PHARMACEUTICAL INDUSTRY

profile 2006

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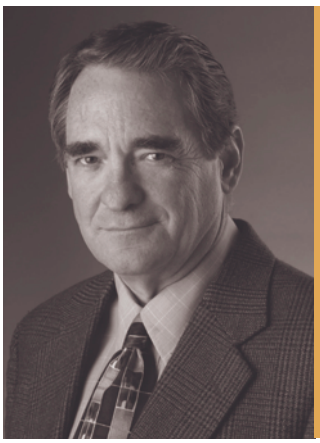
Letter from PhRMA's President and CEO



The men and women of America's research-based pharmaceutical companies do their jobs everyday with one goal in mind: helping patients. By working to discover medicines to prevent and cure disease, these men and women show their dedication to enabling people to live longer, healthier and more independent lives. And the member companies of the Pharmaceutical Research and Manufacturers of America (PhRMA) lead the world in developing innovative new medicines.

PhRMA is pleased to present the 2006 edition of the *Pharmaceutical Industry Profile*. This year's *Profile* shows how PhRMA member companies are accomplishing this goal and promoting access to treatments. For example, they are working hard on public policy initiatives to help patients get access to the medicines they might otherwise not be able to afford. In 2005, this meant working with a nationwide network of health care professionals, patient and community organizations to help prepare Medicare beneficiaries for the new, first-time Medicare prescription drug benefit that became effective in January 2006.

Last year, PhRMA members joined with a nationwide group of public and private organizations to create the Partnership for Prescription Assistance (PPA). The program is dedicated to helping the underinsured and uninsured get access to the medicines they need. During this past year alone, PPA matched over 1.3 million patients to prescription assistance programs, including 180 programs sponsored by pharmaceutical companies.

PhRMA's 2006 *Industry Profile* also highlights data from our 2006 PhRMA membership survey. The results tell the story of U.S. research-based pharmaceutical companies' commitment to investing in expanded research and development. Companies' investments now will mean new treatments in the future for some of the most tragic diseases plaguing patients—from HIV/AIDS to Alzheimer's disease, from cancers to new influenza strains.

The data in the 2006 *Profile* depict a vibrant industry, but it can only be fully appreciated as part of the larger story of individual patients whose lives have been saved and improved because of a prescription medicine. Finding new, better medicines to end suffering and pain is what PhRMA member companies do best. The hope that a life can be saved or a debilitating condition improved is why our companies continue to make record investments in researching and developing new medicines.

Billy Tauzin
President and CEO
Pharmaceutical Research and Manufacturers of America

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Working for Patients

"Being in the health care business brings awesome responsibilities. Every day, our member companies face difficult, fundamental questions. The answers to those questions profoundly affect patients' lives. Which diseases should we study? How can we best advance research? Where is the balance between risk and benefit? Answering these questions wisely requires that we make decisions that benefit society for the long term and that put patients' interests first."

— William C. Weldon, PhRMA Chairman, Chairman and CEO Johnson & Johnson

The biopharmaceutical research industry is unlike many others. It invents products that people need to avoid illness, maintain their health and save their lives. In fact, saving and improving lives is our fundamental mission. The importance of our products for individual and public health sets up high expectations for performance and commitment. This year's *Pharmaceutical Industry Profile* highlights some of the ways the industry fulfills its commitment to patients.

Shared Priorities, Common Values

A recent study showed that most consumers believe prescription drugs have a positive impact on people's lives.[1] But, that positive impact only occurs when new medicines satisfy rigorous safety standards, provide new hope and good outcomes to sick patients, are widely accessible to patients, and offer good value.

This *Profile* details the processes, policies and programs that are helping the industry

achieve these goals for patients. First, it looks at the research and development (R&D) process, describing the rigorous safety and benefit assessments required for meaningful treatment advances and other important aspects of the innovation process. Second, it describes groundbreaking government and industry programs to expand patient access to innovative medicines. Then, it presents facts that underline the value of medicines from the patient's perspective, such as longer, more fulfilling lives and fewer trips to the hospital. Finally, it shows some of the other ways that the biopharmaceutical research industry helps patients in need, through extensive philanthropy programs.
The appendix contains the newest data from PhRMA's annual member survey.

Endnotes

[1] The Henry J. Kaiser Family Foundation, "Views On Prescription Drugs And The Pharmaceutical Industry," *Kaiser Health Poll Report* (Washington, DC: Kaiser Family Foundation, January/February 2005), http://www.kff.org/healthpollreport/feb_2005/index.cfm (18 January 2006).

Research and Development: Safety + Benefit = Hope for Patients

I

Research and Development: Safety + Benefit = Hope for Patients

When the U.S. Food and Drug Administration (FDA) considers whether or not to approve a new medication, two issues are paramount:

- Do the results of well-controlled studies provide substantial evidence of effectiveness?
- Do the results show the product is safe; do the drug's benefits appear to outweigh its risks?

To answer these questions, biopharmaceutical companies conduct on average **10–15 years**[1] of research on the new medication; the results of which are provided to the FDA with an application for approval. Industry and FDA standards are rigorous: **For every 5,000–10,000 compounds tested, only one receives FDA approval** and becomes a new treatment.[2] Because long-term safety can be fully assessed only after many people have taken a medicine over time, drugs that are approved continue to be monitored for safety and effectiveness for many years after approval.

In 2005, the entire biopharmaceutical industry spent an estimated **$51.3 billion*** on R&D.[3] This figure represents contributions made by PhRMA member companies, as well as U.S. biotechnology firms that are *not* PhRMA members but are often supported through business ventures and funding from PhRMA member companies. PhRMA member companies alone spent an estimated **$39.4 billion*** in 2005. [Appendix Table 1] Researchers are working hard to get new medicines to patients.

This chapter explains the thorough safety and benefit assessments that occur in each step of the pharmaceutical R&D process—resulting in drugs that have been tested far more comprehensively for safety than almost any other consumer product.

The Numbers

R&D Investments: Large Industry Commitment to New Treatments, Despite Large Risks

- Cost of developing one new medicine: about $800 million[4] (over 10–15 years)[5]
- Estimated total biopharmaceutical R&D expenditures in 2005: $51.3 billion[6]*
- Estimated PhRMA member company R&D expenditures in 2005: $39.4 billion*

* The biopharmaceutical industry figure includes PhRMA research associates and nonmembers, which are not included in the PhRMA member companies number.

In Their Own Words: What Motivates Pharmaceutical Company Researchers?

"It was always difficult to call an end to the day. ...We knew that the work that we were doing was going to have an impact."

— Dace Madore, Ph.D., retired
Wyeth Pharmaceuticals

"It inspires us to know that our daily work is important and that we come back to our desks thinking of those faces, thinking of those families. And, say, that even if we could help one patient or one family—even if it's not in our generation, even if it's 20 years from now—that's still fascinating for us to keep working."

— Sudeep Chandra, Ph.D., MBA,
Director, Imaging Sciences
Millennium Pharmaceuticals, Inc.

"I chose this industry because...I saw the best chance of being able to apply my ideas in a practical way that actually could turn into real treatments that help patients at the end of the day."

— Jeff Hanke, Ph.D.,
Vice President of Cancer Research, R&D Boston
AstraZeneca Pharmaceuticals LP

"Once the drug was approved, we got to hear from the patients. ...And, to hear how their life had been changed by being on that drug, ...it was probably the most wonderful thing I've been through."

— Karen Ragland, BSN, MS,
Senior Manager, Clinical Development
Otsuka Maryland Research Institute, Inc.

Meet the researchers: You can see videos on the R&D process including these researchers at www.innovation.org.

Pharmaceutical R&D: A Rigorous Process With Safety/Benefit Assessments in Each Step

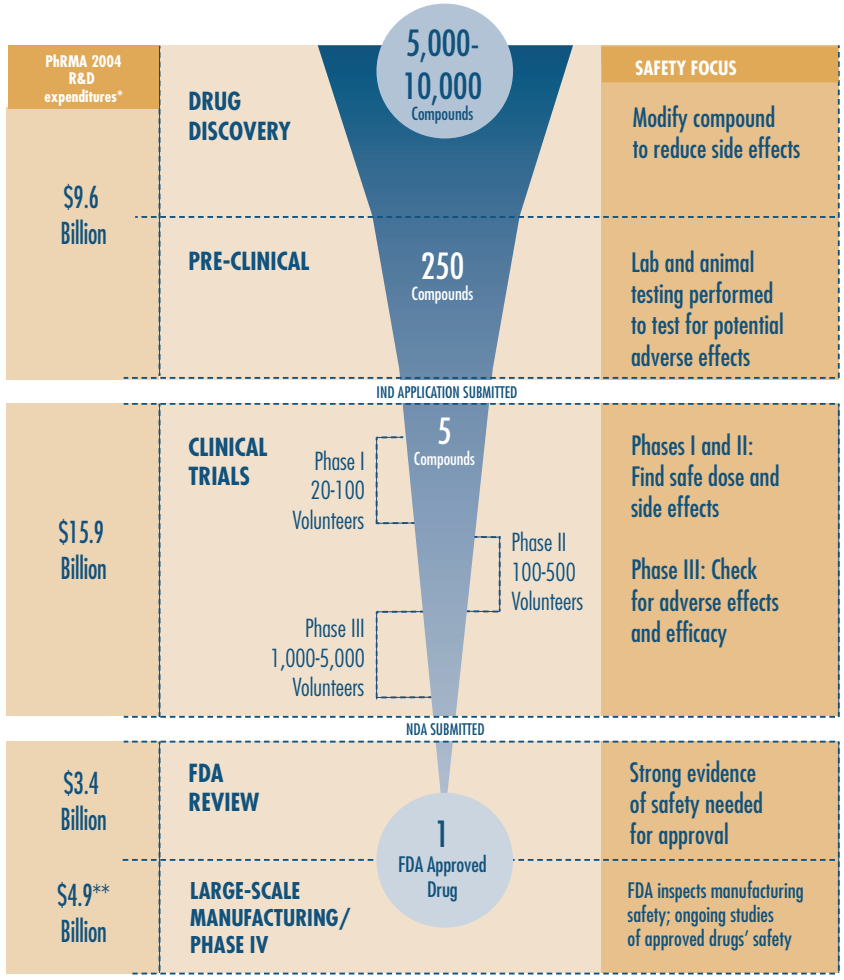
Drug Discovery

To make a new medicine, the first step is to identify a specific target that is a promising focal point for a medicine, such as a protein that plays a crucial role in a particular disease. Teams of chemists, pharmacologists and biologists then screen thousands of compounds—or chemically or genetically engineer new ones—and modify them to increase disease-fighting activity and/or minimize undesirable side effects for patients. Hundreds of potential drugs emerge from this process. However, because of the complexity and uncertainty of drug development, most of these potential drugs will never be approved for patients.

Preclinical Testing

Potential drug candidates identified during drug discovery receive years of additional testing. During this phase, both

Figure 1: The R&D Process—Developing Safe and Effective Medicines for Patients



* Adapted from Appendix Table 4, uncategorized: $3.2 billion.
** This figure includes Phase IV testing only.

laboratory and animal studies may be used to evaluate a drug's safety and demonstrate that it has biological activity against the disease target. For example, chemistry tests establish the compound's purity, stability and shelf life, while other studies explore possible dosing, packaging and formulation (e.g., pill, inhaler, injection) options. Only drugs with strong evidence of safety and potential benefit move forward to testing in people. In fact, **for every 250 compounds that enter preclinical testing, only five make it into clinical trials**.[7]

Investigational New Drug Application

Before researchers can test a candidate drug in people, they must submit an Investigational New Drug (IND) application with the FDA. The FDA then reviews all the findings from the laboratory and animal studies to make sure people will not be exposed to unreasonable risks in clinical trials.

Clinical Trials

In clinical trials, volunteers take a candidate drug to determine if it is safe for people and effective for the disease in question. Clinical trials take place in three phases, and during any of these phases, the FDA can halt the study if there are safety concerns.

- **Phase I:** The medicine is tested in a small group of about 20 to 100 healthy volunteers to determine its safety, including the safe dose range.
- **Phase II:** About 100 to 500 volunteer patients participate in controlled trials to determine whether the medicine effectively treats the disease. Researchers continue to evaluate the drug's safety, look for side effects, and determine optimal dose strength and schedule (how often the drug is taken).
- **Phase III:** From 1,000 to 5,000 volunteer patients take the potential new drug (or, for comparison purposes, a placebo or an existing treatment). Researchers closely monitor patients to confirm that the drug is effective and identify any side effects. Even after all the years of studies leading up to Phase III trials, about half the drugs that reach this point fail.[8]

Clinical trials are becoming more rigorous and extensive. The time required to complete the clinical phase rose from an average of 3.1 years in the 1960s to 8.6 years in the 1990s.[9]

New Drug Application/FDA Review

If clinical trials demonstrate that the experimental medicine is both safe and effective, the innovator company files a New Drug Application (NDA) with the FDA. Because NDAs contain study results from all previous steps, they typically include 100,000 or more pages of data for FDA review.

To assist in the review process, the FDA uses independent advisory committees that consider the evidence and vote on whether a new drug should be approved by the FDA for use by patients. Usually, the FDA follows the committee's recommendation. Even after many years of careful—and expensive—research, about 10 to 15 percent of potential new drugs

are rejected because they do not satisfy the FDA's strict safety and effectiveness standards.[10]

Large-Scale Manufacturing

Because companies can never be sure a product will receive FDA approval, construction or repurposing of manufacturing facilities—another expensive enterprise—begins late in the R&D process. Once again, safety is a major focus. Facilities must meet the FDA's strict requirements for Good Manufacturing Practice, to achieve uniform high quality of the products patients will use.

Ongoing Safety Monitoring

Even after an approved drug is manufactured and on the market, companies continue to gather information and sponsor research to review how the drug is working. Larger-scale experience with a medicine may reveal adverse effects or benefits not seen in more limited research use; companies submit any instances of problems reported by physicians and patients to the FDA. The FDA may also require a company to conduct additional "Phase IV" research studies to monitor the long-term safety of approved medicines or to learn how an approved medicine affects a particular group of patients.

Future of R&D: Targeted Personalized Medicines to Improve Treatment, Reduce Side Effects

Physicians have recognized for years that individuals respond differently to medicines. For example, a medicine for depression that works well for one patient may have less of an effect on another, who may have to try several different products before finding the right treatment.

Now, scientists' better understanding of the human genome is shedding new light on the role genes play in how we respond to medicines.

This emerging field of "personalized medicine" holds promise to improve medical care in the coming years as new treatments are developed based on specific genetic traits, and, through the use of pharmacogenomic markers, physicians gain the ability to select the safest and most effective medicine for each patient.

The Numbers

New Medicines in Development[11] (Clinical or Later Development)

Cardiovascular disorders: 303	Cancer: 682
Neurologic disorders: 531	Psychiatric disorders: 190
HIV/AIDS: 95	Diabetes: 62
Arthritis: 88	Infections: 341
Alzheimer's disease and dementia: 55	Asthma: 60

New diagnostic tests and treatments to enable the shift to personalized medicine already are being introduced. For example:

- The breast cancer drug trastuzumab was one of the first such targeted therapies to be developed using tools of personalized medicine. This medicine specifically targets the 20 to 25 percent of patients with breast cancer tumors that are positive for the HER2 protein, and it has been shown to significantly improve survival.
- Improved dosing for the anticoagulant warfarin offers another example. Warfarin requires careful dosing and patient follow-up because of bleeding risk and significant inter-patient variability in drug response. Approximately 20 to 30 percent of Caucasian patients receiving long-term warfarin therapy have a genetic variation associated with an increased risk of over-anticoagulation and bleeding complications. Scientists have recently confirmed that by detecting a variation in the CYP2C9 gene, doctors will be able to improve warfarin dosing, which should reduce complications.[12]

Supporting Continued Innovation: Strong Patent Protections Are an Essential Ingredient

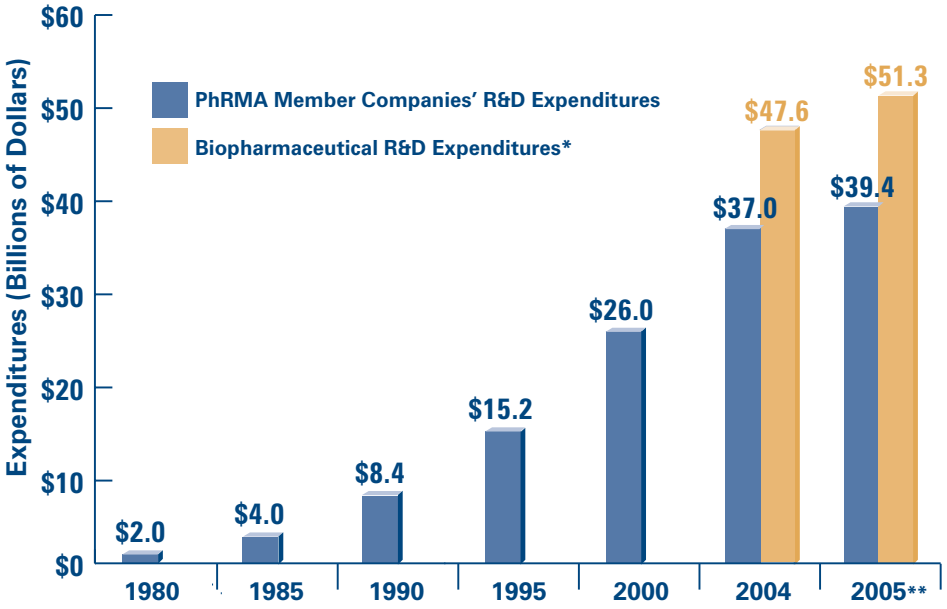
Patent protection in the United States gives researchers and inventors the exclusive right to sell an invention for 20 years before others may copy and sell it. U.S. laws and the Constitution have established a system to grant patents, as an incentive for individuals and companies to invest the time, effort and dollars needed to develop new ideas and products. Weakening patents can slow or stifle innovation by making it hard to recoup the investments made to develop the product.

It takes 10–15 years on average to develop a new medicine from the earliest stages of compound discovery through FDA approval. As a result, significant portions of the patent term for a new drug are lost before a product enters the market.* In fact, **the average effective patent life for medicines is 11.5 years.**[13] Under current law, generic drug manufacturers can begin to prepare copies of drugs for FDA approval before an innovator company's patent has expired. In an increasing number of instances, generic copies have entered the market years before patents expire.

Notwithstanding patents, brand drugs face vigorous competition long before generic copies arrive on the market. A recent study from Tufts University researchers showed that the amount of time between the entry of the first and

*Since 1984, the terms of some pharmaceutical patents have been extended to partially compensate patent holders for some of the effective patent life lost during clinical testing and FDA review periods.

Figure 2: Investment in Research and Development Continues to Grow



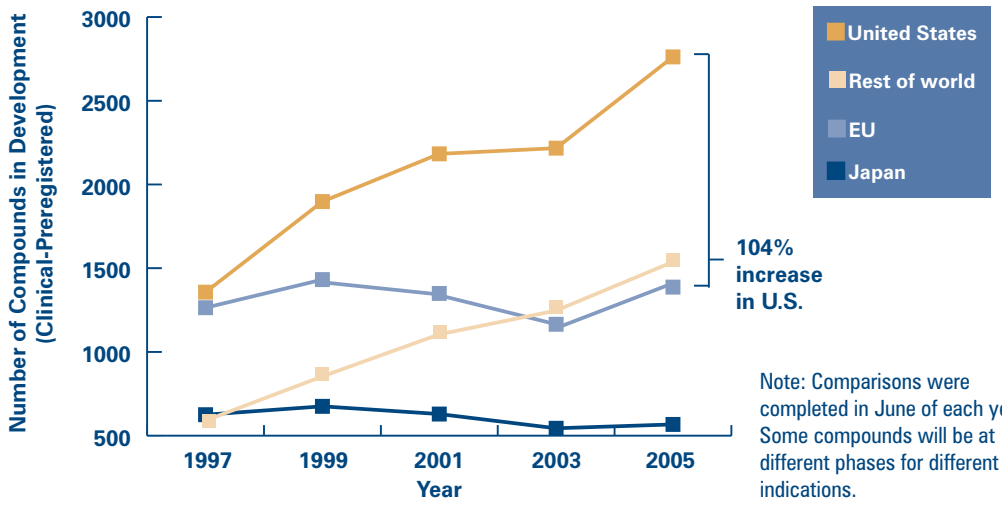
Sources: Burrill & Company, analysis for Pharmaceutical Research and Manufacturers of America, 2006.

Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 2005).

* 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.

Figure 3: Late-Stage Pipeline, 1997-2005, U.S. Leads the World



Source: Adis R&D Insight Database, customized run (December 2005).

second drug in a class has fallen by about 78 percent since 1970. They attribute this to vigorous competition between companies who work for many years to be the first to develop a drug in a needed area.[14]

U.S. R&D Remains Strong

During the past few decades, investment in R&D has continued to grow in the United States. [Figure 2] Accompanying this increased investment is a doubling of the number of drugs in clinical or later development, from more than 1,300 in 1997 to more than 2,700 in 2005.[15]

Growth in the drug pipeline in the United States contrasts with trends in Europe, where rigid government policies have discouraged continued pharmaceutical discovery. There, the number of drugs in development has declined.[16] Policies

including price controls and access restrictions have had a chilling effect on innovation and some European companies have relocated employees, facilities and research activities to the United States.[17,18,19] [Figure 3]

Endnotes

[1] J. A. DiMasi, "New Drug Development in the United States from 1963 to 1999," *Clinical Pharmacology and Therapeutics* 69, no. 5 (2001): 286-296.

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[18] G. Aldonas, "Drug Importation: Would the Price Be Right?" testimony before the U.S. Senate Committee on Health, Education, Labor, and Pensions (Washington, DC), 17 February 2005.

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Access to Medications: Patient-Focused Policies Open Doors

2

Access to Medications: Patient-Focused Policies Open Doors

The biopharmaceutical research industry is committed to policies that promote access to innovative treatments. In 2005, two major patient-focused programs set the stage for expanding medication access and related health benefits.

- Medicare Prescription Drug Insurance
- The Partnership for Prescription Assistance

Medicare Prescription Drug Coverage: Improving Access for Seniors and the Disabled

> *"The robust response by prescription drug plans is translating into better benefits and lower costs for people with Medicare, however they prefer to get their Medicare coverage."*
>
> **— Mark B. McClellan, M.D., Ph.D., Administrator, Centers for Medicare and Medicaid Services**

Medicare has covered hospital, physician and other health services for more than 40 years, but it has not covered prescription medicines even as they played an increasingly important role in maintaining good health and effectively treating illness. This changed January 1, 2006, when America's senior citizens and disabled persons began receiving prescription drug insurance through Medicare.

Medicare beneficiaries have a choice among private plans offering prescription drug insurance; they can select a plan that meets their medication needs. The nonpartisan Congressional Budget Office has projected that these competing private plans can contain costs more effectively than a government-controlled benefit, which will mean larger savings for beneficiaries.[1]

Updating Medicare's insurance coverage to reflect how medical care is delivered today offers opportunities for better results:

- **Improved access to needed care.** While all Medicare beneficiaries have had insurance for hospital and physician costs, a large share of Medicare beneficiaries have had no or very limited prescription drug insurance. By making insurance coverage for medicines available to all beneficiaries, access to and use of needed care will be improved.
- **Better prevention of illness.** In recent years, Medicare has expanded coverage of preventive care, including an initial "Welcome to Medicare" physical examination (effective January 1, 2005) and preventive screenings intended to catch illnesses early, when they are most treatable. Now, as conditions, such as

diabetes, hypertension and osteoporosis, are identified, patients will have coverage for and improved access to medicines that, along with lifestyle changes, can keep people healthy and prevent or slow the progression of illness.

- **Savings.** On average, patients will save about 50 percent on their out-of-pocket costs for medicines, and about one-third of beneficiaries with low incomes will save even more.[2] Even healthy beneficiaries are projected to receive significantly more in lifetime benefits from a prescription drug plan than they will pay in premiums.[3] Additionally, better access to medicines that can help maintain health and control illness can lead to savings for the Medicare program, by reducing hospital and nursing facility admissions.[4,5]
- **Security.** Medicare beneficiaries can be secure in the knowledge that prescription drug insurance will be there when they need it. The insurance includes 95 percent coverage of catastrophic costs.

Medicare Prescription Drug Insurance: Key Features

Plan options. Medicare beneficiaries have a wide range of coverage choices. Prescription drug plans must offer coverage that meets standards set by Medicare. Plans can offer either a "standard" benefit design or alternative designs with equal or higher value. Alternative designs include those with multi-tier formularies, no deductible or a reduced deductible, and coverage to fill in the coverage gap, the $2,850 that people otherwise must pay fully out-of-pocket before catastrophe coverage begins. Beneficiaries can receive prescription drug insurance through either Medicare advantage plans that also cover hospital and physician care or through prescription drug plans.

Medicare reports that competition among plans has already lowered the average monthly premium from previous estimates of $37 to $32.20.

Lower premiums. Information published on the Centers for Medicare and Medicaid Services' website shows that in 49 out of 50 states individuals can choose a plan with a monthly premium under $20, and many plans offer lower or no deductibles and lower copayment percentages than the standard. Some plans also provide coverage in the gap.

Expanded coverage for poor and low-income beneficiaries. People with limited incomes often have higher rates of chronic health problems that can be prevented and treated with prescription drugs. Approximately one-third of Medicare beneficiaries are eligible for low-income subsidies due to lower income levels. These beneficiaries will pay reduced or no premiums, reduced or no deductible, smaller copayments, and either no prescription charges or substantially reduced charges in the coverage gap.

Prescription Assistance for Americans in Need

- The new Medicare drug benefit went into effect in January 2006 and provides coverage to 42 million elderly and disabled Americans, about half of whom would not have had catastrophic drug coverage otherwise.[6]
- Since the launch of the Partnership for Prescription Assistance program in April 2005, over 1.3 million patients have been matched with programs that provide free or nearly free medicines.

The Partnership for Prescription Assistance: Helping Patients Get Access to the Medicines They Need

To expand access to needed treatments and promote a healthier nation, more than 1,200 industry, health care provider, patient advocacy and other groups created the Partnership for Prescription Assistance (PPA) in April 2005. These organizations came together because too many Americans lack health insurance and are thus denied the benefits of quality care.

PPA is the largest private effort helping connect patients in need to more than 475 public and private prescription assistance programs, including about 180 programs run by pharmaceutical companies.

"I called the hotline, they mailed me the forms, I sent them in, and, in just a couple of weeks, I got the first medication in the mail. It's just fantastic."

— A. G., Lynwood, IL, PPA user

Because many of those in need do not know that they are eligible for assistance, PPA aims to raise awareness about assistance programs and make them easier for patients and providers to reach and use.

Some assistance programs have existed for as many as 50 years, but this is the most recent effort to make these programs more accessible for millions of Americans who do not have prescription medicine coverage.

"Twenty years ago, I was a Ph.D. student at University of California, San Diego. But, my life changed in a split second when I was riding my bike and became the victim of a hit-and-run accident. I suffered serious brain injuries that day and have had seizures and memory problems ever since.

"Because of the neurological problems, I am not able to hold a full-time job. This means that not only is my income small, but I cannot get health insurance. The medicines to control my epilepsy, as well as anxiety and high blood pressure, cost nearly $1,000 a month. I used to go to Mexico in search of cheaper alternatives and skip doses to save money. I wasn't saving the government any money, though, because I often ended up in the emergency room when my epilepsy got out of control."

— Kendall DePascal, San Diego, CA

This year, Kendall found the Partnership for Prescription Assistance, which can be reached at www.pparx.org or (888) 4PPA-NOW. Through the program, she now gets all of her medicines for free. This program offers a safety net to people who slip through the cracks.

Moving Forward: Expanding PPA Enrollments

PPA has set up chapters in all 50 states to spread the word about enrollment both through local organizations and health care providers who reach patients directly. In addition, PPA uses paid advertising and sponsors two "Help is Here Express" buses that travel nationwide, promoting the program and providing on-the-spot enrollment help.

"Orphan" Drugs: Increasing Treatment Options for Patients with Rare Diseases

According to the National Organization for Rare Disorders, there are 6,000 rare diseases affecting a total of 25 million Americans.[7] Although they are rare individually, in aggregate, rare diseases constitute a real public and individual health issue. Between 85 and 90 percent of rare diseases are serious or life-threatening.

American pharmaceutical companies received approval for over 160 new rare, or "orphan," drugs in the past decade (1995-2005). This compares with 105 approvals in the previous decade (1985-1994) and fewer than 10 approvals in the 1970s.[8] Important advances in the past decade include:

- The first drug to treat the cause of **Fabry disease** rather than just its symptoms was approved in 2003. Fabry disease is a potentially fatal disorder in which fat is not properly broken down, causing burning sensations in the hands and feet, skin rash, excessive sweating and fever. It affects 1 in 117,000 people in the United States.

- Three new medicines have been approved in the past decade to treat **respiratory distress syndrome,** which affects 50,000 premature babies every year in the United States.
- A trailblazing targeted therapy dramatically improved survival for many patients with **chronic myeloid leukemia** when it was approved in 2001. It also caused fewer side effects than previous treatments.

This information was drawn from the PhRMA publication *Decade of Innovation: Advances in the Treatment of Rare Diseases.*

Endnotes

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New Medicines' Value for Patients: Longer, Healthier Lives, Lower Total Health Care Costs

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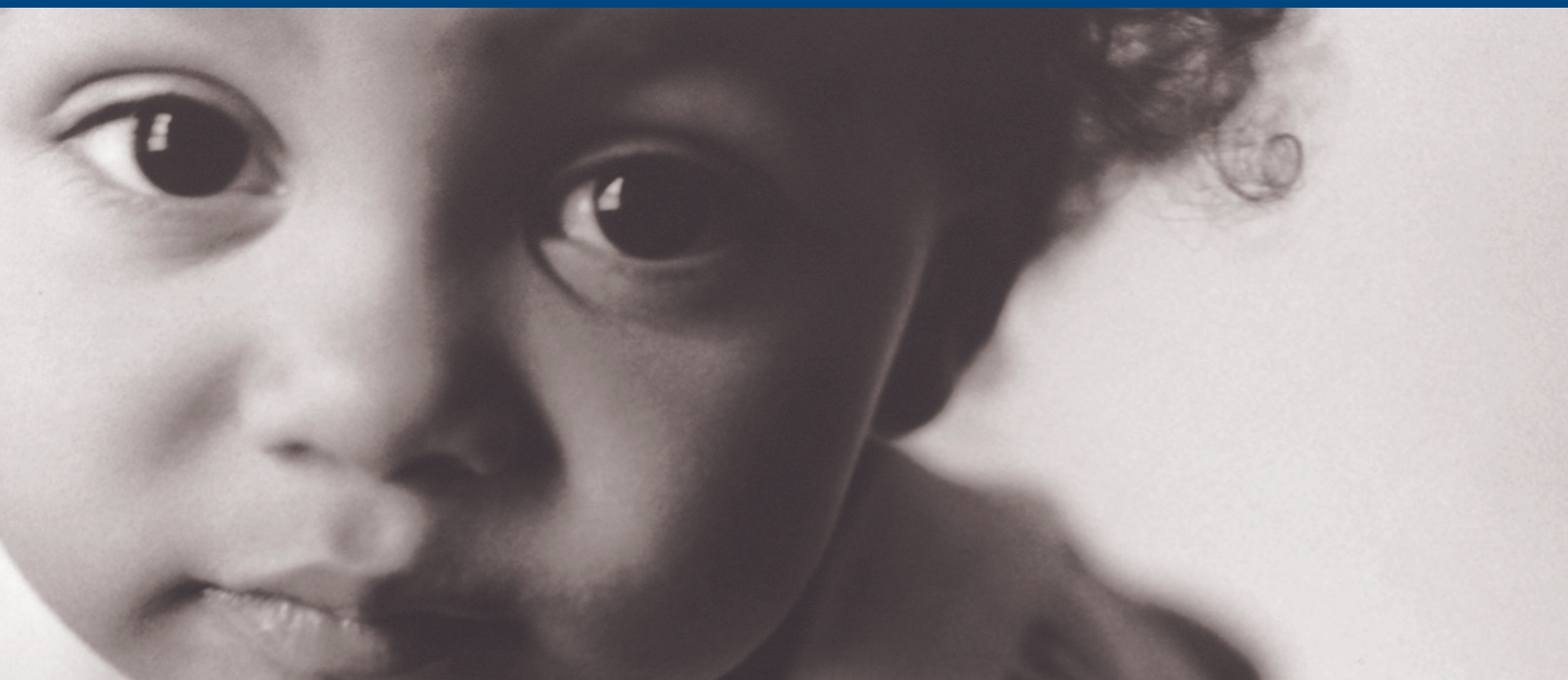


New Medicines' Value for Patients: Longer, Healthier Lives, Lower Total Health Care Costs

For people who are ill and their families, new medicines offer hope of curing or controlling disease, preventing complications, extending life, reducing disability, and improving quality of life. According to the National Center for Health Statistics, these hopes are often fulfilled: "Drugs, both prescribed and over-the-counter, are an increasingly important component of health care. New drugs and new uses for older drugs are improving health outcomes and quality of life, curing some conditions, preventing or delaying disease, and hastening recovery."[1]

Medicines: Value for Health

Life expectancy in the United States hit an all-time high this year at 77.6 years.[2] Since 1900, life expectancy has continued to rise almost uninterrupted in the United States. Today's medicines have helped make this possible. In fact, Columbia University researcher Frank Lichtenberg has found that new medicines account for 40 percent of life expectancy increases.[3] Here are a few examples of how medicines are **saving lives:**

- Since the introduction of effective cocktails of medicines, U.S. AIDS deaths have dropped by about 70 percent in the past decade.[4]
- In one program, increased use of statins, beta blockers, ACE (angiotensin-converting enzyme) inhibitors, aspirin and warfarin in patients who have had a major cardiovascular event reduced death rates for heart failure (-23 percent), coronary heart disease (-19 percent) and heart attack (-21 percent).[5]
- The National Cancer Institute recently reported that cancer death rates are continuing to decline, while the rate of diagnosis remains about the same. The mortality rate for all cancers has been falling since 1993 and the newest data, for 2002, continues that trend. The death rate in 2002 was 193.6 per 100,000,

Joey Procopio

"I can tell you what it was like being a parent watching your child suffer. When you hear that terrible word 'cancer,' you fall into a numbing fog. ...One minute [Joey] was a normal little boy; the very next, he was a cancer patient. He had to start chemotherapy. ...We were blessed that these medications tackled his leukemia, and he was in remission within 10 days of treatment."

— Julie Procopio, Joey's mother

compared with 195.7 a year earlier and 213.5 in 1993.[6] New medicines have likely played an important role in this improvement; recent research shows that new drugs account for 50 to 60 percent of the increase in six-year cancer survival rates since 1975.[7] [Figure 4]

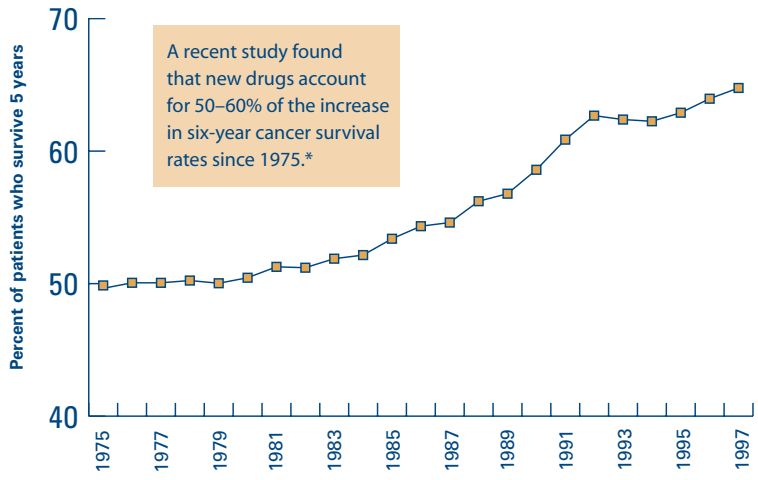
Studies also show that new medicines **improve health and quality of life.** Every day, new medicines help patients return to normal lives by decreasing disability and improving physical function, reducing pain, preventing severe complications, and making it possible to go back to work.

- For example, patients with multiple sclerosis, for which no cure presently exists, often face disability and relapses. However, one study found that those taking a new medication were much less likely to report worsening disability (8 percent) compared to those taking a placebo (25 percent). They also were less likely to report having a relapse or being hospitalized.[8]
- For patients with Alzheimer's disease, medicine can slow cognitive decline, delaying the need for nursing home care by 30 months.[9]

A variety of new medicines also help **prevent or reduce the risk of illness.** Vaccines, for example, can prevent a disease entirely; other medicines, such as diabetes medicines, can prevent debilitating complications from arising. By preventing complications and illness, medicines can help patients avoid hospitalizations and days lost from work.

- Vaccines are a powerful tool for disease prevention. For example, in states that routinely vaccinated children against hepatitis A, incidence of the disease fell by 88 percent.[10] [Figure 5]
- A new drug for Crohn's disease, a rare intestinal disorder, was found to reduce the chances that a patient would visit the emergency room by 66 percent.[11]

Figure 4: Cancer Survival Increasing



* 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).

Source: U.S. National Institutes of Health, National Cancer Institute, *Cancer Trends Progress Report — 2005 Update* (Bethesda, MD: NCI, December 2005), http://progressreport.cancer.gov (26 January 2006).

Medicines: Value for Dollar

The use of pharmaceuticals has grown along with the increasing reliance on medicines as a major component of today's medical care. However, as seen in Figure 6, "Where the Health Care Dollar Goes," prescription medicines still represent only a small fragment of total health care costs. Equally important, this expenditure offers strong value for dollar to patients and the health care system, including:

Reduced hospital, ambulatory care and nursing home costs. As use of medications grew between 1980 and 2000, the number of days Americans spent in the hospital fell by 56 percent, representing 206 million days of unneeded hospital care in 2000 alone.[13] Although this study does not show that drugs *caused* the number of hospitalizations to fall, it is likely that they played a role. In studies on treatment for mental health and substance abuse,[14] diabetes[15] and heart failure,[16] as use of new medicines grew, overall costs of care declined. Looking at new medicines in general, Lichtenberg found that for every $1 spent on new medicines hospital, spending fell by $4.44.[17]

> *"The share of drugs in future medical spending is likely to increase sharply. But, even without full cures, drugs that greatly delay the onset and severity of major diseases will reduce expensive and unproductive time spent in hospitals, nursing homes and under the care of family members."*[12]
>
> **— Gary S. Becker,**
> **University of Chicago Professor and**
> **1992 Nobel Prize Laureate**

Substantial savings when patients adhere to medication treatment plan. Following a doctor's treatment plan for use of medicines makes a patient much less likely to need hospital care, according to a recent study that looked at several chronic conditions. In addition, the study found cost savings increased as the patient's compliance rose. The researchers estimated that for every $1 spent due to increased patient compliance with diabetes medicines there was $7.10 in savings; the savings for $1 spent on cholesterol medicines was $5.10; and the savings for every $1 spent on blood pressure drugs was $4.[18]

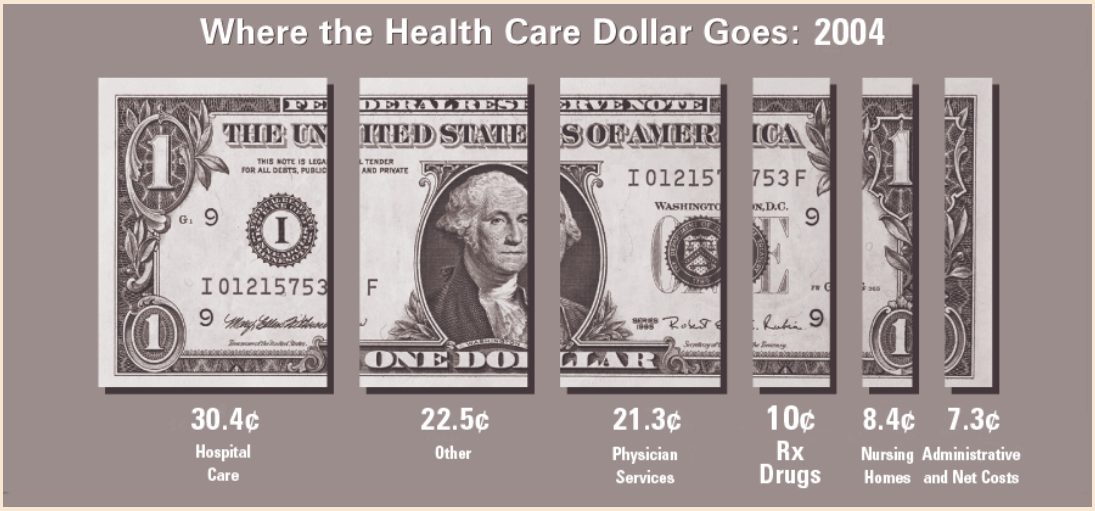
Figure 5: Hepatitis A Incidence Falls to Historic Lows With Increased Use of Vaccine

In 1999, it was recommended that children in 17 states with higher than average hepatitis A incidence be vaccinated routinely.

	Drop in Incidence
States NOT routinely vaccinating children	53%
States routinely vaccinating children	88%
Overall	76%

Source: A. Wasley, T. Samandari and B. P. Bell, "Incidence of Hepatitis A in the United States in the Era of Vaccination," *Journal of the American Medical Association* 294, no. 2 (2005): 194-201.

Figure 6: Where the Health Care Dollar Goes



Source: C. Smith et. al., "National Health Spending In 2004: Recent Slowdown Led By Prescription Drug Spending," *Health Affairs* 25, no. 1 (2006): 186-196.

Increased productivity and less absenteeism on the job. Healthy, active employees can get more done and miss fewer days of work. For example, for employees taking a new migraine medicine, the productivity benefits outweigh drug costs by 10 to 1.[19] The benefits of improving productivity ripple out to affect the entire economy.

Expanding Information: Industry's Direct-to-Consumer Educational Advertising

Direct-to-consumer (DTC) advertising brings FDA-approved information about prescription medicines to patients and families. Research has shown that DTC messages educate consumers about conditions and symptoms that prompt many to visit their physicians. According to a recent survey, 43 percent of patients who visited their physician after seeing a DTC ad received a new diagnosis. Some of the most common new diagnoses were high-priority conditions such as high cholesterol, diabetes and depression.[20] A July 2004 report by the Federal Trade

Commission (FTC) and the Department of Justice found that "...DTC advertising can increase compliance with pharmaceutical usage regimes."[21] Many physicians and patients report that DTC advertising enhances their communications. According to an FDA patient survey, 93 percent of patients who asked about a drug reported that their physician "welcomed the question."[22]

New DTC Advertising Guiding Principles: Education and Accountability

To ensure that DTC advertising remains an important and powerful tool to educate patients while addressing many of the concerns about DTC advertising expressed during the past few years, PhRMA's Board of Directors unanimously approved *Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines* in 2005. These principles, which went into effect January 6, 2006, express the commitment of PhRMA members to deliver DTC communications that contribute to public health. Major features of the voluntary commitment include:

- Presenting a balanced view of a medication's risks and benefits.
- Submitting all new television DTC ads to the FDA *prior* to airing (current law requires submission *on first airing*).
- Including information about healthy behaviors and lifestyle changes proven to effectively address an advertised condition.
- Including information about patient assistance programs for an advertised drug, where relevant and feasible.
- Educating health professionals about a new medicine or a new therapeutic indication before a DTC campaign begins.
- Targeting ad air times to avoid reaching audiences for whom messages are not age-appropriate.

The Facts

- DTC advertising accounts for less than 2 percent of the total U.S. spending for prescription medicines.[23]
- Experts have not found any relationship between drug marketing and drug price. For example, December 2003 FTC comments to the FDA noted, "Consumers receive benefits from DTC advertising with little, if any, evidence that such advertising increases prescription drug prices."[24]
- Spending on DTC ads is much lower than R&D spending: In 2004, an estimated $4.0 billion went to DTC advertising alone,[25] while more than $47.6 billion was spent on R&D.[26]

Endnotes

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[3] F. R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-Level Data from 52 Countries, 1982-2001,* National Bureau of Economic Research Working Paper No. 9754 (New York, NY, and Cambridge, MA: Columbia University and NBER, 16 February 2003).

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[12] G. S. Becker, "Economic Viewpoint: New Drugs Cut Costs, and Medicare Can Help," *BusinessWeek* 3875 (22 March 2004): 32.

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[14] T. L. Mark and R. M. Coffey, "What Drove Private Health Insurance Spending on Mental Health and Substance Abuse Care, 1992-1999?" *Health Affairs* 22, no. 1 (2003): 165-172.

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[17] F. R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-Level Data from 52 Countries,* 1982-2001, *op. cit.*

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

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[24] Federal Trade Commission, comments before the Department of Health and Human Services, Food and Drug Administration, in the Matter of Request for Comments on Consumer-Directed Promotion, Docket no. 2003N-0344 (1 December 2003).

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[26] Burrill & Company, analysis for Pharmaceutical Research and Manufacturers of America, 2006.

Helping Patients at Home and Abroad

4

Helping Patients at Home and Abroad

The pharmaceutical industry is one of the largest global corporate philanthropists. According to *The Chronicle of Philanthropy*, the four biggest corporate donors in 2004 were all pharmaceutical companies.[1] In addition to the U.S. patient assistance programs described in Chapter 2, companies provide millions of dollars each year in free medicines and cash donations to health and relief organizations. The industry also sponsors critical clinical and educational programs that would not exist without humanitarian support. The biopharmaceutical industry's aid in 2005 included responding rapidly to crises, such as Hurricane Katrina and the Asian tsunami, as well as addressing serious long-term health problems around the world.

When Disaster Strikes: Bringing Medicines to Patients in Turmoil

Hurricane Relief

Diabetes patients with no insulin. Mothers with no infant formula. Doctors with no tools, supplies or facilities to treat the injured. By destroying communities and uprooting millions of people, Hurricanes Katrina and Rita created unprecedented medical emergencies in Louisiana, Alabama and Mississippi in August/September 2005. PhRMA members were among the first to provide assistance, contributing nearly $130 million in cash and products for disaster relief to support agencies such as the American Red Cross and The Salvation Army; pledging funds to rebuild area medical facilities; and donating pharmaceuticals, over-the-counter products, and other medical, nutritional and personal care supplies.

In addition, many companies took direct action to bring help where it was desperately needed. For example, **Abbott Laboratories** outfitted and sent three 80-foot-long "labs on wheels" to give mobile hospitals the latest diagnostic equipment. **Eli Lilly and Company** loaded its corporate jet with 1,600 pounds of products, from first-aid supplies to medications, and

> *"Skirting red tape that has hampered some other relief efforts, several pharmaceutical makers have found ways to deliver donations of crucial medicines and medical devices directly into the Katrina disaster zone. ... 'I've never seen an operation like this in my entire career,' said Eugene Banez, chief of pathology and laboratory medicine at Houston's Ben Taub General Hospital, who has been working at the scene."*
>
> — ***The Wall Street Journal,*** **September 8, 2005**[2]

Hurricane Donations

PhRMA member companies donated nearly $130 million in cash and products after Hurricanes Katrina and Rita hit the Gulf Coast in 2005. Here are some highlights:

• FUNDS

Cash donations went to hospitals, shelters, and charitable and relief organizations, including the American Red Cross, America's Second Harvest, AmeriCares, Children's Hospital of New Orleans, Save the Children, MAP International and others.

• PRODUCT DONATIONS

Companies donated many of the products they make, including pharmaceuticals (diabetes products, mental health products, HIV and asthma medicines, antibiotics and antiseptics, vaccines, and more), medical products (first-aid supplies, such as bandages, wound care and surgical products, as well as respirators, and more) and consumer products (infant and children's nutritional products, toothbrushes, cleaning supplies, pet food and more).

• EMPLOYEE INVOLVEMENT

Many companies matched employee donations and some allowed paid time off to employees assisting in relief efforts. Many provided special aid for employees who were directly affected by the disaster.

• UNIQUE EFFORTS

—Many PhRMA member companies worked with pharmacies to provide free prescription medicines to victims of the hurricanes.

—Some companies loaded trucks or company planes with supplies and sent them to the disaster area.

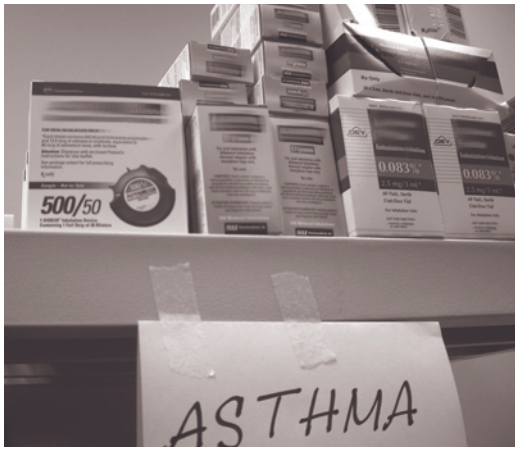
—Companies provided or supported mobile medical labs and clinics.

—They helped displaced patients with places to continue treatment.

—Some companies sent specialists to the area to help with operations, such as managing emergency medicine warehouses.

—They provided office space to relief agencies to facilitate the effort.

See pages 31-33 to learn about specific PhRMA member company donations.



delivered them to Hancock Medical Center in Bay St. Louis, Mississippi. **Johnson & Johnson** contributed $5 million to various relief organizations and donated products valued at $4.4 million, including wound care products, pain relievers and prescription medicines. **Wyeth** and other companies arranged for victims to receive free replacement medicines. **Pfizer Inc.** contributed more than $9 million in cash, including $5.3 million in product donations. (See pages 31-33 for a list of many pharmaceutical companies' contributions in the aftermath of the hurricanes.)

Similar Support for Asian Tsunami Relief

PhRMA members also contributed more than $178 million to disaster relief for the Asian tsunami victims. Immediately after the tsunami on December 26, 2004, PhRMA member companies offered help in the form of medicine, cash donations and expertise, working closely with international relief agencies such as CARE, UNICEF, the World Health Organization, AmeriCares, and the International Federation of Red Cross and Red Crescent Societies. Key donations included millions of doses of antibiotics, antifungals, anti-infectives, analgesics, vaccines for typhoid and hepatitis A, antidiarrhea medicines, pain relievers, anesthetics and antibacterial treatments.

Many companies contributed generously. To find out more, visit www.phrma.org and search for "tsunami."

Giving at Home: Improving the Communities Where We Live

Pharmaceutical companies and employees strive to make their communities a better place, not just through the science they pursue, but also through giving. They work to improve everything from science education in the United States to the care of Americans with serious illnesses.

A major way companies provide help is through patient assistance programs (outlined in Chapter 2). Here are some examples of other ways that America's pharmaceutical companies help here at home:

Amgen encourages better science education by working with Teach For America, a program that recruits recent college graduates to teach in disadvantaged communities. Amgen is offering $5,000 signing bonuses for 25 outstanding math and science majors who join the program during the next two years. In addition, the company underwrites Teach For America costs for recruiting, selecting, training and support.

Genzyme is a longtime partner of the Cambridge Science Club for Girls in

Cambridge, Massachusetts, an afterschool program founded in 1994 to serve diverse at-risk middle and high school girls that promotes interest in science and inspires self-confidence.

Purdue Pharma launched a public service campaign to raise awareness about the dangers of youth abusing prescription medicines, and received the FBI's Law Enforcement Executive Development Association Innovator Award for this work.

Developing Countries: Expanding Medicine Access Where Needs Are Greatest

PhRMA members' philanthropy has many faces with each company making significant contributions both at home and abroad. Every year, pharmaceutical companies help patients in developing countries, where there is a great need for additional resources. Overall, PhRMA members provide about $1.4 billion[3] annually in medicines and services in developing nations, including in Africa and the world's 48 least-developed countries. (This figure does not include disaster relief contributions, such as tsunami aid.)

In January 2005, PhRMA announced its support for the United Nations' Millennium Development Goals for improving health and welfare in the developing world. Following are only a few examples of how PhRMA member companies help these nations' patients suffering with illnesses targeted by the Millennium Goals.

HIV/AIDS

- **GlaxoSmithKline** operates "Positive Action," an international program designed to assist community-based organizations with HIV education, prevention, care and support in 27 developing countries.
- **Boehringer Ingelheim** provides the Viramune® Donation Program to reduce mother-to-child transmission of HIV. This program has reached more than 450,000 mother and child pairs in 52 developing countries.
- **Bristol-Myers Squibb** runs "Secure the Future," a program to improve treatment of children with AIDS in sub-Saharan Africa. Over the next five years, the program plans to create a corps of 250 doctors to treat approximately 80,000 children and train local health care professionals.
- The **Pfizer** Foundation launched the International HIV/AIDS Health Literacy Grants program to complement Pfizer's donation of Diflucan® to treat opportunistic infections related to HIV/AIDS. The grants aim to improve HIV/AIDS health literacy throughout Africa, as well as understanding of and adherence

To Tajikistan, With Heart

Orphan children in Tajikistan.

In October 2005, PhRMA and member company staff traveled on a medical humanitarian mission to Tajikistan with Physicians With Heart*. The goal: to deliver $8.2 million in donated medicines from amoxicillin to aspirin and provide much-needed training to local physicians and nurses.

Tajikistan, with its population of just over 7 million, is the poorest country in the former Soviet block. Situated in highly mountainous terrain between China, Afghanistan, Uzbekistan and Kyrgyzstan, Tajikistan is a beautiful country with few resources and virtually no industry. As a result of limited resources and a debilitating civil war, the country spends only about $5 per person per year on medical care.

The Physicians With Heart team trained local health professionals on the proper use of the donated drugs. They supplied up-to-date educational literature written in Russian (one of Tajikistan's two national languages) and provided training in childbirth techniques and advanced life support procedures, a critical focus given Tajikistan's infant mortality rate is 111 out of every 1,000. In addition, the mission brought equipment, clothing and school supplies to several local orphanages.

*Physicians With Heart is an international humanitarian project sponsored by the American Academy of Family Physicians (AAFP), the AAFP Foundation and Heart to Heart International. Pharmaceutical companies provide donated medicines and the U.S. State Department supplies transportation.

to treatments. To date, the Diflucan Partnership has donated 4 million doses of antifungal medication to treat opportunistic infections.

- **Roche** teamed up with the Cambodian Ministry of Health and the University of New South Wales, Australia, to launch the Cambodia Treatment Access Project. This project aims to increase treatment, train local health care professionals, build a clinic and increase screening in Cambodia, estimated to have the highest prevalence of HIV in adults in Asia.[4]

Tuberculosis

- **AstraZeneca** works with the British Red Cross to deliver a program to combat tuberculosis (TB) in Kyrgyzstan, Turkmenistan and Kazakhstan, where TB rates are among the highest in the world. The program provides support and education and has reached 200,000 people.

Polio

- **Sanofi Pasteur** donated more than 120 million doses of vaccine to the Global Polio Eradication Initiative and elsewhere in its effort to help eradicate polio.

Leprosy

- **Novartis Pharmaceuticals** supports the Global Alliance to Eliminate Leprosy, aiming to cure all 2.8 million leprosy patients. It funds health professional training, social marketing to encourage treatment, and informational and educational efforts in countries, including India, Sri Lanka and Brazil.

Onchocerciasis (River Blindness)

- **Merck** donates Mectizan® for all who need it for as long as needed. Since 1987, Merck has provided more than 1 billion tablets, treating more than 40 million people annually in more than 30 endemic countries in Africa, Latin America and the Middle East.

Hurricane Donations: Detailed List

Here are some examples of how pharmaceutical companies responded to Hurricane Katrina with swift and generous aid.

Abbott provided $5.5 million in funds and product donations to relief organizations. This included $3.5 million in nutritional, medical and pharmaceutical products. Abbott also provided three 80-foot-long "labs on wheels" with the latest diagnostic equipment for health care staff working at mobile hospitals.

Amgen contributed more than $2.5 million to relief organizations and established a company-wide Hurricane Katrina Relief Program. The Amgen Foundation matched almost $500,000 in employee contributions. Another $275,000 went to America's Second Harvest and local Red Cross chapters.

Amylin donated $100,000 to the American Red Cross and matched employee donations up to an additional $100,000. Amylin also donated $50,000 to the Pennington Biomedical Research Center at Louisiana State University for the establishment of an emergency diabetes clinic.

Astellas donated $250,000 to the American Red Cross and matched employee donations up to another $75,000.

AstraZeneca provided approximately $5 million in free medicines, as well as a $1 million cash donation to the American Red Cross, $250,000 for an emergency psychiatric assistance program to aid community health centers with displaced residents, $325,000 to other organizations and a matching program for employee donations.

Bayer contributed nearly $4 million dollars in cash and goods and matched employee donations of close to $400,000.

Bayer and its employees donated and shipped two tractor-trailer loads of supplies.

Berlex replaced lost or destroyed products to patients free of charge and matched employee contributions to the American Red Cross.

Boehringer Ingelheim made contributions of $600,000 to relief and charitable organizations, provided more than $2 million in product donations and ensured that the company's patient assistance program quickly responded to the affected areas. Boehringer Ingelheim also funded a mobile medical clinic operated by AmeriCares Free Clinics.

Bristol-Myers Squibb (BMS) donated $1.1 million in cash to the American Red Cross, as well as more than $450,000 through the company's employee matching gift program. BMS sent $2 million in product donations, $700,000 in infant and children's nutritional products, and $200,000 in wound care and skin care products.

Cephalon matched employee donations to hurricane relief and donated a product to emergency workers that treats excessive sleepiness associated with shift work.

Daiichi donated $10,000 to the American Red Cross and matched employee contributions to hurricane relief, resulting in another $25,000.

Eli Lilly donated $1 million to the American Red Cross, $1 million in insulin products to Heart to Heart International, $2.2 million in direct shipments of insulin and mental health products to more than 53 hospitals, and $284,000 through its employee matching gift fund program. Lilly also worked with retail pharmacists to dispense free Lilly medicines. Employees were allowed paid time off to assist in relief efforts.

Genzyme made product donations and matched employee contributions.

GlaxoSmithKline (GSK) donated $1 million to relief funds, matched employee gifts and contributed $7 million in prescription drug products, including medicines for diabetes, heart disease, antibiotics, asthma and vaccines. In addition, $1.5 million in medicines were distributed by international relief organizations to hospitals and shelters. GSK also donated consumer products, such as toothbrushes and pain relievers.

Johnson & Johnson gave $5 million in cash to charitable organizations and $4.4 million of essential disaster relief products to MAP International, and the company matched employee and retiree contributions. Donations included prescription and non-prescription medicines, wound care and surgical products.

Merck contributed $1 million to the American Red Cross and donated more than $10.8 million in medicines and vaccines to relief efforts. Merck also committed to replacing prescription medicines and matched employee and retiree gifts.

Millenium gave more than $17,000 to the American Red Cross and AmeriCares. The company worked with physicians and patients on the VELCADE Reimbursement Assistance Program hotline to help physicians and patients locate new treatment facilities for displaced patients.

Novartis donated more than $10.5 million in pharmaceuticals and over-the-counter products, as well as $1 million in cash to the relief effort, including employee gift matching.

Organon made cash donations, matched employee donations and independently raised money for relief efforts.

Otsuka made a cash donation to the American Red Cross and provided products.

Pfizer sent teams of specialists to manage emergency medicine warehouses in the Gulf Coast area. Additionally, the company

contributed more than $9 million in cash. This included $5.3 million in products, such as antibiotics and first-aid supplies. Pfizer worked with hospitals and pharmacies to ensure patients received the medicines they needed and matched employee contributions.

Proctor & Gamble (P&G) shipped more than 130 truckloads of supplies, in total, donating $8 million in cash and products, such as pharmaceuticals, cleaning supplies and pet food. P&G also worked to help employees in the affected areas.

Purdue Pharma matched donations, up to $50,000, made by employees to AmeriCares and the American Red Cross. The company also worked with AmeriCares to provide antibiotics, antiseptics and other medicines, including $800,000 worth of antiseptics.

Roche donated a wide range of medicines, including HIV products, immunosuppressive drugs and antibiotics, and worked with pharmacies to provide free drugs to hurricane evacuees. The company also allowed employees to volunteer their services (matching employee's time off) and matched employee contributions to the American Red Cross. Roche also gave special aid to employees affected by the disaster.

Sanofi-Aventis donated more than $4 million in products, including diabetes medicines, tetanus vaccines and influenza vaccines. Additionally, Sanofi-Aventis gave $500,000 to Children's Hospital in New Orleans and $500,000 to Save the Children. The company matched employee donations to hurricane relief organizations.

Schering-Plough converted 15,000 square feet of office space in its Memphis, Tennessee, location into a Red Cross "satellite" office. The company also donated $5 million in medicines and supplies and provided $500,000 in cash contributions to relief organizations. Schering-Plough made medicines available to people in the affected areas through its patient assistance program.

Schwarz Pharma donated $50,000 to the American Red Cross and provided $100,000 of free products. The company also matched employee donations.

Sepracor offered an employee matching gift program.

Serono provided assistance to employees impacted in the region, donated products and offered a matching gift program for employee donations.

Solvay donated more than $100,000 to the American Red Cross as part of its employee matching gift program. The company also provided products, including first-aid kits and pharmaceuticals.

3M contributed $2.5 million to the relief effort, including $1.5 million from the company's employee and retiree matching gifts programs and $1 million in donated products, such as respirators, insect repellent and bandages.

Valeant matched employee donations, provided medicines to the relief effort and allowed time off for employees providing assistance.

Wyeth donated $1 million, which went to several organizations providing relief to hurricane victims, and the company established initiatives to provide access to prescription medicines and provide free replacement products to major retail pharmacies. Wyeth also matched employee contributions and donated needed products.

In addition to PhRMA member company giving, several PhRMA associate members and international affiliates also gave money, supplies and medicines.

For a more complete list of donations, visit www.phrma.org and search for "hurricane donations."

Endnotes

[1] I. Wilhelm, "Corporate Giving Rebounds," *The Chronicle of Philanthropy,* 4 August 2005, http://philanthropy.com/premium/articles/v17/i20/20000701.htm (1 February 2006).

[2] M. Chase, "In Katrina's Wake: Drug Companies Handle Their Own Deliveries — Bypassing Rules, Red Tape, Firms Provide Medicines Directly to Areas of Need," *The Wall Street Journal,* 8 September 2005.

[3] Pharmaceutical Research and Manufacturers of America, *Millenium Development Goals: The Industry's Contributions* (Washington, DC: PhRMA, January 2005).

[4] Roche Diagnostics, *Commitment and Care Across the Globe: Making a World of Difference in HIV,* http://www.roche.com/pages/downloads/sustain/pdf/rochehivbro_e.pdf.

Conclusion

When "Customers" Are Patients, Industry Has Special Obligations

5

Conclusion

When "Customers" Are Patients, Industry Has Special Obligations

This year's *Profile* has focused on our commitment to patients. The biopharmaceutical industry recognizes the hope that patients get from the promise of new medicines, the benefit new medicines represent for millions and the importance of expanding access to medicines so patients with few options have somewhere to turn. Our commitment to patients includes:

- Continuing to invent safe and effective new medicines. Although biopharmaceutical R&D is an expensive, high-risk venture that only occasionally results in a viable new product, the quest for better drug treatments is imperative for patient welfare, public health and the health care bottom line. Today's medicines illustrate the growing value our products represent—for longevity, symptomatic relief, quality of life and disease prevention, as well as controlling overall medical care costs.
- Supporting public and private sector policies that help patients gain better access to new medicines. Programs such as Medicare prescription drug insurance and the Partnership for Prescription Assistance are helping patients obtain the medicines they need.

- Responding vigorously with humanitarian assistance, both with short-term aid in times of crisis and as a long-term policy of helping patients in greatest need at home and around the world. Helping those in need through philanthropy is a high priority for PhRMA members and their employees. Ultimately, it is one of the most important ways we can fulfill our mission of helping people live longer, healthier lives around the world.

Appendix

6

Member Companies

Abbott Laboratories
Abbott Park, IL

Amgen Inc.
Thousand Oaks, CA

Amylin Pharmaceuticals, Inc.
San Diego, CA

Astellas Pharma Inc.
Deerfield, IL

AstraZeneca LP
Wilmington, DE

Bayer Corporation Pharmaceutical Division
West Haven, CT

Berlex Laboratories, Inc.
Montville, NJ

Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, CT

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

Cephalon, Inc.
West Cester, PA

Daiichi Sankyo Company, Limited
Montvale, NJ

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 Pharmaceuticals Corporation
East Hanover, NJ

Organon USA, Inc.
Roseland, NJ

Otsuka America, Inc.
San Francisco, CA
Otsuka America Pharmaceutical, Inc.
Otsuka Maryland Research Institute

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

SCHWARZ PHARMA, INC.
Mequon, WI

Sepracor, Inc.
Marlborough, MA

Serono, Inc.
Norwell, MA

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

3M Pharmaceuticals
St. Paul, MN

Valeant Pharmaceuticals International
Costa Mesa, CA

Wyeth
Madison, NJ
Wyeth Pharmaceuticals
Wyeth Research

International Affiliates

ALTANA Pharma US
Florham Park, NJ

Eisai Inc.
Teaneck, NJ

Novo Nordisk Inc.
Princeton, NJ

Sigma-Tau Pharmaceuticals, Inc.
Gaithersburg, MD

Takeda Pharmaceuticals North America, Inc
Lincolnshire, IL

Associates: Researchers

Alkermes, Inc
Cambridge, MA

Celgene Corporation
Summit, NJ

Corus Pharma Inc.
Seattle, WA

Enzon, Inc.
Piscataway, NJ

ICOS CORPORATION
Bothell, WA

Idenix Pharmaceuticals, Inc.
Cambridge, MA

Ovation Pharmaceuticals, Inc.
Deerfield, IL

Theravance, Inc.
South San Francisco, CA

Associates: Contract Research Organizations

Compugen Ltd.
Jamesburg, NJ

Quintiles Transnational Corp.
Research Triangle Park, NC

Associates: Advertising & Communication Services

CommonHealth, L. P.
Parsippany, NJ

Euro RSCG Life Worldwide
New York, NY

Harte-Hanks, Inc.
Shawnee, KS

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

IMS HEALTH
Plymouth Meeting, PA

Medi-Promotions, Inc.
Hasbrouck Heights, NJ

Nelson Communications Worldwide
New York, NY

PDI, Inc.
Upper Saddle River, NJ

Publicis Healthcare Communications Group
New York, NY

Saatchi & Saatchi Healthcare, Inc.
New York, NY

Thomson Healthcare
Montvale, NJ

Associates: Consultants & Drug Discovery Software Firms

Accenture
Philadelphia, PA

Automsoft Inc.
Princeton, NJ

The Boston Consulting Group
Boston, MA

Cytel Inc.
Cambridge, MA

Dendrite International, Inc.
Morristown, NJ

Ernst & Young
New York, NY

KPMG LLP
Short Hills, NJ

NOP World Healthcare
E. Hanover, NJ

SAIC
San Diego, CA

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.

- **Basic Research:** Domestic expenditures on research projects that represent original investigation for the advancement of scientific knowledge and that do not have specific commercial objectives, although they may be in fields that are of present or potential interest.
- **Applied Research:** Domestic expenditures on research projects that represent original investigation in discovery of new scientific knowledge and that have specific commercial objectives with respect to either products or processes.
- **Development:** Domestic expenditures on research projects that represent technical activities concerned with non-routine problems encountered in translating research findings or other general scientific knowledge into products or processes.

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.

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Table 1
Domestic R&D and R&D Abroad,** PhRMA Member Companies: 1970–2005

(dollar figures in millions)

Year	Domestic R&D	Annual Percentage Change	R&D Abroad**	Annual Percentage Change	Total R&D	Annual Percentage Change
*2005	$31,444.2	6.4%	$7,987.1	7.0%	$39,431.3	6.5%
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%**		**15.6%**		**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.

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, 2006.

Table 2
R&D as a Percentage of Sales, PhRMA Member Companies: 1970–2005

Year	Domestic R&D as a % of Domestic Sales	Total R&D as a % of Total Sales
*2005	19.2%	15.8%
2004	18.4	15.3
2003	18.3	15.7
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

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2006.

Table 3
Domestic R&D and R&D Abroad,* PhRMA Member Companies: 2004

(dollar figures in millions)

	2004
R&D Expenditures for Human-Use Pharmaceuticals	
Domestic	$29,273.6
Share	79.1%
Abroad*	$ 7,356.9
Share	19.9%
Total Human-Use R&D	**$36,630.5**
Share	99.0%
R&D Expenditures for Veterinary-Use Pharmaceuticals	
Domestic	$ 281.9
Share	0.8%
Abroad*	$ 105.7
Share	0.3%
Total Vet-Use R&D	**$ 387.6**
Share	1.0%
TOTAL R&D	**$37,018.1**
	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, 2006.

Table 4
R&D By Function, PhRMA Member Companies: 2004

(dollar figures in millions)

Function	Dollars	Share
Prehuman/Preclinical	$9,585.7	25.9%
Phase I	2,473.3	6.7
Phase II	3,770.4	10.2
Phase III	9,682.1	26.2
Approval	3,415.3	9.2
Phase IV	4,902.9	13.2
Uncategorized	3,188.4	8.6
TOTAL R&D	**$37,018.1**	**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, 2006.

Table 5
R&D By Geographic Area,* PhRMA Member Companies: 2004

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Africa	$ 24.1	0.1%
Americas		
United States	$29,555.5	79.8%
Canada	380.5	1.0
Latin America (South and Central America, Mexico and all Caribbean nations)	122.0	0.3%
Asia-Pacific		
Asia-Pacific (except Japan)	$ 94.1	0.3%
India and Pakistan	7.9	0.0
Japan	945.4	2.6
Australia		
Australia and New Zealand	$ 96.9	0.3%
Europe		
France	$ 410.2	1.1%
Germany	524.2	1.4
Italy	213.1	0.6
Spain	175.6	0.5
United Kingdom	1,947.3	5.3
Other Western Europe nations	2,251.5	6.1
Central and Eastern European nations (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia and Malta)	109.1	0.3
Other Eastern European nations (including Russia and the Newly Independent States)	35.5	0.1
Middle East		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, Turkey and Qatar)	$ 35.2	0.1%
Uncategorized	$ 90.0	0.2%
TOTAL R&D	**$37,018.1**	**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, 2006.

Table 6
Domestic Sales and Sales Abroad,** PhRMA Member Companies: 1970–2005

(dollar figures in millions)

Year	Domestic Sales	Annual Percentage Change	Sales Abroad**	Annual Percentage Change	Total Sales	Annual Percentage Change
*2005	$164,152.4	2.1%	$85,879.6	5.5%	$250,032.0	3.3%
2004	160,751.0	8.6	81,364.0	14.9	242,115.0	10.6
2003	148,038.6	6.4	70,782.2	31.8	218,820.8	13.5
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		**10.9%**		**11.1%**		**10.8%**

*Estimated

**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.

***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, 2006.

Table 7
Sales By Geographic Area,* PhRMA Member Companies: 2004

(dollar figures in millions)

Geographic Area*	Dollars	Share
Africa		
Africa	$ 944.5	0.4%
Americas		
United States	$160,751.0	66.4%
Canada	5,594.5	2.3
Latin America (South and Central America, Mexico and all Caribbean nations)	5,514.6	2.3
Asia-Pacific		
Asia-Pacific (except Japan)	$ 3,871.1	1.6%
India and Pakistan	623.0	0.3
Japan	8,885.2	3.7
Australia		
Australia and New Zealand	$ 2,939.9	1.2%
Europe		
France	$ 8,790.3	3.6%
Germany	5,969.8	2.5
Italy	6,383.3	2.6
Spain	4,712.1	1.9
United Kingdom	5,367.3	2.2
Other Western European nations	10,421.2	4.3
Central and Eastern European nations (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia, Bulgaria, Lithuania, Latvia, Romania, Slovakia and Malta)	2,272.3	0.9
Other Eastern European nations (including Russia and the Newly Independent States)	516.1	0.2
Middle East		
Middle East (Saudi Arabia, Yemen, United Arab Emirates, Iraq, Iran, Kuwait, Israel, Jordan, Syria, Afghanistan, Turkey and Qatar)	$ 2,105.0	0.9%
Uncategorized	$ 6,453.8	2.7%
TOTAL SALES	**$242,115.0**	**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: Total values may be affected by rounding.

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2006.

Table 8
Domestic Sales and Sales Abroad* By End Use and Customer, PhRMA Member Companies: 2004

(dollar figures in millions)

	Human Use	Vet Use	Total
To Private Sector	$ 135,687.4	$ 1,080.9	$ 136,768.3
To Public Sector	21,878.3	873.6	22,751.9
Uncategorized	1,230.8	–	1,230.8
Total Domestic Sales	**$ 158,796.5**	**$ 1,954.5**	**$ 160,751.0**
Exports	$ 301.2	$ 46.7	$ 347.9
Foreign Sales	78,237.9	2,205.2	80,443.1
Uncategorized	573.0	–	573.0
Total Sales Abroad*	**$ 79,112.1**	**$ 2,251.9**	**$ 81,364.0**
Total Sales	**$ 237,908.6**	**$ 4,206.4**	**$ 242,115.0**

*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: Total values may be affected by rounding.

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2006.

Table 9
Domestic R&D Scientific, Professional and Technical Personnel By Function, PhRMA Member Companies: 2004

Function	Personnel	Share
Prehuman/Preclinical	28,838	35.3%
Phase I	5,981	7.3
Phase II	7,955	9.7
Phase III	15,839	19.4
Approval	5,116	6.3
Phase IV	11,681	14.3
Uncategorized	1,770	2.2
Total R&D Staff	**77,180**	**94.5**
Supported R&D Nonstaff	4,516	5.5
TOTAL R&D PERSONNEL	**81,696**	**100.0%**

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2006.

Key Facts

Research and Development

Developing a drug requires time and money. It takes an average of 10–15 years to develop a new medicine.[1] And, the costs continue to rise.

R&D Spending

Investment in R&D has increased dramatically in the past 25 years.

R&D Spending — 1980-2005

Year	PhRMA Members (in billions)	Total Industry (in billions)
2005	$39.4 (est.)	$51.3 (est.)[2]
2004	$37.0	$47.6[3]
2000	$26.0	not available
1990	$8.4	not available
1980	$2.0	not available

Total National Institutes of Health budget

Part of this budget is allotted for developing drugs.

- 2005 = $28.6 billion[4]
- 2004 = $28 billion[5]

Percentage of sales that went to R&D in 2005

- **19.2 percent** (est.) — Domestic R&D as a percent of domestic sales
- **15.8 percent** (est.) — Total R&D as a percent of total sales

Development Costs

As regulatory requirements become more stringent and the amount of information needed grows, the cost to develop a drug continues to go up.

Average Cost to Develop One Drug

Year	Cost (in millions)
2000	$800[6]
1987	$318
1975	$138

Drug Approvals

- The FDA approved **28** new drugs in 2005.[7, 8]
- Only **3 of 10** marketed drugs ever produce revenues that match or exceed R&D costs.[9]
- In the past decade (1995-2005), **over 160** orphan drugs have been approved.[10]
- The average *effective* patent life for pharmaceuticals is **11.5 years.**[11]

Value of Medicines

- New medicines generated **40 percent** of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000.[12]
- For every dollar spent on newer medicines in place of older medicines, total health care spending is reduced by **$6.17.**[13] In addition, every additional dollar spent on health care in the United States over the past 20 years has produced health gains worth **$2.40 to $3.00.**[14]

Prescription Medicine Sales

- A total of **3.6 billion** prescriptions were filled in the United States between October 2004 and September 2005.[15]
- In July 2005, the ratio of generic/brand share of market by volume (weighted average) was **54/46**. In 2006, it is estimated to be **58/42.**[16]

Endnotes

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[3] *Ibid.*

[4] U.S. Department of Health and Human Services, National Institutes of Health, *Summary of the FY 2007 President's Budget* (Bethesda, MD: NIH, 6 February 2006), http://officeofbudget.od.nih.gov/pdf/Press%20info%20final.pdf (16 February 2006).

[5] U.S. Department of Health and Human Services, National Institutes of Health, *Summary of the FY 2006 President's Budget* (Bethesda, MD: NIH, 7 February 2005), http://www.nih.gov/news/budget/FY2006presbudget.pdf (2 February 2006).

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

[7] "New Molecular Entities Approved in 1005," *The Pink Sheet* 68, no. 2 (9 January 2006) 29-30.

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[13] F. R. Lichtenberg, "Benefits and Costs of Newer Drugs: An Update," NBER Working Paper No. 8996, National Bureau of Economic Research (Cambridge, MA: NBER, June 2002).

[14] MEDTAP International, The Value of Investment in Health Care: Better Care, Better

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[16] PharmaLive, "Forecast of weighted average generic use in 2006 and 2010" (chart), *Med Ad News* (November 2005), http://www.pharmalive.com/magazines/medad/view.cfm?articleid=2702 (2 February 2006).

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