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Bad Drug Good Drug

MARKET OVERVIEW

The global pharmaceutical market is a multibillion-dollar industry. The 10 largest drug companies control over one-third of the market, several with sales of more than \$10B a year and profit margins of 30%. Six of these companies are based in the U.S. and four are in Europe. It is predicted that North and South America, Europe, and Japan will continue to dominate by accounting for 85% of the world's pharmaceutical market. Companies currently spend one-third of all sales revenue on marketing, which is roughly twice of what they spent on R&D ("Pharmaceutical Industry"). The cost of innovation proves to be very high as the drug business is very risky; 1 out of 10,000 discovered compounds are approved for sale. Since 2001, the Center for Drug Evaluation and Research averaged 22.9 approvals per year. Only 3 out of 20 approved drugs bring in adequate revenue to cover the R&D costs and only 1 out of 3 approved drug generate enough revenue to cover previous failures. According to a study by Bain & Company, the cost of discovering, developing, and launching a new drug rose to approximately \$1.7 billion in 2003, taking into account opportunity costs, marketing, and other business expenses ("Pharma Markets").

SUPPLY

The major factor affecting supply is the advancement of technology. The development of simulation and data analysis tools condenses the drug's process time from development to full-scale production. Process tomography and high frequency camera systems help hasten products from clinical trial stage to commercial availability. Integrated sensors are being used to monitor the performance and quality parameters of drug manufacturing processes on a real-time basis in order to ensure the quality of the

medicine being produced and to gather data necessary for optimizing future productions. According to an Industry Week article, technology trends are likely to continue influencing the pharmaceutical industry for the next 5 to 10 years (Accenture). The enhanced flow of information due to advanced technology and the utilization of social media can help pharmaceutical companies identify the best-targeted and most cost-effective products, enhancing the supply of products by providing more effective pharmaceuticals in a more timely manner (“Six Tech Trends”). Globalization also continues to have profound effects on supply chain. As more R&D and manufacturing move to Asia, the pharmaceuticals industry must cope with more widely distributed resources as well as a greater potential for pandemics. The geographical expansion of the industry also meant expanding the number of products offered and modifying the nature of the products in order to cater to a diverse group of disease types in various parts of the world (“Pharma Markets”).

DEMAND

Demand in the pharmaceutical industry proves to be a complex combination of push and pull factors. Third parties make decisions on the formularies that affect prescription behavior whereas drug companies use various campaigns to influence the FDA, pharmacy benefit providers, doctors and patients in order to prolong the patent, promote the formulary, prescribe and request their products (Prest). BRIC nations are set to power the growth of pharmaceutical sales outside of usual western markets in the future. By 2014, emerging markets are expected to represent approximately a quarter of world's trade in pharmaceuticals. As countries in the developing world become more affluent, there is increasing demand for “sophisticated, modern healthcare and healthcare products such as pharmaceuticals” (Prest). By 2020, China is forecasted to spend 7% of its GDP on healthcare, which is equivalent to almost \$1 trillion. Changing lifestyles, rising income, and increased government spending on healthcare in countries such as Russia and neighboring countries in the Commonwealth of Independent States further spike the demand for healthcare products. A double-digit expansion in

Russian pharmaceuticals market is expected to propagate the market to \$37 billion by the end of 2016 (Prest). Gulf countries in the Middle East are also expanding their pharmaceutical markets. PricewaterhouseCoopers estimated that between 2010 and 2020, healthcare spending in BRIC and OECD countries will increase 51% to a cumulative total of more than \$71 trillion.

PRICE

Pharmaceutical companies, or what critics like to call “big pharma,” have often been condemned for charging prices above marginal cost and price discriminating between different countries. One of the primary reasons for outrageous prices is the astronomical cost of drug R&D (Herper). The average drug developed by a major company cost anywhere from \$4B to \$11B (Herper). While the drug industry commonly claims costs to be \$1B, the estimate goes up to \$4B for every approved drug after adjusting for failures. Researchers at Forbes have taken into account inflation and discovered that AstraZeneca has spent \$12B in research for every new drug approved; Amgen spent just \$3.7B. Included in these numbers are the combined cost of clinical trials (a single one costs \$100M) and manufacturing. The main expense, however, proves to be failure. AstraZeneca, who has so few new drugs hitting the market, accrues a higher cost per drug compared to Eli Lilly, who spent about the same amount of R&D but received twice as many new drug approvals over the same time period and spent just \$4.5B per drug (Herper). A major factor for driving down the price of drugs is the generic drugs as substitutes for the name brands. Strict FDA regulations require that generics have the same compound (active ingredient), dosage form, high quality, strength, purity, and stability as brand name originals, making them excellent substitutes. Generic forms are allowed for production when FDA-approved drugs lose the patent or the exclusivity protection (“Generic Drugs”). Generic producers are able to sell their products for lower prices because they only have to account for manufacturing costs. Once a generic form appears on the market, the competition often leads to substantially lower prices for both the original product and the generic forms.

PRICE AND INCOME ELASTICITY

There is some empirical evidence on the price elasticity of demand, at least for the U.S. and Canada. After analyzing the before and after data of a study of Mississippi Medicaid recipients for the effects of insurance on pharmaceuticals, the price elasticity is approximately 0.4, signifying a 0.4% decrease in demand if price increase by 1% (Vogel 105). Lacking empirical evidence on the income elasticity of demand for pharmaceuticals by specific countries, cross-country regression analyses for OECD countries indicated that the income elasticity of demand for health care expenditures ranges from 1.3-1.8, meaning a 1% increase in per capita income in these countries is likely to result in a 1.3-1.8% increase in health care spending (106). Evidences suggest that pharmaceutical demand is price inelastic but income elastic. This explains the price discrimination between countries (108). For countries with higher per capita income, drugs are much more expensive because people are willing to pay more for medication whereas medications in poorer areas are lower priced. Both the demand theory and available empirical evidence showed that pharmaceutical prices play a significant role in the health care system; however, as the prevalence of health insurance for pharmaceutical purchase increases, the out-of-pocket price at the time of purchase become less important as a decision variable (107).

PUBLIC POLICIES

The Federal Food, Drug, and Cosmetic Act, with its numerous amendments, is the basic food and drug law in the U.S. and the most extensive of its kind in the world (“How Are Drugs”). This law ensures safety, sanitation, and effectiveness of food and drugs as well as label clarity. Another important law in this industry is the patent law, which is based on the Patent Act of 1952 and prohibits others from making, selling, using, offering to sell, or importing into U.S. the patented item for usually 20 years (Schacht). The pharmaceutical industry has been described as a “patent-intensive”

industry, with enterprises frequently obtaining patent protection and enforcing patent rights (Schacht). When a firm launches a new approved drug, the patent prevents other manufactures, granting the supplier a monopoly, essentially, as it is able to name a profit-maximizing price without any competition. The Food and Drug Administration Amendments Act in 2007 provided FDA the suitable resources to regulate and review the pharma industry. FDA's Center for Drug Evaluation and Research division deals with new drug application and the evaluation of the drug for safety and effectiveness. FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) ensures that drug advertising and promotional materials are truthful, balanced, and non-misleading ("How Are Drugs"). The World Health Organization also develops and maintains global norms and international guidelines for pharmaceutical companies in terms of safety, quality, and efficacy of drugs ("Norms"). The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) made a major impact on the industry as it incentivized innovation in the pharma industry and expedited the marketing of lower cost generic drugs. This act is important for the generic substitutes as it abbreviated the approval process for generic drugs and extended the patent terms for innovator drugs to reflect delays in obtaining the approval (Schacht). The Hatch-Waxman Act also empowers the FDA with certain authorities to offer periods of marketing exclusivity for a drug independent of the rights bestowed by patents.

PREDICTIONS

Over the next few years, the global market for pharmaceuticals is expected to make a recovery from the recent sales slump due to expiring patents on some of the biggest-selling medicines (Silverman). According to an annual report from IMS Health, global spending is forecasted to grow from \$956B (2011) to \$1.2T (2016), reflecting a compounded annual growth of 3-6%. This increased spending reflects an increase in global demand as people are spending more on pharmaceuticals. Thanks to expansion in emerging markets, the growth in annual global spending is predicted to more than

double by 2016; however, the disparity between nations is striking. In developed markets (U.S., Europe, and Japan) spending will drop to 57% of the global total due to expiring patents of popular brand name drugs and increased cost containment measures. Japan, however, proves to be different as it is achieving emerging market growth rate due to its aging population (“Health Care in Japan”). Sales growth for the top 8 multinational pharmaceutical companies in Japan in 2011 ranged from 12-31% (“Health Care in Japan”). The Japanese government is also deregulating in areas of new drug reviews, pricing system, and generics. The expanded Pharmaceuticals and Medical Devices Agency has cut review time since 2008 and increased the number of new approvals; previously the price of new drugs in Japan would be lowered every 2 years, now the price of new medicines will be upheld through the patent, making drugs much more profitable; and lastly, the authorities have set the goal of generics taking up 30% of the market in volume (“Health Care in Japan”). This series of actions helps to increase supply and lower prices to a certain extent. The maintenance of price throughout a drug’s patent keeps the price high, but the greater volume of generics will help lower the prices of some other medications. Emerging markets, on the other hand, are expected to reach 30% of global spending by 2016 as both population and economic growths contribute to higher demand for drugs. These nations are predicted to double the spending on pharmaceuticals over the next 5-year period. Compounded annual growth spending in emerging markets is forecasted to reach 12-15%, compared to global rate of 3-6% (Silverman). From 2011 to 2016, spending on brand names is anticipated to increase from \$596B to \$615B, mostly in developed markets; global generic spending is projected to increase from \$242B to \$430B (2016), of which \$224B – \$244B is expected to come from emerging markets (Silverman). These facts further emphasize the significance of emerging markets, especially for the generic drug industry. For the big brand name firms, developed markets remain their target consumer base since they are the ones able to and willing to purchase the higher priced medications. In the U.S., patent expirations will save consumers \$127B in the next 5 years, a number that will be offset by \$21B of projected spending on generics, resulting in a \$106B “patent dividend” in 2016

(Silverman). As for the price, the IMS believes that discounts and rebates will represent an estimate of \$180B – \$190B in 2016 and would lower estimated global spending by 15-16%. Drugmakers are anticipating an improved market thanks to a new wave of blockbuster medicines for cancer, diabetes, heart disease, multiple sclerosis, and hepatitis (Hirschler). As companies emerge from the “patent cliff” of 2012, a number of crucial R&D bets on potential multibillion-dollar-a-year products are expected to play out in 2013 (Hirschler). Simon Friend, global pharmaceutical leader at PwC, warns that as “Productivity is starting to turn the corner – the other big issue is whether the industry can get the prices it needs for new products,” hinting further at price as a major challenge for both the sellers and the buyers as the pharmaceutical industry expands (Hirschler).

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