

Financial Aspects and the Future of the Pharmaceutical Industry in the United States of America

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ABSTRACT

Introduction: The U.S. pharmaceutical industry is defined by the U.S. Census Bureau as “companies engaged in researching, developing, manufacturing and marketing of medicines and biological for human or veterinary use”. Besides its main role in improving human health, the US pharmaceutical industry represents one of the most critical, key decision makers’ lobbying prone and competitive sectors in the economy. The cost in the environment of very limited government price regulation remains one of the major problems fuelling aggregate health care cost inflation. Pharmaceuticals have created huge benefits for public health and economic productivity by the means of saving lives, increasing life expectancy, reducing illness related suffering, preventing surgeries and decreasing hospital stays. **Purpose:** The goal of this review paper is to show the present conditions and future trends of the pharmaceutical industry in the U.S. **Methodology:** This paper represents a thorough literature review of the multifaceted sources including: studies, books, peer reviewed journals, U.S. government sources (i.e. U.S. Census Bureau, U.S. Bureau of Economic Analysis, etc.). **Discussion:** In the thirty years pharmaceutical companies have consistently developed and launched new medicines, bringing hope to sick or – at risk patients. They also usually provide above the average financial returns for its shareholders. U.S. pharmaceutical companies had as their goal to discover blockbuster drugs. Blockbuster drugs are generally defined as drugs that solve medical problems common to hundreds of millions of people and, at the same time generate large sales increases and profits for the pharmaceutical companies. The main approach of these companies includes huge investments in research and development (R&D), innovation, marketing and sales. The trend analysis shows that for the most part the era of blockbuster drugs is nearing an end. **Conclusion:** Numerous blockbuster drugs will be coming off patent in the next few years, opening the way to generics and eliminating a major source of the industry’s profits. Still, there is plenty of room for improvement in the medications people take while there is no shortage of human suffering to alleviate. It is doubtful whether big pharmaceutical firms will be able to pursue these goals within the old model of developing exclusive new drugs that can be sold further in the future. In the past, medicines for the ailments that were never before addressed, like anti-cholesterol or anti-depression drugs were developed. Currently, and in the future, it is expected that only blockbuster modifications will be developed. This phenomenon is expected to create market saturation, which will significantly reduce profits. The business model that drove the major drug makers’ success is not working anymore. Pharmaceutical companies must create new ways and to bring new ideas. The survivors will be those that market strategies supported by innovative approaches and winning capabilities. **Key words:** pharmaceutical companies, blockbuster drugs, generic drugs, research and development (R&D), innovation, strategic planning, structural change.

1. INTRODUCTION

Powerful, diversified, influential and globalized the U.S. pharmaceutical industry plays a crucial role in the U.S. economy. According to the 2007 Economic Census, there were an estimated 1,552 companies in the U.S. that develop, manufacture and market drug and biological products. For statistical purposes, the U.S. Government classifies all medicines as part of the pharmaceutical industry, including products developed through

the use of biotechnology. In 2010, total prescription drug sales exceeded U.S. \$250 billion, which represents almost 30 percent of the global total of \$850 billion. In the last 35 years, and at a rate that especially accelerated in the 1990s, the United States of America became the worldwide leader for pharmaceutical research, clinical testing, marketing and sales. The worldwide pharmacy influence shifted from Germany, Switzerland and France to the United States. The U.S. pharmaceutical indus-

try is knowledge intensive and employs a significant number of highly educated technology workers. The Bureau of Labor Statistics estimates that as of May 2010 the industry employed about 416,000 persons at pharmaceutical manufacturing and biotechnology research firms. Manufacturing firms employed 278,000 workers (i.e. with employment highest in California, New Jersey, Puerto Rico, Pennsylvania, New York, Indiana and North Carolina). Biotechnology research firms employed an additional 138,000 people. The largest concentration of biotechnology companies were in: Massachusetts, California, Pennsylvania, Maryland, New Jersey, North Carolina and Illinois. Average annual wages in 2008 were in the span from \$96,000 in pharmaceutical manufacturing to \$105,000 in biotechnology research. The employment in the industry reached its peak of 295,000 in 2007 and has declined by 5.8% due to restructuring and is expected to decline even more due to industry consolidation. According to a study by the National Science Foundation, the pharmaceutical industry is a close second to the computer and electronics sector as far as R&D investment is concerned. The industry invests around 19% of sales revenues to R&D. Pharmaceutical and biotechnology firms spent \$65 billion on R&D in 2009 worldwide, out of which, the most, or 70% was spent in the United States. R&D investment has been under pressure in the recent past and spending by large firms has declined 4% since 2007. The pharmaceutical industry stated that the number of medicines in development has increased from 1,800 in 2000 to 2,950 in 2010. More than 600 of these products were derived from biotechnology. The main goals of R&D investment were treatments for malignant neoplasms, HIV/AIDS, autoimmune and infectious diseases and other diseases like Alzheimer's and multiple sclerosis, for which, currently, there are no effective cures. (1, 2, 3, 4).

The major fields of the pharmaceutical industry were defined as: originator chemical drugs, generics, over-the-counter drugs, active pharmaceutical compounds, excipients, biological and biosimilar agents.

Originator chemically – synthesized medicines are designed and developed through the extensive R&D. They are additionally derived through clinical trials in humans and animals before they are being approved by the U.S. Food and Drug Administration (FDA). These medications rely on patents and other forms of intellectual property rights to justify the investment spent to bring a new medicine to the market. The pharmaceutical industry is heavily dependent on the development of new compounds to replace the revenue stream of older drugs that have come close to the expiration of their patent terms. The studies show that in the U.S. the cost of bringing a new drug to market has been estimated from \$500 million to more than \$2 billion, depending on the target treatment. According to the Pharmaceutical Research Manufacturers of America (PhRMA), only one in 1,000 compounds that enter preclinical testing makes it to human clinical trials, one out of five drug candidates tested in humans is approved, and two out of ten marketed drugs generate revenues that exceed R&D costs (5, 6, 7, 8).

Generic drugs are defined as duplicative copies of originator chemically-synthesized drugs. They contain the same active ingredient, and are identical in strength, dosage form, and route of administration. The producer then can manufacture a generic drug that references an originator drug that was approved under the Drugs and Cosmetic Act. Only then, the FDA grants final

approval to the applicant for the product. According to the law, the generic drug version must be bioequivalent to the originator drug and meet all other regulatory requirements. Generic drug does not have to duplicate the clinical trial requirements for market approval with the exception of bioequivalence trials. Generics that are sold under the chemical name are known as “commodity generics.” Commodity generics are often manufactured by more than one company and compete mainly on price. “Branded generics” are marketed by a drug company under its own label and typically command higher prices than non-brand generics. Over-the-Counter (OTC) drugs are distinguished from originator and generic drugs, in that, consumers do not need physicians' prescriptions to purchase drugs (9, 10, 11, 12).

2. PURPOSE

The goal of this review paper is to show the present conditions and future trends of the pharmaceutical industry in the US.

3. METHODOLOGY

This paper represents a thorough literature review of the multifaceted sources including studies, books, peer reviewed journals, US government sources, (such as US Census Bureau, US Bureau of Economic Analysis, etc.)

4. DISCUSSION

The U.S. pharmaceutical market is the largest in the world. Its value was estimated at U.S. \$300 billion in 2009. In recent years sales growth has slowed due mainly to an increase in the number of drugs losing patent protection and replacement by generic equivalents. New product introduction has not kept pace. New products such as specialty and so called orphan drugs could not match sales of the previous generations of the blockbuster drugs. Orphan drugs only targeted small populations. Safety issues have also raised scrutiny of drugs in development and on the market. Other reasons for slowing growth are the impact of increased patient co-pays and the economic recession. In recent years, the fastest growing segments of the pharmaceutical market are biologicals and generics. Biotechnology-derived medicines, valued at \$58.4 billion in 2008, are a growing component of the pharmaceutical industry, accounting for a quarter of all new drugs in clinical trials or awaiting FDA approval. Over the years, large pharmaceutical companies have acquired numerous biotechnology firms. Amgen, Genzyme and Biogen Idec represent some among the top purchased independent biotechnology companies. The U.S. generic drug market is estimated at about \$34 billion, thus representing 41 percent of global sales. Generic drugs' share of filled prescriptions has increased from 19 percent in 1984 to 75 percent in 2009. The driving factor behind this growth can be seen through the savings that generics offer. In the U.S., generics with multiple competing firms can cost between 70-80 percent less than reference originator drugs. Automatic substitution in the U.S. requires a pharmacist to dispense the lowest cost pharmaceutical and therapeutically equivalent drug, unless a physician writes a specific prohibition on the prescription. Generic drug sales are expected reach its highest level in history, reaching \$54 billion in U.S. sales by 2014, due to an unprecedented number of patented drugs going off-patent in the next five years. The largest generic manufacturers operating in the U.S. are: Teva, Sandoz (Novartis), Mylan, and Watson. The nonprescription drug or OTC market segment is driven

by pharmaceutical firms converting drugs from prescription to OTC status and marketed under their own labels. Some of the factors underlying its growth are expansion within the older population, and a growing consumer trend to self-medicate. Its strengths include a robust intellectual property system that recognizes and rewards innovation and a science-based regulatory system that is considered the most rigorous in the world (13, 14).

FDA approval facilitates regulatory approval in other countries, especially in developing economies. The U.S. is the world's largest market by value and its reimbursement and pricing environment is considered by industry as the most favorable in terms of recognizing the value of innovative drugs. Moreover, the U.S. also has the world's largest scientific research base fostered by decades-long government biomedical research funding that has been instrumental in supporting medical product development. These factors, along with capital markets and technology transfer laws, have helped foster the formation of the largest global concentration of biotechnology companies. According to an industry survey by Ernst and Young, the U.S. accounts for over 60 percent of the world's employment in dedicated biotechnology firms and 70 percent of R&D. Significant biotechnology clusters are found in California, Massachusetts, New Jersey, New York, Pennsylvania, and Maryland. Pharmaceutical players, both foreign and domestic, have established facilities near leading universities and research hospitals. Acquisitions of biotechnology companies, in-licensing of products, and R&D alliances have been popular routes for established pharmaceutical companies to diversify into biologicals. To encourage the development of new drugs for unmet needs, the US Government enacted the Orphan Drug Act (ODA) in 1983 (15, 16). The ODA allows manufacturers that develop drugs used to treat diseases that affect less than 200,000 people in the U.S. to obtain market exclusivity for seven years following FDA approval and tax credits for R&D. In the decade before the adoption of ODA, only ten drugs had been developed for the treatment of rare diseases; since its passage, more than 350 orphan drugs have been approved by the FDA. Nearly one-third of all new approved drugs and biologics are orphan products (17).

According to IMS Health out of ten largest pharmaceutical companies in the world in 2009, five are headquartered in the United States. The largest companies according to sales revenue was Pfizer with US \$57 billion, followed by Merck with \$39 billion. The third place was held by the Swiss company Novartis with \$38.5 billion. In addition, IMS Health made the report of geographic sales by world regions in 2009. The U.S. commands the largest portion with the annual sales of US \$300.3 billion (35.9%), and it is followed by Europe with \$263.9 billion (31.5%), Asia, Africa and Australia \$106.6 billion (12.7%), Japan \$95.0 (11.3%), Latin America \$47.8 billion (5.7%) and Canada \$23.5 billion (2.8%). It is interesting to note that according to IMS Health, MIDAS, annual reports for the period from 2003 through 2013, the U.S. and Japan have been holding first and second place as far as global sales are concerned. Peoples Republic of China has replaced Germany and France as the third largest sales market in 2013.

The U.S. Food and Drug Administration (FDA) regulates the testing, approval, production and marketing of drugs and biologics. The level of regulation is different for different types of product and levels of potential risk. New drugs and biologics are subject to the most rigorous evaluation to prove safety

and efficacy for its end customers' intended use. The FDA is under severe pressure from the pharmaceutical companies to simplify and shorten the period of approval for new drugs to enter the market. The U.S. drug supply is one of the safest in the world. The globalization of the pharmaceutical industry and production has increased challenges for the FDA and manufacturers, in ensuring that imported ingredients and finished dosage drugs meet safety and efficacy standards. For example, China and India have become the largest sources of active pharmaceutical ingredients (APIs) and generic drugs for the U.S. market, respectively (18). The FDA has been working with its counterpart regulatory authorities to build cooperation and regulatory capacity. FDA has been increasing inspections and established field offices in China, India, Russia and Brazil, whereupon manufacturers of drugs sold in the U.S. will be relied upon to build in necessary safety procedures throughout the production. The healthcare reform law (PPACA) is expected to have a significant impact on the pharmaceutical industry by both expanding the pool of insured potential consumers by 32 million people over the next decade and by requiring manufacturers that participate in Medicaid and Medicare to share some of the costs. The cost to participating firms is estimated at \$100 billion over ten years through reduced reimbursement rates and fees. The world pharmaceutical market in 2009 was estimated at \$837 billion, according to IMS Health, a leading provider of pharmaceutical industry data (19, 20).

The U.S. accounts for about 36 percent of global pharmaceutical sales, and the U.S., Europe and Japan collectively account for over three-quarters of global expenditures. The top 10 global markets in 2009 were: the United States, Japan, France, Germany, China, Italy, Spain, UK, Brazil, and Canada. Sales of biotechnology-derived drugs are expanding faster than the overall industry, exceeding \$120 billion in 2008 and comprised 17 percent of the global market. The world generic drug market was estimated at \$88 billion in 2009 and forecast to reaching \$130 billion by 2014. Various industry estimates place the global over the counter (OTC) market in the \$100 billion range (21).

According to "Datamonitor Publishing" from November 2009, the average operating margin for Pharmaceuticals was 29%, Biologics 25%, Devices and Diagnostics 22%, Consumer Health Care/OTC 20%, Generic drugs 12%, Services 8% and drug wholesalers 2%. From the publishing we can see that the largest profit margins are enjoyed for the pharmaceutical agents. To survive, pharmaceutical firms need to make some choices about the way the future of the industry will unfold, and design their diversification strategies to position them for success. New lines of business will expand firm's portfolios and minimize the volatility of revenue and earnings, but doing this, pharmaceutical companies will need to accept lower levels of profitability. Analyzing financial performance of major pharmaceutical companies we concentrate on two major factors – profitability and risk analysis. In the near future some pharmaceutical companies, (which narrowly focus on only few potential blockbuster drugs), could become vulnerable in the situation of the reduction in sales (22, 23).

In today's world the pharmaceutical companies are feeling pressure from many sides — from regulators making the rules for drug safety and effectiveness, from managed care organizations and employers pushing back on reimbursement and prescription drug costs, from competitors coming to market

with alternative brands or generics, and from never satisfied shareholders. The number of new formulas in pharmaceutical companies' pipelines is shrinking, and the risk/reward ratio for research and development outlays is worsening. In general, these trends have resulted in lower revenue, reduced profitability, and declining price/earnings (P/E) valuation ratios for the most influential pharmaceutical firms. The question, however, is more fundamental than what pharmaceutical companies intend to do in the when the blockbuster era ends. The question is whether they can survive at all in their present form and without radical change. There is no consensus about what comes next, as evidenced by the different strategic actions the major companies have made with mergers, acquisitions, and divestitures in recent years. Some companies have chosen to double down on branded pharmaceuticals, planning that the bad times cannot last forever. By increasing new therapeutic areas or becoming more adoptable at using technology these businesses can continue to generate large profits from their exclusive patents. The other pharmaceutical companies have set their aim elsewhere, and have expanded into such sectors as: generic drugs, consumer health, biosimilars, nutrition, wellness and diagnostics (24, 25).

According to Capital IQ Database publishing covering the period from 2004 to 2010, the chaotic acquisition activity pattern among the ten largest pharmaceutical companies have been observed. The largest number with 39 acquisitions had occurred in the Pharmaceutical sector, followed by 31 in the Biological drugs, 11 in Generics and 10 in Consumer healthcare/OTC sector. The numerous conducted studies have been showing that pharmaceutical companies were, for the most part, not being capable to release the new blockbuster drugs, as they did in the past. The number of best blockbuster drugs that command the largest profit margins has been decreasing steadily. None of the new businesses into which the pharmaceutical companies are expanding have the same margins as branded drugs. This development raises doubts about whether pharmaceutical companies will be able to maintain their past levels of profitability. Still, the cost for the consumers presents the great burden in the environment of fairly restricted government price regulation. The drugs produced by subsidiaries of the major U.S. pharmaceutical companies with the same quality are sold for the fraction of cost in Europe and overseas markets where the government intervention keeps the prices at reasonable level. Unfortunately, in general, this is not the case in the U.S. market, where, through potent lobbying activities, the pharmaceutical companies create an environment of largely excessive profit margins. The development seems to be aimed on diagnostics, medical devices, prescription drugs, consumer healthcare/OTC, etc. Companies need to make new strategies and need to create new judgements to focus their strategic planning on areas that use capabilities that they already have - or that they could develop. The companies that established the excellent system for communicating with doctors, for example, would want to make sure that their strategic planning take advantage of that capability (the generic drug business as a strategic planning avenue would significantly benefit from this capability). The firms that possessed world-class expertise in cancer therapy, with its many challenges, would want to make sure that their strategies benefited from that unique expertise (as it might if the strategic move were in a direction of a nutrition line optimized for the needs of cancer, auto-immune diseased and organ transplanta-

tion patients). The intricate complexities of the development of immunosuppressive medications for cadaveric or live donor organ transplantation can be some of the future focus avenues. It is very important to know that if a strategic planning suggests that new capabilities will be needed, they should be developed in such a way that the company's overall capability system remains coherent. If the company's system is not coherent, the strategic planning will be significantly prone to failure (26, 27).

Identifying the right strategic planning avenues should be the highest strategic priority for the company, and the effort should be led by the all three levels of management (top, middle and entry-level) because in most cases these steps will lead to a different or substantially modified strategic direction for the company (28, 29). The majority of research analysts suggest a multi-step process:

a) Accepting change as inevitable.

All efforts of the scientists today, did not enable that the company releases the so called, „wonder drug“ within a short period of time. The process of discovering of the blockbuster drugs is not a straight-line process, but it is rather complicated and difficult. The majority of potential new drugs have been rejected before they ever reach the clinical trial level. The significant number of drugs will be rejected in the late „clinical trial“ phase, due to harmful and unwanted side effects. The current “blockbuster” model, defined as relying on traditional capabilities, faces its cessation. The issue here is changing the mentality of all levels of management. For companies where this attitude prevails and new capabilities are not developed, survival is a real question mark. After billions of dollars spent in research, the medications for cancer and auto-immune diseases have still not produced a life-saving cure, all of which suggest to the extreme complexity of beginnings and even more difficult attempts to stop the development of these diseases (29,30,31,32,33).

b) Creating a strategy for numerous potential future scenarios.

Every company need to create a strategy or a vision for all possible potential future outcomes. This is a very difficult and sophisticated task. To reach this ambitious goal a dynamic evaluation of potential future situations can help companies develop effective strategies how disease management will develop. All of these actions have the ultimate goal to reduce costs and secure solid profit margins for pharmaceutical companies (34,35).

c) Comprehending the core capabilities.

The present time brings inevitable changes for all pharmaceutical companies. The standard techniques and technologies in approaches and production must be changed with a new ones. Repeating what drug companies have usually performed in the past is unlikely to be effective. Having that in mind, it is vital to have a clear sense of what is differentiating about their capabilities system. Having acquired this knowledge, companies can decide which new capabilities they should be pursuing (36,37).

d) Selecting strategic actions that can position the company as a winner.

All three levels of management (and especially, the top-strategic planning level) are faced with the extraordinary task to pick up the right course of strategic action. No matter which future scenario materializes, companies will need to determine the capability sets that are required to win for each of the strategic plans. In the same manner, it will be very important to prepare and inform all of company's human resources in order

to support the new strategic directions. (38, 39,40, 41).

5. CONCLUSION

U.S. firms play a key role in the world pharmaceutical industry. Eight out of fifteen leaders of this market are headquartered in the United States. The United States represents the largest and the most attractive pharmaceutical market in the world. The majority of the largest U.S. companies are not segment and product diversified. Some of them receive almost all of their revenues from the sales of pharmaceutical products, and others receive over half of their revenues from them. Other products with minor revenue shares include: medical devices, consumer, nutritional and animal healthcare products.

Americans pay more for brand name prescriptions than anyone else in the world, due to hefty prices associated with “research and development” of drugs. The university research shows that the U.S. pharmaceutical industry spends almost double amount on promotion as it does on research and development. The aggressive advertisement helps to boost sales. The newest trends point to the facts that pharmaceutical sales and marketing (out of which the most do not have the adequate pharmaceutical and medical background) in many instances manage to persuade the physicians to accept and offer their more expensive medications, even though these new medications do not produce any better medical outcomes in comparison with the previously utilized cheaper ones. The cost for pharmaceutical products, in the environment of very limited government price regulation, which is reported among the largest among the developed countries, remains one of the major problems fuelling aggregate health care cost inflation.

Pharmaceutical companies need a strategic plan for innovating their corporate cultures, creating a new business models and building new capabilities as future scenarios unfold and the external environment changes. If anything, the challenges that pharmaceutical companies face seem to be mounting, especially in the U.S., the biggest market for prescription drugs. Generic drugs now account for more than 75 percent of all prescriptions in the U.S., versus 56 percent in 2005. Pharmaceutical firms have fewer resources, having lost 150,000 jobs, many of them in sales. The Food and Drug Administration (FDA) as the U.S. Government agency has become much more restrictive and control-oriented as far as safety is concerned. Many of the specialized drug treatments that are coming to market — priced at \$30,000 a year and higher - confront stiff resistance from powerful intermediaries between doctors and patients, the insurance companies, that are questioning their value and refusing to pay. In present time the pharmaceutical industry is entering the stochastic periods, but this period is not expected to last for a long period of time. Cyclically, it is expected to be replaced by the deterministic period which will enable the firms to leave behind the old ways of strategic planning and pursue a new, more effective strategies.

For U.S. and other big pharmaceutical companies in the world, the challenge will be to make strategic actions, first in order to survive today, and second to position themselves for the next phases of deterministic growth. When this transition occurs, the U.S. based pharmaceutical companies will be very differently shaped enterprises in comparison from what they look like today.

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