Inaccessibility and Unaffordability of Prescription Drugs in the United States: Assessment of Contributing Factors and Methods for Improvement

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Abstract

Many pharmaceutical products come with heavy financial burdens for the patients who take them. This standard is able to exist in the United States for a number of reasons. Significant historical developments driven by pharmaceutical companies such as vaccine technologies or antibiotics boost the image of the industry in the eyes of American citizens, allowing more discrete practices to occur in the modern day that contribute to excessive drug prices. Pharmaceutical companies currently engage in many actions that advance a concept known as pharmaceuticalization, where everyday problems are promoted as medical issues treatable with prescription drugs (Abraham, 2010). The expansion of mental health issues treatable with medications, extensive marketing schemes, complex patent portfolios, and high government lobbying expenditures are all significant factors in the advancement of pharmaceuticalization in the United States. The resulting trend is perpetuation of issues with affordability and accessibility to prescription drugs, and it will require a great deal of effort from both the industry itself and the American people to create positive change.

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Introduction

Pharmaceutical products improve the quality of life for people all over the world, but many still experience significant barriers in accessibility to life-changing medicines. This is especially true in the United States, where $1,126 per capita is spent on prescription medications versus $552 on average in comparable countries (Kurani et al., 2022). Not only do Americans spend more on prescription drugs than citizens of other first-world countries, they also often face the choice between obtaining their prescriptions or making other ends meet. It has been estimated that as many as 10% to 20% of patients may neglect to use a treatment due to the associated financial burden among all prescription medications (Kantarjian, 2014). However, as the price increases, more people neglect to fill their prescriptions. For medications that cost over $500, as many as 60% of Americans will neglect to receive their treatments (*Medicine Spending*, 2020).

Additionally, more advanced medical treatments can be so expensive that a typical American could not even dream of having access to their benefits. Monoclonal antibody (mAb) therapeutics, for example, demand annual average payments of $96,731 for their treatment plans (San-Juan-Rodriguez et. al, 2020). This exceeds the median household income of $67,521 in the United States by a significant margin. These are few of many statistics that illustrate the problems with prescription drug pricing in the United States, so this work seeks to explore these issues further.

This thesis aims to support the claim that pharmaceuticals have become so ingrained in our society that the manufacturing companies are able to set prices that overwhelmingly increase their profit margins at the expense of the patients. I will subsequently explore various modes

through which companies in the industry and the American people can take action and improve accessibility and affordability of life-changing medicines.

I am completing the work in this thesis in accordance with my motivation for all of the work in my thesis portfolio, in that the overall goal is to define problems with prescription drug accessibility and affordability in the United States and propose practical methods of improvement. I will begin this research and argument by discussing the history of the industry. I will use this history to illustrate the favorable view of the industry, a view that stems from the industry's investments in not only innovative, but also essential healthcare technologies. Next, I will describe several concepts and practices of the industry that have perpetuated the aforementioned problems with accessibility and affordability. I will then conclude my research with the description of methods through which these issues can be addressed.

Historical Developments of the Pharmaceutical Industry: 19th Century to Present Day

The development of the pharmaceutical industry into what it is today coincides with many groundbreaking discoveries of the 19th and 20th centuries. Despite over 1,200 new chemical agents being introduced to the market since 1940, there are a few keystone products that have been crucial in driving innovation in the industry (Scherer, 1993). One of these advancements was the discovery of penicillin–the first known antibiotic–by Alexander Fleming in 1928. The breakout of World War II prompted researchers to isolate the compound and conduct clinical trials; the success of these trials catalyzed collaboration between researchers in Great Britain and pharmaceutical companies in the United States to mass produce penicillin (Gaynes, 2017). US companies began to scale-up production 1941 and were able to supply the entirety of the Allied forces by 1943, reducing death rates in bacterial pneumonia from 18% to 1% (Bradford, 2019). Following the war, research and development of antibiotic compounds

increased dramatically; today, many diseases that would have been severely crippling if not fatal 75 years ago can now be effectively treated with the aid of antibiotics, all of course being produced by large pharmaceutical companies. It should be noted that there were many institutions that also contributed to the successes of these products. For example, the War Production Board employed over 20 companies, 5 academic institutions, and other government agencies such as the Department of Agriculture to promote penicillin production on a scale that would meet the demands of the war (Quinn, 2013). However, commercialization of these products have shifted towards corporations as time has passed.

but as time has gone on, their commercialization has shifted much more towards corporations.

Another significant set of developments driven by pharmaceutical companies is the progression of vaccine technologies. The concept of vaccination was first pursued in a scientific sense in 1796 when Edward Jenner found that infection with cowpox, which had no effect in humans, could provide protection against infection from smallpox, a disease that killed 400,000 people annually during the 18th century in Europe (Riedel, 2005). This discovery provided a scientific basis for further vaccine research for a wide variety of infectious diseases. By the mid-20th century, smallpox was eradicated in the US, and vaccines had been developed for diseases like polio, rabies, influenza, yellow fever, and more. This was made possible by independent research entities that discovered vaccines, governments that provided funding for vaccine research and production, and pharmaceutical companies that had the means to produce vaccines at a global scale as well as conduct their own research. In the present day, many pharmaceutical companies continue to produce vaccines that are essential for modern society, so much so that public schools in all 50 US states mandate the DTaP (diphtheria, tetanus, and pertussis), IPV (polio), and Varicella (chicken pox) vaccines (ProCon.org, 2021). Additionally,

such companies as Pfizer, Moderna, and Johnson & Johnson are vital in their production of vaccines for COVID-19.

The vaccine and antibiotic technologies discussed herein, as well as products of many more medicinal fields such as oncology and psychiatry, have been monumental achievements in modern medicine, and pharmaceutical companies have been pivotal in their successes. The industry has allowed a vast majority of society to live long and healthy lives, because if not for these products, countless Americans would still face the dangers of bacterial and viral infection from many life-threatening diseases.

The Pharmaceutical Industry's Present Contributions to Unaffordability

While the pharmaceutical industry as a whole has been a key driver in healthcare technological advancements and innovations, creating products that continuously save countless lives every day, many companies engage in practices that both reinforce society's reliance on their products beyond life and death scenarios and establish drug prices that boost their profitability exceedingly high at the expense of the patients and consumers. The industrial trends and practices studied in this thesis will include the concept of pharmaceuticalization, the strategies for drug marketing and political lobby, and the manipulations of patent law.

The Pharmaceuticalization of American Society

The pharmaceutical industry maintains societal reliance on its products through a variety of manners that lie within the scope of a concept referred to as pharmaceuticalization. Abraham defines this idea as "the process by which social, behavioral, or bodily conditions are treated or deemed to be in need of treatment, with medical drugs by doctors or patients" (2010). According to this definition, corporations in the industry actively employ practices that prompt consumers to take medications for their previously non-medical problems. The evidence of this concept as a

factor in the growth of the American pharmaceutical industry is quite apparent. Prescription drug sales tripled globally from the 1980s to 2002 and the US industry grew to nearly $200 billion in spite of practically stagnant sales between the 1960s and 1980s (Angell, 2005). To further characterize the emergence and growth of pharmaceuticalization, Abraham highlights five key factors of analysis: medicalization, biomedicalism, drug promotion and marketing, consumerism, and regulatory affairs of the governing state (2010). All of these factors have some contribution to one aspect of the argument in this thesis, and they will be presented in order of the outline in the introductory section.

The most closely related of the five factors and arguably the most significant is medicalization, of which pharmaceuticalization can often be viewed as an extension. This term refers to the "process by which non-medical problems become defined and treated as medical problems, usually in terms of illness or disorders" (Conrad, 1992). Pharmaceuticalization may extend from this definition in that a medicalized condition can subsequently be treated with a pharmaceutical product. The most prominent example of pharmaceuticalization growth as an extension of medicalization is the case of Prozac, where the field of medicine began to focus heavily on mental health conditions such as depression and anxiety. In this case, the sales of Prozac doubled within a span of six years in the 1990s, and many other drugs of similar effects had been introduced to the market (Abraham 2010). Pharmaceuticalization is not always an extension of medicalization, however. For patients with ADHD, much of the increase in Ritalin–a common stimulant for ADHD–can possibly be attributed to the decisions of patients to treat the condition with medication as opposed to psychotherapy (Abraham, 2010). While this particular metric is impossible to accurately gauge, it along with the other presented information indicate that medicalization is an important factor in the growth of pharmaceuticalization.

Complex Marketing Strategies

The most significant factor that fosters the pharmaceuticalization of American society is the drug promotion and marketing schemes of pharmaceutical corporations. While the strategies that each individual company may employ are quite complex, direct-to-consumer advertising (DCTA), marketing budgets, and broad manipulations of public perceptions of products are a few general aspects of said strategies that not only amplify the growth of pharmaceuticalization, but also directly affect the problems with affordability and accessibility of prescription drugs. The marketing strategies of pharma companies are also closely related to the other factors that Abraham uses in his analysis, including medicalization, consumerism and regulatory affairs.

DCTA is the general practice of promoting prescription products to patients themselves, bypassing the typical middle man of healthcare practitioners (Ventola, 2011). Consequently, consumers become more conscious and active in decision making about their health in regards to medications. Pharma companies benefit from DCTA because it increases a consumer's exposure to information about drug products significantly considering that the primary mediums are television and the internet. For instance, the average person sees a television ad for a drug 9 times per day, which greatly exceeds the amount of time a person can spend with a healthcare practitioner. Advertising through the internet is even more effective in increasing consumer exposure. DCTA can clearly have a profound effect on the consumers given the amount of information one could possibly view in one day, which gives reason to it being illegal in most western countries except the US and New Zealand (Ventola, 2011).

Several misrepresentations of information through advertising are quite common in the US pharmaceutical industry, including but not limited to the overstating of benefits of certain drugs, promotion of drugs before enough safety studies have been complete, and other

misleading facts that distort the patient's knowledge. Pharma companies often overstate the efficacy and target group to which they should be prescribed. For example, one study in the 2000s found that several of the most prescribed SSRI antidepressants showed clinical efficacy only for cases of severe depression despite being marketed for mild to moderate cases as well (Kirsch et at., 2008). Another common practice of pharmaceutical marketing campaigns is to promote drugs that have yet to show clinical efficacy or safety reliability. This can take the form of first class drugs that are advanced quickly through the FDA approval process or for drugs that are marketed off label (Abraham, 2011; Ventola, 2011). This can generate both unnecessary spending for patients and dangers to a patient's health. Other information that pharmaceutical companies may misrepresent are the prevalence of risk and the promotion of a drug as the single solution to a problem, dismissing other lifestyle changes patients can make (Ventola, 2011). The marketing practices of the pharmaceutical industry presented thus far have been to demonstrate the progression of pharmaceuticalization in our society, thereby indicating the high degree to which these companies have influence over our lives.

The pharmaceutical industry supports their marketing strategies with exceedingly high capital expenditures, indicating their active and conscious contributions to pharmaceuticalization. Between 1995 and 2005, the marketing staff for pharmaceutical companies grew by 59%, while research and development staff was reduced by 2%. In the year 2000, double the amount of capital spent on research and development was spent on marketing (Abraham, 2010). Today, pharmaceutical companies may spend up to 45% of their revenue on marketing campaigns (Kantarjian, 2014). Because the industry requires so much capital to support their marketing strategies, they are in turn able to set and maintain prescription drug

prices at levels that contribute to the problems with accessibility and affordability as mentioned in previous sections.

The evidence presented on the growth of pharmaceuticalization in tandem with the complexities of the marketing strategies support the thesis statement in each aspect. The concept of pharmaceuticalization and many of the marketing tactics develop the idea that American society is so reliant on the pharmaceutical industry and its products that companies have the freedom to do as they please in regards to pricing of their drugs. This creates a feedback loop where companies must maintain high drug prices in order to provide the necessary funding for their marketing practices. While this is a central idea that makes significant contributions to the problems with accessibility and affordability of prescription drugs, the industry also engages in some practices outside of direct consumer relations that also allow them to maintain exceedingly high drug prices.

Manipulations of Legal System

Many large pharmaceutical companies engage in a variety of exploitations of certain aspects of the legal system in order to keep their drug prices, and therefore their profits, problematically high. One path through which companies can use the system to their advantage is through the creation of large and complex patent portfolios for their products. One of the most well documented instances of this is the case of AbbVie's Humira®, which is the most profitable drug product currently available on the market. AbbVie initially filed standard patents for their product in 2002, patents that would give the company and its product protection until at least 2016 (Moorkens et al., 2021). In order to prolong the market exclusivity for their product, and therefore continue reaping all of the profits, AbbVie developed a series of secondary patents on various aspects of the entire process from manufacturing methods to formulations and dosages.

They were able to attain dozens of secondary patents that have prolonged their exclusivity in this market until 2034, nearly doubling the original length (Moorkens et al., 2021). This is not the only instance of a company compiling patents to prolong their exclusivity in various markets. When this occurs, the manufacturer of the original product is generally able to keep prices as high as they wish, which is partly to blame for Humira® being the most profitable drug while only being approximately the 150th most prescribed drug (Rowland, 2020). Fortunately, at least five companies have been able to successfully engage in patent litigation with AbbVie, reaching settlements that would allow said companies to bring biosimilar drugs to the market by 2023 (Moorkens et al., 2021). However, AbbVie has still managed to increase prices despite these companies receiving FDA approval (Rowland, 2020). Patent litigation has therefore proven to be an advantageous and very difficult to overcome tool for companies to maintain prices that cause affordability and accessibility issues but greatly increase profits.

Another method many pharmaceutical companies employ to achieve high profits through high drug prices is extensive lobbying and campaigns donations in the American government. In this practice, companies in the pharmaceutical industry are able to allocate capital resources towards both lobbying, where representatives from the company are paid to share information about regulatory affairs that the company wish to exert control over, and campaign donations for representatives in the federal and state governments that are more likely to vote on policies in their favor. Between 1999 and 2018, the pharmaceutical and health product industry as a whole was reported to have spent $64.3 billion on lobbying for Congress and various federal agencies (Wouters, 2020). This metric was the highest of all industrial sectors. In that same time frame, an estimated $414 million in donations to political campaigns in the federal-level and $877 million to campaigns in state-level elections (Wouters, 2020). These metrics are not representative of a

large portion of the revenue generated by the industry, as it is approximately 0.1% of the multi-trillion dollar estimated combined revenue. However, slim to none of the donations or lobbying efforts were done so on behalf of the interests of the patients. For example, most of the industry supported the passage of the Affordable Care Act, but this came with certain provisions that ensured that companies could remain highly profitable, such as disallowment of both drug price negotiations for Medicare and parallel imports of cheaper medicines from Canada (Wouters, 2020). Lastly, the capital resources pharma companies gain from exceedingly high drug prices allow them to spend relatively little compared to organizations that would lobby and donate on behalf of the patients and consumers. Therefore, the industry utilizes lobbying and campaign donations to sway certain policies in their favor in order to maintain high profitability at the expense of consumers.

Counterarguments and Opposing Viewpoints

The research conducted in this thesis is sound, but there is still plenty of room to dispute these findings from a different perspective and to propose viable counterarguments. In the historical analysis of the pharmaceutical industry, it could be argued that the pharmaceutical industry did not have as significant an impact on the development of antibiotic and vaccine technologies as I have presented. This is true to some extent, as much of the discovery research was led by Universities and research institutes; for example, Fleming made his initial discovery of penicillin while working at a hospital in London (Gaynes, 2017). Despite this, it is still true that pharmaceutical companies have been critical in mass producing a vast majority of vaccines and antibiotics, with the most recent example being production of COVID-19 vaccines in the US by Pfizer and Moderna. So, it is still accurate to say that American society has become highly dependent on the pharmaceutical industry through these groundbreaking discoveries.

There are also many arguments that could be made to support the denial of the existence of pharmaceuticalization in American society. Several of the key factors Abraham defines denote alternative or negative arguments against pharmaceuticalization (2010). Biomedicalism theory, as Abraham specifies, argues that the trends that I have presented as a product of pharmaceuticalization are actually driven by scientific and technological innovation within the industry. In other words, biomedicalism theory claims that the discovery and characterization of new medical conditions is a form of progress led by research. This argument fails under multiple scopes. With reference to ADHD, Abraham describes that increases in diagnoses and prescriptions is not necessarily a reflection of research and may be attributed to the broadening of the criteria for diagnosis, citing a study that found as many as 50% of school-age children may exhibit ADHD symptoms (2010). The counterargument is therefore invalid due to the inconclusivity of the reasoning behind the trends.

A counterargument against the notion that DCTA has a profound impact on societal reliance on the pharmaceutical industry would be to highlight positive results from DCTA. These results include but are not limited to the information and education provided to the consumer, the encouragement of patient to physician contact, and the promotion of a dialogue between healthcare providers and consumers (Ventola, 2011). In reality, the negative realities regarding the spread of misinformation likely outweigh the impacts of these positives. In either case however, the American people are still being subjected to increased interactions with the industry through DCTA, in turn promoting a state of reliance on their products by adding to the growth of pharmaceuticalization. In terms of the rest of the drug marketing analysis and the legal system interactions, there are few if any arguments that may refute the claims I have illustrated. As the

purpose of industry spending on consumer marketing and government lobbying is all but irrefutable.

Routes to Improvement: Accessibility and Affordability

Approaching the problem as it has been outlined is a daunting task even without consideration of the claims of this thesis and the corresponding supporting evidence. Generally, there are two routes through which change can be achieved, and they both likely need to work in tandem. The first of these routes is through the corporations in the industry themselves. As this thesis claims, the pharmaceutical industry has actively created and fostered the growth of the system today. Accordingly, the companies in the industry also have the means to make the necessary changes on their own, but one might wonder why any corporation would choose to reduce their profits in any way. All corporations with the proper means should do so according to the principle of the corporate duty to rescue (CDTR). Wolitz (2019) states that "in the biopharmaceutical context,… pharmaceutical companies have a moral obligation to increase access to medications. Rescue efforts are conceived as including in-kind donations to needy patients, reducing product prices, or tinkering with the management of a company's intellectual property" as his definition of the CDTR. This concept may be interpreted as a call to action upon the industry to take action upon itself for the benefit of the consumers. In the capitalist economy of the United States, however, this task appears especially challenging.

To address this challenge, there would likely need to be a large-scale movement driven by the American people. A survey from the Kaiser Family Fund (KFF), indicates that many Americans may already be in favor of such a movement. The survey of reference provides several key findings; about 60% of US adults take at least one prescription medication, with nearly a quarter taking more than four different prescriptions; 83% of US adults say the cost of

prescription drugs in unreasonable, but nearly 70% say that it is relatively easy to afford them; those who say that it is difficult to afford their prescriptions are most likely taking four or more prescriptions in total, they are of middle-age, there health conditions are serious, or they are of low-income households. These metrics provide some insight into the preferences of Americans and their sense of urgency on the matter. Some of these statistics may not be in the range of what is possible for enough people to join in a cause for activism, but it is certainly a reasonable starting point.

Conclusion

The research into the history of the pharmaceutical industry, the direct-to-consumer relations of the present day, and the pivotal capital expenditures in the political and legal sectors support the claim that the pharmaceutical industry and its products have become ingrained in our society to the extent that corporations have the freedom to charge disproportionately high prices for prescription drugs that perpetuate clear issues in Americans' accessibility and affordability of said products. The past successes in paradigm changing innovations in vaccine and antibiotic technologies cemented the foundation for reliance on the pharmaceutical industry. Various techniques that fall under the scope of pharmaceuticalization have further nurtured this dependence, including the concepts and practices of medicalization and direct-to-consumer advertising. Direct-to-consumer advertising has also reinforced this dependence through the spread of misinformation in several forms. Many corporations also undergo development of extensive patent portfolios that delay the introduction of price competition from biosimilar drugs. Lastly, the capital investments into marketing strategies and political lobbying allow the industry to further manipulate the system by driving more dependence on their products and gaining favor over policy change to protect the status quo.

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