What goes into the cost of prescription drugs?

...and Other Questions About Your Medicines.
Table of Contents

List of Figures ................................................................. ii

Introduction ................................................................. 1

“What goes into the Cost of Prescription Drugs?” ........................ 2

“What Value do Prescription Drugs Provide Patients?” .............. 4

“What Role do Prescription Drugs Play in Improving Health Care?” ................................. 6

“Doesn’t the Government Invent Most New Medicines?” .................... 8

“Why Do Some Prescription Drugs Cost Less in Canada?” ................. 9

“What’s Wrong with Government Price Controls?” ......................... 10

“Why is it Risky to Import Prescription Drugs from Canada?” ............ 12

“How Does the Free Market System Help Create New Medicines?” ..... 15

“Do Pharmaceutical Companies Help People Who Can’t Afford Their Medicine?” ......................... 16

“Does Pharmaceutical Marketing Add to the Cost of Prescription Drugs?” ......................... 17
List of Figures

FIGURE 1: Pharmaceutical Research Companies Represent One of America’s Most Research-Intensive Industries

FIGURE 2: The Cost of Developing a New Drug Has Greatly Increased

FIGURE 3: Only Three of Ten Marketed Drugs Produce Revenues That Match or Exceed Average R&D Costs

FIGURE 4: Medicines Prolong Life: Early HIV Therapy Prolongs Life

FIGURE 5: New Medicines Account for 40% of Increase in Life Expectancy

FIGURE 6: Benefits of Increased Health Care Spending

FIGURE 7: Pharmaceutical Research Company Scientists Earned FDA Approval for an Average of 33 New Medicines a Year Over the Past Decade

FIGURE 8: New Drugs Reduce Visits to Hospital and ER: Asthma Management Program Improves Outcomes for Children with Asthma

FIGURE 9: Where the Health Dollar Goes: 2003

FIGURE 10: PhRMA Member Companies’ R&D Expenditures Exceed Total NIH Operations Budget: 1995–2004

FIGURE 11: U.S./Canadian Price Comparisons

FIGURE 12: American Pharmaceutical Research Companies Lead the World in R&D

FIGURE 13: Shares in terms of U.S. Patent Citations, By Nationality of Assignee

FIGURE 14: Birth of a Drug


FIGURE 17: Direct-to-Consumer Advertising Encourages Patients With Undiagnosed Conditions to Visit Their Physicians

FIGURE 18: R&D Spending Exceeds Promotional Dollars, 2003
Whenever we talk about what goes into the cost of prescription drugs, one part of the cost equation overshadows all others: The cost of disease. The cost of disease includes the cost of medications, hospitalizations, doctor visits, physical therapies and surgeries. The cost of disease is growing and it is a burden that falls hardest on patients and their families. It saps financial resources while taking a devastating physical and emotional toll. And, every year, the cost of disease is rising.

Disease, in short, is our common enemy. And it is disease that America’s biopharmaceutical research companies are fighting on behalf of every American who confronts disease in all of its miserable forms.

While the fight against disease is certainly not yet over, many important victories have already been won. An ongoing medical revolution over the last few decades has resulted in new and better treatments for a host of diseases that once devastated patients’ lives and burdened the health care system. Breakthrough biopharmaceutical research by America’s pharmaceutical makers has produced an unparalleled stream of new treatments and cures. Many patients now live longer lives, free from pain and disease because of these medicines. Patients and physicians confronting diseases from diabetes to Alzheimer’s to cancer eagerly await every new research advance hoping for a cure and a chance for a better life.

Yet, amid this abundance of new medicines and medical options, many have questions about the cost of medicines.

The question of what goes into the cost of prescription drugs is today at the heart of the healthcare debate. As in any debate, it is important that the public be well informed. Here, we present facts to try to answer some of these questions about the cost of medicines. There is, however, no single answer—there are many. Some answers may be surprising because of popular misconceptions about the costs of medicines compared to other health care services. Others—like the fact that researching and developing new medicines is a long and expensive process—will seem like nothing more than plain common sense.

Helping patients get the prescription medicines they need is the goal of every doctor, health care advocate and America’s biopharmaceutical research companies. In this effort, it is important for patients, doctors and the public to understand more about the value of pharmaceuticals both in their own lives and in creating more effective and accessible health care for everyone.
“What goes into the Cost of Prescription Drugs?”

Just as the cost of paper and ink does not determine the cost of a textbook and the cost of surgery has little to do with the price of a scalpel, the cost of a prescription medicine is more than the cost of its ingredients. Like every product that results from research and creativity, medicines are really made of knowledge—knowledge that prevents and cures disease and relieves suffering.

The knowledge needed to discover and develop new medicines does not come easily. Discovering, developing, testing, and gaining regulatory approval for a new medicine takes a long time and the risk that a promising line of research won’t pan out is great. Nonetheless, America’s biopharmaceutical research companies are among the country’s most research-intensive companies and their continuing efforts to develop new medicines have produced impressive results and created new hopes for finding tomorrow’s cures (Figure 1).

● Significant time and money is needed to research and develop new, safe and effective medicines. Economists estimate that it takes an average of 12 to 15 years to discover and develop a new medicine and, on average, it costs $800 million (Figure 2).

● On average, only five of every 10,000 compounds investigated are tested in clinical trials. Of those five, only one is ever approved for patient use. Revenues from one successful medicine must cover the costs of the vast number of “dry holes.”

● On average, only three of every 10 prescription medications available to treat Americans generate revenues that meet or exceed average R&D costs (Figure 3).

![Figure 1. Pharmaceutical Research Companies Represent One of America’s Most Research-Intensive Industries](image1)


![Figure 2. The Cost of Developing a New Drug Has Greatly Increased](image2)


FOR MORE INFORMATION ON HOW MEDICINES ARE DEVELOPED VISIT: WWW.INNOVATION.ORG
Although developing new medicines is very expensive, the time that companies have to recoup their investment is shrinking due to increased competition from other branded and generic drugs.

Companies must fund research into new medicines as well as improvements to existing medicines with revenues from medicines already on the market. One of every five dollars in revenue is poured back into research and development. Currently, pharmaceutical companies are working on over 1,000 new medicines now in clinical trials for Alzheimer’s disease, stroke, cystic fibrosis, arthritis, and many other diseases. For cancer alone, there are almost 400 medicines in the pipeline.

The cost of medicines reflects their enormous value to patients, to society, and to the health care system. If we focus too much on cutting the cost of medicines without recognizing the growing role that medicines play in creating affordable health care, we may lose sight of their value and jeopardize future pharmaceutical research and development.

A capsule or medicine bottle may contain:

- Years of scientific education
- State-of-the-art research tools
- 12–15 years worth of research and development
- Independent and active lives for elderly Americans
- A higher quality of life for children with asthma
- More productive, illness-free workdays for employees

How do you put a value on good health? What is the value of the smile of a child no longer feeling the pain of cancer? What is the value of giving a grandfather with congestive heart failure the energy to go camping with his grandson?

Quantifying the value of good health is difficult. But, we can often quantify the value of medicines to patients, to society and to the health care system. Here are a few examples.

STROKE—A study sponsored by the Agency for Health Care Policy and Research found that increased use of a blood-thinning drug would prevent 40,000 strokes a year, saving $600 million annually.

HIV/AIDS—New medicines have made a major contribution to the decline in the death rate from HIV/AIDS in the U.S. over the last 10 years (Figure 4). Since the mid-1990s, when researchers developed a new wave of medicines to treat HIV/AIDS, the U.S. death rate from AIDS has dropped about 70 percent.

HIGH CHOLESTEROL—Changes in the recommended use of statins reflects the increasingly important role that they can play in reducing the incidence of heart disease. Several studies have found that using statin therapy to treat people with high cholesterol reduces hospital admissions and invasive cardiac surgeries. For example, a study of one statin showed that it reduced hospital admissions by a third during five years of treatment. It also reduced the number of days that patients had to spend in the hospital when they were admitted, and it reduced the need for bypass surgery and angioplasty.

CANCER—A February 2004 study by Columbia University Prof. Frank R. Lichtenberg found that new cancer drugs have accounted for 50 to 60 percent of the gains we have made in cancer survival rates since 1975. Since 1971, when the U.S. declared war on cancer, our arsenal of cancer medicines has tripled. During that time, the survival rate has risen from 50 percent to 62.7 percent. Overall, new cancer drugs have contributed a remarkable 10.7 percent of the increase in life expectancy at birth in the U.S.

HEART FAILURE—A January 2004 study by Duke University researchers found that five years of treatment for heart failure without beta-blockers cost a total of $52,999. With beta-blockers added to treatment, total treatment costs fell by $3,959, patient survival increased by an average of about three-and-a-half months, and patients needed fewer overnight hospital stays.

DIABETES—One recent study published in the Journal of the American Medical Association found

that effective treatment of diabetes with medicines and other therapy yields annual health care savings of $685 to $950 per patient within one to two years.

**ALZHEIMER’S DISEASE**—A study of the effects of a new Alzheimer’s medicine, donepezil, on costs in a Medicare managed care plan showed that, although the prescription costs for the group receiving the drug were over $1,000 higher per patient, the overall medical costs fell to $8,056 compared with $11,947 for the group not receiving drug treatment.

**DEPRESSION**—A December 2003 study in the *Journal of Clinical Psychiatry* showed that newer, better medicines are reducing the cost of treating people with depression. The study found that per-patient spending on depression had fallen by 19 percent over the course of the previous decade.

**AGING**—A recent study of the National Bureau of Economic Research noted that new medicines account for 40 percent of the increase in longevity (Figure 5). Between 1980 and 2000 alone, life expectancy in women increased from 77 to 79, and in men from 70 to 74 (Figure 6).

**FIGURE 5. New Medicines Account for 40% of Increase in Life Expectancy**

Scientists from research pharmaceutical companies have successfully developed, on average, 33 new medicines a year over the past decade. 38 new medicines were approved in 2004 alone (Figure 7). The use of new medicines often reduces overall health care costs.

**FIGURE 7. Pharmaceutical Research Company Scientists Earned FDA Approval for an Average of 33 New Medicines a Year over the Past Decade**

Significant underdiagnosis and undertreatment of serious diseases is a growing health care problem in America. Americans would be healthier—and overall health care costs might actually decrease—if more patients were properly diagnosed and treated.

Prescription medicines play an important and growing role in basic health care. They are helping patients remain independent and productive. For example, the need for more expensive health care services such as long hospitalizations and surgeries can be reduced by using prescription medicines (Figure 8).

Currently, prescription drug expenditures account for less than 11 cents of every health care dollar (Figure 9). The good news is that while that percentage has increased in recent years, this increase means that more people are benefiting from more and better medicines. In fact, a study by Columbia University economist Frank Lichtenberg found that while treating conditions with newer medicines instead of older ones increases medicine costs, it significantly lowers non-drug medical spending. The study found that each additional dollar spent on using a newer prescription medicine (instead of an older one) saves roughly $7.20 in other health care costs.

**FIGURE 8. New Drugs Reduce Visits to Hospital and ER: Asthma Management Program Improves Outcomes for Children with Asthma**

<table>
<thead>
<tr>
<th>Percent of Patients</th>
<th>Before Program</th>
<th>After Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>ER Visits</td>
<td>85%</td>
<td>35%</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>35%</td>
<td>55%</td>
</tr>
<tr>
<td>90</td>
<td>90</td>
<td></td>
</tr>
</tbody>
</table>


**FIGURE 9. Where the Health Care Dollar Goes: 2003**

Utilization vs. Price Increases

There are several factors behind increasing medicine expenditures:

**A STEADY STREAM OF NEW MEDICINES**—Many new medicines replace higher-cost surgeries and hospital care. In 2004 alone, pharmaceutical companies added 38 new treatments to the nation’s medicine chest. Over the last decade, 330 new medicines have become available for treating patients. These include important new medicines for some of the most devastating and costly diseases including: AIDS, cancer, glaucoma, heart disease, schizophrenia, and Alzheimer’s disease. Additionally, there are over 1,000 new medicines in the research and development pipeline.

**GREATER TREATMENT OF PREVIOUSLY UNDIAGNOSED AND UNTREATED PATIENTS**—For example, over 19 million American adults are annually affected by depression. Unfortunately, despite therapeutic advances and efforts to increase depression awareness and diagnosis, depression remains widely untreated. However, the federal government’s 2003 report *Healthy People 2010 Psychiatry* found that per-patient spending on depression fell by 19 percent during the 1990s, largely as a result of a switch from hospitalization to medication as a first line treatment.

**AN AGING POPULATION**—The nation’s population is aging, and the elderly use more medicines than do younger people. People 65 and older, on average, fill their prescriptions more than 25 times a year compared to those 64 and younger who average around seven refills per year.

Using prescription drugs to treat uncontrolled high blood pressure is one example of how prescription drugs can both save lives and reduce overall health care expenditures.

**NEW GUIDELINES ON THE USE OF MEDICINES**—For example, the National Institutes of Health (NIH) has recommended that more Americans take cholesterol-lowering drugs. According to an NIH official, if these recommendations were followed, heart disease would cease to be the leading cause of death in the U.S.

Despite the fact that more people are benefiting from medicines, under-treatment continues to be a major health care concern.

For example:

- More than 23 million Americans who should be taking cholesterol-lowering drugs are not taking them, according to the National Institutes of Health.
- Over 19 million Americans suffer from depression and fewer than half seek treatment.
- Almost 6 million Americans have diabetes but don’t know it or are not being treated for it.
No. There's a persistent misconception that the National Institutes of Health (NIH), a taxpayer-funded research institute, does most of the heavy work in discovering new medicines.

- In fact, the vast majority of the medicines patients use today were developed by pharmaceutical research companies.

- America's research-based pharmaceutical companies spend far more on biomedical research and development than does the NIH, and they discover the vast majority of the medicines in the U.S. In 2004, PhRMA member companies invested over $38 billion in new research and development. The total NIH budget—including support for basic biomedical research—was $27.9 billion (Figure 10). Since 1980, pharmaceutical companies' R&D budgets have increased 19-fold—a $4 billion increase last year alone. Additionally, when R&D by non-PhRMA member is counted, non-government biopharmaceutical investment now tops $49 billion.

The value of both public- and private-sector research to patients is priceless. We need to keep funding public research, and we need to keep the incentives for private-sector research strong.

- The NIH reported to Congress in 2001 that it found a significant government investment in only four of 47 medicines with sales of $500 million or more. The Government Accountability Office (GAO) reviewed the top 100 medicines purchased by both the Department of Defense (DoD) and the Department of Veterans Affairs (VA). The GAO found that the government had licensing rights in only six of the top 100 medicines purchased by DoD and only four of those bought by the VA.

Government and NIH-funded academic scientists do a terrific job in advancing basic knowledge about biology and disease. Their work improves our understanding of diseases. But, pharmaceutical company scientists lead the way in translating basic science into practical medicines that help and heal patients.
“Why Do Some Prescription Drugs Cost Less in Canada?”

The major reason drugs (other than generics) are sometimes cheaper in Canada is government-imposed price controls. Canada, like many nations with nationalized health systems, has restrictive government regulations that keep prescription drug prices artificially low.

Also, not all medicines are cheaper in Canada (Figure 11). Many generic medicines, for example, cost more in Canada than in the U.S.

Here’s how it works. Governments, like Canada’s, are the main purchasers of pharmaceutical products. They have near-total control of the local health care market. Many governments use this control to obtain drugs at prices significantly below what they would cost in a free market, and thus avoid the large expense of paying for developing new medicines.

As the sole buyer of medical goods and services, such governments not only set uniform prices, but some have also demanded large “rebates” from pharmaceutical manufacturers, controlled the amount of profits that a pharmaceutical manufacturer in that country can make, controlled the amount that a pharmaceutical manufacturer in that country can sell, limited the information about medicines and new treatments available to physicians and patients, and mandated highly restrictive lists (formularies) of

<table>
<thead>
<tr>
<th>Drug (Strength and Amount)</th>
<th>Medical Use</th>
<th>Price Paid by Patient from CanadaRx in USD*</th>
<th>CanadaRx</th>
<th>U.S. Pharmacy Price**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone 200mg (100)</td>
<td>Rapid Heart Beat</td>
<td>$116.97</td>
<td>$134.90</td>
<td>$41.89</td>
</tr>
<tr>
<td>Verapamil SR 240mg (100)</td>
<td>High Blood Pressure</td>
<td>$83.90</td>
<td>$93.95</td>
<td>$43.97</td>
</tr>
<tr>
<td>Lisinopril 20mg (100)</td>
<td>High Blood Pressure</td>
<td>$83.59</td>
<td>$97.90</td>
<td>$16.19</td>
</tr>
<tr>
<td>Lisinopril 5mg (100)</td>
<td>High Blood Pressure</td>
<td>$47.96</td>
<td>$67.90</td>
<td>$13.99</td>
</tr>
<tr>
<td>Terazosin 2mg (100)</td>
<td>High Blood Pressure, Prostate</td>
<td>$43.98</td>
<td>$52.90</td>
<td>$17.09</td>
</tr>
<tr>
<td>Digitek .25mg (250)</td>
<td>Heart Medication</td>
<td>$51.30</td>
<td>n/a</td>
<td>$24.97</td>
</tr>
<tr>
<td>Diltiazem CD 240mg (100)</td>
<td>High Blood Pressure</td>
<td>$139.75</td>
<td>$145.00</td>
<td>$127.99</td>
</tr>
<tr>
<td>Hydrochloro-thiazide 25mg (100)</td>
<td>High Blood Pressure</td>
<td>$12.73</td>
<td>n/a</td>
<td>$6.29</td>
</tr>
<tr>
<td>Warfarin 5mg (100)</td>
<td>Prevention of Blood Clotting</td>
<td>$18.60</td>
<td>$24.90</td>
<td>$20.69</td>
</tr>
<tr>
<td>Aricept 10mg (30)</td>
<td>Alzheimer’s Treatment</td>
<td>$128.65</td>
<td>$147.96</td>
<td>$140.69</td>
</tr>
</tbody>
</table>


*Shipping charges by Canadian pharmacies not included, but range from $15–$30; **Based on prices available Oct. 4–5, 2004.
drugs that the government makes available to its citizens and for which it is willing to reimburse them.

The American health care system is structured very differently. So is the way medicines are paid for. In the U.S., free-market competition determines prices and there is a wide variation in rates and discounts. Market forces and competition work to keep prices down. For American patients this means they often have access to new medicines sooner than do patients in countries with government price controls. Additionally, patients and their doctors often have more medicine choices when designing a course of treatment to meet a patient’s individual needs.

In fact, Canadian prices are no real bargain for the nearly 75% percent of Americans with health insurance coverage and for whom institutional purchasers negotiate often deeply discounted medicine prices. One recent study found: “to the extent that ‘list’ prices fail to report the impact of discounts and rebates in the United States, alleged price advantages in Canada are overestimated. It is likely that only those Americans who find themselves without prescription drug coverage are charged prices that exceed Canadian prices.”

To compare Rx prices across countries is difficult because countries have different types of health systems.

“What’s Wrong with Government Price Controls?”

They don’t work. Throughout history, price controls have been tried numerous times and have never worked. Instead, they produce shortages and black markets. Price controls on oil and natural gas in the 1970s led to nation-wide artificial shortages and long lines at gasoline pumps. Price controls on rental property led to housing shortages and the deterioration and neglect of existing housing.

Price controls on medicines will likely only hurt patients by discouraging needed investment in new research. On average, it costs over $800 million and takes from 12 to 15 years to bring a new medication to medicine cabinets. Unless there is a possibility of a return on that investment commensurate with the high risk of getting a new medicine all the way through the research and development pipeline, investors will probably put their money elsewhere.
Even the threat of price controls can push down research spending just when new treatments are needed most. In 1994 and 1995, just after price controls were proposed as part of the Clinton health care reform plan, the increase in research and development spending dropped from double digits to single digits.

The negative effects of government price controls can be seen abroad. In many foreign countries, there are highly restrictive medicine formularies that limit prescribing to mostly older medications because they are the least expensive. This makes it hard for patients in those countries to get the latest medication for their condition. For example:

- In Germany, 87 percent of all patients with coronary heart disease are not provided with modern lipid-lowering drugs (statins). In Italy, 83 percent do not receive statins.

- In Australia, an important osteoporosis medication that can actually prevent the onset of the disease, is only reimbursed after a patient has broken a bone.

Price controls also discourage research and development of new medicines. One reason that the U.S. is now the worldwide center of research and development is because the European Union’s system of price controls on pharmaceuticals—where governments simply set low prices for pharmaceuticals—gives little incentive to create new drugs (Figure 12). These policies have driven research and development once done in Europe to the United States, where there are market-based incentives for developing new drugs. Today, the U.S. increasingly leads the world in new pharmaceutical and biotechnology patent filings. This is just one more indication that many of the world’s new medicines are being developed in the U.S. and explains why U.S. patients often have access to new medicines before patients in other countries (Figure 13).
Importing medicines, whether from Canada or anywhere in the world, is the wrong answer for patients and America. Patients seeking to import medicines from Canada and other countries face significant safety risks. The Canadian government, for instance, regulates prescription medicines used by Canadians. But few people realize that the Canadian government doesn’t regulate drugs that are transshipped through Canada on their way to a third country such as the United States.

There are other risks:

- Patients have no guarantee they will get what they paid for. For example, according to the Acting FDA Commissioner in July 2004, the FDA found evidence of a Canadian Web site advertising “Canadian generic” drugs, when in fact it was selling fake, contaminated and substandard versions of three commonly prescribed medicines. In addition, the FDA has identified drugs being imported into the U.S. arriving from unreliable sources in such places as the Bahamas and Pakistan. Media reports have found that some Canadian pharmacies are now shipping drugs from all over the world, including Belize,
Israel, India, Chile, New Zealand, Ireland and Great Britain. So a drug that a consumer assumes is coming from Canada, may in fact originate almost anywhere in the world.

According to Canadian Health Minister Ujjal Dosanjh: “Canada cannot be the drug store of the United States.” In November 2004, Dr. Dosanjh told a conference at Harvard University “...It is difficult for me to conceive of how a small country like Canada could meet the prescription drug needs of approximately 280 million Americans without putting our own supply at serious risk.” Additionally, Diane Gorman, Assistant Deputy Minister, Health Canada, said “the Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States, or any country for that matter.”

Opening U.S. borders to imported drugs could increase the flow of counterfeit drugs into the U.S., increasing the risks for all patients. Those charged with protecting American patients have all concluded that allowing imported drugs would mean opening the U.S. to risks including counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired and contaminated drugs, and drugs stored under inappropriate and unsafe conditions. The list of those concerned over the safety of imported drugs includes:

▲ The Secretary of Health and Human Services;
▲ The Commissioner of the Food and Drug Administration; and
▲ A Commission headed by the U.S. Surgeon General assembled to study whether importing drugs could be done safely.

There is no guarantee that importing medicines will actually save consumers money. In fact, there is strong evidence to the contrary. For example, one study of top-selling generic medicines found that, on average, Canadian prices were more than double those in the U.S. for the same medication. In a similar study, the FDA found that generic medicines in the U.S. are cheaper than both Canadian branded drugs and Canadian generic drugs, because U.S. market competition lowers prices.

Yet another important reason is that it is illegal unless otherwise specified under the FDA’s “personal use clause.” Congress banned drug importation in order to protect patients as well as the safety of the nation’s medicine supply from numerous hazards. Potential problems with imported medicines include: poor manufacturing practices; erroneous or misleading labels; poor packaging, storage and shipping. In addition, there has been a significant increase in the incidence of counterfeit medicines in recent years, all too often with tragic results for unwary patients.

Importing prescription medicines from Canada imports Canadian government imposed price controls. Some members of Congress have proposed Canadian-style price controls as one way to reduce prescription medicine costs. Americans should be skeptical of this approach. While the Canadian government-controlled prices for brand-name drugs are sometimes below the prices available to Americans, these low prices come at a high cost.

Patient access to the latest and most innovative prescription medicines is often limited by Canada’s government-controlled health care system and its emphasis on cost containment. Several recent studies raise some alarming issues:
In British Columbia, some Canadians being treated with one effective medicine are switched to a substitute simply because the government health system mandates it. This can result in patient confusion, greater noncompliance, and a worsening of symptoms.

Canadian patients are often denied easy access to certain medicines that, for them, would have minimal side effects, because the government requires that they must first endure therapy with the “cheaper,” potentially less-effective medicines. Only when serious side effects appear—sometimes requiring hospitalization, for example—does the government allow the more efficacious drug to be prescribed.

Canadians wait, on average, seven months longer than Americans for new medicines to be approved by their government regulatory agency. Even after a medicine is approved, patients wait an average of five to 13 months longer before the medicine is put on and reimbursted by each province’s formulary. Many other state-of-the-art therapies are simply unavailable to patients through the provincial-level health care system.

Canada ranks third-from-last in the developed world on the availability of medical technology, according to the Organization for Economic Cooperation and Development (OECD).

Safe alternatives to importation exist. For example, pharmaceutical companies and numerous public and private health care advocates and providers sponsor patient assistance programs. These programs help qualifying patients get the medicines they need, often for free or significantly discounted prices. In April, 2005, the nationwide Partnership for Prescription Assistance Program was launched. Now, with one toll-free phone call (1-888-4PPA-NOW or 1-888-477-2669) or convenient website visit (www.pparx.org), qualifying patients lacking prescription coverage can access more than 275 private and public programs that will help them get the prescription medicines they need. This includes over 150 PhRMA member company sponsored programs.

In addition, the new Medicare prescription drug benefit, which will begin in early 2006, will help millions of seniors and disabled Americans afford the medicines they need. Consumers can also find significant savings by using appropriate generic medicines where available and comparison shopping among several pharmacies.

FOR MORE INFORMATION ON THE HAZARDS OF IMPORTED DRUGS VISIT: WWW.BUYSAFEDRUGS.INFO

Americans rely on market forces and competition to control costs, and they have the best, most innovative health care system in the world. We don’t want to dilute the quality of our system or trade it for second-rate care.
“How Does the Free Market System Help Create New Medicines?”

America’s pharmaceutical companies are dynamic, successful and high-growth companies operating in a free market economy. Pharmaceutical company profitability typically reflects this fact. More importantly, the free market plays a key role in creating new medicines and treatments for patients.

How? Pharmaceutical company profitability attracts new investment. New investment, in turn, funds new research. And new research yields new medicines and, hopefully, new cures. However, new cures and medicines come at a significant cost. The research and development cost of each medicine approved by the FDA is, on average, $802 million.

The free market and the ability to make a profit are thus essential to continue fueling new medicine research and development. However, when assessing pharmaceutical company profitability, several factors should be kept in mind.

**FIVE IN 10,000 AND THREE IN 10**—For every 10,000 compounds investigated, only five are ever tested as potential medicines in a clinical trial. Of those five, only one is ever approved for patient use. Of all the drugs finally approved for patient use, only three out of 10 generate revenues that meet or exceed average research and development costs. (See Figure 14). According to a study by Duke University and Tufts University economists, 20 percent of the products with the highest returns generate 70 percent of the returns. In other words, companies must rely on a limited number of highly successful products to finance continuing R&D for new treatments.

**COMPETITIVE INDUSTRY IN A GLOBAL ECONOMY**—
As one of the nation’s most competitive manufacturing sectors in an increasingly competitive global market, pharmaceutical companies need to be profitable to attract the capital needed to sustain innovation. On average, it takes nearly 12 to 15 years and hundreds of millions of dollars to develop a new drug. In the global competition for capital, if potential investors can’t see the possibility of profits commensurate with the high risk of drug R&D, they will invest in an area that affords that possibility.

**ACCOUNTING ANOMALY**—Economists say that, properly measured, pharmaceutical manufacturing profits are only slightly above the average for all industries. This is true because standard accounting methods generally write off R&D—atypically high in the pharmaceutical field—as current expenses. If those costs were depreciated over time, the rate of return would be lower.

---

**FIGURE 14. Birth of a Drug**

Source: www.innovation.org
“Do Pharmaceutical Companies Help People Who Can’t Afford Their Medicine?”

They do.

For years, PhRMA-member companies have sponsored over 150 patient assistance programs for low-income Americans. In 2004 alone, millions of patients across America received an estimated 22 million prescriptions with a wholesale value topping $4.17 billion. In 2003, by comparison, patients received over 18 million prescriptions with an estimated wholesale value of $3.4 billion (Figure 15).

The Partnership is a national effort made up of research pharmaceutical companies, doctors and other health care providers, patient advocates and community groups. It was created to help millions of patients who do not have prescription coverage or who are having trouble affording their medicines.

In addition to supporting the Partnership for Prescription Assistance, research pharmaceutical companies distributed over $16 billion worth of free samples to office-based physicians in 2003. According to the Journal of Family Practice, free samples are an important part of the health care safety net for low-income and uninsured patients.

The real key to good access to medicines is good insurance coverage. America’s research pharmaceutical companies understand that our medicines are useless for patients unable to afford them. For far too many people, access to affordable prescription medicine is a personal crisis, not a policy debate. That’s why America’s pharmaceutical research companies are committed to expanding prescription drug access to all patients. Beginning in January 2006, 41 million seniors and disabled Americans will have a voluntary Medicare prescription drug benefit. This is a start. But we want every American to be able to have coverage. And we want every patient to acquire medicines at competitive prices, as do those now in private plans, which take advantage of competition to lower prices.

PhRMA member companies are ready and eager to work closely with the public, health care professionals and policy leaders to find answers to the challenge of providing greater access to medicines and making them more affordable.


Source: Pharmaceutical Research and Manufacturers of America, Member Company Patient Assistance Programs Survey 2003.

Today, America’s pharmaceutical companies are more committed than ever to assisting patients get the medicines they need. In 2005, PhRMA along with partners in both the private and public sector launched the Partnership for Prescription Assistance (PPA). One phone call to 1-888-4PPA-NOW (1-888-477-2669) or a visit to the Partnership’s website (www.PPARX.org) provides access to 275 private and public patient assistance programs, including the 150 sponsored by PhRMA members.
“Does Pharmaceutical Marketing Add to the Cost of Prescription Drugs?”

No. Experts have not found any relationship between drug marketing and drug price. A Harvard University and the Massachusetts Institute of Technology joint study, for instance, found that direct-to-consumer (DTC) advertising accounts for less than 2 percent of the total U.S. spending for prescription medicines. Pharmaceutical companies spend more on research and development than they do on promotion (Figure 16).

A quarter of adult patients who visit their physician after seeing a direct-to-consumer ad receive a new diagnosis of a condition, according to a recent Harvard University/Massachusetts General Hospital and Harris Interactive Survey on health care experiences associated with DTC advertising of prescription drugs.

An FDA patient survey on direct-to-consumer advertisements revealed that nearly one in five patients reported speaking to a physician about a condition for the first time because of a direct-to-consumer ad; thirty-two percent of patients reported that direct-to-consumer ads helped them have better discussions about their health with their doctor; and 43 percent of patients said an ad for a prescription drug caused them to look for more information about the drug or about their health.

In addition, advertising also likely helps moderate drug prices. According to a report by the Federal Trade Commission, advertising puts downward pressure on prices by spurring competition among competing therapies.

In fact, DTC advertising has many documented health benefits. It raises consumer awareness of health problems and possible solutions and brings patients to doctor’s offices. In this way, advertising helps solve the important public health problem of disease under-diagnosis and undertreatment (Figure 17).

Significantly more invested in R&D than spent on DTC advertising

Yet another concern raised often about DTC advertising is that pharmaceutical companies spend more money on DTC than they do on research and development.
The facts tell a different story. In 2003 alone, pharmaceutical research and development spending exceeded all types of pharmaceutical marketing spending by 36% percent—including DTC. PhRMA member companies spent $34.5 billion on research and development in 2003 while only $3.3 billion of total marketing expenses were spent on DTC. Remaining marketing expenses—$25.3 billion in 2003—included the retail value of free samples provided to doctors and health care facilities, office promotion, hospital promotion and journal advertising. In fact, $16.4 billion given away in free samples represented the largest portion of PhRMA member companies’ advertising expenditures in 2003 (Figure 18).

**FIGURE 17. Direct-to-Consumer Advertising Encourages Patients With Undiagnosed Conditions to Visit Their Physicians**


**FIGURE 18. R&D Spending Exceeds Promotional Dollars, 2003**

What goes into the cost of prescription drugs?

...and Other Questions About Your Medicines.

New Medicines. New Hope.

Pharmaceutical Research and Manufacturers of America
1100 Fifteenth Street, NW
Washington, DC 20005
www.phrma.org
www.innovation.org
www.buysafedrugs.info
www.pparx.org

June 2005