Section A -Research paper
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The Future Drug Development by Big Pharma and Its Contenders

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Abstract — There are a number of quirks in the pharmaceutical industry's structure and operations that set it apart from other business sectors. While the general public may not be aware of these quirks, they have a major bearing on the time and effort required to bring new pharmaceuticals to market. Developing a new treatment is a long and costly process that comes with a lot of uncertainty about whether or not it will be effective. This article analyses the difficulties of doing research and development, particularly those posed by the natural world. Future commercial and technological advances in the area, such as the creation of a greener pharmacy, will be studied once the economic realities and restrictions of the company and its current issues have been reviewed.

Keywords— Health and Well-being, Pharmaceutical Industry, Pathophysiologic, Clinical Chemistry, Biochemistry

I. INTRODUCTION

Pharma has much to celebrate. In the recent decade, immunotherapy, cell therapy, and gene therapy have improved, giving patients hope. During a global pandemic, COVID-19 vaccines were produced quickly. Despite groundbreaking advancements, pharmaceutical companies couldn't keep up with the financial markets. Pharmaceutical returns were around one third lower than the S&P 500, and biotech returns were significantly worse. The top 50 pharmaceutical companies' stock performance has grown more disparate. In 2021, PwC found that pharma firms in the top quintile had a 29% five-year total shareholder return (TSR), while those in the worst quintile had an 11% TSR. As performance expectations climb, investors are evaluating pharma companies to determine which are most likely to succeed and allocating their investments accordingly. (Campbell et al., 2018)

II. OBJECTIVE

The research aimed to fulfill the following objectives:

- To study Implications for the Environment
- What role Prospective Market Competition in the Pharmaceutical Industry
- Prospective Market Competition in the Pharmaceutical Industry

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III. METHODOLOGY

The pharmaceutical industry is distinctive from other types of businesses in a number of respects. Public trust surveys frequently place the business as one of the least trusted in the economy, drawing parallels to the nuclear power sector despite the industry's indisputable good influence on society and people's health and happiness over the course of a century. Even though it's one of the riskiest businesses to put money into, many individuals still consider it to be incredibly lucrative. Even though these companies properly market themselves as research-based organizations, many people are under the false impression that they spend more money on advertising than on genuine research. It is still frequently believed that drugs should be made available regardless of whether or not they are really needed. In this first chapter, we'll cover the fundamentals of the field and attempt to explain away any lingering confusion. We hope that providing some company history would help readers better appreciate the complexities of the drug pollution problem. It is important to realize that the terms "medicine," "pharmaceutical," especially "drug" are often used interchangeably, and that the term "drug" may refer to either a legal or criminal substance depending on the context in which it is used. In this chapter, we will use the term "pharmaceuticals" to refer to the finished goods of the pharmaceutical industry. In the pharmaceutical sector, "drug" almost often refers to a medication that is still in the development stage.

IV. WHAT ROLE DOES CHEMISTRY PLAY IN THE HUMAN HEALTH?

Although everyone should know what a pharmaceutical is, our inquiry may cause some consternation. However, there is currently no accepted scientific explanation for this problem, despite its apparent simplicity. Unlike phthalates and PCBs, drugs do not make up a larger class of chemicals. In terms of chemistry, physics, structure, or biology, there is not the slightest resemblance between the two. As a result, there is no proof that medicines should be seen as a homogenous group of compounds. Many people believe that medications can only be found in the form of complex chemical molecules, however this is not always the case. According to research (Van Pham, 2016), Nitroglycerine, a vasodilator (1,2,3-trinitroxypropane), is aliphatic (MW 558.5), while the commonly used anaesthetic propofol is aromatic (2,6-diisopropylphenol). ((3R,5R) -7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-propan-2-ylpyrrol-1-yl] 3-Hydroxy-5-pentanoic acid. Future medication research is most likely to focus on extremely large molecular weight biopharmaceutic-ticals like insulin (MW 5800 Da). It has been shown that

Drugs are grouped together under the umbrella term "pharmaceutical" because of their shared goal of curing disease in humans and other animals. This opens the door to the possibility that in the future, any chemical may be considered a drug. This explains why many medicines available by prescription are also used for entertainment reasons. For instance, nitroglycerine (developed by Alfred Nobel as the explosive component of dynamite) was solely used for explosive purposes until William Murrell20 discovered its vasodilatory properties. Originally developed as a rat poison at the University of Wisconsin, nowadays warfarin (R, S)-4-hydroxy-3-(3-oxo-1-phenylbutyl)-2H-chromen-2-one) is the most widely prescribed anticoagulant in the world. (Pham, 2016) This is more than interesting background information. Dimethyl fumarate is one such compound that has found widespread application as a mound inhibitor. (Jones, 2012) It is worth noting that 22-dimethylfumarate, sold under the brand name Tecfidera, was approved for treatment of multiple sclerosis in 2013, just a year after the European Union implemented the new REACH rule drastically restricting its usage as a PDE inhibitor. 23 For example, the worldwide inventory of chemical compounds did not include dimethyl fumarate as a medication until 2013. Several writers have argued that medications need special regulatory consideration since they are "designed to be biologically active"24. According to this logic, this is all that's needed to tell medications apart from other chemicals. However, this is not correct since it is based on a misunderstanding of how pharmaceuticals are developed and implies that medications have physiological effects that natural chemicals do not. To be more precise, substances that have an impact on animals (including humans) are evaluated for prospective use in medications based on their safety.

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High-throughput screening technologies, which can screen 410,000 compounds daily, are used to discover the vast majority of novel drugs. These approaches may be used to chemical "libraries" containing several million molecules. Since it is well-established that the vast majority of compounds exhibit at least some biological activity, the screening test is designed to focus on only those molecules that exhibit the required biological activity. First-stage screenings can provide hundreds of potential leads, most of which must be eliminated before further investigation can begin. Every one of these first possible leads has the sought-after biological activity, but some also have unfavorable toxicological properties and must be discounted. Toxicological screening helps narrow down potential candidates to those with the desired bio-logical activity while maintaining few or no unfavorable traits by weeding out compounds with worse profiles. (2020)

Future Pharmaceutical Market Competition

Due to multiple simultaneous issues, the pharmaceutical industry's research sector is in crisis. 1984 (Bedor) Since GSK launched the first blockbuster drug, cimetidine, in the 1970s, the pharmaceutical industry and its regulators have believed the "blockbuster model" was the best long-term approach. Drug research and development were risky and expensive, therefore generic versions of these medications were anticipated to cut retail costs after patent expiry. However, regular "blockbuster" drugs would generate enough revenue to fund future R&D. After a temporary patent monopoly, the pharmaceutical industry could continue to create cutting-edge medications at reasonable prices. For many years, several of the large pharmaceutical companies' R&D divisions released a regular stream of "blockbuster" drugs. However, "pulling the handle" on R&D equipment wasn't enough to keep "blockbuster" products coming out. (Ramamoorthy et al., 2015) The pharmaceutical industry's R&D efficiency has been declining for decades. Inflation-adjusted, the number of approved new drugs per billion US dollars spent on R&D has declined 80-fold since 1950. Many major mergers and acquisitions followed by even larger ones solved these problems. After mergers, nine pharmaceutical research organizations remained in 2010. Pfizer alone had merged with American Cyanamid, American Home Products, Pharmacia, Upjohn, Warner-Lambert, and Wyeth and bought Monsanto's pharmaceutical sector. This was done to reduce overhead and save money without losing innovation or research and development for each pharmaceutical pipeline. Capital markets liked this technique, but its long-term benefits to shareholder wealth were unclear. Heilman, 1978 Even while R&D increased, new products did not.

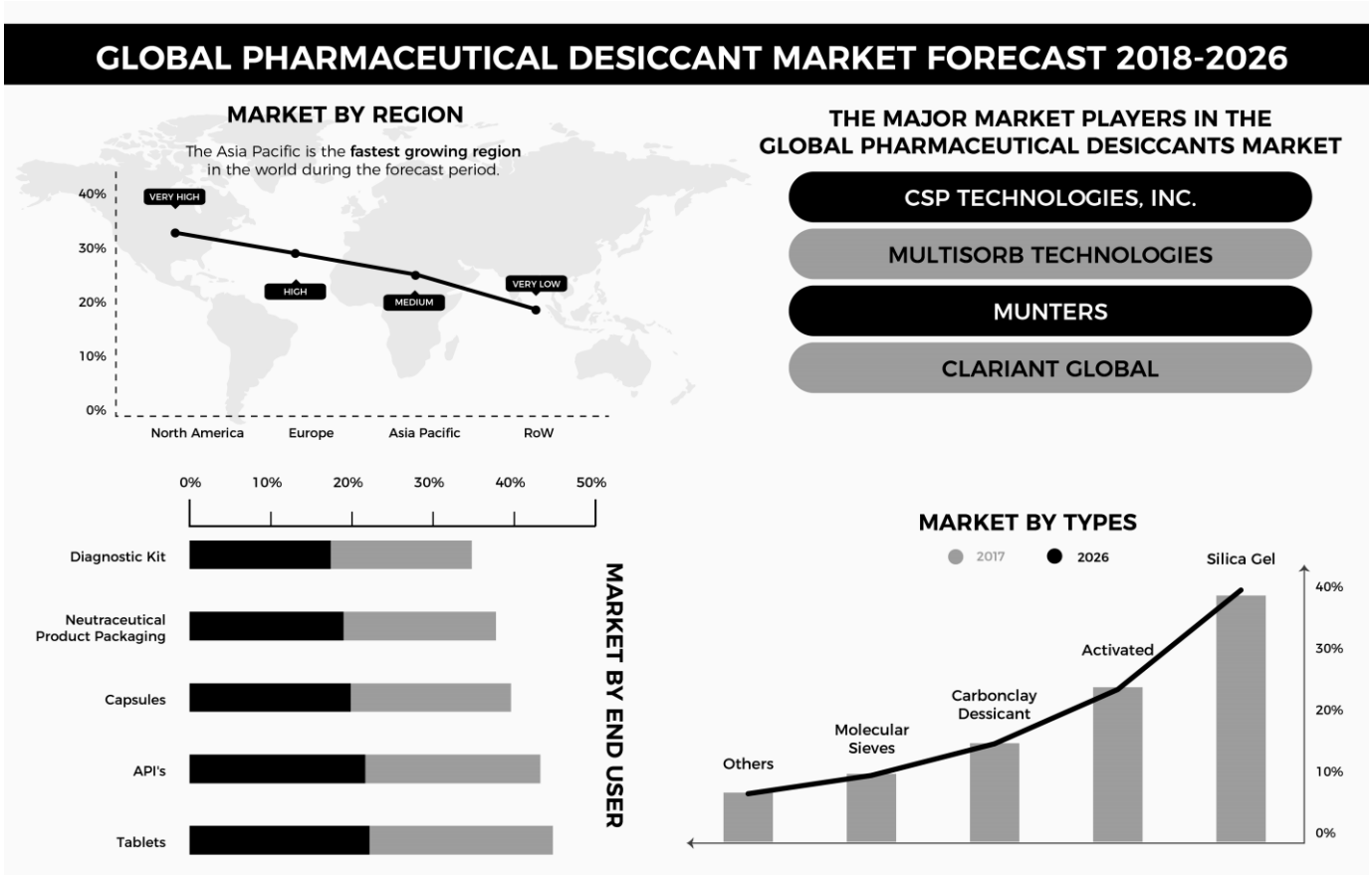

FIGURE 1. PHARMACEUTICAL INDUSTRY

V. IMPLICATIONS FOR THE ENVIRONMENT

Scientists and policymakers thought the pharmaceutical sector had minimal environmental effect until the late 1990s. Small and well-regulated industrial activities were criticized for environmental damage. Due to the limited volume and high cost of production, only minuscule amounts of biologically active pharmaceuticals spilled into the environment during manufacturing. In 1994, pharmaceutical residues in water altered that. When German waterways showed colibri acid in 1994, pharmaceutical residues were tested. Mid-1980s Richardson and Boron predicted their existence in surface streams. Groundwater, estuaries, rivers, and drinking water contain residues. (Pinesap, 2012) Wastewater may surpass mgl1. Manufacturing effluents, unused and expired medicine disposal, and patient excretion release pharmaceuticals. Although specific statistics for each medication are difficult, scientists assume that waste from manufacture and consumption accounts for the majority of environmental input globally, while effluent discharges and the disposal of unnecessary pharmaceuticals account for a small percentage. Industrial pollution and hospital discharges may produce high local concentrations in developing countries. Kannan (1985) Most academic, government, regulatory, and corporate investigations revealed no acute effects from environmental medicines on aquatic life. Environmental harm is unlikely. Researchers are improving long-term effect assessments. Medication has environmental impacts. The Asian vulture's devastation from diclofenac and EE2's potential role in fish feminization suggest otherwise. Thus, medications should be evaluated separately. Hormones, a potentially important class of molecules, are being widely investigated. However, further research advises assessing hormonally active medications separately rather than as a group. Medicines' long-term effects on plants and animals are novel study. Then there's antibiotic resistance. Antimicrobial resistance is a major 21st-century public health issue. MRSA (methicillin-resistant staphylococcus aureus) has

spread due to antibiotic resistance. Kannan (1985) Discharged antibiotics may spread antibiotic resistance. Despite a lack of proof, this field is nevertheless active. (Lawrence, 2001)

Medical care

Many believe that just a handful of pharmaceutical giants—including AstraZeneca, GlaxoSmithKline (GSK), Eli Lilly, Merck, Novartis, Roche, and Pfizer—exist. The pharmaceutical industry is ridiculed in BioPharma. This is a trick. Teva, the world's 11th biggest pharmaceutical company, is little unknown outside of the industry. It's possible that you gave them medication. The pharmaceutical industry is similar to an iceberg. The generic pharmaceutical companies that make up 80% of the industry are largely unknown to the public, despite the fact that they generate 40% of the market's revenue. Thus, generic drugmakers make most of the world's medications. 84% of the 4 billion US prescriptions filled in 2013 were generic. (Li, 2014) Since big pharma spends billions on drug research and development, the patents system is to blame for this disparity. Most proposed drugs are rejected due to inefficacy or patient damage. The patent system grants exclusivity to a few new medications each year. After the patent expires, "generic pharmaceutical" production and sales are unrestricted. Generic drugmakers commercialize patent-expired drugs. Generic drugmakers seldom produce duds, unlike research pharmaceutical businesses. This changes the company's structure, operations, and character. Generic drugmakers have low profit, risk, and cost. They create and market proven products. Some generic companies engage in R&D to provide cheaper, process-oriented manufacture. (Pinesap, 2012) The industry produces few units at cheap cost despite strict controls. Kannan (1985) Marketing costs are low since the products are well-known and in demand. Generic pharmaceutical companies function similarly to commodities markets, where distinction is typically determined primarily by price and profitability is often connected to market share. (2017) Research pharmaceutical companies have a distinct financial approach. Innovative companies release innovative pharmaceuticals to customers. It's expensive, risky, and time-consuming. Most pharmaceutical R&D expenses go to development, notably clinical trials after pre-clinical research. Pharmacological intervention may enhance health when sickness and dysfunction are studied. High-throughput screening and other approaches may find drug candidates. The best preclinical candidates enter clinical trials. The drug's effectiveness and safety are crucial. Investigating whether the active substance can be turned into a pharmaceutical or delivered to the patient is also crucial. Only 1% of drugs in the pipeline reach retail shelves. This rate has been dropping due to increased regulatory requirements and risk aversion.

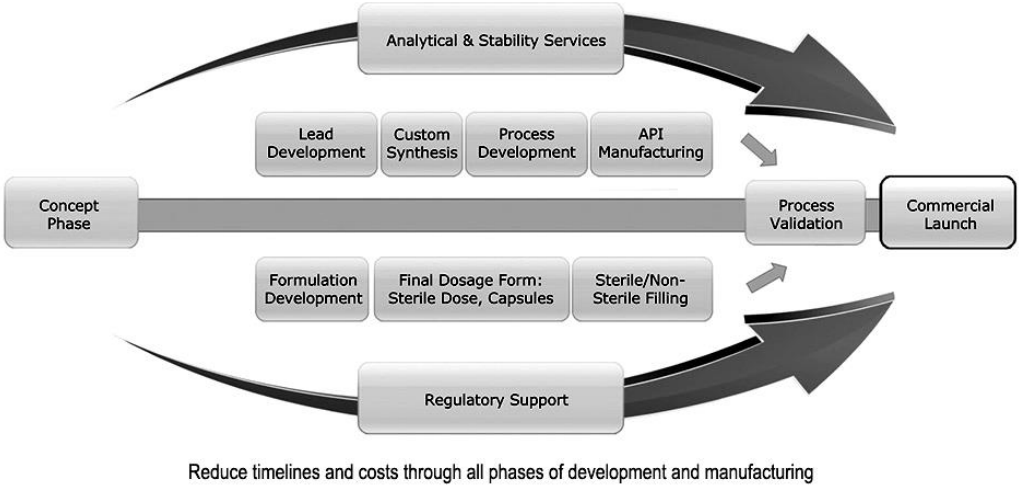

FIGURE 2. PHARMACEUTICAL RESEARCH INDUSTRY

CONCLUSION

Still, the pharmaceutical research sector faces a number of challenges, few if any of which seem to have obvious solutions. Although it has the right to sell the medicine exclusively throughout the patent period,

rising regulatory burdens are raising development costs and timeframes. Because of this, there are fewer years left before the patent expires, the introduction of new pharmaceuticals has slowed, and patient populations and regulatory bodies are less willing to take risks, all of which contributes to a lower success rate. The combined effects of these variables are decreasing the rate of success. However, we may be certain that the residues in the environment from the use of the future generation of human medications will be substantially lower than those caused by the use of existing medicines, since biopharmaceuticals are progressively dominating the drug development pipelines. This is due to the fact that biopharmaceuticals are far more effective than their conventional counterparts. This is because biopharmaceuticals are quickly becoming the frontrunner in the race to bring forth novel medicinal treatments.

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