7 |
| 2004 | 29,555.5 | 9.2 | 7,462.6 | 1.0 | 37,018.1 | 7.4 |
| 2003 | 27,064.9 | 5.5 | 7,388.4 | 37.9 | 34,453.3 | 11.1 |
| 2002 | 25,655.1 | 9.2 | 5,357.2 | -13.9 | 31,012.2 | 4.2 |
| 2001 | 23,502.0 | 10.0 | 6,220.6 | 33.3 | 29,772.7 | 14.4 |
| 2000 | 21,363.7 | 15.7 | 4,667.1 | 10.6 | 26,030.8 | 14.7 |
| 1999 | 18,471.1 | 7.4 | 4,219.6 | 9.9 | 22,690.7 | 8.2 |
| 1998 | 17,127.9 | 11.0 | 3,839.0 | 9.9 | 20,966.9 | 10.8 |
| 1997 | 15,466.0 | 13.9 | 3,492.1 | 6.5 | 18,958.1 | 12.4 |
| 1996 | 13,627.1 | 14.8 | 3,278.5 | -1.6 | 16,905.6 | 11.2 |
| 1995 | 11,874.0 | 7.0 | 3,333.5 | *** | 15,207.4 | *** |
| 1994 | 11,101.6 | 6.0 | 2,347.8 | 3.8 | 13,449.4 | 5.6 |
| 1993 | 10,477.1 | 12.5 | 2,262.9 | 5.0 | 12,740.0 | 11.1 |
| 1992 | 9,312.1 | 17.4 | 2,155.8 | 21.3 | 11,467.9 | 18.2 |
| 1991 | 7,928.6 | 16.5 | 1,776.8 | 9.9 | 9,705.4 | 15.3 |
| 1990 | 6,802.9 | 13.0 | 1,617.4 | 23.6 | 8,420.3 | 14.9 |
| 1989 | 6,021.4 | 15.0 | 1,308.6 | 0.4 | 7,330.0 | 12.1 |
| 1988 | 5,233.9 | 16.2 | 1,303.6 | 30.6 | 6,537.5 | 18.8 |
| 1987 | 4,504.1 | 16.2 | 998.1 | 15.4 | 5,502.2 | 16.1 |
| 1986 | 3,875.0 | 14.7 | 865.1 | 23.8 | 4,740.1 | 16.2 |
| 1985 | 3,378.7 | 13.3 | 698.9 | 17.2 | 4,077.6 | 13.9 |
| 1984 | 2,982.4 | 11.6 | 596.4 | 9.2 | 3,578.8 | 11.2 |
| 1983 | 2,671.3 | 17.7 | 546.3 | 8.2 | 3,217.6 | 16.0 |
| 1982 | 2,268.7 | 21.3 | 505.0 | 7.7 | 2,773.7 | 18.6 |
| 1981 | 1,870.4 | 20.7 | 469.1 | 9.7 | 2,339.5 | 18.4 |
| 1980 | 1,549.2 | 16.7 | 427.5 | 42.8 | 1,976.7 | 21.5 |
| 1979 | 1,327.4 | 13.8 | 299.4 | 25.9 | 1,626.8 | 15.9 |
| 1978 | 1,166.1 | 9.7 | 237.9 | 11.6 | 1,404.0 | 10.0 |
| 1977 | 1,063.0 | 8.1 | 213.1 | 18.2 | 1,276.1 | 9.7 |
| 1976 | 983.4 | 8.8 | 180.3 | 14.1 | 1,163.7 | 9.6 |
| 1975 | 903.5 | 13.9 | 158.0 | 7.0 | 1,061.5 | 12.8 |
| 1974 | 793.1 | 12.0 | 147.7 | 26.3 | 940.8 | 14.0 |
| 1973 | 708.1 | 8.1 | 116.9 | 64.0 | 825.0 | 13.6 |
| 1972 | 654.8 | 4.5 | 71.3 | 24.9 | 726.1 | 6.2 |
| 1971 | 626.7 | 10.7 | 57.1 | 9.2 | 683.8 | 10.6 |
| 1970 | 566.2 | ------ | 52.3 | ------ | 618.5 | ------ |
| **Average** | | **11.8%** | | **15.5%** | | **12.3%** |

*R&D Abroad includes expenditures outside the United States by U.S.-owned PhRMA member companies and R&D conducted abroad by the U.S. divisions of foreign-owned PhRMA member companies. R&D performed abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded. Domestic R&D, however, includes R&D expenditures within the United States by all PhRMA member companies.

**Estimated.

***R&D Abroad affected by merger and acquisition activity.

Note: All figures include company-financed R&D only. Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 2

## R&D as a Percentage of Sales, PhRMA Member Companies: 1970–2008

| Year | Domestic R&D as a Percentage of Domestic Sales | Total R&D as a Percentage of Total Sales |
|---|---|---|
| 2008* | 20.3% | 17.4% |
| 2007 | 19.8 | 17.5 |
| 2006 | 19.4 | 17.1 |
| 2005 | 18.6 | 16.9 |
| 2004 | 18.4 | 16.1** |
| 2003 | 18.3 | 16.5** |
| 2002 | 18.4 | 16.1 |
| 2001 | 18.0 | 16.7 |
| 2000 | 18.4 | 16.2 |
| 1999 | 18.2 | 15.5 |
| 1998 | 21.1 | 16.8 |
| 1997 | 21.6 | 17.1 |
| 1996 | 21.0 | 16.6 |
| 1995 | 20.8 | 16.7 |
| 1994 | 21.9 | 17.3 |
| 1993 | 21.6 | 17.0 |
| 1992 | 19.4 | 15.5 |
| 1991 | 17.9 | 14.6 |
| 1990 | 17.7 | 14.4 |
| 1989 | 18.4 | 14.8 |
| 1988 | 18.3 | 14.1 |
| 1987 | 17.4 | 13.4 |
| 1986 | 16.4 | 12.9 |
| 1985 | 16.3 | 12.9 |
| 1984 | 15.7 | 12.1 |
| 1983 | 15.9 | 11.8 |
| 1982 | 15.4 | 10.9 |
| 1981 | 14.8 | 10.0 |
| 1980 | 13.1 | 8.9 |
| 1979 | 12.5 | 8.6 |
| 1978 | 12.2 | 8.5 |
| 1977 | 12.4 | 9.0 |
| 1976 | 12.4 | 8.9 |
| 1975 | 12.7 | 9.0 |
| 1974 | 11.8 | 9.1 |
| 1973 | 12.5 | 9.3 |
| 1972 | 12.6 | 9.2 |
| 1971 | 12.2 | 9.0 |
| 1970 | 12.4 | 9.3 |

*Estimated.

**Revised in 2007 to reflect updated data.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 3

## Domestic R&D and R&D Abroad,* PhRMA Member Companies: 2007

(dollar figures in millions)

| | Dollars | Share |
|---|---|---|
| **R&D Expenditures for Human-use Pharmaceuticals** | | |
| Domestic | $ 36,178.3 | 75.5% |
| Abroad* | $ 11,006.4 | 23.0% |
| **Total Human-use R&D** | **$ 47,184.7** | **98.5%** |
| **R&D Expenditures for Veterinary-use Pharmaceuticals** | | |
| Domestic | $ 430.0 | 0.9% |
| Abroad* | $ 288.4 | 0.6% |
| **Total Vet-use R&D** | **$ 718.4** | **1.5%** |
| **TOTAL R&D** | **$ 47,903.1** | **100.0%** |

*R&D abroad includes expenditures outside the United States by U.S.-owned PhRMA member companies and R&D conducted abroad by the U.S. divisions of foreign-owned PhRMA member companies. R&D performed abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded. Domestic R&D, however, includes R&D expenditures within the United States by all PhRMA member companies.

Note: All figures include company-financed R&D only. Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 4

## Domestic R&D by Source, PhRMA Member Companies: 2007

(dollar figures in millions)

| Type | Dollars | Share |
|---|---|---|
| Licensed-in | $ 6,294.2 | 17.2% |
| Self-originated | 27,126.9 | 74.1 |
| Uncategorized | 3,187.3 | 8.7 |
| **TOTAL R&D** | **$36,608.4** | **100.0%** |

Note: All figures include company-financed R&D only. Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 5

## R&D by Function, PhRMA Member Companies: 2007

(dollar figures in millions)

| Function | Dollars | Share |
|---|---|---|
| Prehuman/Preclinical | $ 13,087.4 | 27.3% |
| Phase 1 | 3,547.7 | 7.4 |
| Phase 2 | 6,251.0 | 13.0 |
| Phase 3 | 13,664.7 | 28.5 |
| Approval | 2,413.8 | 5.0 |
| Phase 4 | 6,439.9 | 13.4 |
| Uncategorized | 2,498.6 | 5.2 |
| **TOTAL R&D** | **$ 47,903.1** | **100.0%** |

Note: All figures include company-financed R&D only. Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 6

## R&D by Geographic Area,* PhRMA Member Companies: 2007

(dollar figures in millions)

| Geographic Area* | Dollars | Share |
|---|---|---|
| **Africa** | | |
| Africa | $ 28.6 | 0.1% |
| **Americas** | | |
| United States | $36,608.4 | 76.4% |
| Canada | 612.4 | 1.3 |
| Mexico | 63.0 | 0.1 |
| Brazil | 81.2 | 0.2 |
| Other Latin America (Other South American, Central American, and all Caribbean nations) | 217.9 | 0.5% |
| **Asia-Pacific** | | |
| Japan | $ 954.2 | 2.0% |
| China | 62.9 | 0.1 |
| India | 33.3 | 0.1 |
| Other Asia-Pacific | 191.8 | 0.4 |
| **Australia** | | |
| Australia and New Zealand | $ 161.0 | 0.3% |
| **Europe** | | |
| France | $ 521.8 | 1.1% |
| Germany | 714.7 | 1.5 |
| Italy | 240.1 | 0.5 |
| Spain | 235.5 | 0.5 |
| United Kingdom | 2,892.9 | 6.0 |
| Other Western European | 3,568.6 | 7.4 |
| Turkey | 39.0 | 0.1 |
| Russia | 40.1 | 0.1 |
| Central and Eastern Europe (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, Malta and the Newly Independent States) | 481.8 | 1.0 |
| **Middle East** | | |
| Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan and Qatar) | $ 29.7 | 0.1% |
| **Uncategorized** | $ 124.2 | 0.3% |
| **TOTAL R&D** | **$ 47,903.1** | **100.0%** |

*R&D abroad includes expenditures outside the United States by U.S.-owned PhRMA member companies and R&D conducted abroad by the U.S. divisions of foreign-owned PhRMA member companies. R&D performed abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded. Domestic R&D, however, includes R&D expenditures within the United States by all PhRMA member companies.

Note: All figures include company-financed R&D only. Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 7

## Biologics and Biotechnology R&D, PhRMA Member Companies: 2007

(dollar figures in millions)

| Type | Dollars | Share |
|---|---|---|
| Biotechnology-derived Therapeutic Proteins | $10,075.7 | 21.0% |
| Vaccines | 1,159.9 | 2.4 |
| Cell or Gene Therapy | 95.3 | 0.2 |
| All Other Biologics | 796.5 | 1.7 |
| **Total Biologics/Biotechnology R&D** | **12,127.4** | **25.3** |
| **Non-biologics/Biotechnology R&D** | **32,178.3** | **67.2** |
| Uncategorized R&D | 3,597.4 | 7.5 |
| **TOTAL R&D** | **$ 47,903.1** | **100.0%** |

Note: All figures include company-financed R&D only. Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

## TABLE 8

### Domestic Sales and Sales Abroad,* PhRMA Member Companies: 1970–2008

(dollar figures in millions)

| Year | Domestic Sales | Annual Percentage Change | Sales Abroad* | Annual Percentage Change | Total Sales | Annual Percentage Change |
|---|---|---|---|---|---|---|
| 2008** | $189,260.5 | 2.2% | $99,025.0 | 12.3% | $288,285.5 | 5.4% |
| 2007 | 185,209.2 | 4.2 | 88,213.4 | 14.8 | 273,422.6 | 7.4 |
| 2006 | 177,736.3 | 7.0 | 76,870.2 | 10.0 | 254,606.4 | 7.9 |
| 2005 | 166,155.5 | 3.4 | 69,881.0 | 0.1 | 236,036.5 | 2.4 |
| 2004*** | 160,751.0 | 8.6 | 69,806.9 | 14.6 | 230,557.9 | 10.3 |
| 2003*** | 148,038.6 | 6.4 | 60,914.4 | 13.4 | 208,953.0 | 8.4 |
| 2002 | 139,136.4 | 6.4 | 53,697.4 | 12.1 | 192,833.8 | 8.0 |
| 2001 | 130,715.9 | 12.8 | 47,886.9 | 5.9 | 178,602.8 | 10.9 |
| 2000 | 115,881.8 | 14.2 | 45,199.5 | 1.6 | 161,081.3 | 10.4 |
| 1999 | 101,461.8 | 24.8 | 44,496.6 | 2.7 | 145,958.4 | 17.1 |
| 1998 | 81,289.2 | 13.3 | 43,320.1 | 10.8 | 124,609.4 | 12.4 |
| 1997 | 71,761.9 | 10.8 | 39,086.2 | 6.1 | 110,848.1 | 9.1 |
| 1996 | 64,741.4 | 13.3 | 36,838.7 | 8.7 | 101,580.1 | 11.6 |
| 1995 | 57,145.5 | 12.6 | 33,893.5 | **** | 91,039.0 | **** |
| 1994 | 50,740.4 | 4.4 | 26,870.7 | 1.5 | 77,611.1 | 3.4 |
| 1993 | 48,590.9 | 1.0 | 26,467.3 | 2.8 | 75,058.2 | 1.7 |
| 1992 | 48,095.5 | 8.6 | 25,744.2 | 15.8 | 73,839.7 | 11.0 |
| 1991 | 44,304.5 | 15.1 | 22,231.1 | 12.1 | 66,535.6 | 14.1 |
| 1990 | 38,486.7 | 17.7 | 19,838.3 | 18.0 | 58,325.0 | 17.8 |
| 1989 | 32,706.6 | 14.4 | 16,817.9 | -4.7 | 49,524.5 | 7.1 |
| 1988 | 28,582.6 | 10.4 | 17,649.3 | 17.1 | 46,231.9 | 12.9 |
| 1987 | 25,879.1 | 9.4 | 15,068.4 | 15.6 | 40,947.5 | 11.6 |
| 1986 | 23,658.8 | 14.1 | 13,030.5 | 19.9 | 36,689.3 | 16.1 |
| 1985 | 20,742.5 | 9.0 | 10,872.3 | 4.0 | 31,614.8 | 7.3 |
| 1984 | 19,026.1 | 13.2 | 10,450.9 | 0.4 | 29,477.0 | 8.3 |
| 1983 | 16,805.0 | 14.0 | 10,411.2 | -2.4 | 27,216.2 | 7.1 |
| 1982 | 14,743.9 | 16.4 | 10,667.4 | 0.1 | 25,411.3 | 9.0 |
| 1981 | 12,665.0 | 7.4 | 10,658.3 | 1.4 | 23,323.3 | 4.6 |
| 1980 | 11,788.6 | 10.7 | 10,515.4 | 26.9 | 22,304.0 | 17.8 |
| 1979 | 10,651.3 | 11.2 | 8,287.8 | 21.0 | 18,939.1 | 15.3 |
| 1978 | 9,580.5 | 12.0 | 6,850.4 | 22.2 | 16,430.9 | 16.1 |
| 1977 | 8,550.4 | 7.5 | 5,605.0 | 10.2 | 14,155.4 | 8.6 |
| 1976 | 7,951.0 | 11.4 | 5,084.3 | 9.7 | 13,035.3 | 10.8 |
| 1975 | 7,135.7 | 10.3 | 4,633.3 | 19.1 | 11,769.0 | 13.6 |
| 1974 | 6,740.4 | 13.8 | 3,891.0 | 23.4 | 10,361.4 | 17.2 |
| 1973 | 5,686.5 | 9.1 | 3,152.5 | 15.9 | 8,839.0 | 11.5 |
| 1972 | 5,210.1 | 1.3 | 2,720.2 | 10.6 | 7,930.3 | 4.3 |
| 1971 | 5,144.9 | 13.0 | 2,459.7 | 18.0 | 7,604.6 | 14.6 |
| 1970 | 4,552.5 | ------ | 2,084.0 | ------ | 6,636.5 | ------ |
| **Average** | | **10.4%** | | **10.6%** | | **10.4%** |

*Sales Abroad includes sales generated outside the United States by U.S.-owned PhRMA member companies and sales generated abroad by the U.S. divisions of foreign-owned PhRMA member companies. Sales generated abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded. Domestic sales, however, includes sales generated within the United States by all PhRMA member companies.

**Estimated.

***Revised in 2007 to reflect updated data.

****Sales Abroad affected by merger and acquisition activity.

Note: Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

TABLE 9

## Sales by Geographic Area,* PhRMA Member Companies: 2007

(dollar figures in millions)

| Geographic Area* | Dollars | Share |
|---|---|---|
| **Africa** | | |
| Africa | $ 1,246.6 | 0.5% |
| **Americas** | | |
| United States | $185,209.2 | 67.7% |
| Canada | 6,693.0 | 2.4 |
| Mexico | 2,987.1 | 1.1 |
| Brazil | 2,438.7 | 0.9 |
| Latin America (Other South American, Central American, and all Caribbean nations) | 3,463.6 | 1.3% |
| **Asia-Pacific** | | |
| Japan | $ 9,089.4 | 3.3% |
| China | 1,586.0 | 0.6 |
| India | 589.4 | 0.2 |
| Other Asia-Pacific | 4,348.6 | 1.6 |
| **Australia** | | |
| Australia and New Zealand | $ 3,284.2 | 1.2% |
| **Europe** | | |
| France | $ 8,923.3 | 3.3% |
| Germany | 6,774.4 | 2.5 |
| Italy | 6,206.6 | 2.3 |
| Spain | 5,567.0 | 2.0 |
| United Kingdom | 5,607.4 | 2.1 |
| Other Western European | 10,584.7 | 3.9 |
| Turkey | 1,449.6 | 0.5 |
| Russia | 925.2 | 0.3 |
| Central and Eastern Europe (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, Malta and the Newly Independent States) | 3,755.5 | 1.4 |
| **Middle East** | | |
| Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan and Qatar) | $ 1,643.7 | 0.6% |
| **Uncategorized** | $ 1,049.6 | 0.4% |
| **TOTAL SALES** | **$273,422.6** | **100.0%** |

*Sales Abroad includes expenditures outside the United States by U.S.-owned PhRMA member companies and sales generated abroad by the U.S. divisions of foreign-owned PhRMA member companies. Sales generated abroad by the foreign divisions of foreign-owned PhRMA member companies are excluded. Domestic sales, however, includes sales generated within the United States by all PhRMA member companies.

Note: Total values may be affected by rounding.

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey,* 2009.

TABLE 10

## Domestic R&D Scientific, Professional and Technical Personnel by Function, PhRMA Member Companies: 2007

| Function | Personnel | Share |
|---|---|---|
| Prehuman/Preclinical | 30,023 | 31.1% |
| Phase 1 | 6,117 | 6.3 |
| Phase 2 | 10,098 | 10.5 |
| Phase 3 | 18,579 | 19.3 |
| Approval | 4,108 | 4.3 |
| Phase 4 | 13,332 | 13.8 |
| Uncategorized | 3,613 | 3.7 |
| **Total R&D Staff** | **85,870** | **89.0** |
| Supported R&D Non-staff | 10,616 | 11.0 |
| **TOTAL R&D PERSONNEL** | **96,486** | **100.0%** |

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2009.

## ENDNOTES *(continued from inside front cover)*


[1] J. A. DiMasi, "New Drug Development in U.S. 1963–1999," *Clinical Pharmacology & Therapeutics* 69, no. 5 (2001): 286–296; M. Dickson and J. P. Gagnon, "Key Factors in the Rising Cost of New Drug Discovery and Development," *Nature Reviews Drug Discovery* 3 (May 2004): 417–429; 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.

[2] J. A. DiMasi and H. G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics* 28 (2007): 469–479.

[3] J. A. DiMasi, R. W. Hansen, and H. G. Grabowski, *op. cit.*

[4] Tufts Center for the Study of Drug Development, "Average Cost to Develop a New Biotechnology Product Is $1.2 Billion, According to the Tufts Center for the Study of Drug Development," news release, 9 November 2006, http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=69 (accessed 9 January 2007).

[5] Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 1980–2009).

[6] Burrill & Company, analysis for PhRMA, 2005–2009, includes PhRMA research associates and nonmembers; Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 2005–2009).

[7] Pharmaceutical Research and Manufacturers of America, *op. cit.*

[8] L. R. Burns, The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels (Washington, DC: Archstone Consulting, LLC, March 2009).

[9] "New Molecular Entities Approved in 2008," *The Pink Sheet* 71, no. 2 (12 January 2009): 8–10.

[10] U.S. Food and Drug Administration, "List of Orphan Designations and Approvals," 16 May 2008, www.fda.gov/orphan/designat/allap.rtf (accessed 13 February 2009).

[11] Adis R&D Insight Database, Wolters Kluwer Health, accessed 13 February 2009.

[12] Adis R&D Insight Database, Wolters Kluwer Health, Customized Run, December 2007.

[13] E. Sun, *et al.,* "The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology, and End Results (SEER) Database," *Journal of Clinical Oncology* 26, suppl. 15 (2008): Abstract 6616.

[14] F. Lichtenberg, "The Expanding Pharmaceutical Arsenal in the War on Cancer," National Bureau of Economic Research Working Paper 10328, February 2004.

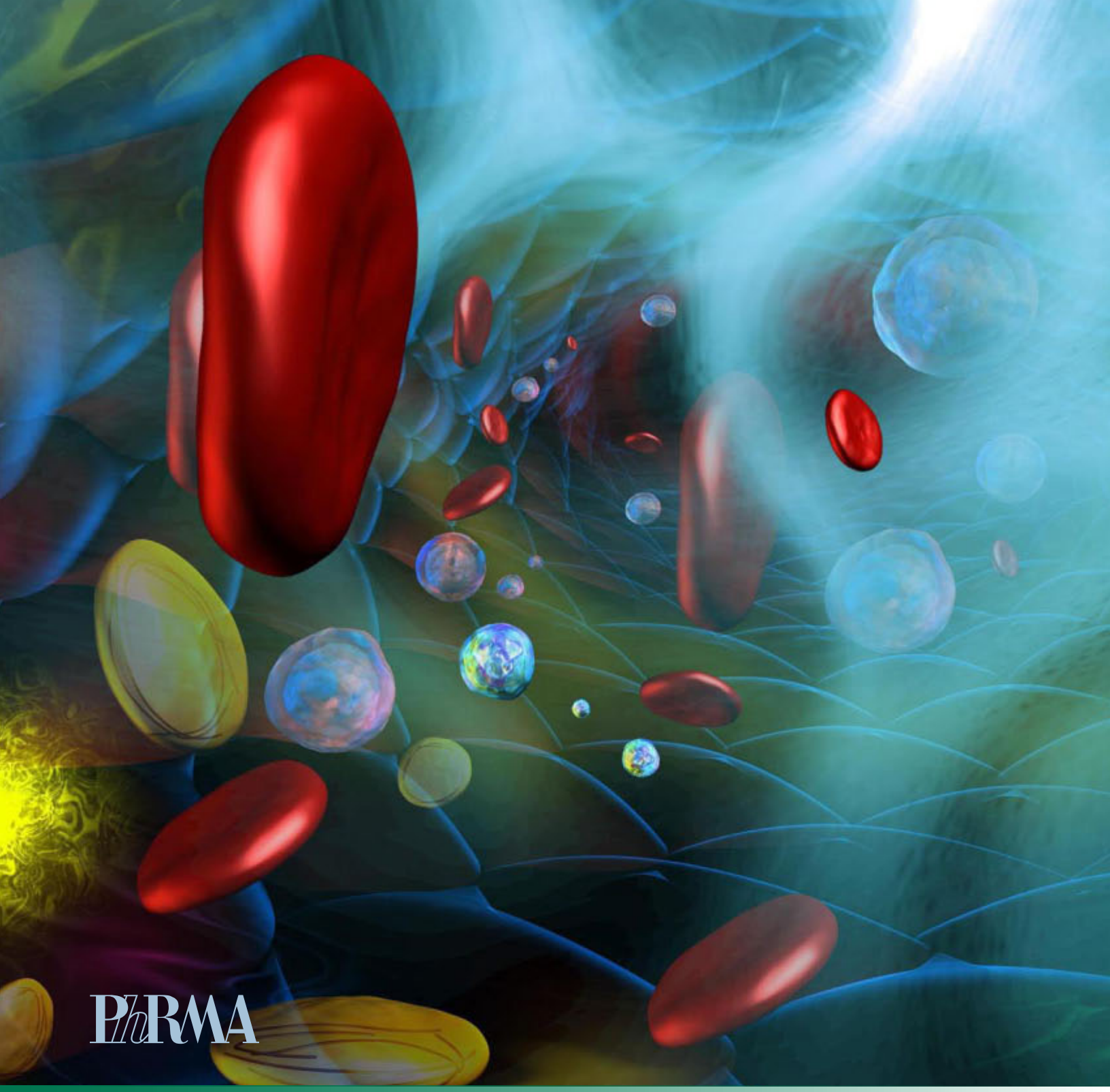
[15] D. Lloyd-Jones, *et al.,* "Heart Disease and Stroke Statistics 2009 Update. A Report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee," *Circulation* 119 (2009): e21–e181.

[16] American Heart Association, "Heart and Stroke Death Rates Down, Some Risk Factors Still Too High," news release, 15 December 2008, http://americanheart.mediaroom.com/index.php?s=43&item=626 (accessed 22 January 2009).

[17] U.S. Department of Health and Human Services, U.S. Centers for Disease Control and Prevention, National Center for Health Statistics, Health, United States, 2006 with Chartbook on Trends in the Health of Americans (Hyattsville, MD: HHS, November 2006).

[18] IMS Health, National Sales Perspectives, National Prescription Audit, March 2009.

[19] J. Vernon, J. Golec, and J. A. DiMasi, "Drug Development Costs when Financial Risk is Measured Using the Fama-French Three Factor Model," unpublished working paper, January 2008.



PhRMA

PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA

950 F STREET, NW
WASHINGTON, DC 20004

www.phrma.org | www.innovation.org