Introduction

The pharmaceutical industry produces prescription and over-the-counter drugs as well as biologic products primarily intended to treat human illnesses. Biologic products are created through the use of living systems and include vaccines, blood and blood components, gene therapy and tissues. A brand name drug is an innovator drug which has undergone an extensive research and development (R&D) process and is initially protected by patents. A generic drug is chemically equivalent to a brand name drug that has lost patent protection and is sold at significantly discounted prices. The Center of Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) is the government agency in charge of regulation and oversight of this industry.

Brand Name versus Generic Pharmaceuticals

Although brand name and generic pharmaceutical companies produce nearly identical products, the two industries are in direct competition. It costs a brand name pharmaceutical company an estimated $1.2 billion (in 2005 dollars) over ten to fifteen years to develop and gain approval for a single new drug.\footnote{1} As a whole, the pharmaceutical industry spent $67.4 billion in R&D during 2011, including phase IV clinical trials, which are conducted after a drug is approved for market.\footnote{11}

Generic pharmaceutical companies can bypass the entire lengthy discovery process and costly clinical trials, which include thousands of volunteers. In copying an innovator drug, a generic drug must “deliver the same amount of active ingredients into a patient’s bloodstream in the same amount of time as the innovator drug,” known as bioequivalence. Bioequivalence can be shown with a 24-36 healthy volunteer study in which the generic drug must behave exactly like its brand name counterpart. The low barriers for delivering a generic drug to market are what allow generic pharmaceutical companies to provide inexpensive options to brand name drugs. Brand name pharmaceutical companies expend 19.0-20.5\%\footnote{14} of their revenue on R&D whereas generic pharmaceutical companies only spend 4.5-5.5\% of their revenue on R&D.\footnote{17} To allow brand name pharmaceutical manufacturers to recoup the high costs of developing a drug, they receive patent protection for a maximum of fourteen years.\footnote{18}

Key Takeaways

**From brand names to generics**

- The generic pharmaceutical industry depends on the innovation of the brand name pharmaceutical industry.
- Brand name and generic pharmaceutical industries combine to share 1.34\% of the GDP and employ over 321,000 workers.

**Closely watched regulatory negotiations**

- The reauthorization of PDUFA V aims to improve the FDA’s drug review process.
- FDA and industry have paved the way for a user fee program for generic drugs.

**The “Patent Cliff” and its growth impact**

- The annual growth of the generic pharmaceutical industry (7.3\%) is three times as high as the annual growth of the brand name pharmaceutical industry (2.4\%).
- Many of the highest grossing brand name drugs will lose patent-protection between 2011 and 2012, leading to an estimated loss of $140 billion to generic competition by 2017.
Major Markets, Products and Determinants Driving Demand

Both brand name and generic pharmaceutical products are sold to similar markets with the primary difference being the total revenue generated. In 2012, the sale of brand name pharmaceuticals is estimated to generate $156.3 billion in revenue whereas the sale of generic pharmaceuticals will generate $52.8 billion. The top three classes of drugs based on spending in 2010 were oncologics (cancer drugs), respiratory agents, and lipid regulators. Over the past five years, Lipitor ($7.2 billion) and Nexium ($6.3 billion) have been the number one and two top selling drugs in terms of healthcare spending in the United States.

Demand for prescription drugs is based on population demographics, insurance coverage and economic prosperity. Chronic diseases and disabilities have a greater likelihood of developing as life expectancies are lengthening, prompting an increase in demand for prescription drugs. As the ever growing population of seniors reaches the age of 65, they become eligible for Medicare Part D, making drugs more affordable, also contributing to an increased demand for prescription drugs. Direct to consumer advertising by pharmaceutical companies also drives drug demand, but concurrently, generates awareness for conditions that may otherwise be overlooked by consumers. In the end, the economy backdrop plays one of the most important roles in determining demand. With the recent market drops and high unemployment rate, consumers may be unable to afford to pay for the recommended dosages and will cut spending on lifestyle drugs like Viagra and botanical products.

Economic Impact (Table 1)

Brand name and generic pharmaceutical industries combine to share 1.34% of the economy with combined revenue of over $209 billion. The 3810 companies in the industry employ over 321,000 workers and paid over $28 billion in employee wages.

Table 1: Pharmaceutical Industry Statistics 2012

<table>
<thead>
<tr>
<th>Pharmaceutical Industry</th>
<th>Revenue ($b)</th>
<th>Profit ($b)</th>
<th>Companies</th>
<th>Employment</th>
<th>Wages ($b)</th>
<th>Share of the Economy (% GDP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name</td>
<td>156.3</td>
<td>30.0</td>
<td>2,707</td>
<td>244,607</td>
<td>22.0</td>
<td>1.00</td>
</tr>
<tr>
<td>Generic</td>
<td>52.8</td>
<td>7.8</td>
<td>1,103</td>
<td>76,641</td>
<td>6.0</td>
<td>0.34</td>
</tr>
<tr>
<td>Combined</td>
<td>209.1</td>
<td>37.8</td>
<td>3,810</td>
<td>321,248</td>
<td>28.0</td>
<td>1.34</td>
</tr>
</tbody>
</table>

Figure 1: Major Market Segmentation
Major Companies

*Brand Name Pharmaceutical Companies (Table 2):* Seven major companies control 65.4% of the market share in the brand name pharmaceutical industries (Figure 2). These players are the manufacturers of the most profitable drugs in the United States including Lipitor (Pfizer), Nexium (AstraZeneca), and Plavix (Bristol-Myers Squibb). In order to recoup the high costs of developing a new drug, brand name pharmaceutical companies rely on patents of their drugs to fend off generic “me-too” drugs. Pfizer is set to lose patent protection on drugs that represent 42% of its revenue between 2010 and 2012.\textsuperscript{xiv} To combat this large loss in revenue, Pfizer is looking to join the generic market by forming an alliance with Claris Lifesciences Ltd. To commercialize some of its injectable drugs that will be coming off patent-protection.

![Figure 2: Brand Name Pharmaceutical Industry Market Share](image)

<table>
<thead>
<tr>
<th>Company</th>
<th>Revenue ($ million)</th>
<th>% change from previous year</th>
<th>Operating Income ($ million)</th>
<th>% change from previous year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merck and Co. Inc.</td>
<td>23,967</td>
<td>-5.6</td>
<td>8,097</td>
<td>+8.5</td>
</tr>
<tr>
<td>Pfizer</td>
<td>26,641</td>
<td>-7.7</td>
<td>10,497</td>
<td>-8.0</td>
</tr>
<tr>
<td>AstraZeneca PLC</td>
<td>13,020</td>
<td>-3.0</td>
<td>3,393</td>
<td>-16.4</td>
</tr>
</tbody>
</table>

*Generic Pharmaceutical Companies (Table 3):*

The market share of generic pharmaceutical companies is much more segmented as the top four companies account for only 28.1% of the total (Figure 3). Revenue earned by the top generic pharmaceutical companies pales in comparison to the revenue generated by brand name pharmaceutical companies. Although the Israeli-based Teva Pharmaceuticals is known to be primarily a generic drug company, its top three selling drugs, ProAir HFA, Copaxone and Qvar are proprietary formulations developed by Teva.\textsuperscript{xvii} The revenue indicated in Table 3 does not include revenue generated by its proprietary drugs.

![Figure 3: Generic Pharmaceutical Industry Market Share](image)

**Table 2: 2012 US Statistics for the Top Three Brand Name Pharmaceutical Companies**\textsuperscript{xv}

**Table 3: Market Share for the Top Four Generic Pharmaceutical Companies**\textsuperscript{xi}

www.OperationHealthcareChoice.org
Between the years of 2012 and 2017, the brand name pharmaceutical industry will have an annual growth of 0.4%.xx Over the same time span, the generic pharmaceutical industry will have an annual growth of 6.3%.xx There are similarities and differences in the outlook for brand name and generic pharmaceutical companies. Perhaps the biggest detriment to the brand name pharmaceutical industry is the loss of patent-protection for many of the highest grossing brand name pharmaceutical drugs (Lipitor, Plavix, Seroquel, Actos, Singulair, and others) between 2011 and 2013. This “patent cliff,” accounts for $140 billion of expected total sales lost from patent expiration from 2012 to 2017. To put this number into perspective, the loss of total sales between 2006 and 2010 was $80 billion.xxi The loss to the brand name pharmaceutical industry comes as a boon for the generic pharmaceutical industry due to its ability to bring to market generic versions of these popular drugs. According to the IMS Institute for Healthcare Informatics, a generic drug will capture 60% of a brand name drug’s sales volume within six months of patent loss. xxii

Another blow to industry performance will come from the implementation of the Patient Protection and Affordable Care Act (PPACA). The PPACA will expand coverage to 32 million Americans through state-run Health Insurance Exchanges, which is expected to increase drug sales in 2015,xxiii when the exchanges must be up and running. The year 2015 also brings into effect Independent Payment Advisory Board (IPAB) proposals in efforts to curb the growth of Medicare. Because Medicare Parts A and B are off-limits to IPAB’s initial proposals, Part D, the prescription drug coverage program, will likely be the target of the budget cuts. Reducing drug coverage to seniors will negatively affect both brand name and generic pharmaceutical companies.

The pharmaceutical industry has oft criticized the FDA’s drug approval process for being slow and innovation-stifling. The priority review process is designated for drugs that treat the most serious diseases or show the most significant improvements over current options. Although this risk-averse behavior of the FDA directly impacts brand name pharmaceutical companies, generic pharmaceutical companies are also negatively affected because there are fewer innovative drugs in the pipeline that can be turned into generic products. The reauthorization of the Prescription Drug User Fee Act V will improve on the efficiency of the FDA’s drug approval process.
The American Action Forum is a forward-looking policy institute. The Forum produces real-time, fact-based, innovative policy analysis and solutions for policy makers and the public alike. Our mission is to promote commonsense, innovative and solutions-based policies that will reform government, challenge outdated assumptions, and create a smaller, smarter government.

Operation Healthcare Choice is the Forum’s public policy center focused on promoting high-value healthcare and higher quality health insurance that expands consumer choice. Operation Healthcare Choice experts conduct research, offer commentary, and develop policies aimed at eliminating healthcare’s burden on the economy.

References


vi Congressional Budget Office. How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry. 1998.


xi Adapted from Snyder S. Op cit. “IBISWorld Industry Report 32541a: Brand Name Pharmaceutical Manufacturing in the US.”


xiii Adapted from Snyder S. Op cit. “IBISWorld Industry Report 32541a: Brand Name Pharmaceutical Manufacturing in the US.”

xiv Adapted from Snyder S. Op cit. “IBISWorld Industry Report 32541a: Brand Name Pharmaceutical Manufacturing in the US.”

xv Adapted from Snyder S. Op cit. “IBISWorld Industry Report 32541a: Brand Name Pharmaceutical Manufacturing in the US.”

www.OperationHealthcareChoice.org

Adapted from Snyder S. Op cit. “IBISWorld Industry Report 32541a: Brand Name Pharmaceutical Manufacturing in the US.”


