profile

PHARMACEUTICAL INDUSTRY

2010

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
  2005 = $1.3 billion[2]
  2001 = $802 million[3]
  1987 = $318 million[3]
  1975 = $138 million[3]
- Cost to develop a biologic
  2005 = $1.2 billion[4]

R&D Spending

Year	PhRMA members[5]	Total industry[6]
2009	$45.8 billion *(est.)*	$65.3 billion *(est.)*
2008	$47.4 billion	$63.7 billion
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 2009[7]

Domestic R&D
As a percentage of domestic sales = 19.0%

Total R&D
As a percentage of total sales = 16.0%

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 2009 = 34[9]
- In the 27 years since the *Orphan Drug Act* was established, nearly 350 orphan drugs have been approved.[10]
- Only 2 of 10 marketed drugs return revenues that match or exceed R&D costs.[11]

Medicines in Development

2010 = 2,950 compounds[12]

1999 = 1,800 compounds[13]

Value of Medicines

- **Cancer:** Since 1980, life expectancy for cancer patients has increased about **3 years,** and 83% of those gains are attributable to new treatments, including medicines.[14] Another study found that medicines specifically account for 50% to 60% of increases in survival rates since 1975.[15]
- **Cardiovascular Disease:** According to the American Heart Association (AHA), death rates for cardiovascular disease fell a dramatic **26.4%** between 1999 and 2005.[16] The AHA lists better control of high blood pressure and high cholesterol, and reduced tobacco use, as factors in the improvement.[17]
- **HIV/AIDS:** Since new medicines were approved in 1995, the AIDS death rate has dropped **more than 70%.**[18] Between 2006 and 2007 the death rate fell 10% – the largest single-year decline since 1998.[19]

Sales

- Generic share of market[20]
  2000 = 49%
  2009 = 74%

See inside back cover for endnotes.

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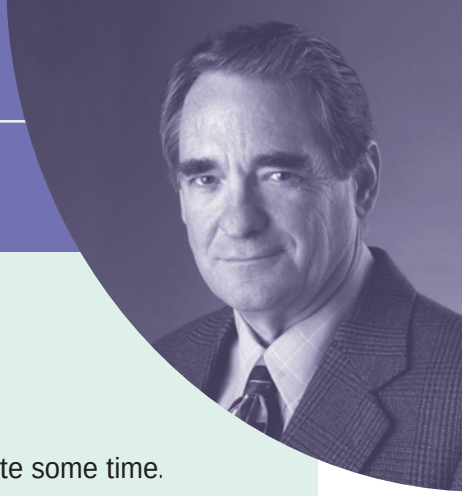


Letter from PhRMA's President and CEO

The past year was one of the most challenging our country has faced in quite some time. We were left shaken by an uncertain economy and all the trials that came along with it. Biopharmaceutical research companies were hit by some of the same economic challenges as other businesses in the U.S. and some had to make tough decisions in order to adapt.

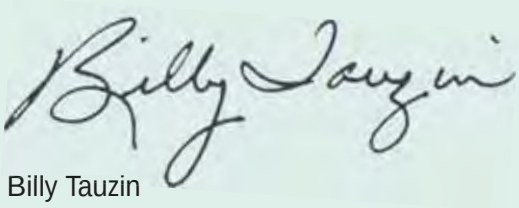
As a whole, though, our sector epitomizes the resilience of the American people. In 2009, America's pharmaceutical research and biotechnology companies continued to make the world's largest investment in pharmaceutical R&D, holding steady with $65.3 billion spent on R&D, including $45.8 billion by PhRMA members alone.

These investments not only hold promise for advancing medical science and bringing new treatments and cures to patients, but they also help move us a step closer to economic recovery by supporting high-quality jobs in the biopharmaceutical industry and related sectors.

It also was a year of intensive debate about the future of America's health care system. Our companies actively engaged in this national discussion with the shared goals of making treatments more readily available to patients, improving the quality of care, controlling health care costs and promoting future research.

Although comprehensive health care reform has not yet become a reality, America's biopharmaceutical research companies continue to support these vitally important objectives. Science today holds enormous potential to improve patients' lives, but without more research and greater access to affordable, high-quality health care, the promise will never be realized.

I am pleased to present PhRMA's 2010 *Pharmaceutical Industry Profile,* which highlights the contributions of biopharmaceutical companies to advancing research, improving the economy, and supporting new solutions for the American health care system.



Billy Tauzin
President and CEO
Pharmaceutical Research and Manufacturers of America

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Part of the Solution: Health Care and the Economy

The state of our economy and health care reform dominated American discourse and agendas in 2009. The biopharmaceutical research sector has shared this national focus.

Despite significant economic challenges, the biopharmaceutical research sector has shown resolve in weathering the downturn and maintaining its commitment to research and development (R&D) of new medicines. This requires an enormous, ongoing investment of resources, scientific expertise, advanced technologies, and project management capabilities. It also takes commitment and long-term vision to build for the future incrementally, as science often does. Today, new techniques and technologies are reinventing the process of research and discovery, and new treatments are in the pipeline for some of the world's most serious diseases.

Biopharmaceutical companies have supported and continue to support health care reforms that put patients' needs first. Key goals include: health

> "Over the long run, few issues are as important to a nation's long-term economic security and global standing as being a leader in moving life sciences forward." [1]
>
> *– Lawrence Summers, Current Director, National Economic Council, 2007*

"I am confident that if we recommit ourselves to discovery… if we have the vision to believe and invest in things unseen, then we can lead the world into a new future of peace and prosperity."[2]

– Barack Obama, President of the United States

care access for all Americans; a commitment to health care quality; increased emphasis on disease prevention; and continued medical progress through advances in research. The sector has helped the United States move toward these important goals in 2009 through policy support, financial commitment, and scientific focus.

As a result, the biopharmaceutical sector continues to be an important partner in advancing the nation's health care and economic progress. This year's *Profile* highlights the sector's contributions toward:

- Improving outcomes for patients
- Energizing economic recovery for our nation
- Increasing access to health care for all Americans, and
- Catalyzing continued progress through R&D

[1] L. Summers, "The U.S. must not surrender its lead in life sciences," *Financial Times,* 29 January 2007, http://blogs.ft.com/economistsforum/2007/01/america-must-nohtml/.

[2] B. Obama, Remarks of the President-Elect Barack Obama, Science Team Rollout Radio Address, 17 December 2008, http://change.gov/newsroom/entry/the_search_for_knowledge_truth_and_a_greater_understanding_of_the_world_aro/.

CHAPTER 1

IMPROVING OUTCOMES FOR PATIENTS

IMPROVING OUTCOMES FOR PATIENTS

CHAPTER 1

Better Results: The Impact of Today's Medicines

Today's medicines – the results of decades of biopharmaceutical R&D – are making important contributions to both improving the quality of health care and building a strong, innovative U.S. economy. Some medicines are completely changing the treatment paradigm for the illnesses they target, rapidly advancing patient care compared even to a few years ago. Others are dramatically improving survival rates for serious diseases such as cancer, heart disease, and HIV/AIDS, adding years of life for patients of all ages. Medicines are also helping to prevent hospital admissions, surgeries, and nursing home admissions, offering potential for better controlling Americans' health care expenditures as the U.S. population ages.

Changing the Course of Disease

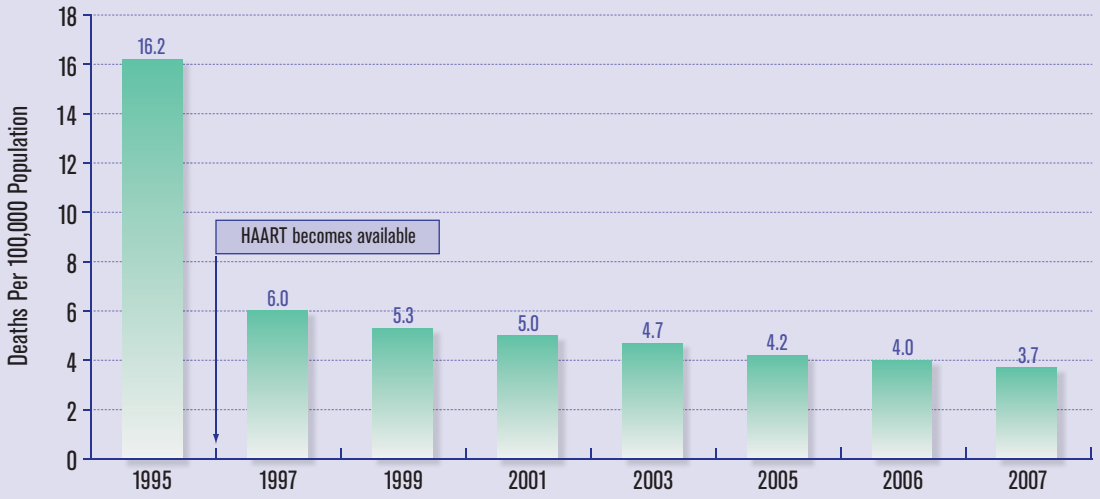
We are living in an era of tremendous scientific potential and fast-paced advances. According to the Congressional Budget Office, the biopharmaceutical industry's substantial investments in R&D have been accompanied by "major therapeutic gains."[1] In some cases the gains have literally changed the course of disease. For example:

- For women with a certain type of breast cancer, a targeted medicine called trastuzumab (Herceptin®) is achieving "a dramatic and perhaps permanent perturbation of the natural history of the disease, maybe even a cure."[2]

In a 2008 study on rheumatoid arthritis, the "primary outcome was to achieve *actual clinical remission of disease activity,* rather than an incremental percentage improvement in a standard outcome measure – a primary outcome that would have been *unthinkable in the 20th century.*"[3]

– E. Sun, et al. in the Journal of Clinical Oncology

FIGURE 1: **HIV/AIDS Death Rate Continues to Decline**



SOURCES: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, Health, United States, 2003 With Chartbook on Trends in the Health of Americans (Hyattsville, MD: HHS, 2003); Health, United States, 2009 With Chartbook on Medical Technology (Hyattsville, MD: HHS, 2010); J. Xu, K. D. Kochanek, and B. Tejada-Vera, "Deaths: Preliminary Data for 2007," *National Vital Statistics Reports* 58, No. 1, p. 5, (Hyattsville, MD: National Center for Health Statistics, August 2009), www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_01.pdf (accessed 4 December 2009).

- A report in *Health Affairs* states that "protein enzymes, receptors, or channels identified by the pharmaceutical industry as 'drugable targets' have led to striking, remarkable, and repeated achievement"[4] in cardiovascular treatment.
- New biological medicines are making complete remission possible for some people with severe rheumatoid arthritis, rather than providing periodic symptomatic relief.[5]

Increased Survival in Serious Illness

In recent years we have continued to see great improvements in survival and quality of life for patients with many serious and life-threatening diseases.

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.[6] Medicines specifically account for 50% to 60% of increases in survival rates since 1975.[7]

In 2009, 12 out of 15 major advances in the understanding of cancer and cancer patient care identified by the American Society of Clinical Oncology were related to new medicines, better ways to use existing medicines, or newly discovered benefits of approved medicines.[8]

HIV/AIDS

Following the approval of the highly active antiretroviral treatments (HAART) in 1995, deaths from HIV/AIDS in the United States fell dramatically – by more than 70%.[9] (See Figure 1 above.) Remarkably, the death rate continues to fall, and new medicines continue to become available. The Centers for Disease Control and Prevention (CDC) recently reported that between 2006 and 2007 the HIV/AIDS death rate fell 10%, which was the largest single-year decline since 1998.[10]

As a result of ongoing research and incremental improvements, medicines have also become easier to use – adding to their effectiveness. For example, a new once-daily, single-pill tablet combines the active ingredients of three antiretroviral drugs, eliminating the need for patients to remember and take multiple doses. Missing doses can lead the AIDS virus to mutate and become resistant to medicines.[11]

University of Chicago economists report that the aggregate value of new treatment-related increases in HIV/AIDS survival is $1.4 trillion.[12] For cancer, they found that the total value of survival advances was $1.6 trillion to $1.9 trillion.[13]

Cardiovascular Disease

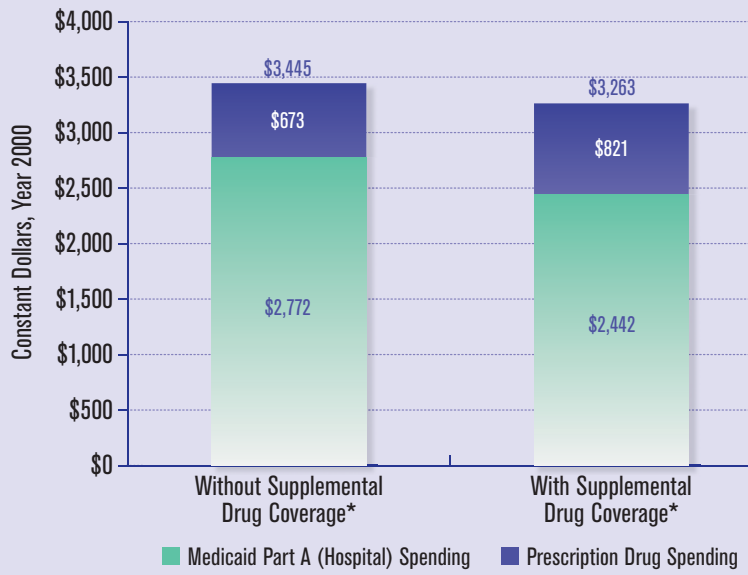
The death rate for cardiovascular disease fell 26.4% between 1999 and 2005.[14] This includes a 29.7% decrease in stroke death rates and a 34.3% drop in death rates for coronary heart disease. Nearly half of the decline is attributable to medical treatments, including increased use of prescription medicines such as cholesterol drugs and blood thinners.[15]

In addition, greater use of effective medicines offers hope for future decreases in cardiovascular disease deaths. In 2007, U.S. adults reached an average total cholesterol level in the ideal range (below 200) for the first time in 50 years.[16] This achievement is attributed to the increased use of cholesterol-lowering medicine in the over-60 population.[17]

Substantial Savings for Patients and the Health Care System

Controlling costs is an important focus of the health care reform debate, and medicines can make a significant contribution to this goal. A large body of research shows that proper use of medicines can help offset overall medical costs by preventing or delaying the need for other costly services, such as emergency room visits and hospitalizations. For example, a 2009 Medicare study found that use of prescription drugs reduced hospitalization costs for Medicare beneficiaries.[18] In another study, a $1.00 increase in prescription drug spending saved $2.06 in hospital spending.[19] (See Figure 2.) Conversely, treatment gaps and lack of adherence to prescribed medicines often lead to poor health outcomes and higher spending on other medical services.

FIGURE 2: **Spending on Medicines Can Lead to Lower Hospital Costs**



*Data from 1992–2002 MCBS – prior to Medicare Part D Prescription Drug Plan.

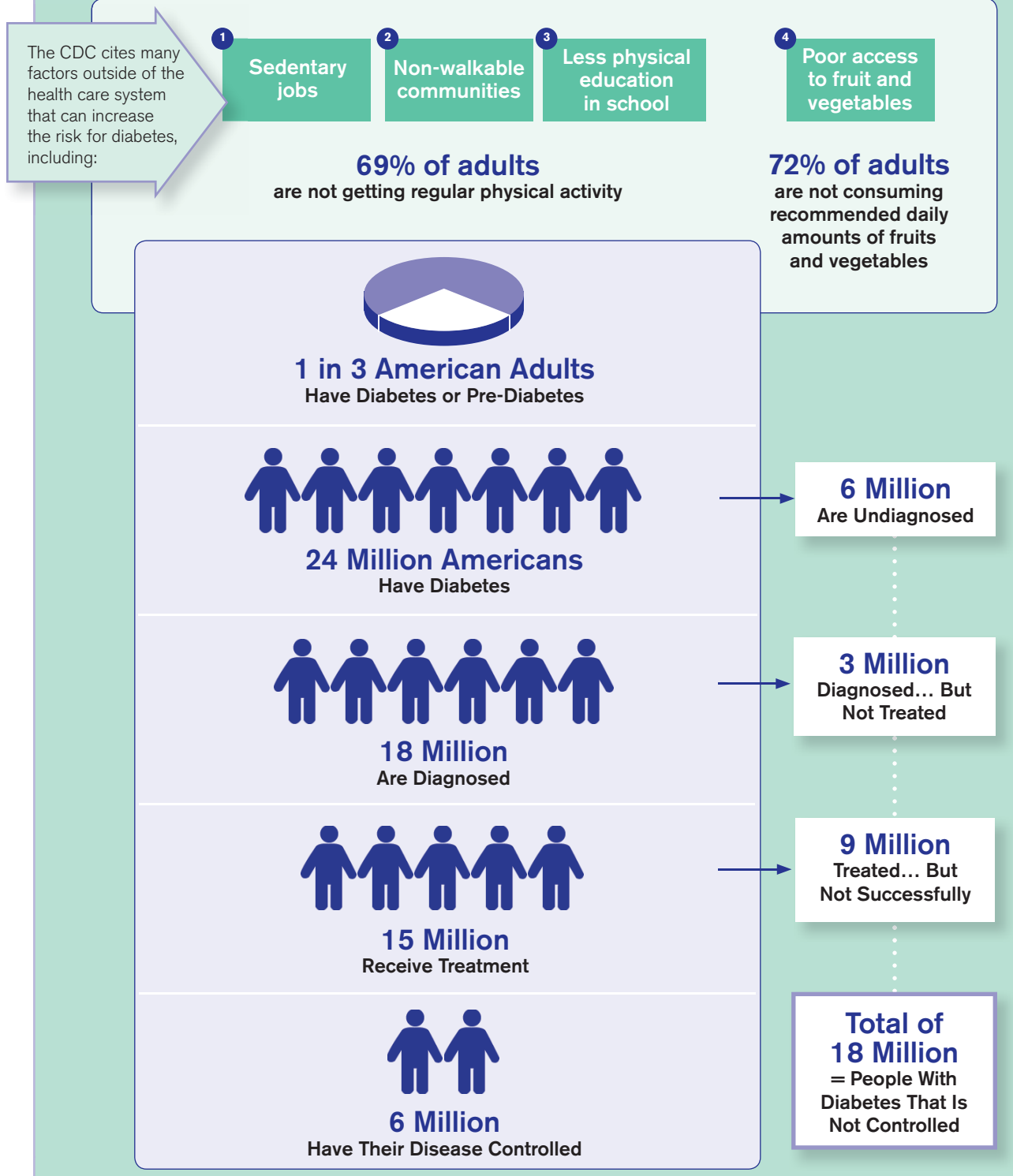
SOURCE: B. Shang and D. P. Goldman, "Prescription Drug Coverage and Elderly Medical Spending," National Bureau of Economic Research Working Paper 13358, September 2007.

The Challenges of Chronic Disease

Effective medicines can improve chronic disease outcomes. Yet many people with chronic diseases still go undiagnosed or untreated, or fail to properly follow treatment regimens. The diabetes example in the graphic on the next page (Figure 3) outlines some of the varied obstacles to achieving the full potential of medicines and improving patients' health.

The potential for proper use of medicines to help keep costs down is particularly significant for the growing number of Americans suffering from chronic health conditions such as diabetes. In one study, increased patient adherence to diabetes medicines saved $7 for every additional dollar spent on medicines. Patients with the highest level of medication adherence were significantly less likely to be hospitalized and had significantly lower total medical spending than less adherent patients.[20]

FIGURE 3: **Diabetes: Effective Medicines Exist, but Challenges Limit Impact**



SOURCE: PhRMA analysis of data from National Health and Nutrition Examination Survey for 2003–2004 and 2005–2006; Centers for Disease Control and Prevention, *National Diabetes Fact Sheet,* 2007.

[1] Congressional Budget Office, Research and Development in the Pharmaceutical Industry, October 2006.

[2] G. N. Hortobagyi, "Trastuzumab in the Treatment of Breast Cancer," *New England Journal of Medicine* 353, no. 16 (2005): 1734–1736.

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

[4] M. L. Weisfeldt and S. J. Zieman, "Advances in the Prevention and Treatment of Cardiovascular Disease," *Health Affairs* 26 no. 1 (2007): 25–37.

[5] J. M. Kremer, *op.cit.*

[6] 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.

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

[8] N. J. Petrelli, *et al.,* "Clinical Cancer Advances 2009: Major Research Advances in Cancer Treatment: Prevention and Screening: – A Report From the American Society of Clinical Oncology," *Journal of Clinical Oncology* 27, no. 35 (2009): 6052–6069.

[9] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, Health, United States, 2009 With Chartbook on Medical Technology (Hyattsville, MD: HHS, 2010).

[10] J. Xu, K. D. Kochanek, and B. Tejada-Vera, "Deaths: Preliminary Data for 2007," *National Vital Statistics Reports* 58, no. 1 (Hyattsville, MD: National Center for Health Statistics, August 2009).

[11] D. Hamilton, "New AIDS Pill Simplifies Treatment — FDA Is Close to Approving A Once-a-Day Medicine That Combines Three Drugs," *Wall Street Journal,* 10 July 2006.

[12] A. B. Jena and T. J. Philipson, Innovation and Technology: Adoption in Health Care Markets (Washington, DC: AEI Press, 2008).

[13] E. C. Sun, *et al.,* "An Economic Evaluation of the War on Cancer," National Bureau of Economic Research Working Paper 15574, December 2009.

[14] 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, available at: http://circ.ahajournals.org/cgi/content/abstract/CIRCULATIONAHA.108.191261v1.

[15] American Heart Association, "Heart and Stroke Death Rates Down, Some Risk Factors Still Too High," press releases, 15 December 2008, http://americanheart.mediaroom.com/index.php?s=43&item=626.

[16] S. E. Schober, M. D. Carroll, D. A. Lacher, and R. Hirsch, "High Serum Total Cholesterol — An Indicator for Monitoring Cholesterol Lowering Efforts: U.S. Adults, 2005–2006," NCHS data brief no. 2, (Hyattsville, MD: National Center for Health Statistics, 2007).

[17] Associated Press, "First Time in 50 Years, Average American Adult's Cholesterol in Ideal Range," 12 December 2007, www.foxnews.com/story/0,2933,316562,00.html.

[18] B. C. Stuart, J. A. Doshi, and J. V. Terza, "Assessing the Impact of Drug Use on Hospital Costs," *Health Services Research* 44, no. 1 (2009): 128–144.

[19] B. Shang and D. P. Goldman, "Prescription Drug Coverage and Elderly Medical Spending," National Bureau of Economic Research Working Paper 13358, September 2007.

[20] M. C. Sokol, *et al.,* "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care* 43, no. 6 (2005): 521–530.

CHAPTER 2

BOLSTERING THE U.S. ECONOMY

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CHAPTER 2

Like other industries, biopharmaceutical research companies have felt the effects of the recent economic downturn. Many companies faced the difficult necessity of layoffs. Several large companies have merged, and some firms have left the high-risk drug discovery business altogether.

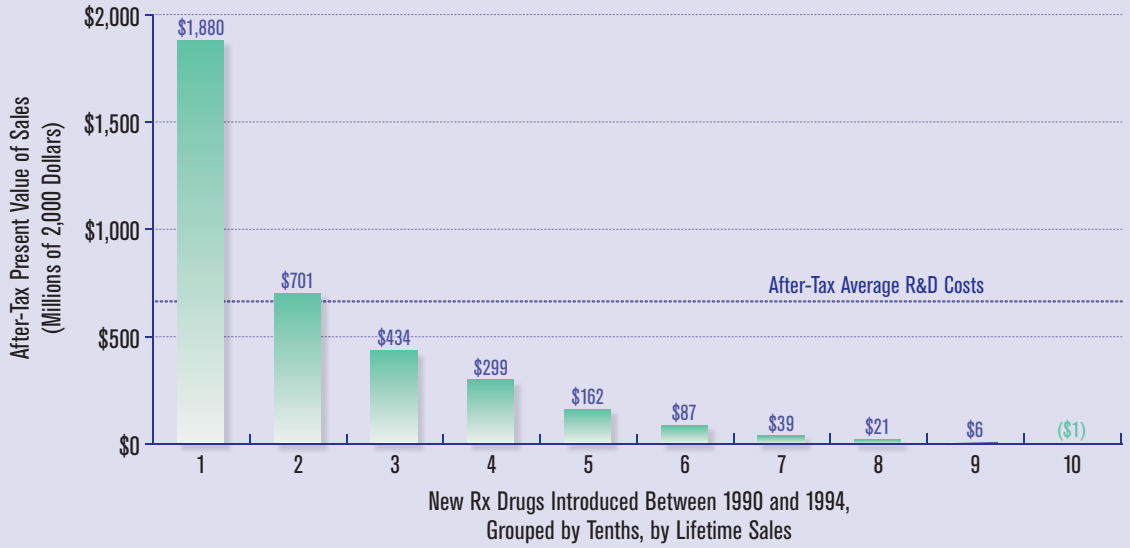
Additional challenges are also affecting the economic landscape for biopharmaceutical companies. Today's market is a difficult one, with increased and earlier competition for new medicines. Generic products now account for 74% of prescriptions filled – up from 49% in 2000.[1] Recent research from the Tufts Center for the Study of Drug Development shows that the time until new medicines have competitors within their class has decreased from 10.2 years in the 1970s to 2.5 years in 2000 through 2003.[2] Further, only two in 10 medicines recoup the investment made by companies in developing them.[3] (See Figure 4.)

Despite these challenges, biopharmaceutical companies continue to focus on R&D and are making valuable contributions to the U.S. economy.

Good Jobs for Americans

In 2006, the most recent year for which data are available, the biopharmaceutical sector supported more than 3.2 million American jobs through direct hiring or ripple effects.[4] Although there have been job losses since then, the biopharmaceutical sector remains a strong source of high-quality jobs.

FIGURE 4: **Just 2 in 10 Approved Medicines Recoup R&D Costs**



Note: Drug development costs represent after-tax out-of-pocket costs in 2000 dollars for drugs introduced from 1990–94. The same analysis found that the total cost of developing a new drug was $1.3 billion in 2006. Average R&D Costs include the cost of the approved medicines as well as those that fail to reach approval.

SOURCES: J. A. Vernon, J. H. Golec, and J. A. DiMasi, "Drug Development Costs When Financial Risk Is Measured Using the Fama-French Three-Factor Model," *Health Economics Letters* (2009); J. DiMasi and H. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics* 28 (2007): 469–479.

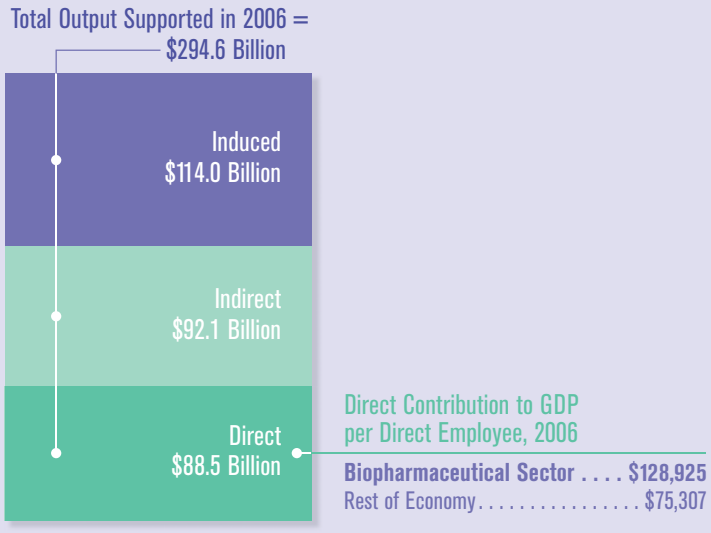
Outstanding Productivity

The sector's contribution to the 2006 gross domestic product was $88.5 billion – triple the average contribution per sector in the rest of the economy.[5] (See Figure 5.)

Strong Drivers of Local Economies

Biopharmaceutical companies also drive local economies by acting as a magnet for bioscience research. In a number of areas around the country, concentrations of universities, biopharmaceutical companies, medical device companies, established and emerging life sciences companies, technology spinoff companies, and other start-ups – all interacting in a network – are creating environments

FIGURE 5: **Contributing to the Economy: Biopharmaceutical Sector Productivity**



SOURCE: Archstone Consulting, LLC and 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, March 2009).

that encourage other companies to establish operations. Throughout the country, growth of these bioscience "clusters" continues.

These research-oriented centers create good jobs and have positive economic effects on their regions. For example:

- About 15% of all economic activity and one out of every six jobs in Greater Philadelphia can be traced back to the life sciences cluster in the Delaware Valley (which includes parts of Pennsylvania, New Jersey, and Delaware).[6]
- More than 500 biotechnology companies are headquartered in North Carolina, especially in the Research Triangle area around Raleigh/Durham. These companies employ about 58,000 people, with an estimated $4.5 billion payroll in 2006.[7]
- In Colorado bioscience clusters, medical research grew more than 72% between 2002 and 2006, nearly twice the national average of 37%. The number of related companies grew by 58% between 2001 and 2006, and bioscience cluster employment growth outpaced total job creation across all other sectors.[8]
- As of 2009, companies with Washington State branches or headquarters were developing about 46 new cancer treatments and 18 new heart disease treatments. Overall, 119 new medicines developed in Washington labs are now being tested in clinical trials.[9] In 2006, Washington employed 67,000 people in the biopharmaceutical sector and tens of thousands more in research institutions. The life science sector stimulates an estimated $10.5 billion annually in state economic activity.[10]

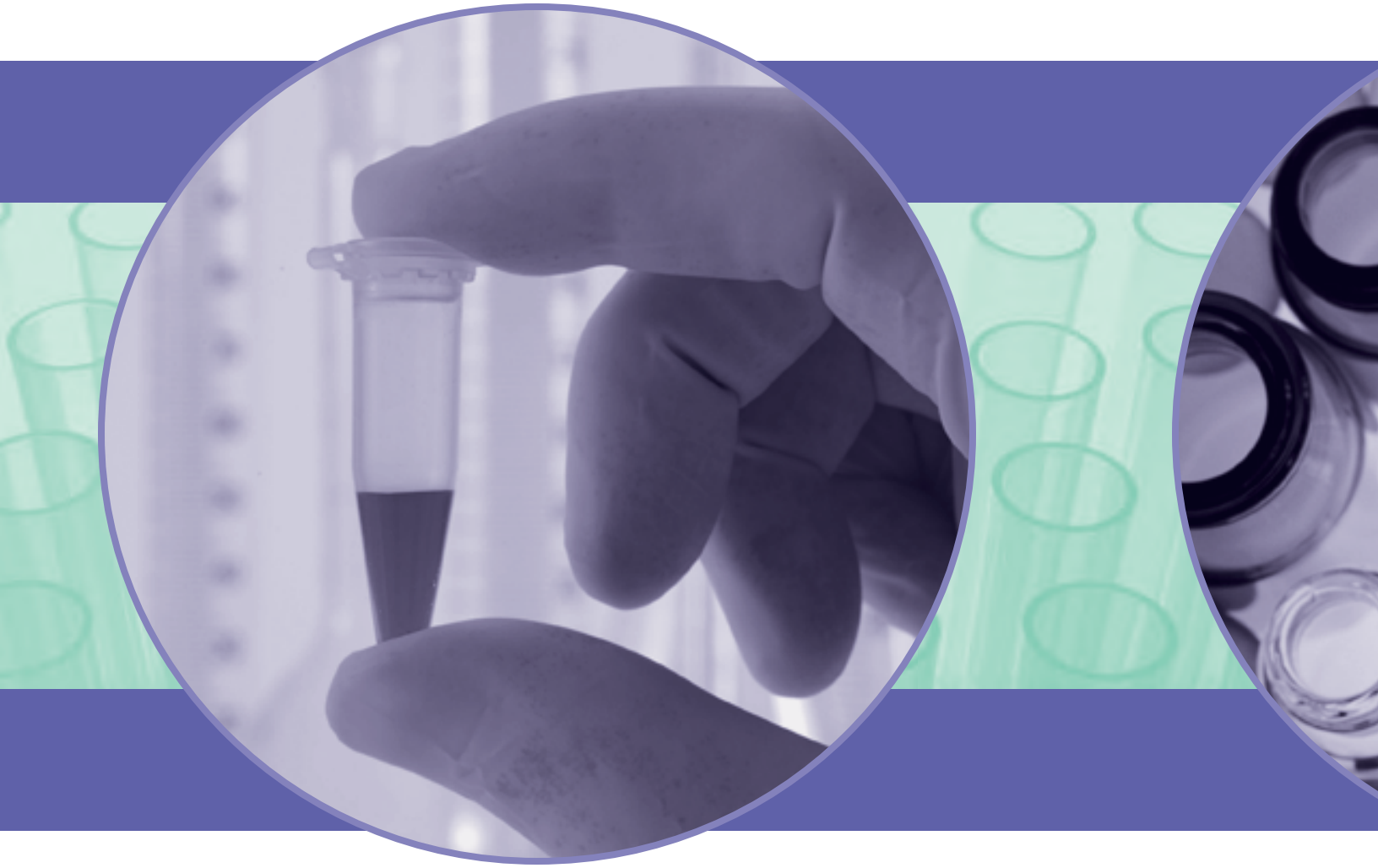
"We must redouble our efforts to give our world-leading innovators every chance to succeed. We cannot rest on our laurels while other countries catch up"[11]

– U.S. National Economic Council

Economic Recovery and Growth: Innovation Is Key

According to the National Science Foundation, "Innovation is a key to economic competitiveness."[12] New medicines are one area identified by the National Economic Council as addressing the "'grand challenges' of the 21st century" by helping to "improve our quality of life and establish the foundation for the industry and jobs of the future."[13] The United States continues to be the world leader in biopharmaceutical research.[14] For example, the United States:

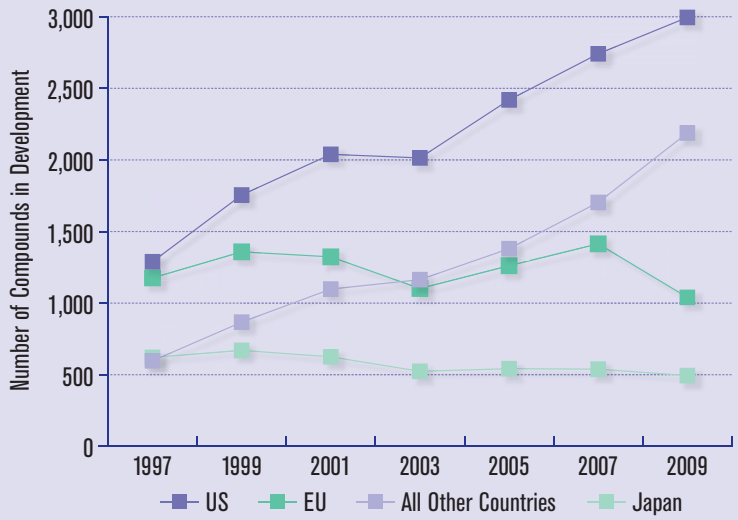
- Holds the intellectual property rights to the majority of new medicines[15]
- Conducts 80% of the world's R&D in biotechnology[16]



- Has about 2,950 compounds in clinical trials or awaiting approval in 2010.[17] (See Figure 6.) Having so many trials in the United States gives American patients early access to experimental treatments, which is particularly crucial for diseases that don't yet have many treatment options.

Today, many other countries are also strategically focusing on the potential of innovation to spur economic recovery and growth. (See sidebar, "World Economies Recognize Value of Innovation.")

FIGURE 6: U.S. Market Drives Global Development of Medicines*



*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, custom data runs, February 2009, January 2010.

World Economies Recognize Value of Innovation

Fast-growing economies such as China, India, Singapore, and Korea are committing significant resources to biopharmaceutical R&D. They are also changing public policies to promote R&D, such as intellectual property protections and shortening approval times for new drug applications. For example:

- The Chinese government has earmarked $9.2 billion for new technology, including biotechnology, to stimulate economic growth.[18] The government's investment is "in line with the government's increasing support to drug innovation in China."[19] The biotechnology sector was one of five sectors identified by the Chinese government as key to China's economic growth.[20]
- The Indian government has pledged to develop more than 20 biotech parks and has committed more than $1.7 billion to grow the sector.[21]
- Singapore's vision is to be the "biopolis" of Asia, an international biomedical sciences cluster advancing human health.[22]

These emerging competitors are working to take advantage of the significant economic opportunities they foresee in the biopharmaceutical sector. Global competition helps research to thrive, and means the United States must work to keep the good jobs and positive economic impact innovation has created.

Promoting U.S. Innovation

To help promote America's global competitiveness, leaders from research, medicine, academia, education, labor, business, health care and policy have joined together to form the Council for American Medical Innovation. This partnership is urging Congress to adopt a national policy agenda that promotes medical innovation and the good American jobs it provides, including:

- Increasing incentives for investment in research, development and its application
- Increasing investment in the life sciences
- Ensuring a highly skilled and trained work force to support scientific R&D

For more information, go to: www.americanmedicalinnovation.org.

[1] IMS National Prescription Audit, December 2009.

[2] Tufts Center for the Study of Drug Development, "Marketing Exclusivity for First-in-Class Drugs Has Shortened to 2.5 Years," *Tufts CSDD Impact Report* 2, no. 5 (2009).

[3] J. A. Vernon, J. H. Golec, and J. A. DiMasi, "Drug Development Costs When Financial Risk Is Measured Using the Fama-French Three-Factor Model," *Health Economics Letters* (2009).

[4] Archstone Consulting, LLC and 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, March 2009).

[5] *Ibid.*

[6] R. C. DeVol, *et al.,* The Greater Philadelphia Life Sciences Cluster 2009: An Economic and Comparative Assessment (Santa Monica, CA: Milken Institute, May 2009), www.milkeninstitute.org/publications.

[7] North Carolina Biotechnology Center, "North Carolina Biotechnology Industry Facts," North Carolina Biotechnology Center Web site at: www.ncbiotech.org/news_and_events/media_center/fast_facts.html.

[8] Battelle Technology Partnership Practice, Colorado Bioscience Roadmap 2008 (Columbus, OH: Technology Partnership Practice, January, 2009), www.cobioscience.com/stateplan08.pdf.

[9] E. H. Schwartz, "Biotech Gaining Ground in Washington State, Report Says," *Xconomy Seattle,* 30 June 2009, www.xconomy.com/seattle/2009/06/30/biotech-booming-in-washington-state-report-says/.

[10] Washington Biotechnology & Biomedical Association, *2009 Annual Report,* www.washbio.org/associations/11076/files/WBBA%202009%20Annual%20Report%20printable.pdf.

[11] Executive Office of the President, National Economic Council, Office of Science and Technology Policy, A Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs, September 2009.

[12] E. Thornton and F. Jespersen, "Drug, Biotech Research Spending Hangs Tough," *Business Week,* 27 August 2009, www.businessweek.com/bwdaily/dnflash/content/aug2009/db20090827_362578.htm.

[13] Executive Office of the President, National Economic Council, Office of Science and Technology Policy, *op. cit.*

[14] Archstone Consulting, *op. cit.*

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CHAPTER 3

INCREASING HEALTH CARE ACCESS FOR ALL AMERICANS

INCREASING HEALTH CARE ACCESS FOR ALL AMERICANS

America's biopharmaceutical research companies have supported and continue to support health care reform that would guarantee that all Americans have access to high-quality, affordable health care coverage and services. Expanding access is key to a health care system that emphasizes prevention and control of chronic disease for all while providing excellent care for those who do become acutely ill.

PhRMA's member companies have supported important efforts that have helped improve access to medicines and other health care for Americans. These include supporting enrollment efforts in the Medicare Part D prescription drug program, expanding the Children's Health Insurance Program, and sponsoring the Partnership for Prescription Assistance.

CHAPTER 3

The Medicare Prescription Drug Plan

Medicare prescription drug coverage (Part D) continues to play a pivotal role in increasing access to prescription medicines for older and disabled Americans. In just its fourth year of operation, more than 26 million enrollees have joined Medicare Part D,[1] about 14 million of whom previously were uninsured or lacked comprehensive prescription drug insurance.[2] As a result of Part D, more than 90% of

Lack of Insurance Is a Growing Problem

U. S. Census Bureau estimates[3]:

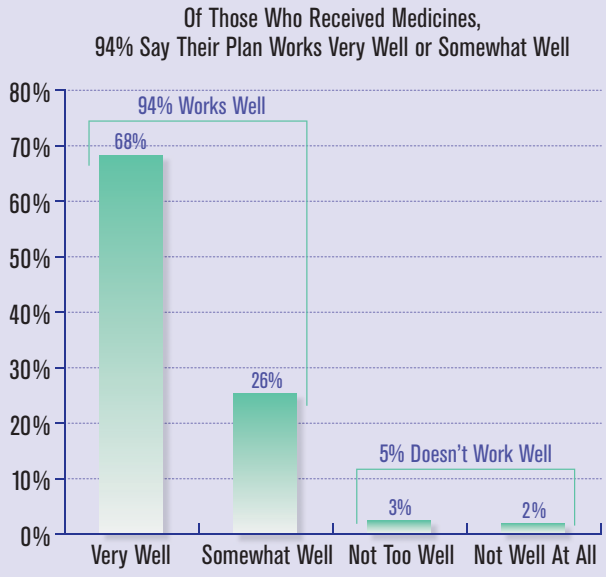
- 46.3 million individuals (15.4%) lacked health insurance coverage in 2008.
- The number of Americans without health insurance increased by nearly 700,000 in 2008.
- Employer-sponsored health insurance coverage declined to 58.5% (176.3 million) in 2008.
- People with lower incomes ($25,000 per year or less) are more likely to lack health coverage.

all Medicare beneficiaries now have prescription drug coverage.[4] Consequently, many seniors' spending fell significantly; from 2005 to 2007, the average monthly out-of-pocket cost for prescription drugs went from $73 for those without prescription drug coverage in 2005 to $42 in 2007 for those who had enrolled in Part D.[5]

The Medicare prescription drug plan has proven to be a clear success for seniors.

- **High Satisfaction.** Overall, 88% of seniors enrolled in Medicare Part D are satisfied with the program – an increase of 10% since the benefit began.[6] Of those who receive medicines through their plans, more than nine out of 10 say their plans work well.[7] (See Figure 7.)

FIGURE 7: Seniors' Satisfied with Medicare Prescription Drug Plan



SOURCE: KRC Survey for *Medicare Today*, "Seniors' Opinions About Medicare Rx: Fourth Year Update," April 2009.

"...Part D was associated with a 16% annual decrease in out-of-pocket spending and a 7% increase in the number of prescriptions."[8]

– G.F. Joyce, et al. in the American Journal of Management Care

- **Greater Access and Use.** Older Americans who previously lacked prescription drug coverage now can get the prescription medicines they need. Overall, underuse of and non-adherence to medicines important to senior health has declined significantly.[9] In particular, seniors' access to medicines has increased for chronic conditions such as hypertension, high cholesterol, and diabetes,[10] which can lead to heart disease, stroke, and other serious health problems.
- **Lower Medicine Expenses.** Among beneficiaries who had no prescription medicine insurance prior to the Medicare prescription drug plan, most have reduced their out-of-pocket spending on medicines even while increasing the number of medicines they obtain.[11]

The Children's Health Insurance Program

PhRMA strongly supported efforts to reauthorize and expand the Children's Health Insurance Program (CHIP), an important program that provides high-quality, affordable health insurance coverage for millions of low-income children. In February 2009, President Obama signed the reauthorization act into law, which is estimated to extend health insurance coverage to more than 4 million uninsured children.[12]

In addition, the CHIP reauthorization law enhances states' options for subsidizing employer-sponsored health care insurance for low-income children and families, supporting combined public/private efforts to increase access. The law also includes development of consensus-based pediatric quality of care measurements, which holds promise in improving the quality of children's health care.

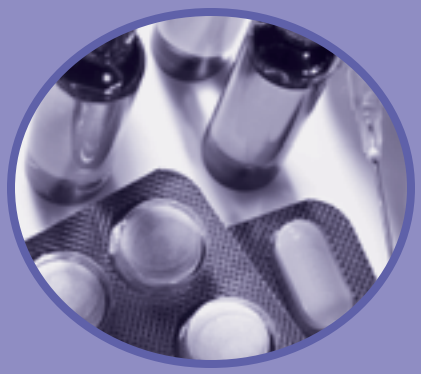
Increasing Access to Treatment for Neglected Diseases

The developing world faces daunting challenges when it comes to increasing access to health care. Many diseases that significantly affect developing countries have no effective vaccines, diagnostics or medicines. In addition, limited infrastructure and financial resources restrict distribution of medicines and other care to patients.

In the past several years, many organizations, companies, and public-private partnerships have invested in increasing access to care for previously neglected diseases. And according to Tufts University, R&D funding for neglected diseases increased 25-fold between 1999 and 2008.[13]

With a total contribution of $390.2 million to R&D on neglected disease treatments in 2008, the pharmaceutical industry was one of the highest funders of R&D related to neglected diseases.[14] In some instances, the contributions of individual companies were greater than those of individual countries. In addition, a number of pharmaceutical company initiatives have provided workforce training, education programs targeting health care providers, and support of local health infrastructure for neglected diseases.

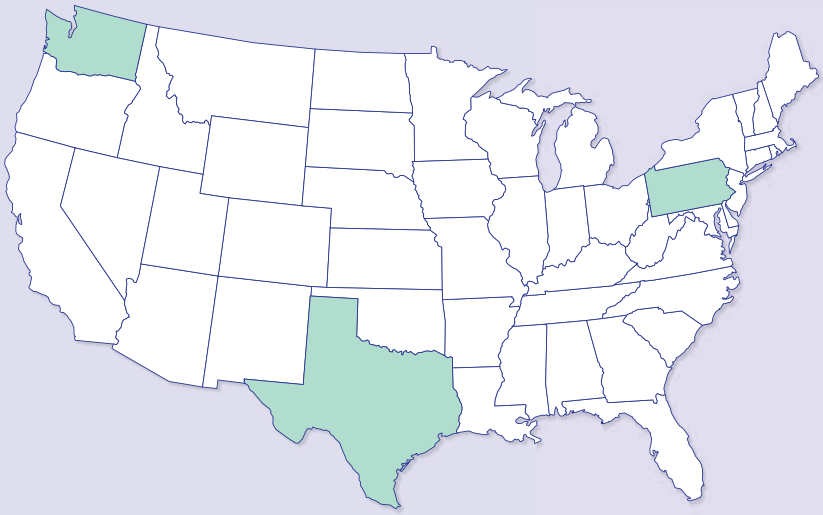
Despite these achievements, there is much left to do, and pharmaceutical companies are committed to making a difference around the world.



Impact for Patients With Neglected Diseases

Between 2000 and 2008, 26 new drugs were approved for neglected diseases, including malaria, HIV/AIDS, diarrheal diseases, bacterial meningitis, and kinetoplastid disease. In addition, 74 products for neglected diseases are in the clinical development pipeline.[15]

PPA: Helping Patients Around the Country



The Partnership for Prescription Assistance

The Partnership for Prescription Assistance (PPA) is a nationwide effort sponsored by America's pharmaceutical research and biotechnology companies. PPA (www.pparx.org) links uninsured and financially strained Americans to programs that provide prescription medicines for free or nearly free. The help PPA provides is particularly important in these troubled economic times, when Americans have increasingly faced layoffs and the loss of health benefits.

Free and confidential, PPA serves as a single point of access to information on more than 475 public and private patient assistance programs, including nearly 200 programs offered by pharmaceutical companies. PPA member programs offer more than 2,500 brand-name and generic medicines. In the last five years, more than 6 million people received assistance through PPA.

Washington

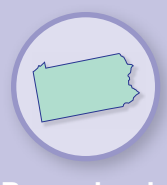
"PPA has assisted me in a way that really allows me to manage and take care and take control of my health. HIV is not a death sentence anymore, you know. It's a very manageable disease, and it literally is a gift through PPA."

– Patrick "Fergie" Ferguson, Seattle, Washington

Texas

"I am a full-time student and a full-time mother and not having to worry about paying for my medicine has lifted a huge weight from me – what a wonderful feeling."

– Colleen Thurman, Richland Hills, Texas



Pennsylvania

"Calling the PPA is the easiest thing I have ever done in my entire life. I appreciate all the sincere help I have received and the simplicity of getting the medications I need to maintain a normal life."

– Wendy Hauser, Pittsburgh, Pennsylvania

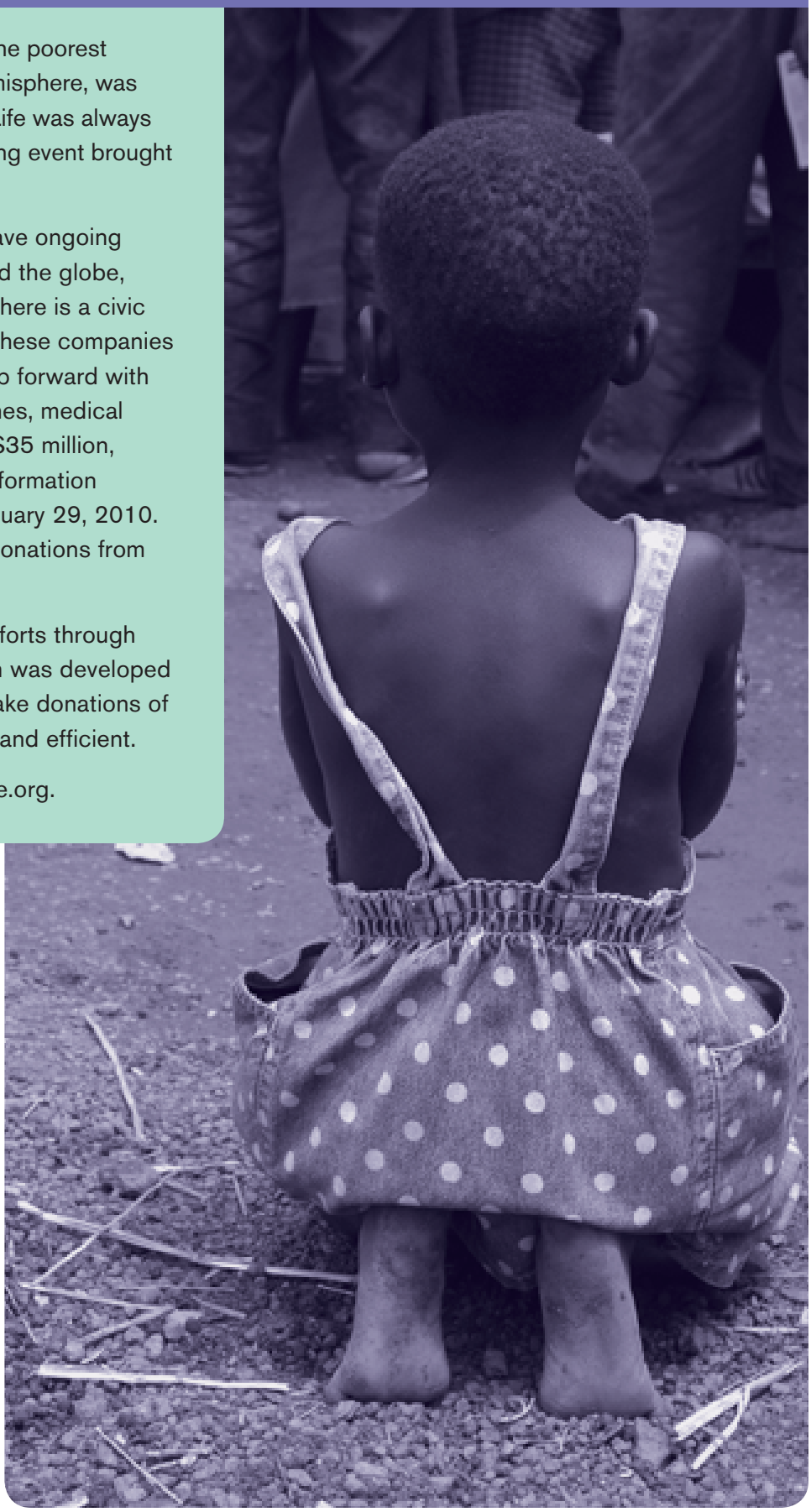
A Helping Hand for Haiti

On January 12, 2010, Haiti, the poorest country in the Western Hemisphere, was struck by a massive earthquake. Life was always difficult in Haiti, but this devastating event brought the country to its knees.

Biopharmaceutical companies have ongoing philanthropy commitments around the globe, but in times of such acute need there is a civic responsibility to contribute, and these companies are always among the first to step forward with aid. Donations, including medicines, medical supplies and cash, totaled over $35 million, according to publicly available information compiled by PhRMA through January 29, 2010. Many companies also matched donations from their employees.

Companies helped coordinate efforts through the Rx Response program, which was developed following Hurricane Katrina to make donations of medical products more effective and efficient.

Find out more at www.rxresponse.org.



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CHAPTER 4

CATALYZING CONTINUED MEDICAL PROGRESS THROUGH R&D

CATALYZING CONTINUED MEDICAL PROGRESS THROUGH R&D

CHAPTER 4

U.S. Investment in Biopharmaceutical Research and Development Remains Strong

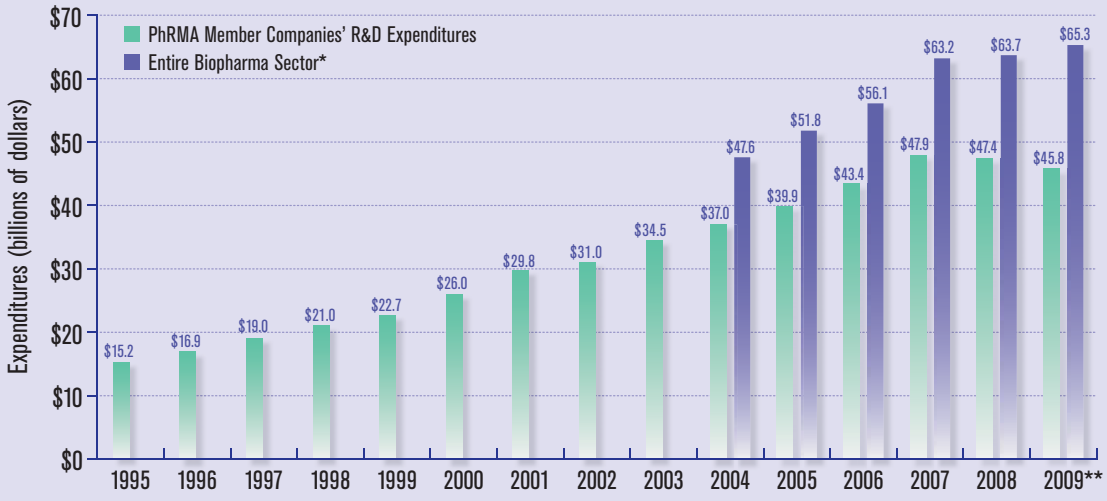
Despite the challenging economic environment, biopharmaceutical companies have continued to make significant investments in research and development. This year the sector increased research and development (R&D) spending to $65.3 billion. (See Figure 8.)

This robust investment and a constructive, collaborative environment enable biopharmaceutical companies to play essential roles in health care progress: advancing scientific knowledge, building on recent discoveries, and providing new treatment options for patients. Yet the already formidable drug discovery and development process has become even more challenging in recent years.

The Long, Uncertain R&D Process: A New Medicine Takes Commitment and Collaboration

Biopharmaceutical R&D is a complex undertaking, with many steps and hurdles. As the graphic, "The Drug Discovery and Development Process" (Figure 9) shows,

FIGURE 8: **Biopharmaceutical Companies' Investment in R&D Remains Strong**



*The "Entire Biopharma Sector" 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 & Co., analysis for Pharmaceutical Research and Manufacturers of America, 2005–2010; Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Member Survey* (Washington, DC: PhRMA, 1981–2010).

FIGURE 9: **The Drug Discovery and Development Process**

RESEARCH

3–6 YEARS

Pre-discovery

Goal: Understand the disease and choose a target molecule.
How: Scientists in pharmaceutical research companies and government, academic, and for-profit research institutions contribute to basic research.

Discovery

Goal: Find a drug candidate.
How: Create a new molecule or select an existing molecule as the starting point. Perform tests on that molecule and then optimize it (change its structure) to make it work better.

Preclinical

Goal: Test extensively to determine if the drug is safe enough for human testing.
How: Researchers test the safety and effectiveness in the lab and in animal models.

DEVELOPMENT

6–7 YEARS

Investigational New Drug Application

Goal: Obtain FDA approval to test the drug in humans.
How: FDA reviews all preclinical testing and plans for clinical testing to determine if the drug is safe enough to move to human trials.

Clinical Trials

Goal: Test in humans to determine if the drug is safe and effective.
How: Candidate drug is tested in clinical setting in three phases of trials, beginning with tests in a small group of healthy volunteers and moving into larger groups of patients.

Phase 1	Phase 2	Phase 3
20–100 Volunteers	100–500 Volunteers	1,000–5,000 Volunteers

0.5–2 YEARS

New Drug Application

Goal: FDA reviews results of all testing to determine if the drug can be approved for patients to use.
How: FDA reviews hundreds of thousands of pages of information, including all clinical and preclinical findings, proposed labeling and manufacturing plans. They may solicit the opinion of an independent advisory committee.

Manufacturing

Goal: Formulation, scale-up and production of the new medicine.

ONGOING STUDIES

5,000–10,000 Compounds

250 Compounds

5 Compounds

One FDA-Approved Drug

it takes on average 10 to 15 years[1] and an estimated $1.2 billion to $1.3 billion[2] to create a successful new medicine. Since very few of the drugs that enter development ever achieve final marketing approval, much of this cost is related to unsuccessful attempts.

Persistence in pursuing promising ideas is necessary, but researchers and investors know from experience how difficult and unlikely it is to move from possibility to product.

Figure 10: **The Growing 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 rate: 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," *Tufts CSDD Impact Report* 10, no. 1 (2008).

Challenging Times for Biopharmaceutical R&D

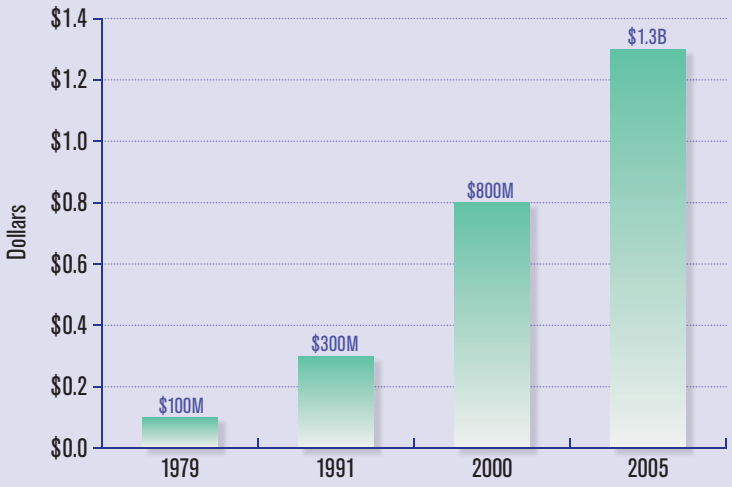
As the costs and complexity of biopharmaceutical R&D have increased, the odds of successful drug development have decreased.

Cost/Complexity Drivers

Key factors in rising costs and complexity are related to clinical trials. Today's drug trials are larger on average and require more participants than ever before. As a result, recruiting participants for trials has become more difficult and more expensive. In addition, as science has expanded knowledge about how to measure safety and effectiveness, trials have become increasingly complicated, with more endpoints to observe and test. (See Figure 10 above.) The post-approval phase has also become longer and more intensive.

Another driver of high costs and complexity is the nature of the science itself. Drug development, especially for chronic and degenerative diseases, increasingly involves more difficult scientific obstacles. While the potential of genomics and molecular biology is great (see sections below), applying this basic knowledge to drug development remains challenging. In fact, the effort and expense of identifying the right candidate among so many options and establishing that the candidate is both efficacious and safe have soared over the last decade. (See Figure 11.)

Figure 11: **Increasing Cost to Develop One New Medicine**



SOURCES: J. A. DiMasi and H. G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics,* 2007; J. A. DiMasi, *et al.,* "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics,* 2003.

Inspiring Continued Commitment: Personalized Medicine and Biologics

Personalized medicine and biologics are two examples of areas of medical research with inspiring potential for progress. Despite R&D challenges, the biopharmaceutical sector is committed to the difficult task of advancing these and other cutting-edge technologies. Many experts believe that research in these areas may be able to transform medical care, based on new ways of approaching disease.

Personalized Medicine

One of the most promising areas of biopharmaceutical research today is personalized medicine, which refers to the tailoring of

"The key to fixing America's broken healthcare system is to measure the value of healthcare instead of its cost .... Individualized medicine ... can significantly improve the value we deliver to patients"[3]

– Denis A. Cortese, M.D., President and Chief Executive Officer, Mayo Clinic

medical treatment to the individual characteristics of subpopulations of patients who differ in their susceptibility to a particular disease or their response to a specific treatment. The potential of personalized medicine lies in the possibility of moving beyond "one size fits all" approaches to health care, using each individual's genetic and molecular profile. This approach can help prevent side effects and improve the chances that a medicine will work for a patient.

Although the science of personalized medicine is extremely complex, biopharmaceutical companies are committed to building on progress already made in this area. Their efforts have already produced targeted products for a number of conditions.

For example:

- **CCR5-tropic HIV-1.** Maraviroc (Selzentry®) specifically targets patients with this type of HIV disease.
- **Acute lymphoblastic anemia.** Dasatinib (Sprycel®) is indicated for the treatment of adults with Philadelphia chromosome–positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.
- **Breast cancer.** One of the most common applications of personalized medicine is trastuzumab (Herceptin®), which is indicated for women whose breast cancer overexpresses the protein HER2.

For more information on personalized medicine, go to: www.ageofpersonalizedmedicine.org

Hope for the Few

Rare diseases affect so few people that most doctors have very little experience with them, and treatment options are often insufficient. Each rare, or "orphan," disease affects fewer than 200,000 people in the United States, and some affect just a handful. Taken together, though, 6,000 rare diseases affect 25 million Americans.[4]

Thanks in part to the Orphan Drug Act of 1983, which provided research incentives, treatment options for patients with rare diseases have increased significantly. Nearly 350 medicines have been approved for rare diseases since 1983.[5] And the outlook has continued to improve in recent years: according to the Tufts Center for the Study of Drug Development, the number of medicines in development designated as "orphan products" more than doubled from 208 in 2000 through 2002 to 425 in 2006 through 2008.[6]

Biologics

Biologics are made from living material and are developed through genetic engineering or recombinant DNA technology. By contrast, conventional, small-molecule drugs that most people are familiar with are produced through organic chemistry.

Research in biologics offers great promise for patients. Biologic medicines allow scientists to target with great specificity the underlying cause of a disease for prevention or treatment. In many cases, biologics are the first treatment available for a particular disease or offer a significant advance in the fight against a given disease.

In recent years, new biologics have helped to transform the treatment

"Biologics have enormous potential to provide breakthrough medical treatments."[7]

– Association of American Universities

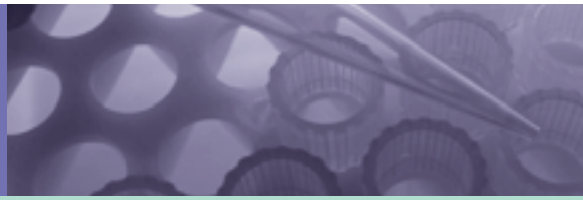
"Biologicals, defined as products of which the active substance is produced by or extracted from a biological source, represent an important and growing part of the therapeutic arsenal."[8]

– Journal of the American Medical Association

"Monoclonal antibodies [a type of biologic] continue to have a great deal of potential as therapeutics for a variety of indications, including diseases that are currently untreatable."[9]

– Tufts Center for the Study of Drug Development

The Nature of Invention: Spotlight on Cancer Treatments



Clinical research is an incremental process that continues long after Food and Drug Administration (FDA) approval, which often marks the "starting point" for a number of additional studies of the therapy. As a larger body of evidence is developed through these studies, researchers learn not only how the drug works in the approved application but also how it may be used:

- at other points in the treatment process
- in other diseases
- in combination with other treatments
- in different patient subpopulations

Gleevec: Post-Marketing Research Shows Full Benefit of Cancer Drug

The timeline of approved indications for the cancer medicine imatinib (Gleevec®)[10] is a good example of how the value and uses of a drug can increase as long-term studies continue to provide new data. Imatinib was originally approved based on surrogate endpoints, which are biological markers that show the drug is having an effect at the molecular level. Six years later, clinical study data showed 88% survival for patients on the drug, compared with 48% prior to taking imatinib.

Gleevec Approvals

2001 – May 2001: Initial Indication – Patients with Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy (IFN)

2002 – Feb 2002: Approval for patients with Kit (CD117)-positive unresectable (unable to be removed through surgery) and/or metastatic malignant gastrointestinal stromal tumors (GIST)

Dec 2002: Approval for newly diagnosed adult patients with Ph+ CML in chronic phase (CP)

2003 – May 2003: Approval for pediatric patients with Ph+ CML-CP recurrence after stem cell transplant or IFN resistance

2006 – Sept 2006: Approval for newly diagnosed pediatric patients with Ph+ CML-CP

Oct 2006: Five new indications, such as adult patients with relapsed or refractory Philadelphia chromosome–positive acute lymphoblastic leukemia (Ph+ ALL) and adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans

2008 – Dec 2008: Approval for adjuvant treatment of adult patients following resection of Kit (CD117)-positive GIST

"The full clinical value of a cancer therapy is often much greater than recognized at the time of initial FDA approval."[11]

– Boston Healthcare

and prevention of several diseases, including rheumatoid arthritis, a variety of cancers, and macular degeneration. Approved biologic drugs are also proving effective for new indications through extensive post-approval research. For example, from 2005 to 2007, 25 biologic drugs for cancer received approval for at least one additional indication.[12]

Collaboration for Progress: Public/ Private Roles in Biopharmaceutical R&D

Major biopharmaceutical companies, smaller companies, academic institutions, and the National Institutes of Health (NIH) all contribute to advancing medical science and treatments. Together they form a vibrant research ecosystem.

Major biopharmaceutical companies are the primary source of R&D funding for new medicines, both for projects in their own laboratories and for research licensed from other sources. Researchers at biopharmaceutical companies conduct both basic and applied research, with a greater emphasis on development. According to PhRMA's 2010 member survey, 77%[13] of R&D spending goes to medicines that come from in-house research.

Smaller companies also drive innovation, conducting basic research, drug discovery, preclinical experiments and, in some cases, clinical trials.

While the NIH provides leadership and funding support to universities, medical schools, research centers and other nonprofit institutions, its principal focus is basic research on the mechanisms of disease, which underpins the biopharmaceutical sector's search for new drugs.

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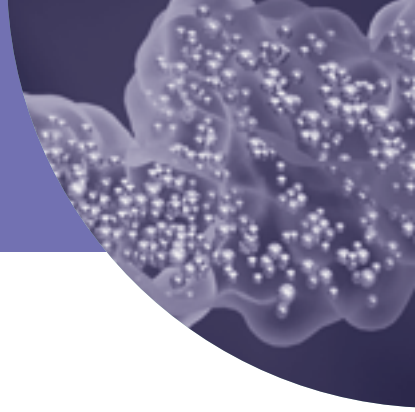
Conclusion



Searching for Solutions: Opportunities and Challenges

The biopharmaceutical research sector's focus on innovation provides many opportunities for achieving the central goals of the health care reform debate and advancing economic recovery in the United States. However, carrying out these opportunities will require creative solutions to real challenges and taking steps to support biopharmaceutical innovation.

Health Care Reform

Throughout the 2009 and 2010 debate, PhRMA members have supported U.S. health care reform that includes: health care access for all Americans, a commitment to health care quality, increased emphasis on disease prevention, and continued medical progress through research advances.

The efforts of the biopharmaceutical sector described in the preceding chapters of this *Profile* are helping to create opportunities to achieve these critical goals. However, the complexity of today's science will require continued research collaboration. With continued investment and persistence, we can move ahead steadily in understanding disease processes as well as applying new knowledge for better treatments. A supportive policy environment for innovation is essential to future medical progress.

In addition, public policy must place greater emphasis on preventing chronic diseases and their complications. Research and development alone cannot shift the "sick care" paradigm. The imminent aging of the U.S. population creates additional urgency for reasons of both patient

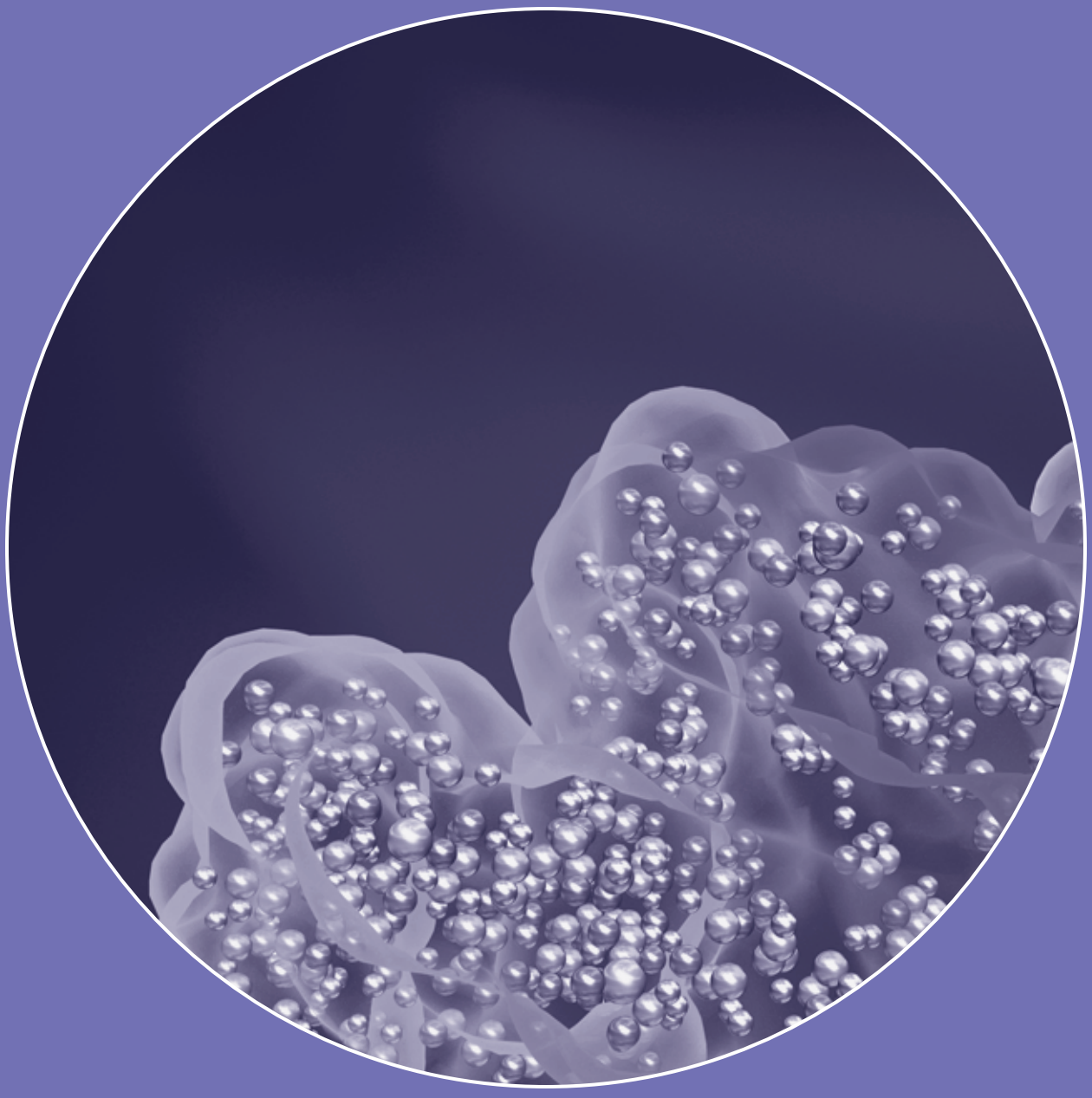
health and well-being and health care cost control.

Economic Recovery

The biopharmaceutical research sector is an important engine of economic recovery: continued support for innovation and growth will help the United States maintain its global leadership in biopharmaceutical R&D. Yet the recession and other competitive and regulatory vulnerabilities continue to challenge the sector. So does strong global competition for future R&D leadership, as foreign governments increasingly recognize the potential of medical research to help propel economic growth. A supportive policy environment for innovation can enable the biopharmaceutical sector to continue its essential contributions to U.S. economic recovery, while spurring medical progress.

PhRMA companies are continuing to pursue the goals of health care reform as well as economic recovery and are working to address our common national challenges. The biopharmaceutical sector's contributions will continue to make a real difference for all Americans.

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
Wayne, NJ

Biogen Idec, Inc.
Cambridge, MA

Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, CT

Bristol-Myers Squibb Company
New York, NY

Bristol-Myers Squibb Company Worldwide Medicines Group

Celgene Corporation
Summit, NJ

Cubist Pharmaceuticals, Inc.
Lexington, MA

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

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 Corporation Pharmaceuticals

East Hanover, NJ

OSI Pharmaceuticals Inc.

Melville, NY

Otsuka America, Inc. (OAI)

San Francisco, CA

- Otsuka America Pharmaceutical, Inc. (OAPI)
- Otsuka Maryland Medicinal Laboratories (OMML)
- Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC)

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

Sigma-Tau Pharmaceuticals, Inc.

Gaithersburg, MD

Takeda Pharmaceuticals North America, Inc.

Deerfield, IL

INTERNATIONAL AFFILIATE

Novo Nordisk, Inc.
Princeton, NJ

RESEARCH ASSOCIATES

Alexion Pharmaceuticals, Inc.
New Haven, CT

Alkermes, Inc.
Waltham, MA

Enzon, Inc.
Piscataway, NJ

Ferring Pharmaceuticals, Inc.
Parsippany, NJ

Inspire Pharmaceuticals, Inc.
Durham, NC

Orexigen Therapeutics, Inc.
La Jolla, CA

Talecris Biotherapeutics
Research Triangle Park, NC

Theravance, Inc.
South San Francisco, CA

Vifor Pharma
Basking Ridge, NJ

Xoma Ltd.
Berkeley, CA

PhRMA Annual Membership Survey Definition 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: 1970–2009

(dollar figures in millions)

Year	Domestic R&D	Annual Percentage Change	R&D Abroad*	Annual Percentage Change	Total R&D	Annual Percentage Change
2009**	$34,806.0	-2.2%	$10,976.1	-7.1%	$45,782.1	-3.4%
2008	35,571.1	-2.8	11,812.0	4.6	47,383.1	-1.1
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		**11.6%**		**15.5%**		**12.2%**

*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,* 2010.

TABLE 2

R&D as a Percentage of Sales, PhRMA Member Companies: 1970–2009

Year	Domestic R&D as a Percentage of Domestic Sales	Total R&D as a Percentage of Total Sales
2009*	19.0%	16.0%
2008	19.4	16.6
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*, 2010.

TABLE 3

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

(dollar figures in millions)

	Dollars	Share
R&D Expenditures for Human-use Pharmaceuticals		
Domestic	$ 34,936.4	73.7%
Abroad*	$ 11,456.0	24.2%
Total Human-use R&D	**$ 46,392.4**	**97.9%**
R&D Expenditures for Veterinary-use Pharmaceuticals		
Domestic	$ 634.7	1.3%
Abroad*	$ 356.0	0.8%
Total Vet-use R&D	**$ 990.7**	**2.1%**
TOTAL R&D	**$ 47,383.1**	**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,* 2010.

TABLE 4

Domestic R&D by Source, PhRMA Member Companies: 2008

(dollar figures in millions)

Type	Dollars	Share
Licensed-in	$ 6,567.3	18.5%
Self-originated	27,474.7	77.2
Uncategorized	1,529.0	4.3
TOTAL R&D	**$35,571.1**	**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*, 2010.

TABLE 5

R&D by Function, PhRMA Member Companies: 2008

(dollar figures in millions)

Function	Dollars	Share
Prehuman/Preclinical	$12,795.6	27.0%
Phase 1	3,889.6	8.2
Phase 2	6,089.7	12.9
Phase 3	15,407.4	32.5
Approval	2,225.8	4.7
Phase 4	6,835.8	14.4
Uncategorized	139.1	0.3
TOTAL R&D	**$47,383.1**	**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*, 2010.

TABLE 6

R&D by Geographic Area,* PhRMA Member Companies: 2008

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Africa	$ 40.7	0.1%
Americas		
United States	$35,571.1	75.1%
Canada	572.2	1.2
Mexico	81.2	0.2
Brazil	96.7	0.2
Other Latin America (Other South American, Central American, and all Caribbean nations)	210.4	0.4%
Asia-Pacific		
Japan	$ 925.3	2.0%
China	93.2	0.2
India	94.4	0.2
Other Asia-Pacific	318.1	0.7
Australia		
Australia and New Zealand	$ 190.3	0.4%
Europe		
France	$ 540.8	1.1%
Germany	781.2	1.6
Italy	284.0	0.6
Spain	301.7	0.6
United Kingdom	2,732.9	5.8
Other Western European	4,046.4	8.5
Turkey	40.6	0.1
Russia	80.4	0.2
Central and Eastern Europe (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, Malta and the Newly Independent States)	338.3	0.7
Middle East		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan and Qatar)	$ 43.2	0.1%
TOTAL R&D	**$ 47,383.1**	**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*, 2010.

TABLE 7

Biologics and Biotechnology R&D, PhRMA Member Companies: 2008

(dollar figures in millions)

Type	Dollars	Share
Biotechnology-derived Therapeutic Proteins	$10,542.3	22.2%
Vaccines	1,600.8	3.4
Cell or Gene Therapy	176.9	0.4
All Other Biologics	1,337.8	2.8
Total Biologics/Biotechnology R&D	**13,657.7**	**28.8**
Non-biologics/Biotechnology R&D	**30,057.5**	**63.4**
Uncategorized R&D	3,667.9	7.7
TOTAL R&D	**$47,383.1**	**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*, 2010.

TABLE 8

Domestic Sales and Sales Abroad,* PhRMA Member Companies: 1970–2009

(dollar figures in millions)

Year	Domestic Sales	Annual Percentage Change	Sales Abroad*	Annual Percentage Change	Total Sales	Annual Percentage Change
2009**	$183,026.4	-0.1%	$103,370.9	0.5%	$286,397.3	0.1%
2008	183,167.2	-1.1%	102,842.4	16.6	286,009.6	4.6
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		**10.3%**		**10.7%**		**10.3%**

*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*, 2010.

TABLE 9

Sales by Geographic Area,* PhRMA Member Companies: 2008

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Africa	$ 1,294.2	0.5%
Americas		
United States	$183,167.1	64.0%
Canada	7,002.8	2.4
Mexico	3,140.9	1.1
Brazil	3,120.9	1.1
Other Latin America (Other South American, Central American, and all Caribbean nations)	4,597.2	1.6%
Asia-Pacific		
Japan	$ 10,496.2	3.7%
China	2,570.0	0.9
India	698.3	0.2
Other Asia-Pacific	4,787.4	1.7
Australia		
Australia and New Zealand	$ 3,687.1	1.3%
Europe		
France	$ 10,342.1	3.6%
Germany	7,780.8	2.7
Italy	7,033.2	2.5
Spain	6,663.8	2.3
United Kingdom	6,297.6	2.2
Other Western European	13,232.9	4.6
Turkey	1,767.4	0.6
Russia	1,318.5	0.5
Central and Eastern Europe (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, Malta and the Newly Independent States)	4,929.2	1.7
Middle East		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan and Qatar)	$ 2,076.0	0.7%
Uncategorized	$ 6.1	0.0%
TOTAL SALES	**$286,009.6**	**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,* 2010.

TABLE 10

Domestic R&D Scientific, Professional and Technical Personnel by Function, PhRMA Member Companies: 2008

Function	Personnel	Share
Prehuman/Preclinical	26,113	28.8%
Phase 1	6,409	7.1
Phase 2	9,526	10.5
Phase 3	21,356	23.5
Approval	5,025	5.5
Phase 4	11,739	12.9
Uncategorized	477	0.5
Total R&D Staff	**80,645**	**88.9**
Supported R&D Non-staff	10,067	11.1
TOTAL R&D PERSONNEL	**90,712**	**100.0%**

SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey,* 2010.

ENDNOTES *(continued from inside front cover)*

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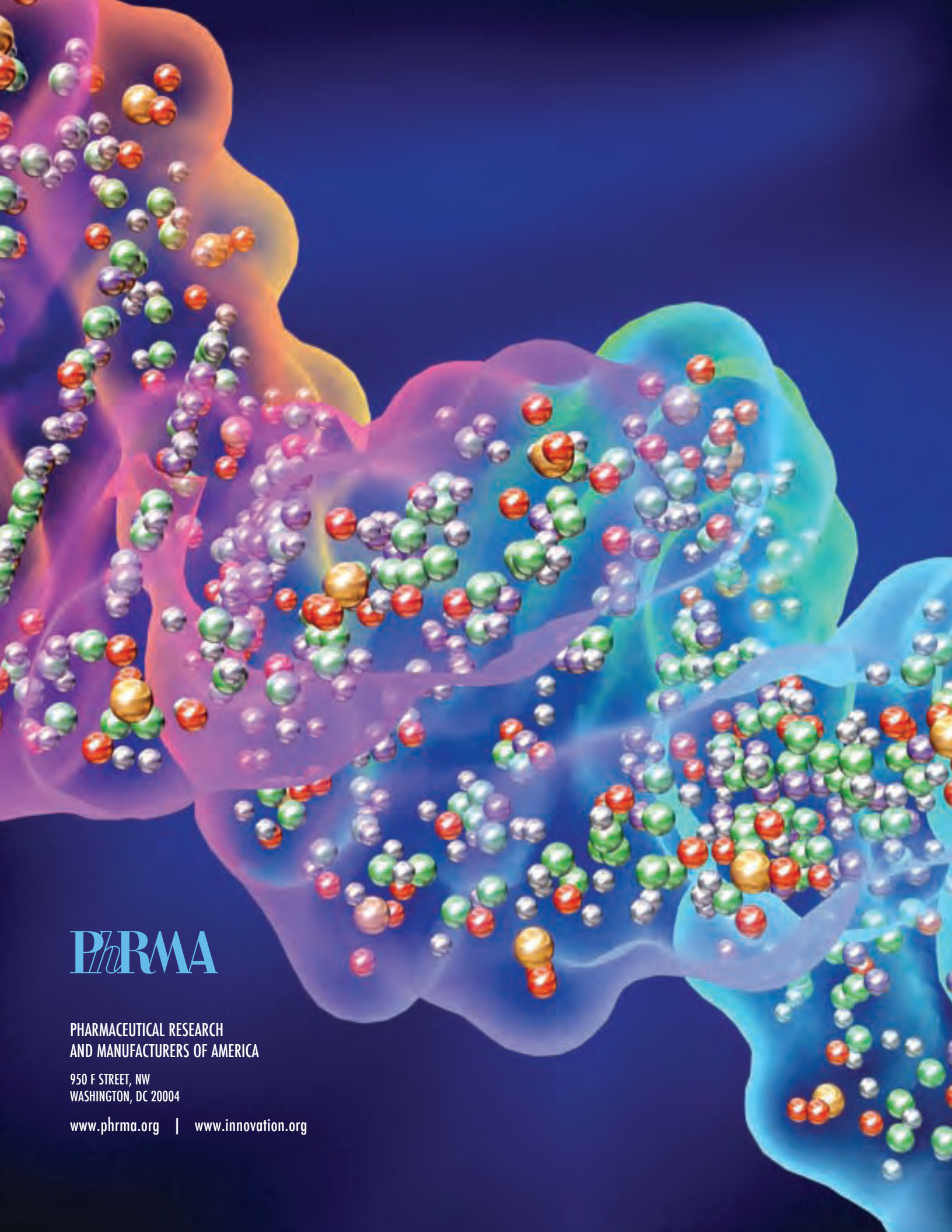

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