

In the Spotlight: The Pharmaceutical Industry

The pharmaceutical industry is an important player of growing significance in the U.S. health care system. And one that is likely to evoke conflicting sentiments depending on perspective. Are big, brand name pharmaceutical companies life-saving, cost-saving innovators, or better described as over-prescribed, government-protected profit hounds? Like many issues within the U.S. health care system, the answer is not simple. There are several different facets to examine when studying the pharmaceutical industry, including: the costs of research and development; the contribution to medical care; lifestyle drugs; advertising; and patents, to name a few. This paper is a brief look at pharmaceuticals, their contributions and constraints, and policy issues in the future ahead.

Pharmaceuticals and the Big Picture

The products of pharmaceutical companies can improve quality of life, and can potentially lower total medical costs compared to treatment alternatives. Pharmaceuticals represent a [modest 11 percent](#) of total health care costs in the United States. However, pharmaceutical use is increasing, as are the average cost of drugs.

Average # of prescription drugs per person increased 44% Costs are increasing for generic and name brand drugs



A central question for policymakers is how to balance the need for reduction in overall medical cost without thwarting the financial incentives for innovation.

Research and Development

The most significant contributor to the costs of drugs is the lengthy and complex research and development process. Pharmaceutical companies prosper or flounder based on their stream of new, cutting edge products. The cost of developing a new drug can be up to [\\$350 million and take 12 years](#). Developing a drug entails laboratory testing and market research, which can take an average of three and a half years before a drug may be submitted to the United States' Food and Drug Administration (FDA). The FDA has a process for approving new drugs and evaluating their risks and benefits. Many brand pharmaceutical companies have argued that receiving approval is arduous; applications for drug approvals can top 100,000 pages and take around two and a half years. In aggregate, the pharmaceutical industry is estimated to spend \$12.6 billion per year on research and development.

Innovative Medical Care

As overall medical costs grow rapidly, pharmaceutical companies have pointed to the ability of their products to help individuals avoid expensive surgeries and hospitalizations. As an example, [Taxol](#), the chemotherapy drug, was developed in the late 1970s. In addition to the obvious quality of life benefits, there are cost benefits for using

Taxol to prevent or delay the need for surgery. Other drugs provide examples as well: using anti-depressant drugs may prevent a future need for hospitalization; diabetes can often be managed with drug therapy; and heart attacks and strokes can be prevented with regular blood pressure and cholesterol medications. All these medicines have, at some point, prevented the need for more expensive medical treatment.

Lifestyle

Beyond the need for medical treatment, some drugs were developed simply to improve quality of life. While these drugs may not be medically necessary, many people have benefitted from the pharmaceutical companies' innovative products. Lifestyle drugs can treat issues like baldness, impotence, and acne. Some critics argue that developing these drugs diverts resources from developing drugs to treat other, medically-threatening illnesses and conditions. However, proponents point out that quality of life has always been a legitimate concern of medicine.

Direct to Consumer [Advertising](#)

Direct to consumer advertising (DTC) is when companies market directly to consumers in an effort to increase the demand for their product. The United States and New Zealand are the [only two countries](#) where prescription DTC drug advertising is legal. While pharmaceutical companies have always been allowed to advertise in professional journals and web sites dedicated to health care professionals, advertising to consumers can be very controversial. The marketing effort seeks to transform the doctor-patient prescribing relationship by having the patient identify with the need expressed in the advertisement and request the particular drug from their doctor. Doctors may feel pressured into writing prescriptions for drugs at their patients' demands for fear of losing a patient to a doctor who will prescribe the requested drug. Although the FDA evaluates prescription drug advertisements, they still may cause patients to [request medicines](#) that are not necessary or may not be the right course at the given time. In May of 2011, the average number of prescriptions for new, advertised drugs was [nine times greater](#) than the number of prescriptions for non-advertised new drugs. Purchasing unnecessary drugs or drugs that are more expensive than common, less costly alternatives raises the cost of care.

Pharmaceutical companies defend DTC. Companies that utilize DTC argue that they arm consumers with more information and can lessen the stigma associated with certain health conditions. They also point out that, as for-profit companies, they have a right to make a profit: for every dollar spent in DTC, they make \$4.00 in [return](#).

Patents and Profits

Patents are a key part of the profitability formula for a pharmaceutical company. A patent prevents any generic drug from entering the market for a period of time, keeping prices on the brand name drug up by providing protection from competition. Brand name drug companies argue that long patents are necessary to recoup their investment in research and development to create the drugs. Generic drug companies believe that long patents keep prices high and inflate medical costs.

Often, a drug will have multiple patents, each involving a certain characteristic of the product. These patents may have different expiration dates. Generic and name brand companies often engage in patent litigation to determine patent validity and expiration date, which can further delay the generic entry into the market. Sometimes brand name companies even pay generic companies not to market an approved generic product for a certain period of time, which can also delay the availability of generic drugs.

Brand name pharmaceuticals rank as the [third most profitable industry](#), pulling in an estimated 19.3 percent profit in 2009. Many generic drug makers feel this high profit margin bolsters their argument for shorter patent periods, touting their estimated [\\$824 billion in savings](#) for use of generics over name-brand drugs over the last decade.

Impact of Patents

The effect of patents has been widely debated. Critics believe that patents that last too long or can be easily extended through tweaks in a tested recipe can prevent innovation and discovery. Long patents prevent competition from entering the market, provide a “lock” on a given treatment and lessen profit motivation to invest in research and development of more new drugs. The crux of the argument in favor of patents is that, in order to motivate companies to invest in research and development of new drugs, they must be assured of a patent long enough to reap financial benefits from making the investment.

ACA Changes

Like most sectors of health care, the Affordable Care Act (ACA) places some responsibility for reforming the health system on pharmaceutical companies. The largest impact to pharmaceuticals is a deal reached to close the coverage gap in [Medicare Part D](#) plans. Pharmaceutical industry impacts include:

- In 2011, pharmaceutical companies now subsidize brand name drugs 50% and Medicare beneficiaries are responsible for the remaining 50%.
- Pharmaceutical companies will have an annual fee to help fund the ACA, divided among the brand name companies, based on their previous year’s sales to government programs (such as Medicare, Medicaid, CHIP, and TRICARE). The fee totals \$2.5 billion in 2011 and will increase each year until 2018 when it will begin to decrease annually.
- ACA also establishes a regulatory path for generic drugs in the biologics market. However, brand name biologics secured a 12-year period of exclusive sales for brand name drugs.
- ACA establishes an accelerated process for resolving litigation of patents while the innovator remains patent-protected.

Uncertain Future

Debate over the pharmaceutical industry is a constant battleground for lawmakers. Lobbyists for generic drug makers continue to request a fully funded Office of Generic Drugs to speed up the process of approval. Name brand drug makers continue to fight for exclusivity and patent protections.

Some have pointed out that the pharmaceutical industry should have been more significantly impacted in the overall health care reform law. Policy proposals are likely to continue to focus on the pharmaceutical industry. As an example, in September of 2011, President Obama sent the Super Committee his [recommendations](#) for budget cuts. Proposals included prohibiting pharmaceutical companies from delaying court decisions about their patents in order to increase the availability of generics. This is projected to save \$2.7 billion over 10 years by allowing Medicare and Medicaid access to lower-cost drugs. Additionally, there is a proposal to reduce the exclusivity period for biologics from 12 to seven years and prohibit additional periods of exclusivity for biologics for to minor changes in produce formulas. This is projected to save \$3.5 billion over the next 10 years, also by allowing more access to lower-cost generics.

It is unclear what the future may hold for drug makers, generic or brand name, as future budget considerations are made.

BCBSNC Views

Blue Cross and Blue Shield of North Carolina (BCBSNC) supports access to quality health care. We know that affordable, quality health care depends on all sectors of the health care industry working together and carrying their share of the financial burden to creating that access. While we welcome and appreciate innovation, we also know

that costs are a primary concern when making health care accessible. BCBSNC has long valued the role that pharmaceuticals play in prevention and treatment of myriad medical issues, but recognize that exclusivity for brand name drugs often drive up the costs of medical care. We encourage the FDA to carefully assess cost implications while working through the issues of exclusivity and patents.

For More Information:

MorganLewis: Impact of Health Care Reform on Pharmaceutical Manufacturers:

http://www.morganlewis.com/pubs/WashGRPP_ImpactOnPharmaManufacturers_LF_15apr10.pdf

Pharmaceutical Researchers and Manufacturers of America: <http://www.phrma.org/>

Generic Pharmaceutical Association: <http://www.gphaonline.org/>

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ⁱ Statistics compiled from internal BCBSNC data.

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