PROFILE 2008
PHARMACEUTICAL INDUSTRY

PhRMA

Key Facts

Research and Development

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

Development Costs

- Cost to develop a drug
  2006 = $1,318 million[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[6]	Total industry
2007	$44.5 billion (est.)	$58.8 billion (est.)[7]
2006	$43.4 billion	$56.1 billion[8]
2005	$39.9 billion	$51.8 billion[9]
2004	$37.0 billion	$47.6 billion[10]
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 2007

Domestic R&D as a percentage of domestic sales = 18.7%[5]

Total R&D as a percentage of total sales = 16.4%[5]

Total National Institutes of Health Funding[11]

(Part of this budget is allotted for developing drugs.)

- 2008 = $28.9 billion
- 2007 = $28.6 billion
- 2006 = $28.5 billion

Approvals

- Drugs approved in 2007 = 23[12]
- Only 2 of 10 marketed drugs ever produce revenues that match or exceed R&D costs.[13]
- In the 25 years since the *Orphan Drug Act* was established, more than 300 orphan drugs have been approved.[14]
- Average effective patent life for major pharmaceuticals in 2005 = 11 years[15]

Medicines in Development[16]

2008 = 2,700 compounds
2003 = 2,000 compounds

Value of Medicines

- One study found that the return on investment (ROI) for a 20% increase in adherence was substantial for disease-related costs: for every $1 spent on …
  - diabetes medicines → $7.10 savings
  - cholesterol medicines → $5.10 savings
  - blood pressure drugs → $4 savings[17]
- Every additional dollar spent on health care in the United States over the past 20 years has produced health gains worth $2.40 to $3.[18]

Sales

- Generic share of market[19]
  2000 = 51%
  2007 = 67%

Endnotes

See inside back cover.

PROFILE 2008
PHARMACEUTICAL INDUSTRY

PhRMA

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2008

Letter from PhRMA's President and CEO

America's biopharmaceutical research companies are dedicated to helping patients fight disease and stay healthy.

Today, Pharmaceutical Research and Manufacturers of America (PhRMA) member companies employ nearly 80,000 researchers, all working toward this goal. It is time-consuming and costly work. On average, researchers spend between 10 and 15 years developing each new potential medicine. Yet, the odds that any new medicine will make it all the way from a laboratory through FDA approval and onto a pharmacy shelf are slim.

Despite long development timelines and even longer odds against finding a successful new treatment, researchers at America's biopharmaceutical companies work tirelessly to discover and develop new medicines for patients. New technologies and new knowledge help guide the industry's scientists, who are committed to finding new treatments to battle complex diseases.

In 2007, America's biopharmaceutical research companies invested a record $58.8 billion — with $44.5 billion invested by PhRMA member companies alone. This spending supports more than 2,000 new medicines, which are in clinical trials or awaiting FDA review in the U.S.

This strong investment comes at a time when the U.S. health care system is facing great challenges, including an aging population and avoidable chronic diseases. Continued biopharmaceutical advances in the form of new medicines and treatment options are a critical part of the solution for improving the health of Americans, controlling health care costs, and enabling patients to live longer, healthier lives.

PhRMA members are particularly committed to helping ensure that all patients have access to the medicines they need. Programs such as the Partnership for Prescription Assistance (PPA) and other PhRMA member company philanthropic efforts are helping to close the gap in access to quality health care.

I am pleased to present PhRMA's *2008 Pharmaceutical Industry Profile,* which details the work of America's biopharmaceutical research companies in their quest to fight disease and help patients by continuing to develop the latest and best new medicines and treatments.

Billy Tauzin
President and CEO
Pharmaceutical Research and Manufacturers of America

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INTRODUCTION
Challenges and Opportunities

Creating better treatments for patients is the research-based biopharmaceutical industry's core mission. Fulfilling this mission involves both successes and setbacks.

R&D: America's biopharmaceutical companies continue to lead the world in investing in the research and development (R&D) of new medicines, and in producing treatment advances. Science today offers more promise for finding better treatments than ever before, thanks to new technologies and new knowledge.

Yet, the process carries the substantial risk of failure inherent in all scientific discovery. It also has exceptionally large costs and long timelines due to the complex scientific challenges of drug development, including the rigorous testing protocols that protect patient safety.

Public Policy: The environment for innovation includes public policies, such as patent protections and incentives for discovery. Today, more research and development of new medicines is taking place in the U.S. than in any other country. Public policies that support medical progress are a critical underpinning of the large-scale effort to discover new medicines that will make progress against disease.

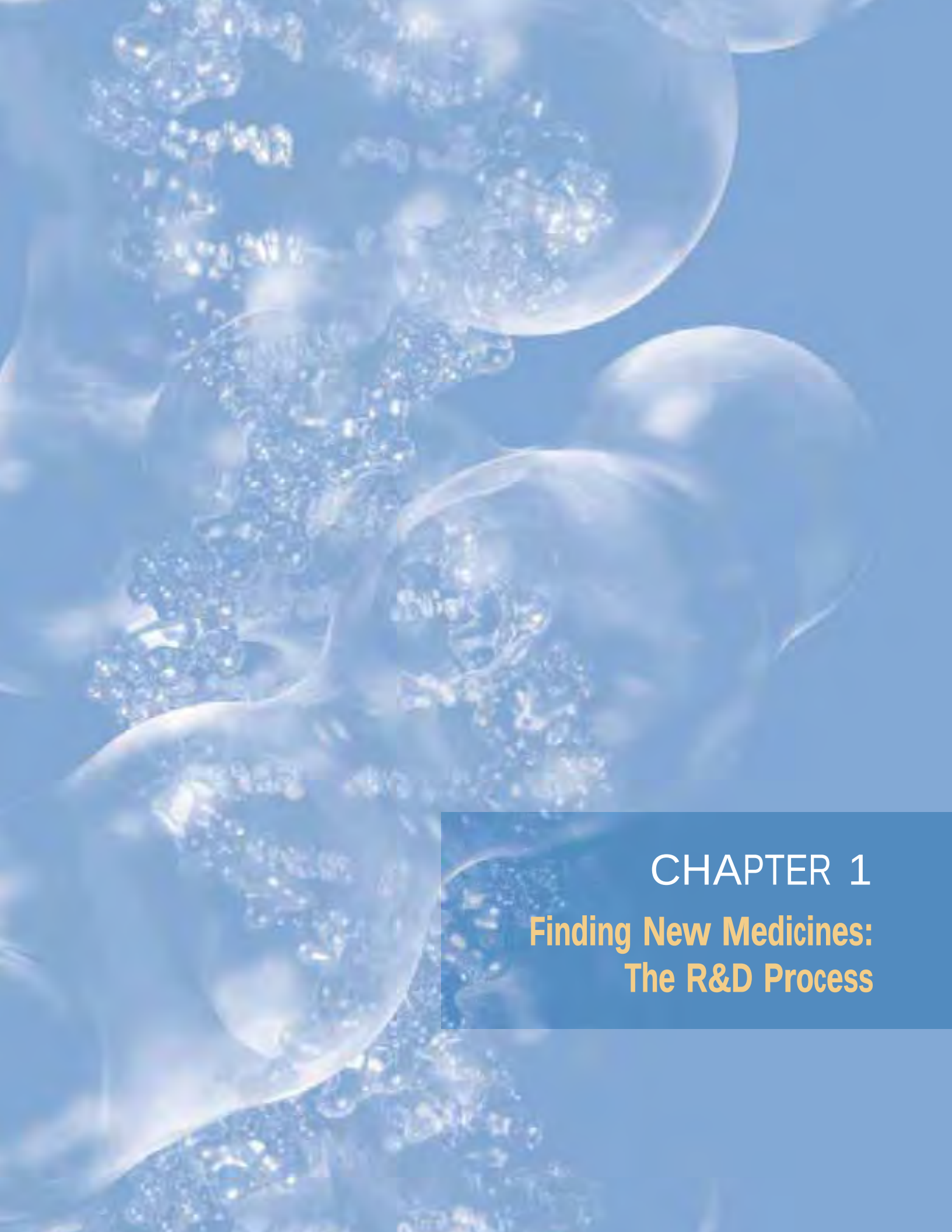
The Burden of Disease: Our health care system has achieved extraordinary results in terms of longer-living, healthier people, a reduction in disability, and a more productive workforce. However, the health care system, as a whole, is facing serious challenges: the aging of our population and the growing prevalence of obesity are converging to create a large burden of chronic disease for individuals and society.

Much of this growing burden of chronic disease can be prevented. With changes to their diets and lifestyles, many Americans could cut their risk of chronic diseases and their complications. Medicines can also help reduce morbidity, mortality and disability, and improve patients' quality of life by controlling disease when it does arise, allowing patients to be healthier for a longer time. Medicines also help control costs by reducing the need for expensive care, such as hospitalization, nursing home admission, and surgery. Supporting

medical research is, thus, supporting a significant health care value: medicines substantially improve outcomes but represent only a small percentage of health care costs.

Access to Medicines: The Medicare Part D program has provided help for the elderly and disabled populations, greatly increasing their access to medicines, while lowering their out-of-pocket costs. Yet, many other Americans are uninsured or under-insured, and do not have sufficient access to medicines and health care. As efforts to improve health coverage continue, the Partnership for Prescription Assistance has connected more than 5 million Americans with programs that provide access to free or nearly-free medicines. Programs like these are important because, in order to do good, medicines must make it to patients.

This year's *Pharmaceutical Industry Profile* highlights the potential challenges and opportunities in improving patients' health with new medicines. It features up-to-date data and survey results that help illuminate today's health challenges and opportunities, including the newest data from PhRMA's annual member survey, which appears in the Appendix.



CHAPTER 1

Finding New Medicines: The R&D Process

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"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."*[1]

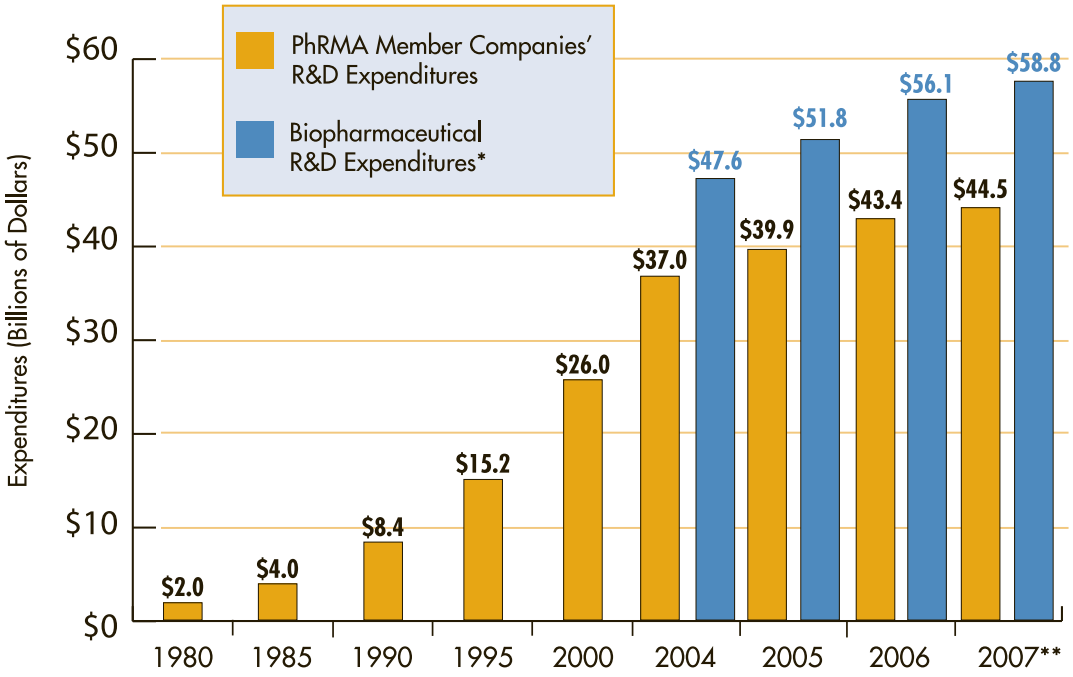
— Congressional Budget Office
October 2006

Making Progress Possible: U.S. Biopharmaceutical Companies Lead the World

Developing a new medicine is a long and rigorous process. But the biopharmaceutical industry is committed to finding new treatments: In 2007, the entire industry invested $58.8 billion in research and development.[2] PhRMA members alone invested $44.5 billion.[3] As Figure 1 shows, industry spending on R&D has continued to grow over the last decade. Although the growth was more modest in 2007, spending, as a percentage of sales, remains high at 18.7% of domestic sales and 16.4% of total sales.[4]

A recent study from the Tufts University Center for the Study of Drug Development puts the average cost of developing a new medicine at $1.3 billion (in year 2005 dollars), including the cost of failures and capital.[5] The same study estimates the cost to develop a biologic (a large molecule treatment produced by a biological system) at $1.2 billion (in year 2005 dollars).[6]

FIGURE 1: Biopharmaceutical Companies' Investment in R&D Remains Strong



Sources: Burrill & Company, analysis for Pharmaceutical Research and Manufacturers of America, 2008; and Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Member Survey* (Washington, DC: PhRMA, 2008).
*The "Biopharmaceutical R&D" 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.

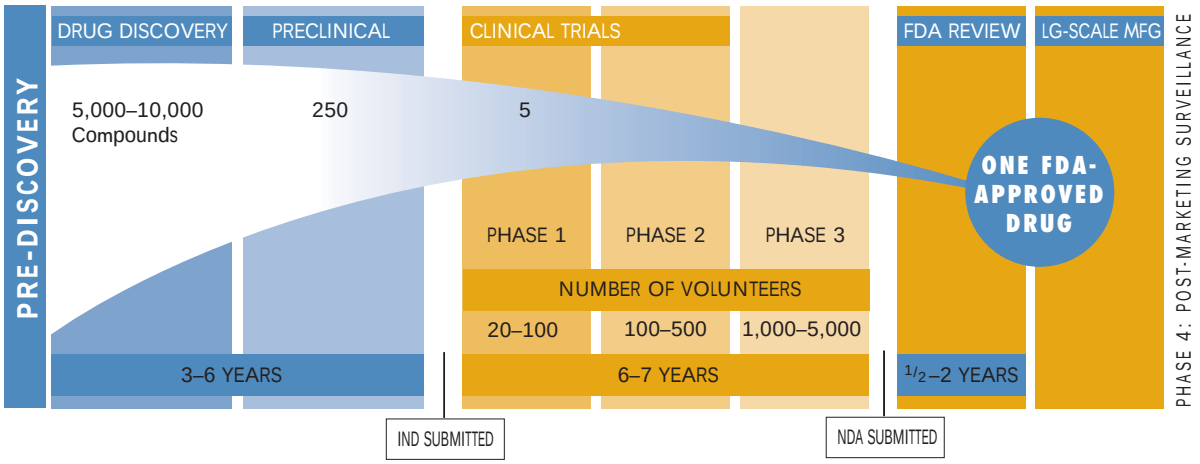
The Uncertain R&D Equation: Many Steps + Many Years = ?

The quest for new medicines takes many people, ideas, dollars, and years — with no guarantee of success. In fact, for every 5,000 to 10,000 compounds tested, just 5 will make it to clinical trials and, of those, only 1 will eventually receive FDA approval.[7]

As Figure 2 illustrates, the R&D process takes an average of 10 to 15 years[8] and involves many discrete steps and activities. First, scientists work to piece together the basic causes of a disease at the level of genes, proteins and cells. Out of this understanding emerge "targets," which potential new drugs might be able to affect. Then, researchers work to:

- Validate these targets;
- Discover the right molecule (potential drug) to interact with the chosen target;
- Test the new compound in the lab and clinic for safety and efficacy;
- Gain FDA approval, and;
- Manufacture and package the new drug so doctors can prescribe it for their patients.

FIGURE 2: The R&D Process: Long, Complex, and Costly



R&D DETAILS

Discovery

Pre-discovery: Understanding the Disease

Before any new medicine can be discovered, scientists study the disease to be treated and the underlying cause of the condition. They work to understand which genes and proteins are involved in the disease and how they interact. They try to determine how a drug interacts with these molecules to prevent or treat the disease.

Discovery: Finding a Drug Molecule

A team of chemists, pharmacologists and biologists screen thousands of compounds — or create a new one — and test them against the target to identify any that show potential. The most promising compounds are then chemically modified to improve safety and effectiveness. Because of the complexity and uncertainty of drug development, most of these potential drugs will never reach approval.

Preclinical: Testing in the Lab

During this phase, potential new drugs undergo laboratory and animal testing to determine if the drug is safe and effective enough for human testing. At this stage, researchers also explore how the drug can be manufactured in large quantities, how it can be formulated, the most effective delivery mechanism, and specific dosing recommendations.

Development

IND: FDA Weighs in Before Clinical Testing Can Start

Before any clinical trial in humans can begin, researchers must file an Investigational New Drug (IND) application with the FDA. The IND provides a detailed clinical trial plan and all

the results of preclinical work. The FDA reviews the IND to help assure that people will not be exposed to unreasonable risks during clinical trials.

Clinical Trials: Extensive Safety and Efficacy Testing in the Clinical Setting

A candidate drug must go through extensive studies in humans, and it must prove to be safe for people and effective against the disease in question before the FDA will approve it. This process involves three phases of clinical trials, beginning with tests in small groups of healthy volunteers and moving into larger groups of patients. Physicians carry out each trial working with volunteer patients in hospitals, offices, and clinics, and coordinating closely with the sponsor company. During any of the three phases, the FDA can halt the study if safety concerns arise.

PHASE I: The candidate drug is tested in people for the first time, in studies usually involving about 20 to 100 healthy volunteers. The goal of Phase I trials is to discover if the drug is safe in humans. Researchers also observe how the drug is absorbed and metabolized in the body, and determine a safe dosing range.

PHASE II: The candidate drug is tested in 100 to 500 volunteer patients with the disease or condition under study. In this phase, researchers try to determine whether the candidate drug effectively treats the disease or condition, and they examine possible side effects and risks associated with the drug.

PHASE III: In this phase, researchers study the candidate drug in 1,000 to 5,000 volunteer patients to determine safety, efficacy, and the overall benefit-risk relationship of the drug.

FDA Review

If results of the clinical trials demonstrate that the benefits of the drug outweigh the risks, researchers file a New Drug Application (NDA) with the FDA, requesting approval to market the drug. The NDA is extremely lengthy, containing all clinical and preclinical findings, and the proposed labeling and manufacturing plans. The FDA reviews all the information in the NDA to determine if the candidate drug is safe and effective enough to be approved for use by patients. The agency can either approve the drug, request more testing, or decline to approve it.

Manufacturing

Going from small-scale to large-scale manufacturing is a major undertaking. To ensure that the drugs are uniform, high-quality, and safe, each facility in which a drug is produced must meet strict FDA guidelines for Good Manufacturing Practices (GMP), and undergo periodic inspections.

Ongoing Studies and Phase IV Trials

Research on a new medicine continues even after approval. As a much larger number of patients begin to use the drug, researchers continue to monitor it carefully and submit periodic safety reports to the FDA. In some cases, the FDA requires additional studies of an approved drug in "Phase IV" studies to further assess aspects of the drug's safety. Other post-approval research may test the efficacy of the medicine for other indications.

Biopharmaceutical R&D: High Risk, High Stakes

The Challenges	The Benefits
* More than $1 billion is spent on research and development for each new drug or biologic.[9] * For every 5,000 compounds tested, only 5 ever make it to clinical trials, and only 1 is ever approved by the FDA.[10] * Half of all experimental drugs in Phase III clinical trials never become approved medicines.[11] * Only 2 in 10 approved drugs bring in enough revenue to recoup their cost of development.[12]	* In the last decade alone, nearly 350 new medicines have been approved by FDA.[13] * Life expectancy increased over the last decade, reaching a new high in 2004. The latest data shows that men live 75.2 years and women 80.4 years on average.[14] * Since 1971, our arsenal of cancer medicines has tripled. Today, there are 3 million more cancer survivors than there were a decade ago.[15] * In 2007 alone, the following were among the new drugs approved: + 2 first-in-class medicines for HIV/AIDS + 1 first-in-class medicine to treat high blood pressure + 2 new medicines for advanced forms of breast cancer + The first-ever patch for the treatment of Parkinson's disease + 6 new "orphan" drugs to treat rare diseases[16]

Medical Advances: Recent Approvals and Medicines in Development

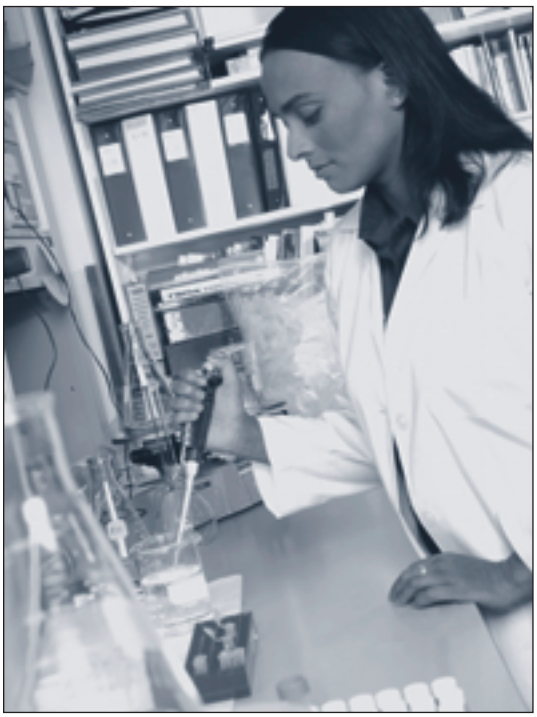
In 2007, new approvals included a first-in-class medicine to treat high blood pressure, as well as two new treatments for advanced forms of breast cancer. Other new approvals included the first-ever skin patch for the treatment of Parkinson's disease, two first-in-class HIV drugs, and new "orphan" drugs to treat various rare diseases.[17]

Although there were important advances in 2007, there have been fewer new approvals in recent years, despite increased investment in research and development. While it may

seem surprising that this slowdown would occur at a time when our understanding of the molecular and genetic causes of disease is better than ever, there are many complex factors at play.

Researchers believe that this new molecular knowledge will take time to bear fruit. Scientists are working with new information and new technologies and it will take several years before we begin to meet the potential of the genomic era.

Furthermore, it has always been very difficult to predict how quickly potential new medicines will proceed through human clinical trials. The fact is, the high failure rate in clinical testing remains one of the key challenges of



Public-Private Collaborations: Partners in Innovation

Modern drug discovery is the product of cooperation. Both public and private organizations play unique but increasingly interdependent roles in the drug research and development process. While major biopharmaceutical companies are the primary source of R&D funding for new medicines and they conduct basic and applied research, small companies also drive innovation, conducting basic research, drug discovery, preclinical experiments, and, in some cases, clinical trials. Researchers in the government, academia, and for-profit research institutions also contribute heavily to basic research. For example, the National Institutes of Health (NIH) stimulates basic research and early-stage development of technologies that enable further targeted drug discovery and development through its leadership and funding support to universities, medical schools, research centers, and other non-profit institutions. Biopharmaceutical companies also contribute extensively to basic science and are largely responsible for translating that research into new treatments.[18] Their investment in R&D ($58.8 billion in 2007) continues to be about twice the total NIH operating budget of $28.6 billion,[19] only a part of which goes to drug development.

pharmaceutical research and development. A treatment that fares well in preclinical animal testing may not do well in volunteer patients. What's more, it is hard to determine the extent to which requests for more safety information affect the time it takes to move pharmaceutical treatments through human clinical testing.

Fortunately, recent reports show that an increasing number of new compounds and therapeutic proteins are moving into clinical testing following FDA review. America's pharmaceutical research companies are continuing to increase research and development spending in their quest to develop newer and better medicines for patients around the world.

The prospects are good for continued progress in the coming years. Today, there are more than 2,700 medicines in clinical trials or undergoing FDA review for 4,600 indications.[20] These medicines in development mean hope for many patients who need more or better treatment options. Among the projects in development, there are 596 medicines in late-stage development for cancer; 71 for HIV/AIDS; 60 for diabetes; 73 for arthritis, and; 57 for Alzheimer's disease.[21] Many of these medicines will never make it to patients, but all are being tested rigorously in the R&D process to determine which will be helpful — and not harmful — to patients.

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

[2] Burrill & Company, analysis for Pharmaceutical Research and Manufacturers of America, 2008; and Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Member Survey* (Washington, DC: PhRMA, 2008).

[3] Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Member Survey* (Washington, DC: PhRMA, 2008)

[4] *Ibid.*

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

[6] *Ibid.*

[7] PhRMA, based on data from Tufts University, Tufts Center for the Study of Drug Development (1995).

[8] 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; and 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.

[9] J. A. DiMasi, and H. G. Grabowski, *op. cit.*

[10] Tufts Center for the Study of Drug Development, *Backgrounder: How New Drugs Move through the Development and Approval Process* (November 2001).

[11] A. C. Von Eschenbach, "Statement Before the Senate Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Subcommittee," U.S. Food and Drug Administration, June 2007, http://www.fda.gov/ola/2007/criticalpath060107.html (accessed 27 November 2007).

[12] J. Vernon, J. Golec, and J. DiMasi, "Drug Development Costs when Financial Risk is Measured Using the Fama-French Three Factor Model," Unpublished Working Paper, January 2008.

[13] Pharmaceutical Research and Manufacturers of America, New Drug Approval Reports, 1997–2006.

[14] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Health United States*, 2007, with Chartbook on Trends in the Health of Americans (Hyattsville, MD: NCHS, 2007), http://www.cdc.gov/nchs/data/hus/hus07.pdf.

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

[16] U.S. Food and Drug Administration, Office of Orphan Products, "Cumulative List of Designated and Approved Orphan Products" (Washington, DC: FDA, 4 October 2007), http://www.hhs.gov/orphan/designat/allap.rtf (accessed 3 March 2008); B. Silverman, "FDA First-Cycle Approval Rate is Silver Lining in Cloud of Low NME Count," *The Pink Sheet* 70, no. 2 (14 January 2008) and B. Silverman, "Year in Review: New Biologics Total Seven in 2007, But Only Four Will See Market," *The Pink Sheet* 70, no. 3 (21 January 2008). Food and Drug Administration, www.fda.gov.

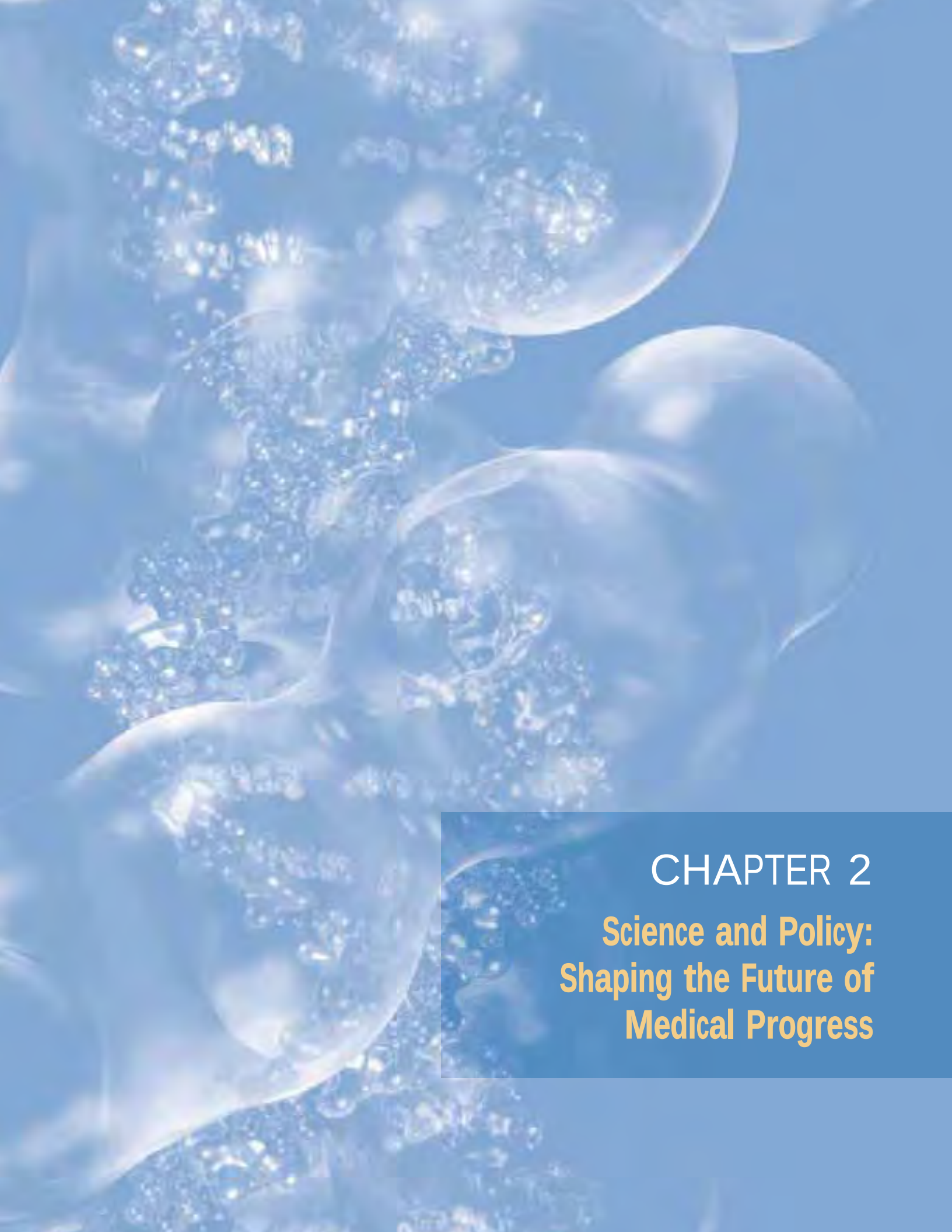
[17] U.S. Food and Drug Administration, *Prescriber Letter,* http://www.prescribersletter.com/pl/newdrugs/FDA2007.pdf?cs=&s=PRL (accessed 18 December 2007).

[18] Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," October 2006. E. Zerhouni, Presentation at Transforming Health: Fulfilling the Promise of Research, Event sponsored by PhRMA and Research!America, Washington DC, 16 November 2007.

[19] U.S. Department of Health and Human Services, *FY 2008 Budget in Brief* (Washington, DC: FDA, 4 October 2007) http://www.hhs.gov/budget/08budget/2008BudgetInBrief.pdf (accessed 20 February 2008).

[20] Adis R&D Insight Database, 27 February 2008.

[21] *Ibid*.



CHAPTER 2

Science and Policy: Shaping the Future of Medical Progress

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Science and Policy: Shaping the Future of Medical Progress

"The dominant role of post-approval research extends to many other drugs used as what are called 'targeted therapies' ... Some of these targeted therapies find value in treating a completely different illness. More successes are, no doubt, on the way."[1]

— Jack Calfee, Ph.D., Economist, Resident Scholar, American Enterprise Institute for Public Policy Research

Americans expect and value medical progress. In fact, a new survey by Research!America and PhRMA shows that nearly 3/4 of Americans believe medical breakthroughs will occur in the next decade for diseases such as diabetes, cancer, and heart disease. More than half say that someone close to them has already been helped by medical research, and 95% feel it is important that the U.S. leads the world in medical innovation.[2] Both science and public policy play roles in meeting these expectations.

Toward Greater Precision in Research and Care

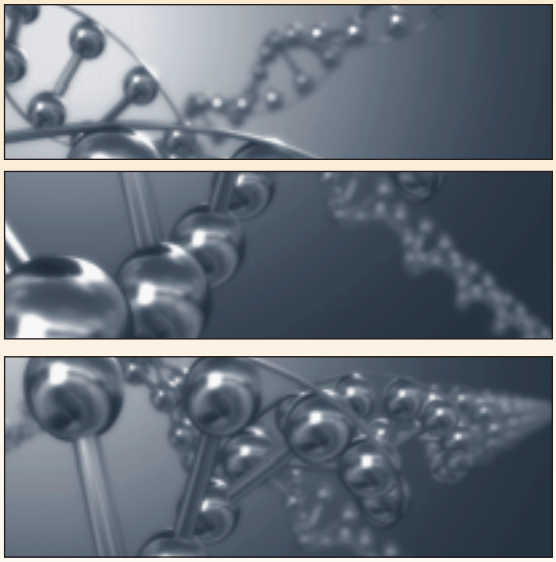
A deeper understanding of genetic and molecular information at the individual level is transforming the way medicines are developed

and used. Several areas show great promise for advancing treatment options:

- **Personalized Medicine: Treatment Options Based on Genetic Makeup**
  As researchers learn more about the human genetic code, they are increasingly working to develop personalized treatments, which can be tailored for specific groups of patients based on their genetic makeup. While scientific challenges remain, this approach has the potential to increase the efficacy and safety of medicines. Many researchers also envision that pharmacogenomics — the study of how genetics affects individuals' responses to drugs — could enhance the efficiency of the drug development process.

- **Biomarkers: New Tools for Diagnosis, Treatment, and Research**
  Biomarkers are molecular, biological or physical characteristics that can help identify risk for disease, make a diagnosis, or guide treatment. They can also help clinicians personalize treatment. In drug development, biomarkers often help researchers select candidate drugs with a better chance of success, which saves time and money, and speeds medicines to patients in need. For example, CD4 and viral load biomarkers enabled development and approval of HIV/AIDS antiviral drugs in only about $3\frac{1}{2}$ years.[3]

Genetic tailoring is already beginning to occur. In 2007, the FDA changed the labeling for the widely-used anti-clotting drug, warfarin, to inform physicians and patients about a genetic test that can predict which patients are likely to be especially prone to bleeding while on the drug.[4] Genetic testing for such indicators — or biomarkers — would enable more precise initial dosing and potentially prevent thousands of complications each year.



Because finding new biomarkers is a highly complex undertaking, PhRMA, the Foundation for the National Institutes of Health, the NIH, and the FDA have formed a public-private partnership to search for and validate new examples. Some initial projects of the new Biomarkers Consortium will:

- Assess the use of Fluorodeoxyglucose-Positron Emission Tomography (FDGPET) as a potential biomarker in non-Hodgkin's lymphoma and non-small cell lung cancer.
- Identify genomic biomarkers for treatment response in major depressive disorder.
- Look for new biomarkers for Type II diabetes that could lead to a more reliable and faster diabetes test.

"The identification of biomarkers is an essential element for the new era of predictive, preemptive, personalized medicine. The consortium enables government, industry, and philanthropy to come together to explore and develop common tools for a common purpose for everyone's benefit."[5]

— Elias Zerhouni, M.D., Director, National Institutes of Health

Incremental Innovation: Cumulative Advances for More Patient Benefit

Medical progress is often cumulative, with incremental advances building on each other to improve treatment options continually for physicians and patients. Researchers may find better ways to formulate a drug so patients only need to take it once a day, or so they experience fewer side effects. New medicines within an existing drug class can offer options for doctors who know that patients respond differently to different drugs. Sometimes, post-approval research shows that a medicine approved for one disease is also helpful for patients with another condition. These incremental innovations help make medicines safer and more effective for patients.

New Indications for Approved Biotech Medicines

An increasingly important aspect of research is the work that happens after a medicine is approved. Many medicines receive an additional indication(s) following approval, but biologics are particularly likely to receive additional approvals once they are on the market. To date, 47% of approved biologic therapies have gained approval for at least one other indication, based on post-approval research.[6] Advances include

Patients Benefit from Incremental Advances

Product and Initial Indication	Innovations From Post-Approval Research	Patient Benefits
Amlodipine and olmesartan — hypertension	New combination of two anti-hypertensive therapies in a once-a-day tablet	Helps avoid medicine errors for high blood pressure patients who need multiple therapies, and; offers great convenience, an important factor in improving compliance
Trastuzumab — advanced breast cancer	First approved to treat all tumors with HER2 proteins; new version specifically targeted to patients with a particular form of HER2 cancer	Allows more precise patient selection for better probability of success
Interferon alpha-2b — hairy cell leukemia	Applied to treating more diseases, such as Hepatitis B and C and malignant melanoma	Gives more patients a new treatment option

Patents Spur Innovation

There are many policy issues that affect innovation. Strong patent incentives, and other intellectual property incentives, for example, are particularly important for research to take place. Patents are the legal protection for inventions, including new medicines. The U.S. government gives the innovator exclusive rights to market the invention for a defined period of time, in exchange for disclosing the research and science underlying the product.

While total patent life in the U.S. is 20 years, for medicines, much of that span is spent in research and development. For example, drugs with more than $100 million in annual sales had an effective patent life of 11 years in 2003 through 2005.[7] There is evidence that effective patent life is shortening and will continue to decline. This is due to the increasing number of patent challenges, which are concentrated at earlier stages.

Weakening patent incentives reduces the chance that investors will accept the risks of the long, risky development process. It's important for the U.S. to maintain patent incentives at home, and support them abroad to bring the greater certainty that encourages continued medical innovation for American patients.

expanding the biologic's approved uses within a specific disease area or adding a completely new indication.

Policy Issues Can Affect Medical Progress

While science offers unprecedented possibilities for research advances, public policies will affect the ability of R&D to flourish. Public policy will also affect patients' ability to access the medicines that are made possible by this research — and it is only when patients can widely access these medicines that progress against a disease can be made.

It is important for the U.S. to maintain an environment that rewards and encourages innovation. Many countries around the world have restrictive policies that do not foster research and, as a result, medical research in the U.S. is outpacing the rest of the world. (See Figure 3.)

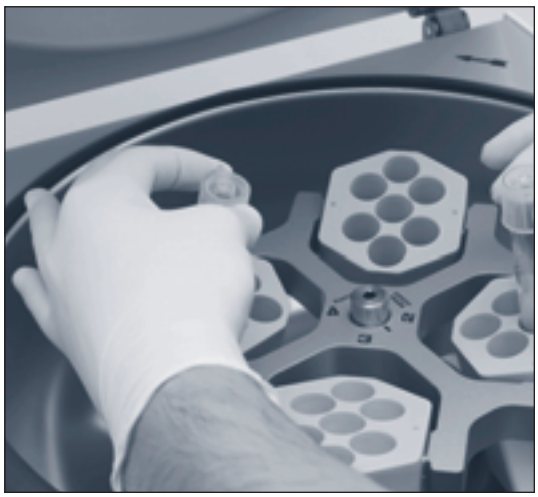
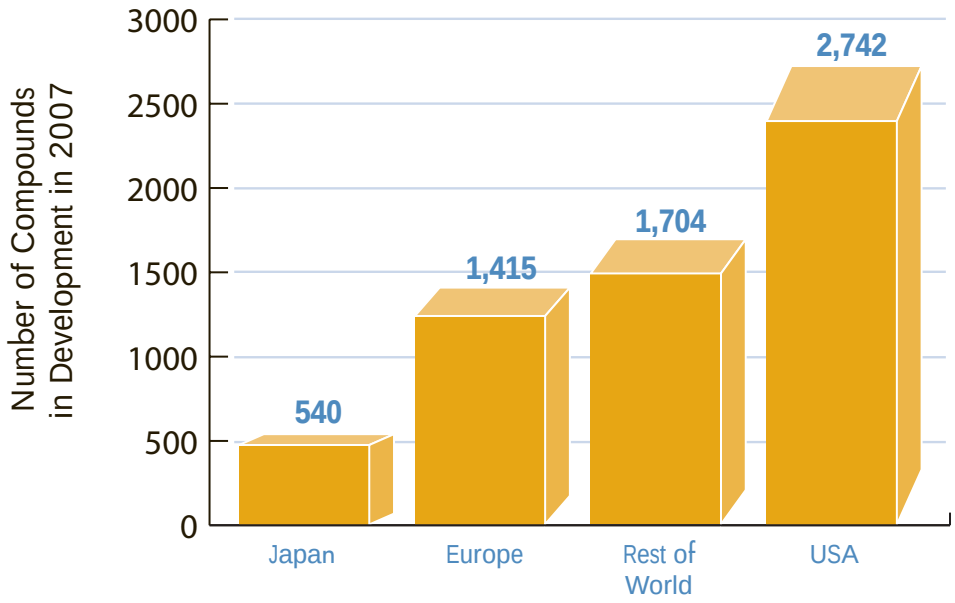


FIGURE 3: Medical Research in the U.S. Outpaces the Rest of the World



Source: Adis R&D Insight Database, customized run (December 2007).

"The U.S. undoubtedly faces significant challenges in improving the quality and affordability of health care... [Policy] proposals should be carefully examined with an eye toward maintaining our global leadership in R&D... A policy shot in the dark could well imperil the next life-saving shot in the arm."[8]

— Kevin Hassett, Ph.D., Resident Scholar and
Director of Economic Policy Studies,
American Enterprise Institute for Public Policy Research

[1] J. Calfee, "The Golden Age of Innovation," *The American*, March/April 2007, http://www.american.com/archive/2007/march-april-magazine-contents/the-golden-age-of-medical-innovation/.

[2] Research!America, *Transforming Health: Fulfilling the Promise of Research, A Public Opinion Study*, November 2007.

[3] The Biomarkers Consortium, Backgrounder, 5 October 2006, http://www.biomarkersconsortium.org/index.php?option=com_content&task=view&id=51&Itemid=61.

[4] *International Herald Tribune*, "U.S. Approves Genetic Test to Promote Safer Use of Blood Thinner," 17 September 2007, http://www.iht.com/articles/ap/2007/09/17/america/NA-MED-US-Warfarin-Genetic-Test.php (accessed 29 November 2007).

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[7] H. G. Grabowski and M. Kyle, "Generic Competition and Market Exclusivity Periods in Pharmaceuticals," *Managerial and Decision Economics* 28 (2007): 491–502.

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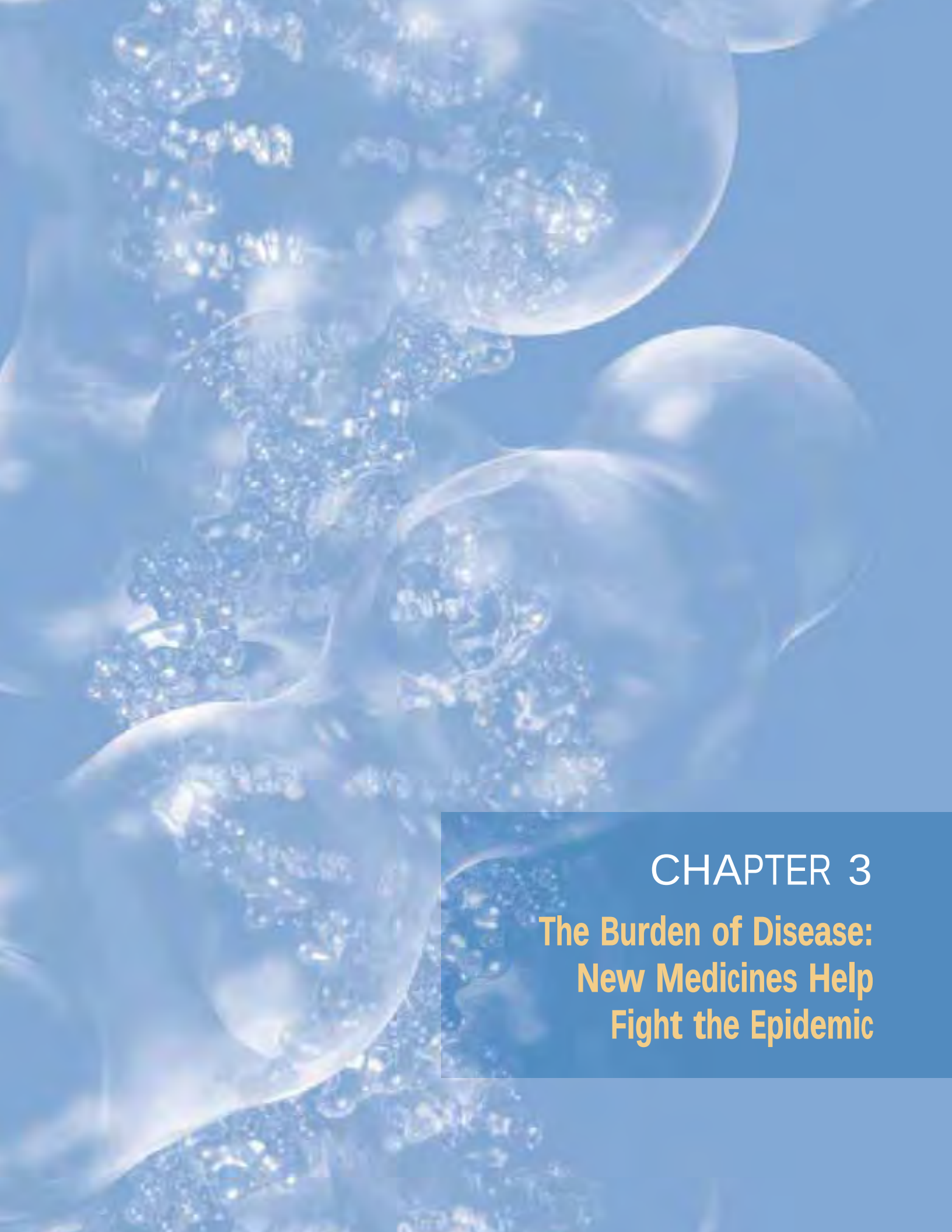

CHAPTER 3

The Burden of Disease: New Medicines Help Fight the Epidemic

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The Burden of Disease: New Medicines Help Fight the Epidemic

"The United States cannot effectively address escalating health care costs without addressing the problem of chronic diseases."[1]

— Centers for Disease Control and Prevention

Chronic Disease in the U.S.: A Growing Problem for Patients and Society

Chronic diseases such as diabetes, heart disease, and stroke are a large and growing burden on the health of Americans and the nation's health care system. Rising rates of chronic disease are responsible for much of the increase in health care spending over the last 15 to 20 years.[2]

The rising prevalence of chronic disease is partly the result of a population that is aging and increasingly obese. In fact, the percentage of obese adults more than doubled in the last 30 years from 14.6% between 1971 and 1974 to 32.1% between 2001 and 2004.[3] As a result, the prevalence of diabetes doubled in the U.S. between 1994 and 2004.[4] A decade ago, one in five Americans had high blood pressure, but now one in four is afflicted.[5]

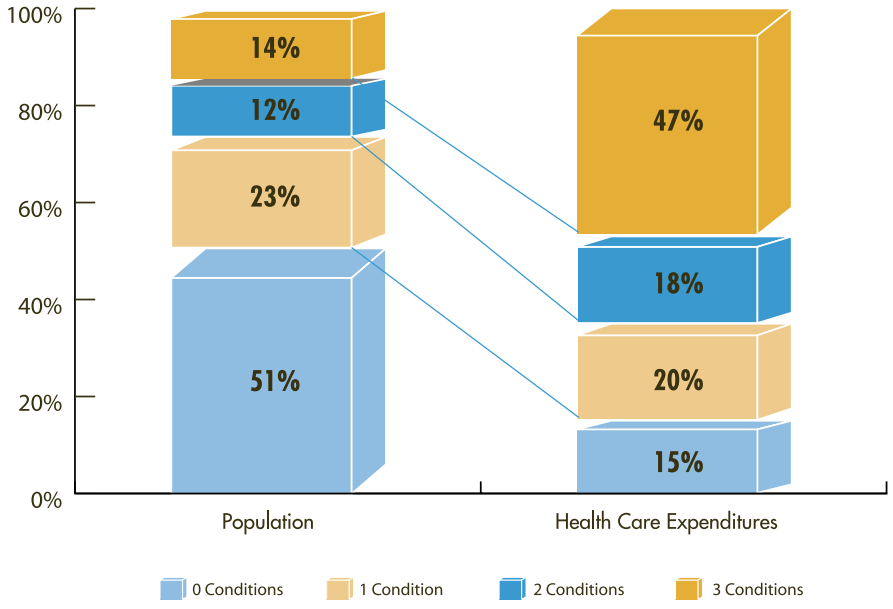
Today, 26% of patients have two or more chronic diseases. These patients account for a disproportionate 65% of total health care spending in the U.S. (See Figure 4.) Eight in 10 deaths are attributable to chronic diseases.[6]

This problem is likely to loom even larger in the coming years. As rates of obesity rise and as our population ages, the prevalence of those suffering from chronic disease will likewise increase. The proportion of the population aged 65 years or older is projected to grow from 12% in 2000 to 20% in 2030. During this timeframe, the number of people with chronic disease is expected to grow by 37%, or 46 million more chronic disease patients.[7] (See Figure 5.)

Chronic Diseases: Costing Lives, Reducing Quality of Life

- Chronic diseases are among the most prevalent, costly, and preventable of all health problems.[8]
- Nearly half — 49% — of all Americans have at least one chronic condition.[9] (See Figure 6.)
- Chronic diseases can be disabling and reduce a person's quality of life, especially if left undiagnosed or untreated. For example, every 30 seconds, a lower limb is amputated as a consequence of diabetes.[10]
- People with chronic conditions are the most frequent users of health care in the U.S. They account for 82% of hospital admissions; 92% of all prescriptions filled; and 79% of all physician visits.[11]
- Chronic diseases are most common in the elderly. More than 25% of young adults, roughly 50% of middle-aged adults, and 69% of the elderly have more than one chronic condition.[12] In the U.S., the proportion of the population over age 65 is projected to increase from 12.4% in 2000 to 19.6% in 2030.[13] People with two chronic conditions have more than five times the health care spending of those with no chronic conditions and are four times as likely to be hospitalized.[14]

FIGURE 4: U.S. Health Care Spending Disproportionate for Patients with Chronic Conditions



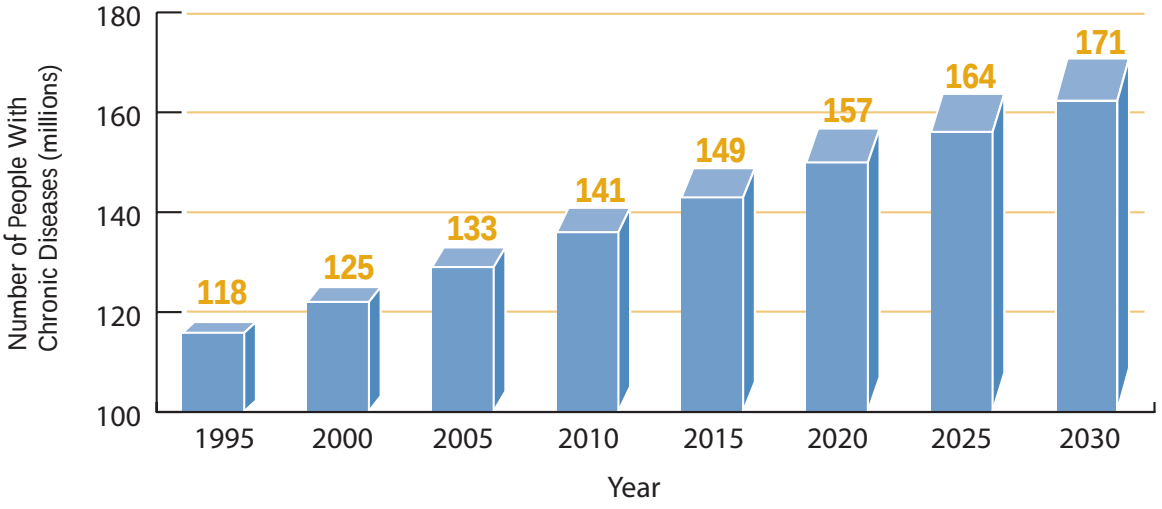
Source: Based on Gerard Anderson, "Chronic Conditions: Making the Case for Ongoing Care," analysis of the 2004 Medical Expenditure Panel Survey, November 2007.

Chronic Diseases: Often Preventable, Frequently Manageable

The good news is that many of the consequences and costs of chronic disease are avoidable through behavior change. The U.S. Centers for Disease Control and Prevention (CDC) estimates that eliminating three risk factors — poor diet, inactivity, and smoking — would prevent: 80% of heart disease and stroke; 80% of type 2 diabetes; and, 40% of cancer.[15]

Another opportunity for improving outcomes and affordability rests in increasing early treatment and adherence to medicines when disease does arise. According to a landmark study by RAND, only about half of all patients are receiving recommended care for chronic conditions such as asthma, high cholesterol and diabetes.[16] (See Figure 7.)

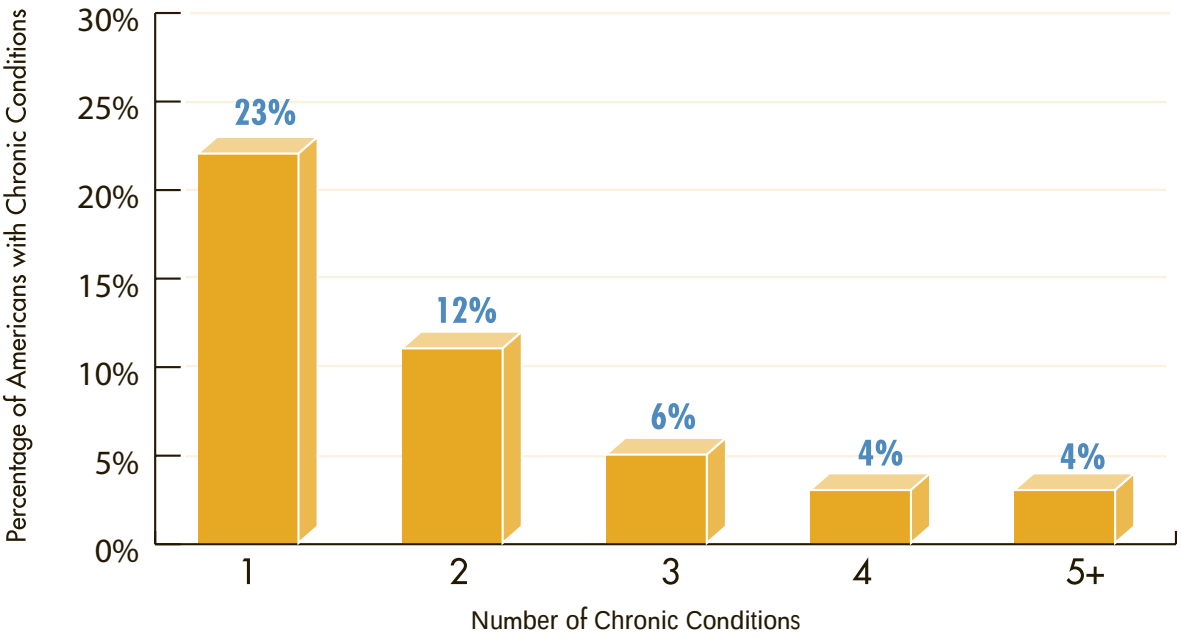
FIGURE 5: Rates of Chronic Disease Projected to Rise



Source: S. Wu, and A. Green, *Projection of Chronic Illness Prevalence and Cost Inflation* (Santa Monica, CA: RAND Health, October 2000).

More aggressive early disease detection and better use of treatments would have a positive effect. A recent analysis by the Milken Institute, conducted with support from PhRMA, shows that even a modest increase in the above steps could lead to 40 million fewer cases of illness and an annual reduction of more than $1 trillion annually in direct and indirect costs (including reduced labor supply and investment) by 2023.[17] (See Figure 8.)

FIGURE 6: Americans with Chronic Conditions, 2004

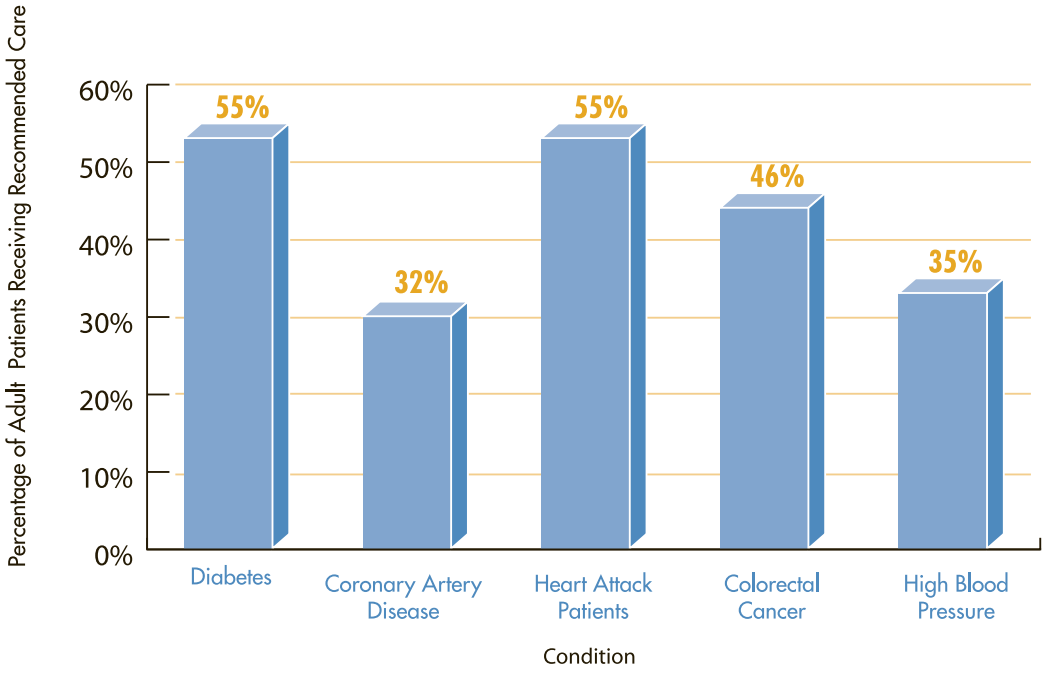


Source: Based on Gerard Anderson, "Chronic Conditions: Making the Case for Ongoing Care," analysis of the 2004 Medical Expenditure Panel Survey, November 2007.

The Partnership to Fight Chronic Disease: Expanding Access to Prevention and Care

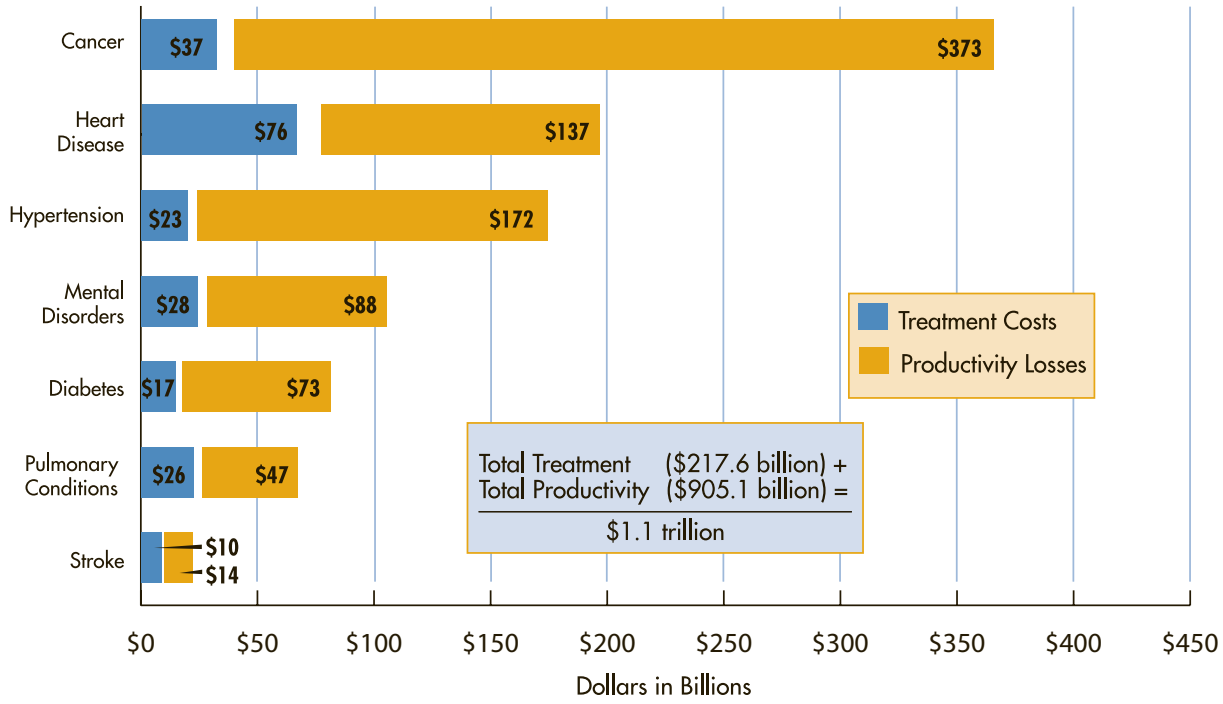
PhRMA is a strong supporter of the Partnership to Fight Chronic Disease (PFCD), a national, bipartisan coalition of patients, providers, community organizations, business and labor groups, and health policy experts committed to raising awareness about the need to stem rising rates of preventable chronic disease.

FIGURE 7: Few Americans Receiving Recommended Care



Source: E. McGlynn, et al., "The Quality of Health Care Delivered to Adults in the United States," *New England Journal of Medicine* 348, no. 26 (23 June 2003): 2635–2645.

FIGURE 8: Avoidable Treatment Costs and Productivity Losses, 2023



Note: Treatment expenditures for individuals in nursing homes, prisons, or under other institutional care are not included. Treatment expenditures for comorbities and secondary effects of listed disease are also excluded.

Source: R. DeVol and A. Bedroussian, "An Unhealthy America: The Economic Burden of Chronic Disease," Milken Institute, October 2007, http://www.milkeninstitute.org/publications/publications.taf?function=detail&ID=38801018&cat=ResRep (accessed 29 November 2007).

The PFCD offers a united voice on this issue at a national level, and is working to educate Americans about policies and practices that can expand chronic disease prevention and care. Its key objectives are to raise awareness of the problem of chronic disease, advocate for public policy-based solutions, and provide information on what others are already doing to make a difference. So far, more than 85 partner organizations from across the country have joined the PFCD. For more information on the partnership, visit: www.fightchronicdisease.org.

[1] U.S. Centers for Disease Control and Prevention, *Chronic Disease Overview* (18 November 2005), http://www.cdc.gov/nccdphp/overview.htm (accessed 29 November 2007).

[2] K. E. Thorpe, C. S. Florence, and P. Joskiu, "Which Medical Conditions Account for the Rise in Health Care Spending?" *Health Affairs Web Exclusive* (25 August 2004): W4-437–W4-445.

[3] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2006* with Chartbook Trends in the Health of Americans (Hyattsville, MD: NCHS, 2006), http://www.cdc.gov/nchs/data/hus/hus06.pdf.

[4] U.S. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Adult and Community Health. Data from the Behavioral Risk Factor Surveillance System. Data computed by the Division of Diabetes Translation, http://www.cdc.gov/diabetes/statistics/prev/state/fPrev1994and2004.htm.

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

[6] Based on: G. Anderson, "Chronic Conditions: Making the Case for Ongoing Care," analysis of the 2004 Medical Expenditure Panel Survey, November 2007.

[7] S. Wu, and A. Green, *Projection of Chronic Illness Prevalence and Cost Inflation* (Santa Monica, CA: RAND Health, October 2000). J. Homer, G. Hirsch, and B. Milstein, "Chronic Illness in a Complex Health Economy: The Perils and Promises of Downstream and Upstream Reforms," *Systems Dynamics Review* 23, no. 2–3 (30 October 2007): 313–343.

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[9] G. Anderson, *op. cit.*

[10] A. J. Boulton, et al., "The Global Burden of Diabetic Foot Disease," *The Lancet* 366, no. 9498 (12 November 2005): 1719–1724.

[11] G. Anderson, *op. cit.*

[12] *Ibid*.

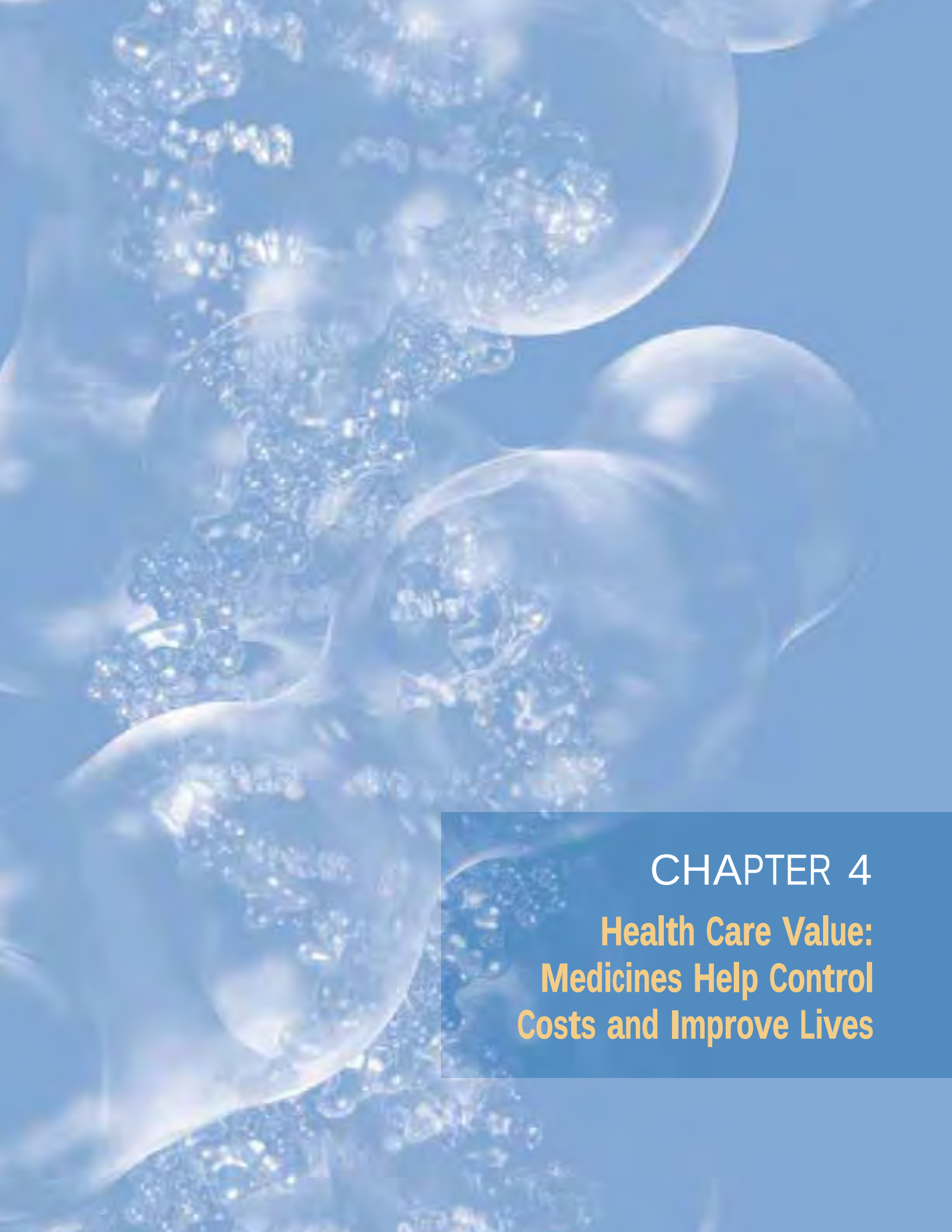
[13] U.S. Census Bureau, International database. Table 094. Analysis of Midyear Population, by Age and Sex, http://www.census.gov/population/www/projections/natdet-D1A.html.

[14] G. Anderson, *op. cit.*

[15] G. Mensah, Global and Domestic Health Priorities: Spotlight on Chronic Disease. National Business Group on Health Webinar, 23 May 2006. Accessible at www.businessgrouphealth.org.

[16] E. McGlynn, et al., "The Quality of Health Care Delivered to Adults in the United States," *New England Journal of Medicine* 348, no. 26 (23 June 2003): 2635–2645.

[17] R. DeVol and A. Bedroussian, "An Unhealthy America: The Economic Burden of Chronic Disease," Milken Institute, October 2007, http://www.milkeninstitute.org/publications/publications.taf?function=detail&ID=38801018&cat=ResRep (accessed 29 November 2007).



CHAPTER 4

Health Care Value: Medicines Help Control Costs and Improve Lives

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Health Care Value: Medicines Help Control Costs and Improve Lives

"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."[1]

— CDC's *Health, United States, 2006*

Prescription medicines are key to improving both our health and our health care finances. Today's advances help add years to our lives, reduce disability, and improve quality of life. Potential new treatments now in the R&D pipeline offer hope for additional benefits. Innovative medicines are also an important part of the solution to chronic disease and to controlling health care costs.

New Medicines: Improving Life for Patients

In 2007 we saw the remarkable effects of progress:

Cancer — A report published in the journal *Cancer* found that cancer death rates have decreased by 2.1% each year from 2002 to 2004, nearly double the annual decrease from the preceding decade.[2] (See Figure 9.)

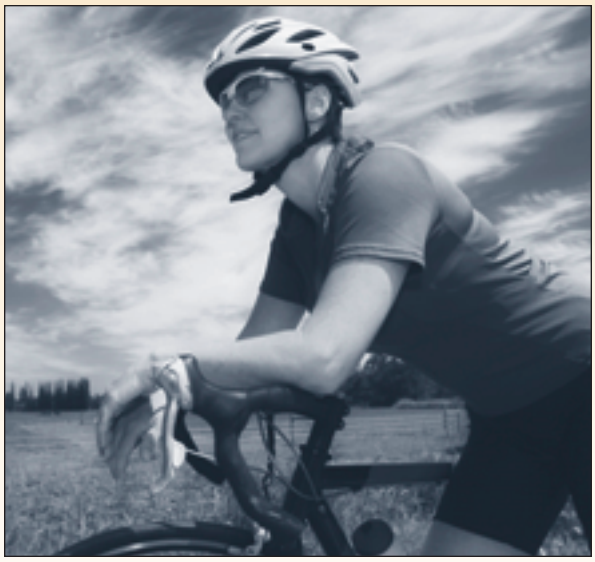
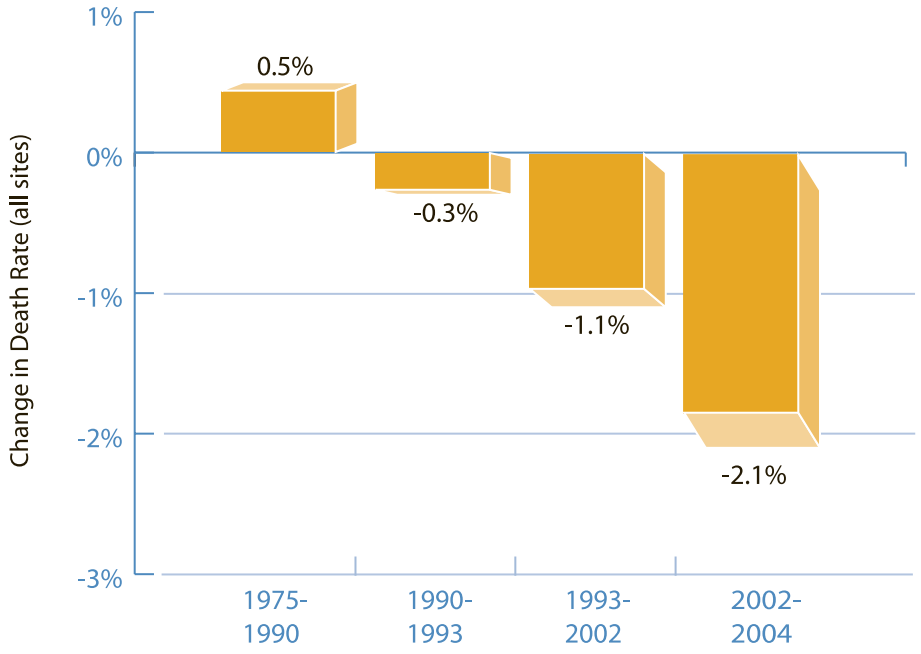


FIGURE 9: Cancer Death Rates Down



Source: D. K. Espy, et al., "Annual Report to the Nation on the Status of Cancer, 1975–2004, Featuring Cancer in American Indian and Alaska Natives," *Cancer* 110, no. 10 (2007): 2119–2152.

Another study published in *Cancer,* which focused specifically on patients with metastatic breast cancer, found that survival times have improved between the early 1990s and the end of the decade, thanks to new medicines.[3]

Cholesterol – Similar improvements have been noted for patients with cardiovascular diseases. The CDC recently reported that adults in the U.S. have reached an average cholesterol level in the ideal range (below 200) for the first time in 50 years.[4] Authors of the report attribute the drop to the use of cholesterol-lowering medicines in the over-60 population.[5]

"I think we really are in the midst of a ***revolution*** *in the treatment of cancer."*[6]

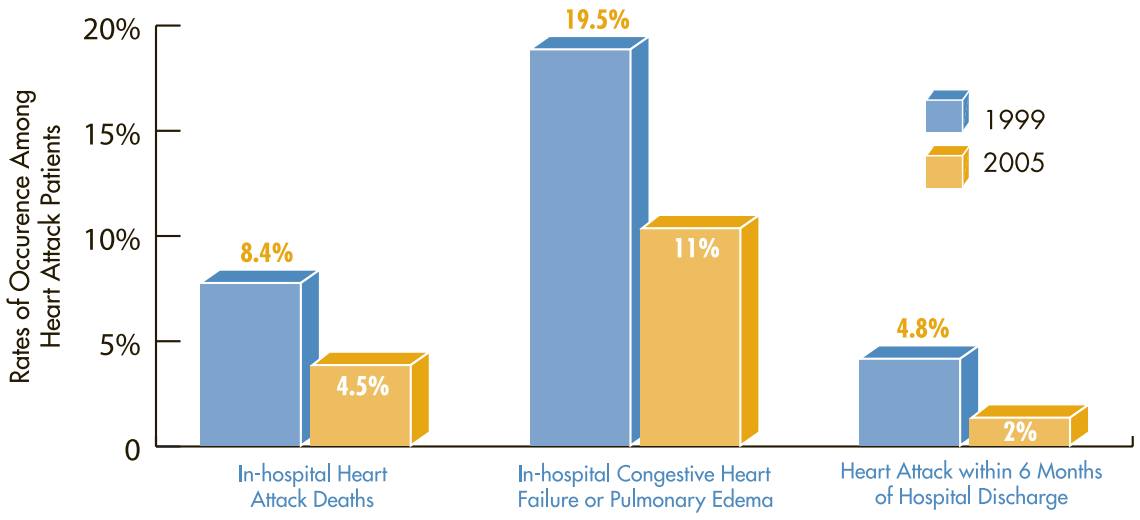
— Dr. Len Lichtenfeld,
American Cancer Society

Heart Disease — There is also good news in treating heart failure. A study published in the *Journal of the American Medical Association* found that between 1999 and 2005, rates of death and heart failure have dropped by nearly half, due mostly to the use of cholesterol drugs, blood thinners, and angioplasties.[7] (See Figure 10.)

New Medicines: Helping Control Health Care Costs

Use of medicines is a valuable tool for promoting more affordable care. Medicines can help limit the potential economic impact of chronic diseases, because they help prevent

FIGURE 10: Heart Failure Rates and Heart Attack Deaths Are Declining



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

the costly consequences. For instance, untreated diabetes can lead to nerve disease, heart failure, and amputation. When patients control these conditions with lifestyle and medicine treatments, they can often prevent these painful and costly complications.

Some forward-looking employers are recognizing the significant benefits of giving their employees better access to medicines — including reduced health care costs and increased productivity. By reducing copayments on medicines and implementing disease management programs, employers can generate a healthier workforce and see real savings.

For a growing number of conditions, medicines offer a less expensive alternative to other medical options, such as surgery, trips to the emergency room, and hospitalizations.

One study found that every additional $1 spent on medicines for blood pressure, cholesterol and diabetes saves $4 to $7 on spending for other medical care.[8]

To Save Later, Employers Offer Free Drugs Now

"Major employers like Marriott International, Pitney Bowes, the carpet maker Mohawk Industries and Maine's state government have introduced free drug programs to avoid paying for more expensive treatments down the road."[9]

— Milt Freudenheim, *New York Times*
Feb. 21, 2007

Lower Copays Improve Adherence

"We found that reductions in drug copayments increased medication adherence."[10]

— Michael E. Chernew, *Health Affairs*
Jan./Feb. 2008

Employers, Insurers Bet on Cutting Drug Copays

"Pitney Bowes Inc., which already gives away diabetes and asthma drugs, has lowered copays this year for osteoporosis treatments, anti-seizure medications and prenatal supplements. For diabetics and heart-attack patients, it has made cholesterol-lowering statins free."[11]

— Vanessa Fuhrmans, *The Wall Street Journal*
May 8, 2007

In addition, medical progress translates into economic gain, as new treatments help reduce the indirect costs of disease, such as lost worker productivity. Here are just a few examples of the dollar-wise value of new medicines:

Hypertension — Every year, 86,000 lives are saved, and 833,000 hospitalizations avoided, thanks to blood pressure medicines. If all hypertension patients were treated according to guidelines, we would avoid an additional 89,000 deaths and 420,000 hospitalizations annually.[12] Preventing the need for expensive health care services, such as hospitalization, is an important role of medicines.

Diabetes — The city of Asheville, N.C., provided free screenings and medicines to patients with diabetes and other chronic conditions. Employees learned to manage their conditions better, resulting in significant health improvements and an average net decrease of 34% in health care costs — $2,000 per patient per year — and a 50% reduction in absenteeism.[13]

Alzheimer's Disease — Developing new treatments that delay the onset or slow the progression of Alzheimer's disease by five years could save $100 billion per year by 2020 in Medicare and Medicaid costs.[14] (See Figure 11.)

Rheumatoid Arthritis — Among workers with rheumatoid arthritis, proper adherence to medicine treatment reduced lost productivity costs by 26%; the savings were more than twice as large as the costs of the medicines themselves.[15]

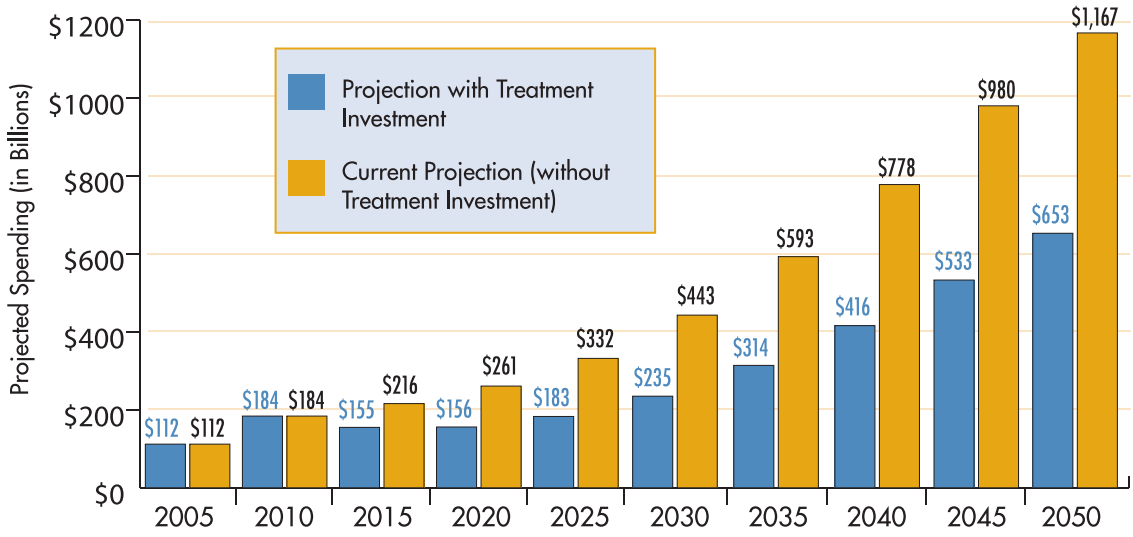
Asthma — A program to improve asthma care for children led to a 47% increase in the use of medicines that prevent asthma attacks, a 56% reduction in outpatient visits and a 91% decrease in emergency room visits for treatment of asthma.[16]

Life expectancy

"[Over] the last century, the value of gains in life expectancy seen in the U.S. is greater than the total value of all the measured growth in our economic output. New drugs are no small part of this medical miracle."[17]

— Mark B. McClellan, M.D., Ph.D., Senior Fellow in Economic Studies, Brookings Institution; Former CMS Administrator and FDA Commissioner

FIGURE 11: New Alzheimer's Treatments Could Save Billions



Source: The Lewin Group, *Saving Lives, Saving Money: Dividends for Americans Investing in Alzheimer's Research* (Falls Church, VA: The Lewin Group, 2004).

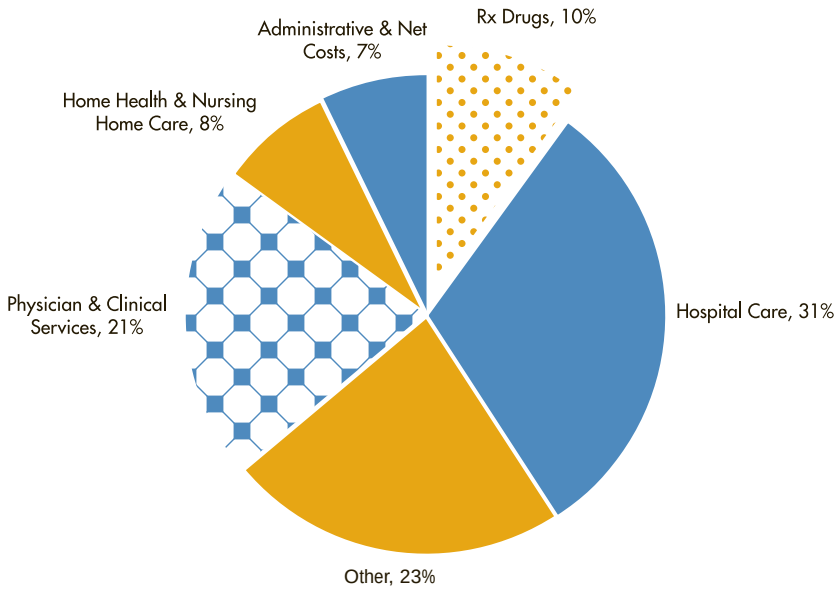
Proportion of Health Care Spending on Medicines Remains Small

Use of medicines is growing because they are playing an increasingly central role in clinical guidelines, and because earlier and preventive treatments are becoming more common. Nonetheless, medicines continue to comprise a small portion of health care spending in the U.S.

According to annual data from the Centers for Medicare & Medicaid Services, in 2006, 10 cents of every dollar spent on health care went to medicines (both brand-name and generic, plus the cost of pharmacies and the remainder of the distribution chain).[18] (See Figure 12.)

Growth in overall prescription drug spending has decreased sharply in recent years, and, in 2006, was at its second-lowest level in a decade at 8.5%,[19] even though 2006 was the first year that many millions of Medicare beneficiaries first gained comprehensive prescription drug insurance. At 10% of health care spending, new medicines are a valuable part of the health care equation.

FIGURE 12: How Each Health Care Dollar Is Spent



Source: Centers for Medicare & Medicaid Services, "National Health Expenditures," 7 January 2008, http://www.cms.hhs.gov/NationalHealthExpendData.

Marketing and Promotion

Activities conducted as part of pharmaceutical marketing and promotion are an important part of educating patients and heath care professionals about new treatments. Direct-to-consumer (DTC) advertisements aim to inform patients of important treatment options, while pharmaceutical sales representatives provide accurate, up-to-date information on medicines to health care professionals.

These efforts have been the subject of debate in recent years, with some questioning their value. A new publication offers facts about pharmaceutical marketing and promotion, which will be important to consider as marketing and promotion are discussed. For example:

- Pharmaceutical sales representatives provide doctors with important information about new treatment options that is factored into prescribing, but studies find that many other factors, including insurers' policies, affect prescribing decisions, often with greater impact.
- Studies show there is significant underdiagnosis and undertreatment of serious conditions that afflict millions of Americans. Pharmaceutical marketing and promotion help address this problem by raising awareness of disease symptoms and treatments and prompting patients to visit their doctor.

Go to www.phrma.org/publications to see the publication and learn more.

[1] CDC, National Center for Health Statistics, "Health, United States, 2006, with Chartbook on Trends in the Health of Americans." www.cdc.gov/nchs/hus.

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

[3] S. K. Chia et al., "The Impact of New Chemotherapeutic and Hormone Agents on Survival in a Population-Based Cohort of Women with Metastatic Breast Cancer," *Cancer* 110, no. 5 (2007): 973–979.

[4] S. E. Schober et al., "High Serum Total Cholesterol — An Indicator for Monitoring Cholesterol Lowering Efforts: U.S. Adults, 2005-2006," NCHS data brief no. 2 (Hyattsville, MD: NCHS, 2007).

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

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

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

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

[9] M. Freudenheim, "Some Employers Are Offering Free Drugs," *The New York Times,* 21 February 2007, http://www.nytimes.com/2007/02/21/business/21free.html?_r=1&oref=slogin (accessed 3 March 2008).

[10] M. E. Chernew et al., "Impact of Decreasing Copayments on Medication Adherence within a Disease Management Environment," *Health Affairs* 27, no. 1 (2008): 103–112.

[11] V. Fuhrmans, "Employers, Insurers Bet on Cutting Drug Copays," *The Wall Street Journal*, 8 May 2007.

[12] D. Cutler et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," *Health Affairs* 26, no. 1 (January/February 2007): 97–110.

[13] C. W. Cranor et al., "The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program," *Journal of the American Pharmaceutical Association* 43 (1 March 2003): 173–184.

[14] The Lewin Group, *Saving Lives, Saving Money: Dividends for Americans Investing in Alzheimer's Research* (Falls Church, VA: The Lewin Group, 2004).

[15] Integrated Benefits Institute, *A Broader Reach for Pharmacy Plan Design,* May 2007.

[16] M. Cloutier et al., "Asthma Guideline Use by Pediatricians in Private Practices and Asthma Morbidity," *Pediatrics* 118, no. 5 (November 2006): 1880–1887.

[17] M. McClellan, speech to First International Colloquium on Generic Medicine (Cancun, Mexico), 25 September 2003.

[18] A. Catlin et. al., "National Health Spending in 2006: A Year of Change for Prescription Drugs," *Health Affairs* 27, no. 1 (2008): 14–29.

[19] *Ibid.*

CHAPTER 5

Health Care Access: Connecting Patients with Scientific Advances

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Health Care Access: Connecting Patients with Scientific Advances

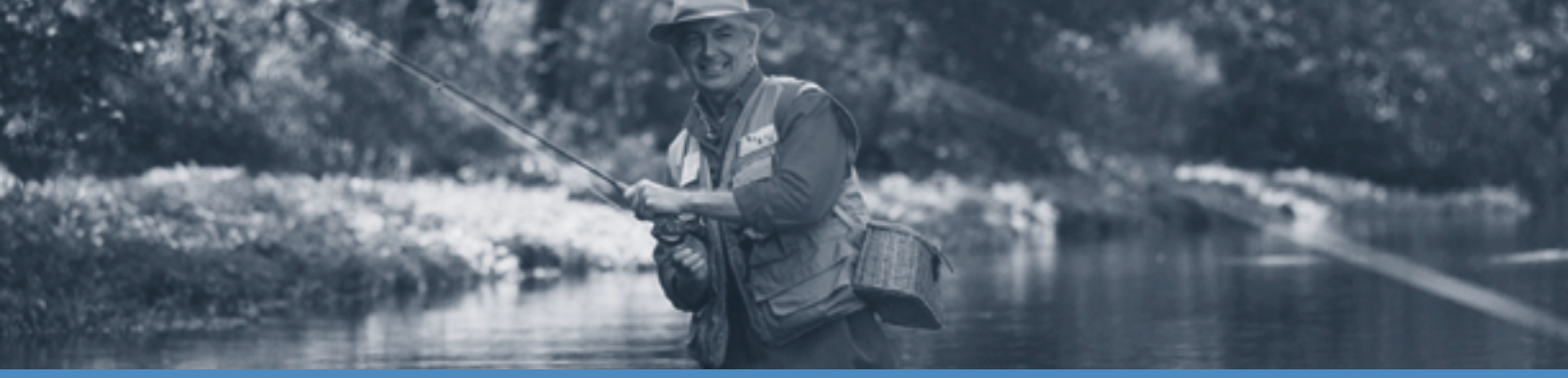
"Medicare drug benefit bids continue to be well below projections because of slower-than-expected growth in prescription drug costs generally, effective plan negotiation of discounts and rebates, and strong competition among plans."[1]

— CMS, August 13, 2007

Patients can only benefit from biopharmaceutical innovations when they have access to the medicines they need. Thus, pharmaceutical companies are committed to improving patients' access to medicines and other health care. Two programs that have had extraordinary success in linking patients to needed treatments are the Partnership for Prescription Assistance and the Medicare Prescription Drug Benefit.

Partnership for Prescription Assistance: Entrée to Progress for Uninsured and Low-income Patients

The world's largest private-sector effort to help low-income patients access their prescription medicines, the Partnership for Prescription Assistance (PPA) includes PhRMA members, doctors and other health care professionals, patient advocacy organizations, community groups, and others. The goal is to help uninsured and financially-struggling patients who lack sufficient prescription



Partnership for Prescription Assistance: Fact Brief

- The PPA offers a single point of access to more than 475 public and private patient assistance programs, including more than 180 programs offered by biopharmaceutical companies. More than 2,500 brand-name and generic prescription medicines are available through the participating programs.
- PPA buses have traveled 150,000 miles to more than 1,500 cities in all 50 states to spread the word about the program.
- So far, the program has helped more than 5 million patients nationwide.
- PPA provides information on nearly 10,000 free health care clinics and has connected more than 220,000 patients with clinics and health care providers in their communities.

coverage access information on programs that provide prescription medicines for free or nearly free. PPA provides a single point of access to 475 public and private patient assistance programs.

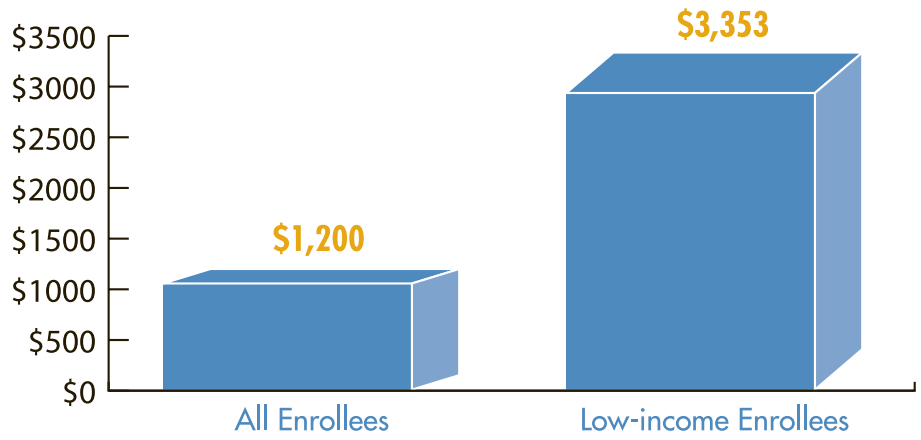
The PPA has a national call center, where trained operators field calls in 150 languages (1-888-4-PPA-NOW), and an easy-to-use Web site (www.pparx.org). In addition, the "Help is Here Express" buses are traveling the country to raise awareness of the program.

Many patients may be eligible for a patient assistance program, but they might not complete the application process because they lack access to a physician. To help address this problem, the PPA is providing patients with information on free health care clinics available in their community.

Better Access to Care, Savings, and High Satisfaction for Medicare Beneficiaries with Part D

The success of the Medicare Part D Prescription Drug Program has continued into 2008. Studies have shown that beneficiaries are getting the medicines they need and are saving money. Today, more than 90% of seniors have coverage, up from 59% in 2005.[2] That new coverage has meant lower out-of-pocket costs for Medicare enrollees. According to CMS, on average, Part D enrollees are saving $1,200 annually.[3] Additionally, those beneficiaries who receive the Part D low-income subsidy save more than $3,300.[4] (See Figure 13.)

FIGURE 13: Savings for Medicare Beneficiaries through Part D

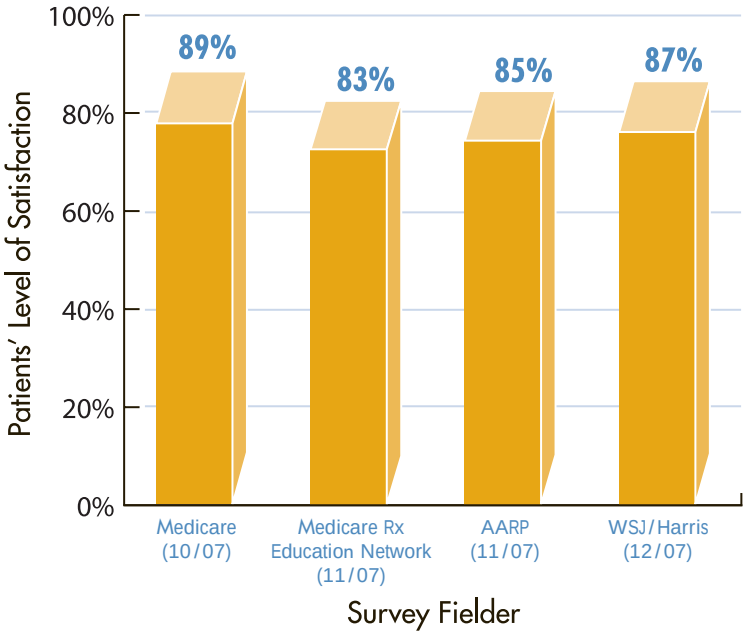


Source: CMS Fact Sheet, "Strong Competition and Beneficiary Choices Contribute to Medicare Drug Coverage With Lower Costs Than Predicted," 13 August 2007, available at www.cms.hhs.gov.

Medicare beneficiaries are overwhelmingly satisfied with their coverage. Four polls conducted in the fall of 2007 by Medicare Today, the Medicare Rx Education Network, AARP, and *The Wall Street Journal* Online/Harris Interactive found that between 83% and 89% of beneficiaries are satisfied or very satisfied with the coverage they are receiving under the Part D program.[5] (See Figure 14.)

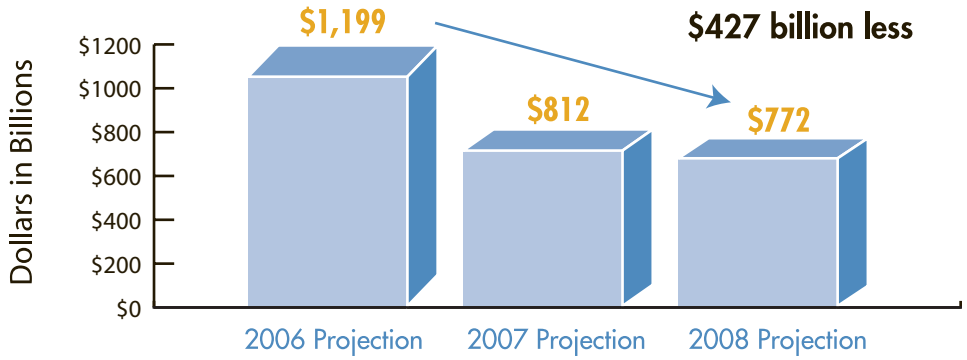
The success of the program has come at a much lower cost than anticipated. Compared to its 2006 estimates, CBO's current 10-year estimate for total Part D spending (FY2007 to FY2016) has fallen $427 billion dollars, or 36%.[6] (See Figure 15.) This is due primarily to competition among Part D plans.[7]

FIGURE 14: Four Surveys Gauge Patient Satisfaction with Part D



Sources: *Medicare Today,* "New Survey Released on Seniors Opinions Regarding Medicare Part D Benefit," November 2007, www.medicaretoday.org; Medicare Rx Education Network, "Senior Impressions of Medicare Part D," November 2007; AARP, "Prescription Drugs and Medicare Part D: A Report on Access, Satisfaction, and Cost," November 2007; *Wall Street Journal* Online, "Seniors Like Their Medicare Drug Plans," 12 December 2007.

FIGURE 15: Congressional Budget Office Lowers Part D Spending Projections



Source: CBO, "The Budget and Economic Outlook: Fiscal Years 2009 to 2018," January 2008, 59; See also, CBO Baseline, March 2007; CBO Baseline, March, 2006.

Biopharmaceutical Research Company Philanthropy Increases Access to Medicines and Health Care Worldwide

Global philanthropy efforts by pharmaceutical companies are key to getting medicines to patients around the world:

- In 2005, PhRMA member companies contributed more than $8 billion in cash and products to philanthropic causes.
- Of that amount, $5 billion went toward patient assistance programs (through the Partnership for Prescription Assistance), and the other $3 billion funded free medicines and health/education programs in the U.S. and abroad.
- The median amount given by 21 companies surveyed was $300 million.[8]

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[1] U.S. Centers for Medicare and Medicaid Services (CMS), "Medicare Part D Plan Premiums for 2008 Show Continued Impact of Strong Competition," Press Release (13 August 2007).

[2] CMS Press Release, January 30, 2007; and Kaiser Family Foundation, June 2007.

[3] CMS Fact Sheet, "Strong Competition and Beneficiary Choices Contribute to Medicare Drug Coverage With Lower Costs Than Predicted," 13 August 2007, available at www.cms.hhs.gov.

[4] *Ibid*.

[5] *Medicare Today,* "New Survey Released on Seniors Opinions Regarding Medicare Part D Benefit," November 2007, www.medicaretoday.org; Medicare Rx Education Network, "Senior Impressions of Medicare Part D," November 2007; AARP, "Prescription Drugs and Medicare Part D: A Report on Access, Satisfaction, and Cost," November 2007; *Wall Street Journal* Online "Seniors Like Their Medicare Drug Plans," 12 December 2007.

[6] See: CBO, "The Budget and Economic Outlook: Fiscal Years 2009 to 2018," January 2008: 59; CBO Baseline, March 2007; CBO Baseline, March 2006.

[7] Congressional Budget Office. "Fact Sheet for CBO's March 2007 Baseline: Medicare" and "Fact Sheet for CBO's March 2006 Baseline: Medicare" available at www.cbo.gov.

[8] Committee to Encourage Corporate Giving, *Corporate Giving Standard,* June 2006.

CONCLUSION

Continued Progress Means Supporting R&D

CONCLUSION

Continued Progress Means Supporting R&D

New medicines continue to offer great hope for improving patients' lives. We are making huge advances in fighting disease, reducing deaths from cancer, offering new treatment options for Parkinson's patients, preventing heart attacks, and finding new treatments for rare diseases. Life expectancy is at an all-time high and expected to continue its upward trajectory.

Our greater understanding of disease at the molecular level is leading to better, more precise medicines, and has the potential to promote a more efficient R&D process.

Lifestyle changes are the first step in reversing the growing burden of chronic illness, but medicines also are a crucial part of the solution to this escalating problem. Chronic diseases are becoming increasingly prevalent and costly in the U.S., and the immediate future promises more of the same as the population grows older and more obese. Medicines will be an important tool for controlling chronic diseases and preventing their costly complications.

To enjoy future health benefits and address pressing health care problems, individuals and society need full-speed medical progress to continue. Today's science offers many of the tools for finding new treatments, and PhRMA members are committed to this undertaking, as are thousands of researchers in government and academia around the world. America's biopharmaceutical companies are also working to make sure every patient has access to the medicines they need.

APPENDIX

Member Companies

MEMBERS

Abbott
Abbott Park, IL

Amgen Inc.
Thousand Oaks, CA

Amylin Pharmaceuticals, Inc.
San Diego, CA

Astellas US LLC
Deerfield, IL

AstraZeneca 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

Cephalon, Inc.
West Chester, PA

Daiichi Sankyo, Inc.
Montvale, NJ

Eisai Inc.
Woodcliff Lake, NJ

EMD Serono
Rockland, MA

Genzyme Corporation
Cambridge, MA

GlaxoSmithKline
Research Triangle Park, NC

Hoffmann-La Roche Inc.
Nutley, NJ

Johnson & Johnson
New Brunswick, NJ
Advanced Sterilization Products
ALZA Corporation
Centocor, Inc.
Cordis Corporation
DePuy Inc.
Ethicon Endo-Surgery, Inc.
Ethicon, Inc.
- Ethicon Products
- Gynecare
- Johnson & Johnson Wound Management

Janssen Pharmaceutica Inc.
Janssen Research Foundation and The R.W. Johnson Pharmaceutical Research Institute
Johnson & Johnson Health Care Systems, Inc.
Mitek
Ortho Biotech Products, L.P.
Ortho-Clinical Diagnostics
Ortho-McNeil Pharmaceutical, Inc.
OrthoNeutrogena
Scios Inc.
Therakos, Inc.
Vistakon

Eli Lilly and Company
Indianapolis, IN

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

Millennium Pharmaceuticals, Inc.
Cambridge, MA

Novartis Corporation
E. 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

The Procter & Gamble Company
Procter & Gamble Pharmaceuticals, Inc.
Mason, OH

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

sanofi-aventis U.S.
New York, NY
sanofi pasteur
sanofi-aventis

Schering-Plough Corporation
Kenilworth, NJ

Sepracor Inc.
Marlborough, MA

Solvay Pharmaceuticals, Inc.
Marietta, GA
Unimed Pharmaceuticals, Inc.

Valeant Pharmaceuticals International
Costa Mesa, CA

Wyeth
Madison, NJ
Wyeth Pharmaceuticals
Wyeth Research

PHARMACEUTICAL AFFILIATES
(None at this time)

INTERNATIONAL AFFILIATES

Novo Nordisk, Inc.
Princeton, NJ

Sigma-Tau Pharmaceuticals, Inc.
Gaithersburg, MD

Takeda Pharmaceuticals North America, Inc.
Lincolnshire, IL

ASSOCIATE (1) (Researchers)

Alkermes, Inc
Cambridge, MA

Enzon, Inc.
Piscataway, NJ

Idenix Pharmaceuticals, Inc.
Cambridge, MA

Ovation Pharmaceuticals, Inc.
Deerfield, IL

Reckitt Benckiser Pharmaceuticals, Inc.
Richmond, VA

Theravance, Inc.
South San Francisco, CA

ASSOCIATE (2) (CROs)

Quintiles Transnational Corp.
Research Triangle Park, NC

ASSOCIATE (3) (CMOs)
(No CMOs at this time)

ASSOCIATE (4)
(Advertising & Communication Services)

CommonHealth, L.P.
Parsippany, NJ

Harte-Hanks, Inc.
Shawnee, KS

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

ASSOCIATE (5)
(Consultants & Drug Discovery Software Firms)

Accenture LLP
Philadelphia, PA

The Boston Consulting Group, Inc.
Boston, MA

Cytel Inc.
Cambridge, MA

Deloitte & Touche USA LLP
New York, NY

Dendrite International, Inc.
Morristown, NJ

Ernst & Young
New York, NY

KPMG LLP
Short Hills, NJ

The Mattson Jack Group
St. Louis, MO

TargetRx, Inc.
Horsham, PA

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 I/II/III 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 IV 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: 1970–2007

(dollar figures in millions)

Year	Domestic R&D	Annual Percentage Change	R&D Abroad**	Annual Percentage Change	Total R&D	Annual Percentage Change
2007*	$35,394.4	2.7%	$9,136.0	1.8%	$44,530.4	2.5%
2006	34,467.8	11.3	8,971.3	0.9	43,439.1	9.0
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		12.2%		16.0%		12.7%

*Estimated

**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 is excluded. Domestic R&D, however, includes R&D expenditures within the United States by all PhRMA member companies.

***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, 2008.

Table 2
R&D as a Percentage of Sales, PhRMA Member Companies: 1970–2007

Year	Domestic R&D as a Percentage of Domestic Sales	Total R&D as a Percentage of Total Sales
2007*	18.7%	16.4%
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, 2008.

Table 3
Domestic R&D and R&D Abroad,* PhRMA Member Companies: 2006

(dollar figures in millions)

	2006
R&D Expenditures for Human-use Pharmaceuticals	
Domestic	$34,111.4
Share	78.5%
Abroad*	$ 8,831.4
Share	20.3%
Total Human-use R&D	$42,942.8
Share	98.9%
R&D Expenditures for Veterinary-use Pharmaceuticals	
Domestic	$ 356.4
Share	0.8%
Abroad*	$ 139.9
Share	0.3%
Total Vet-use R&D	$ 496.3
Share	1.1%
TOTAL R&D	$43,439.1
	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 is 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, 2008.

Table 4
Domestic R&D By Type of Project, PhRMA Member Companies: 2006

(dollar figures in millions)

Type	Dollars	Share
Licensed-in	$ 5,892.9	17.1%
Self-originated	24,224.1	70.3
Uncategorized	4,350.9	12.6
TOTAL R&D	$34,467.8	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, 2008.

Table 5
R&D By Function, PhRMA Member Companies: 2006

(dollar figures in millions)

Function	Dollars	Share
Prehuman/Preclinical	$11,816.1	27.2%
Phase I	2,902.7	6.7
Phase II	5,687.4	13.1
Phase III	12,187.3	28.1
Approval	2,649.3	6.1
Phase IV	5,584.6	12.9
Uncategorized	2,611.6	6.0
TOTAL R&D	$43,439.1	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, 2008.

Table 6
R&D By Geographic Area,* PhRMA Member Companies: 2006

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Africa	$ 25.0	0.1%
Americas		
United States	$34,467.8	79.3%
Canada	528.5	1.2
Mexico	32.2	0.1
Brazil	25.6	0.1
Other Latin America (Other South American, Central American, and all Caribbean nations)	85.7	0.2%
Asia-Pacific		
Japan	$ 826.2	1.9%
China	32.1	0.1
India	8.7	0.0
Other Asia-Pacific	172.2	0.4
Australia		
Australia and New Zealand	$ 135.2	0.3%
Europe		
France	$ 424.9	1.0%
Germany	574.2	1.3
Italy	245.9	0.6
Spain	190.8	0.4
United Kingdom	2,280.4	5.2
Other Western European	2,990.0	6.9
Central and Eastern Europe (Cyprus, the Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, and Malta)	132.2	0.3
Other Eastern European (including Russia and the Newly Independent States)	125.1	0.3
Middle East		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, Turkey, and Qatar)	$ 38.9	0.1%
Uncategorized	$ 97.4	0.2%
TOTAL R&D	$43,439.1	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 is 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, 2008.

Table 7
Biologics and Biotechnology R&D, PhRMA Member Companies: 2006

(dollar figures in millions)

Type	Dollars	Share
Biotechnology-Derived Therapeutic Proteins	$ 8,894.4	20.5%
Vaccines	1,121.4	2.6
Cell or Gene Therapy	64.2	0.1
All other Biologics	577.3	1.3
Total Biologics/Biotechnology R&D	10,657.3	24.5
Non-Biologics/Biotechnology R&D	30,553.4	70.3
Uncategorized R&D	2,228.3	5.1
TOTAL R&D	$43,439.1	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, 2008.

Table 8
Domestic Sales and Sales Abroad,* PhRMA Member Companies: 1970–2007

(dollar figures in millions)

Year	Domestic Sales	Annual Percentage Change	Sales Abroad*	Annual Percentage Change	Total Sales	Annual Percentage Change
**2007	$189,604.6	6.7%	$81,910.8	6.6%	$271,515.4	6.6%
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	5.9	4,633.3	19.1	11,769.0	13.6
1974	6,740.4	18.5	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		10.7%		10.3%		10.5%

*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, 2008.

Table 9
Sales By Geographic Area,* PhRMA Member Companies: 2006

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Africa	$ 1,081.8	0.4%
Americas		
United States	$ 177,736.3	69.8%
Canada	6,239.2	2.5
Mexico	2,567.3	1.0
Brazil	1,836.2	0.7
Other Latin America (Other South American, Central American, and all Caribbean nations)	3,081.2	1.2%
Asia-Pacific		
Japan	$ 8,508.8	3.3%
China	1,039.6	0.4
India	459.9	0.2
Other Asia-Pacific	3,627.7	1.4
Australia		
Australia and New Zealand	$ 2,735.2	1.1%
Europe		
France	$ 7,901.3	3.1%
Germany	5,672.0	2.2
Italy	5,721.7	2.2
Spain	4,762.5	1.9
United Kingdom	4,865.6	1.9
Other Western European	9,549.3	3.8
Central and Eastern Europe (Cyprus, the Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia, and Malta)	3,253.3	1.3
Other Eastern European (including Russia and the Newly Independent States)	867.6	0.3
Middle East		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, Turkey, and Qatar)	$ 2,158.5	0.8%
Uncategorized	$ 941.4	0.4%
TOTAL R&D	$ 254,606.4	100.0%

*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.

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, 2008.

Table 10
Domestic R&D Scientific, Professional, and Technical Personnel By Function, PhRMA Member Companies: 2006

Function	Personnel	Share
Prehuman/Preclinical	27,913	35.0%
Phase I	4,242	5.3
Phase II	8,119	10.2
Phase III	16,921	21.2
Approval	3,625	4.5
Phase IV	8,633	10.8
Uncategorized	2,452	3.1
Total R&D Staff	71,905	90.0
Supported R&D Non-staff	7,951	10.0
TOTAL R&D PERSONNEL	79,856	100.0%

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2008.

Endnotes *(continued from inside front cover)*

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