



# Continuing Education



## Overview of pharmaceutical pricing

### Learning Objectives

**Explain** the reasons for high research and development costs.

**Identify** and describe market forces that affect pharmaceutical prices.

**Describe** issues that contribute to the complexity of pharmaceutical pricing.

**Describe** the benefits provided by pharmaceutical advertising.

**Explain** the rationale behind pharmaceutical company profits.

This second article in a three-part series discusses the many factors that influence the pricing of pharmaceuticals. Topics include: research and development costs, market forces, pricing issues, advertising costs, and pharmaceutical company profits.

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**P**rescription drugs represent an increasing share of the healthcare dollar. However, according to studies, pharmaceutical expenditures accounted for only 11% of total healthcare costs in 2002. The rising costs of prescription drugs reflect the greater numbers of excellent drugs on the market and their increased use by an aging population. Increases in pharmaceutical product use also reflect the fact that drugs are often the most effective and efficient means for providing care. Price can also be affected by the phases that a drug passes through as it is launched, is adopted for use, and then declines as new drugs are introduced and surpass it.

### Research and development costs

It is estimated that the cost of discovering, developing, testing and gaining regulatory approval for a new drug is approximately \$800 million. Much of this cost is tied to the lengthy preclinical and clinical testing required for all pharmaceutical products approved for use in the United States. This testing process includes several steps and often takes up to 10 years, with each step in the process becoming more complex and expensive than the previous one. Pharma-

ceutical companies must go through all these steps for each indication for each drug they develop.

While research and development (R&D) is a long and expensive process, taking 12 to 15 years on average to discover and develop a new medication, it is a crucial one for pharmaceutical companies. Companies must develop and market successful drugs on a regular basis to stay in business, and almost all R&D costs for drugs are borne by the pharmaceutical companies.

Research and development is an expensive and risky venture. The pharmaceutical industry spends over \$30 billion annually on research for new drugs. On average, only one out of every 5,000 pharmaceutical products tested is approved for patient use, and only three of every 10 approved drugs available in the United States generate enough revenue to meet or exceed the average R&D costs.

The use of biotechnology and other scientific innovations is improving the industry's ability to systematically develop drugs, but it also requires costly expenditures on sophisticated equipment. The use of these innovations is expected to increase; however, the risks involved in developing drugs using these

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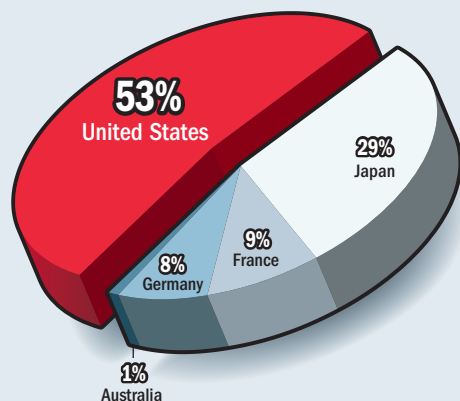
The Certified Medical Representatives Institute is an independent non-profit educational organization established in 1966 to provide a source of professional development and certification for pharmaceutical representatives. The institute provides an up-to-date, approved continuing education curriculum designed to expand and enhance internal company training and development in a cost-effective manner. The curriculum concentrates on providing a general knowledge base and avoids such areas as selling skills and specific product education.

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Figure 1

## U.S. leads in R&D

This chart depicts the percentage of total R&D spent by pharmaceutical companies in five industrialized nations in the year 2000.



Source: Organisation for Economic Co-operation and Development, 2001

methods are huge. Biotechnological research is characterized by high laboratory costs, long lead times and disappointing laboratory results. While the advances in drug development through biotechnology are producing exciting and innovative drugs, they come with higher development costs.

Pharmaceutical development is increasingly focused on drugs for chronic diseases, such as diabetes, asthma and depression, which require more extensive development and testing to determine efficacy and long-term safety. This focus is likely to continue, as these conditions now affect almost half the U.S. population.

## Market forces

Prescription medication prices are also affected by market forces, which can change over the course of a product's time on the market. Several of these factors are discussed below.

**Discounts.** Pharmaceutical companies frequently offer discounts to large and influential buyers, such as wholesalers, retail chain pharmacies, mail-order and Internet pharmacies, pharmacy benefit management companies, government agencies, high-volume group purchasing organizations, and especially large managed care organizations (MCOs). These large buyers have had a huge influence on prices because they account for the majority of drug sales in the United States, with just 38% of patients paying directly for their own prescriptions.

**Competition.** Pharmaceutical companies carefully examine competitors' prices as they launch new products. In some therapeutic areas, the market leader is a high-priced drug, indicating that the market for that drug is not particularly price-sensitive. In other areas, the market leader is a low-priced agent, suggesting that any new drug must be priced

within a certain range to generate sales. Companies may also need to keep in mind the competitors' promotional efforts and discounts provided for competitive products to MCOs and other large buying groups.

**Patient issues.** Patients may influence medication prices through market behavior and lobbying. For example, a lower price for drugs used to treat chronic disease may increase the market share, as patients who use these drugs tend to be more price-sensitive than those using drugs for acute diseases. Patient groups may also actively lobby for access to new drugs as well as for lowered pharmaceutical prices. Patients may also lobby their MCOs to include new drugs on their formularies.

**Liability.** In the United States, patients can sue pharmaceutical companies for injuries caused by any perceived defect in a drug. Consequently, pharmaceutical companies face potentially huge liability costs if a drug becomes associated with any significant adverse events following its launch. This expectation is thus reflected in drug pricing.

**Value-added services.** Value-added services are marketing efforts that aim to provide excellent customer service, and may include such things as patient education materials, hot lines that provide disease and product information, or assistance in setting up outcomes studies to monitor the effects of certain treatment regimens for a healthcare organization.

**Orphan drugs.** Some potentially useful drugs may go undeveloped because their market is not large enough to recoup the costs involved in drug research and development. In 1983, Congress passed the Orphan Drug Amendment, which attempts to provide pharmaceutical companies with tax incentives, grants and patent protection privileges to encourage the development of these orphan drugs.

## Pricing issues

Pharmaceutical pricing is complex and involves numerous issues. For example, the same agent may vary widely in price depending on factors such as: where the drug is administered, whether its price has been discounted for a large buying group, and the competitive environment of the marketplace. In discussions of pharmaceutical prices, it is important to clarify which price is being cited – the average wholesale price, a discounted price or the hospital price. It should be noted that hospitals commonly add dramatic markups to medications.

Drug pricing has been influenced by two major factors:

- The introduction of generic drugs, which led pharmaceutical companies to increase prices for patented products and introduce new drugs at prices higher than those for existing drugs.
- The emergence of MCOs and hospital buying groups that negotiate deep discounts. This has often resulted in the retail price being significantly greater than the contract price for many drugs. Awarding discounts to large buying groups led to mandated discounts for Medicaid patients and the Federal Supply Schedule price. Mandated discounts prompted the pharmaceutical companies to rethink their discounts, and as a result, prices for large-volume purchasers increased in the late 1990s.

Trends that can be expected to encourage reductions in drug prices include: price setting for large buying groups, decision making by non-physicians, growing use of generic drugs, increasing healthcare spending and associated scrutiny of pharmaceutical costs, and increasing demand by customers for discounts.

Drug prices are higher in the United States than in other countries due to the lack of price controls here. Frequently, some American health policy analysts have suggested implementing the types of price controls used in the Canadian healthcare system. However, the implementation of price controls has had a profoundly negative effect on the research and development capabilities of pharmaceutical companies in Canada and other foreign countries where price controls have been implemented. It is impor-

tant to point out that the United States is the world leader in pharmaceutical innovation, spending more money on R&D and bringing more novel drugs to market than any other country.

The differences in prices between the United States and many foreign countries may appear to be even greater due to disparities in exchange rates. Thus, even if the price of a drug stayed exactly the same in the United States, changes in exchange rates – and no other factor – could cause the price of a drug to fluctuate dramatically from country to country over time.

## Advertising costs

According to Fairfield, CT-based IMS Health, \$21 billion was spent on pharmaceutical promotion in 2002 by all pharmaceutical manufacturers. This includes \$12 billion in drug samples and \$2.6 billion in direct-to-consumer (DTC) advertising. This promotional spending was significantly less than the amount members of the Washington-based Pharmaceutical Research and Manufacturers of America spent on R&D (\$32 billion in 2002).

It should be noted that the vast majority of pharmaceutical advertising and promotional activities involve providing information about new drugs to physicians, other healthcare providers and patients. In fact, these activities are often the sole means of introducing patients and physicians to newly available drugs that may present a dramatic improvement in healthcare.

The growing use of DTC advertising has been blamed for increased pharmaceutical prices. But DTC advertising provides several benefits; for example, when patients with particular medical conditions are informed of new therapies, they may then bring them to the attention of their physicians – thus improving physician-patient dialogue. In addition, DTC advertising helps to:

- Empower patients by allowing them to become more involved in their own healthcare.
- Address some of the problems related to under-treatment and underdiagnosis of disease.
- Destigmatize disease.
- Encourage compliance.

Additional activities paid for by pharmaceutical companies include continuing medical education and other educational programs that provide current medical information to physicians.

It is important to realize that all medical marketing must be approved by the Food and Drug Administration to ensure accuracy, balance and full disclosure. It has been suggested that the highly regulated and competitive advertising for pharmaceutical products ensures that physicians and patients are able to adopt new products quickly and safely.

## Pharmaceutical company profits

The profitability of the U.S. pharmaceutical industry is undeniable – this is a successful, high-growth industry that has discovered nearly half of the new

## Article Summary

- **The rising costs of prescription drugs reflect the increased number of excellent drugs on the market and their increased use by an aging population.**
  - Drugs are often the most effective and efficient means for providing care.
- **Price can be affected by the phases that a drug passes through as it is launched, is adopted for use, and then declines as new drugs are introduced and surpass it.**
- **It is estimated that the cost of discovering, developing, testing and gaining regulatory approval for a new drug is approximately \$800 million.**
  - Companies must develop and market successful drugs on a regular basis to stay in business, and almost all R&D costs for drug development are borne by the pharmaceutical companies.
  - The prominence of biotechnological techniques is expected to increase dramatically over the next few decades.
  - Pharmaceutical development is increasingly focused on drugs for chronic diseases, which require more extensive development and testing.
- **Prescription medication prices are also affected by market forces, which can change over the course of a product's time on the market.**
- **Pharmaceutical pricing may vary widely depending on numerous issues.**
  - Factors that affected drug prices in recent decades include the introduction of generic drugs and the emergence of MCOs.
  - Several trends are expected to encourage reductions in drug prices.
  - Prices for drugs in the United States are higher than those in other countries due to the lack of price controls here and the differences in exchange rates.
- **The vast majority of pharmaceutical advertising and promotional activities involve providing information about new drugs to physicians, other healthcare providers and patients.**
  - The growing use of direct-to-consumer advertising has been blamed for increased pharmaceutical prices, but it provides many benefits.
- **The profits earned by pharmaceutical companies reflect their achievements and enable them to attract investors.**

medicines in the world during the last quarter century. The profits earned by pharmaceutical companies reflect their achievements and enable them to attract investors. It is this investment that funds new research to cover the escalating costs of R&D for new drugs. PhRMA member companies spent an estimated \$33.2 billion on researching and developing new medications in 2003 – up from \$32 billion spent on R&D in 2002. These expenditures include equipment costs, employee salaries and benefits, contracted research, the cost of clinical trials with required numbers of patients, and research conducted outside the United States.

It can be argued that the above-average profits earned by the pharmaceutical industry translate into above-average R&D investment. Pharmaceutical companies spend approximately 20% of their sales revenue on R&D, compared with an overall industrial average of less than 2%. A recent study showed that for the year 2000, U.S. pharma companies' research expenditures were far greater than those of Japan, France, Germany and Australia.

In addition, economists at Duke University report that the 20% of products with the highest returns generate 70% of the industry's profits – so companies must rely on a limited number of successful products to cover all their costs.

The next article in the series will focus on improving access to prescription drugs and demonstrating their value.