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Factors Affecting Growth of Pharmaceutical Industry

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Pharmaceutical companies invest billions of dollars in research and development (R&D), hoping to find cures or more effective treatments for many indications. In the process, they hope to recoup their investments and make a profit. Modern health care relies more than ever on pharmaceuticals as maintenance therapy and an alternative to surgery. The role of the industry has grown, but so have the risks. Consumers (patients) expect more than ever, competition from generic drug-makers is stiff and FDA requirements are stringent.

Research and Development

R&D for new medicines and treatments for a variety of disorders has become more complex and specialized. According to the Pharmaceutical Manufacturers Association (PhRMA), a consortium of leading pharmaceutical companies, the industry's expenditures on R&D into new therapies totaled $67.4 billion in 2010. Many of these new compounds were biopharmaceuticals, 300 of which were approved by the FDA between 2000 and 2010. The ability of these companies to recoup their investments and turn a profit depends on how many therapies make it through the approval process, which can take up to a decade. According to the Cato Institute, the cost of drug development has skyrocketed by more than 400 percent in less than 20 years.

The Office of Technology Assessment estimates the cost of developing a new drug averages $394 million. Drug companies must conduct on average 60 clinical trials of each new drug for marketing approval and dozens more to extend that approval to new indications. Afterward, they have only a few years of patent protection before competitor companies are allowed to manufacturer their products at a fraction of the cost.

Government Regulation

The degree of government regulation of the pharmaceutical industry also determines profitability. Each successive federal government administration regulates the pharmaceutical industry to a different degree. Some countries, such as Canada and Germany, have price controls, or caps, on pharmaceuticals sold in their borders. Also, the U.S. government and the FDA exert a great deal of control over pharmaceutical advertising and the "claims" of what a particular drug can and cannot do. Complying with the strictures of these regulating bodies costs pharmaceutical companies millions of dollars per year. According to the Cato Institute, 85 percent of the cost of pharmaceutical development goes to complying with FDA regulations, which amount to a tax on investing in biomedical research.

Consumer Demand

During the past several decades, consumer demand for pharmaceuticals as maintenance therapy, as well as "lifestyle" drugs that enhance one's health and well-being, have grown tremendously. This increase is a major driver of industry growth. "Blockbuster" drugs such as Claritin, Viagra and Lipitor, have been heavily advertised, fueling consumer demand. According to Medical Marketing & Media, direct-to-consumer advertising spending reached a high point of $5.2 billion in 2006. Educated patients have driven the prescription-writing explosion in the doctor's office, driving sales of these drugs to the hundreds of millions of dollars. Also, tailored therapy is becoming a larger portion of pharmaceutical market share as genetic testing allows for new, highly targeted therapies for many conditions. As blockbuster brand-name drugs go off-patent, consumer demand for less expensive, generic versions is increasing.

Insurers and Managed Care

In the United States, prices are set by a free-market system, although individual health care organizations (e.g., Medicare, managed care companies) have formularies that include tiered selections of therapies at different prices. Consumers rarely pay full price for prescription drugs, which most often are paid for by third-party insurers. Third-party payers are able to negotiate lower prices for drugs, thus depressing prices and lowering profit margins for drug companies.

Resources

- Medical Marketing & Media
- CenterWatch
- FDA Center for Drug Evaluation and Research