Title

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ABSTRACT

In our paper, we encompass the topic of socioeconomic disparities intrinsic to drug pricing and look at ways to ensure that every individual in the United States can access antibiotics equally and equitably. In the United States, a multitude of individuals find themselves struggling with high, out-of-pocket costs for necessary antibiotics or medications. These issues are generally caused by factors surrounding monopolistic drug markets, high costs for development, and the severity of disease that an individual is facing. We explore these challenges from a plethora of perspectives, such as; the role of specialty pharmacies, limited distribution networks, and the usage of psychotropic medications among youth with Autism Spectrum Disorders (ASD). High prices and restricted access of certain antibiotics for conditions like Hepatitis C highlight the systemic and intrinsic issues within the pharmaceutical industry and how it affects individuals who suffer from this disease or diseases similar to it. On a similar topic to that, ongoing shortages of ADHD medications continue to show the consistent and heavy impact of supply constraints amongst the pharmaceutical industry in the United States. We discuss potential solutions, including but not limited to, accelerating the approval of basic drugs, implementing ceiling prices to prevent high costs, and better integrating health-system specialty pharmacies. By concentrating on the need for policy reforms within the United States and collaboration amongst the various stakeholders that remain involved with drug pricing disparities, this study aims to offer a varied approach in reducing drug pricing disparities and making necessary medications accessible to every individual in the United States, regardless of socioeconomic or health status.

INTRODUCTION

An individual's ability to access affordable medication is a vital component of healthcare, and still, a multitude of Americans within the United States face the issue of high and prohibitive out-of-pocket costs for their necessary medications. This paper examines socioeconomic and health disparities in prices of medications and delves into different ways of ensuring equitable and equal access to essential drugs. In examining these disparities, we take a look at issues with drug pricing/shortages in medications for Autism Spectrum Disorder (ASD), ADHD, and Hepatitis C for a more well-rounded perspective. By advocating for overall policy reformation, this study aims to bring light to the issue of drug pricing disparities and provide insight on potential solutions that can bring improved accessibility to necessary medications for all Americans within the United States of America.

DISCUSSION

The majority of individuals within the United States have had to get prescriptions for their illnesses and have been met with shockingly high prices. The disparities in drug pricing within the United States affect an extremely high number of individuals. In the article "The high cost of prescription drugs: causes and solutions" by S. Vincent Rajkumar, in 2020 alone, nearly $1.3 trillion was spent worldwide and $350 billion was spent in the United States on drugs, and these numbers are expected to increase anywhere from 3 to 6% globally [5]. It is no surprise that almost 25% of Americans struggle to afford prescription drugs due to high out-of-pocket costs. There are a multitude of reasons behind these high prices which include: a monopolized drug market, the severity of the disease at hand, and the high cost of developing these medications. The drug market is a monopoly because there are not many alternatives for high-cost prescription drugs, as generic brands do not emerge fast enough to counteract the effects of such monopolies. When it comes to the severity of the disease, the high price of the drug is not the initial thought for individuals struggling with the disease, individuals will pay any price to survive. Finally, the high cost of development is because it takes a minimum of twelve years for a drug to get to the final stages of approval, costing nearly $3 billion. Only 10-20% of these drugs successfully make it to the market [5]. On top of that, nearly $220 billion is spent by these pharmaceutical companies on lobbying. Rajkumar provides many solutions within this article to counteract the disparities in the drug market [5]. Some of these solutions include global policy changes, faster

approval of generic drug brands, putting a cap on prices, and compulsory licensing. This article provides eye-opening statistics for great solutions that should be taken into consideration to make drug prices more affordable for the average individual. Hopefully, the necessary changes can be made so people can get life-saving and pain-relieving medication without the stress of whether or not they can afford it.

A means of combating these exorbitantly high drug prices can be achieved through integrated health-system specialty pharmacies (IHSSPs), which are pharmacy services specialized to provide care for those requiring specialty medications, and treating rare and complicated diseases. Their counterparts, Limited Distribution Networks (LDNs), remain present as they help ensure product integrity by limiting which pharmacies can distribute medications, as well as financially benefiting the manufacturer. However, LDNs slow down medication access and affordability for the patient. In a study conducted by Megen E. Peter and his research team called “Exploring healthcare providers’ experiences with specialty medication and limited distribution networks”, they analyzed the experience of fourteen healthcare providers qualitatively, contrasting IHSPPs to LDNs [4]. They found areas of comparison within three categories: impact on workflow, practice, and patient outcomes. Primarily they concluded that IHSPPs streamline patient access to medication, as clinical pharmacists and pharmacist technicians are familiar with the specific requirements needed for the distribution of each medication, thus the required paperwork can be completed efficiently. Other issues such as delays in medication shipment as well as confusion of medication availability are also avoided. In addition, IHSPPs can often reduce costs for the patient, and in some cases using various clinical management protocols can even facilitate free medication storage, access, and fulfillment depending on if the HSPPs are in the distribution network [4]. Finally, when an IHSSP dispenses a drug, a dedicated pharmacy team can help patients who express a need for financial assistance programs, which is extremely beneficial as it is quite difficult for healthcare providers to obtain all of the knowledge for each medication’s respective financial protocol. Thus they, as well as the American Society of Healthsystem Pharmacists, concluded that to combat disparities within specialized drug pricing, there must be increased collaboration between hospital pharmacies, payers, and manufacturers to promote access to LDNs. This would be achieved via medication affordability assistance programs and a more clarified LDN criterion. Finally, more IHSSPs

should be integrated as they optimize the experience for patients and doctors by minimizing costs and allowing for more support within the explanation of financial assistance programs.

As we discuss the topic of drug pricing disparities and the fundamental government and pharmaceutical issues behind it, it is important to consider and discuss individuals who suffer from these high, unmanageable prices. For example, as rates of youth populations prescribed psychotropic drug classes rise, the necessity of lowering federal health insurance costs becomes increasingly urgent. Youth with Autism Spectrum Disorders (ASD) are a vulnerable population of prescription drug users due to the high rate, variability, and cost of prescribed medication [2]. Understanding multi-drug regime affordability and accessibility has critical implications for the mental, behavioral, and developmental outcomes of individuals with ASD. A study by the Medical University of South Carolina found that between 30 and 60 percent of youth with ASD are prescribed psychotropic medication, while 50 percent of this subset are prescribed 2 or more major drug classes [2]. Total pharmacy costs were found to be high among older children prescribed psychotropics, however, younger children may face more side effects. Older children are more likely to refill or obtain new prescriptions to account for the complexity of the condition, necessitating high financial input for families. While the use of prescription medication and associated costs is likely to vary by age among children with ASD, 20 percent of those in a Medicaid-eligible population taking psychotropic medication were taking 3 or more classes. Coupled with ASD youth facing higher medical costs and expenditures than those without ASD, youth on Medicaid require equitable medical consultation and prescription costs. As national psychotropic drug use increases, an evolved approach to federal drug prices must incorporate data from frequent users, and high-risk populations, such as youth with ASD. Methods for documenting ASD youth medication history, particularly those on Medicaid or federal insurance, are critical to targeting systemic inequities of prescription drug costs.

On a similar note, ADHD is a neurodevelopmental disorder characterized by patterns of inattention, hyperactivity, and impulsivity [3]. Stimulant medications, such as methylphenidate and amphetamine salts, are the cornerstone of ADHD management, significantly improving the quality of life for many patients. However, recent years have seen a growing disparity between the demand for these medications and the supply, leading to widespread shortages. This paper seeks to understand the causes of these shortages, their impact on patients and healthcare providers, and to explore viable solutions. The shortage of stimulant medications can be

attributed to several factors. First, there is an increasing recognition and diagnosis of ADHD in both pediatric and adult populations, leading to a higher demand for treatment. Additionally, the controlled nature of these substances, due to their potential for abuse, imposes strict regulatory limits on production and distribution, constraining supply. The COVID-19 pandemic has further exacerbated these issues, disrupting global pharmaceutical supply chains and increasing mental health burdens, thus amplifying demand for ADHD medications. For healthcare providers managing it has led to an increase in administrative burdens and they have to give their patients alternative treatments that are often not the best.

Due to higher usage of new drugs, drug spending in the U.S. has become much higher than other industrialized nations. “Drug pricing & challenges to Hepatitis C treatment access” by Brandy Henry, uses Hepatitis C as a case study to understand how emerging biotechnology leads to problems in high healthcare costs and limited access to care. Among the leading causes of death in the U.S., chronic Hepatitis C affects over 3.7 million people. In 2013, the FDA approved two new biologics, Sovaldi and Olysio, that combined with other drugs, make a comprehensive antiretroviral treatment. Sovaldi has a cure rate of over 90% and is effective across multiple of the six different genotypes of Hepatitis C [1]. The problem lies in the price and large number of people being prescribed Sovaldi. Because the price of the drug is so high, $1,000 for one pill or $84,000 for the entire 12 week treatment, insurers are denying coverage or making specific, documented requirements to qualify for coverage. Additionally, Medicare and Medicaid are becoming more restrictive on coverage, making access more restrictive than what is recommended by professional organizations. Olysio is even more expensive, around $23,600 per month of treatment, and treatment typically lasts six to eight months. These extremely expensive drugs are not affordable; the cost to treat the entire Hepatitis C population would be $310 billion, while total spending on all drugs in 2014 was $360 billion [1]. Spending on Sovaldi in 2014 made up 78% of all Hepatitis C antiviral drug expenditures. Henry gives multiple proposals for solutions to make these new Hepatitis C treatments more accessible and affordable, including price negotiations, prior authorization, direct-to-consumer advertising limits, decreased patent lengths, and easing restrictions on importations. Henry describes many potential flaws with some of these solutions. For example, easing restrictions on drug importations has flawed logic because 86% of drugs sold in the U.S. are manufactured abroad, meaning the U.S. is purchasing drugs abroad and paying more for them. Ultimately, Henry recommends a balanced approach:

sensitive employment of preauthorization to limit high costs of treatment for those that need it, insurance price negotiations, clearing the FDA backlog of drug approvals, enforcing limitations on direct-to-consumer advertising, reducing patent lengths, and increasing insurance coverage and making innovative plans for individuals with Hepatitis C (30% of individuals with Hepatitis C are uninsured). While this is a comprehensive study on the detrimental effects of high drug costs on healthcare spending and access, it is very specific to Hepatitis C drugs, leaving room to wonder how other high-cost drugs fall into this problem. Additionally, Henry recognizes successes and flaws to her proposed solutions, but they seem to be limited to Hepatitis C and may not apply to all diseases, for example those that affect a much smaller population. This leads to questions on how this model and case study can be applied more broadly to the general issue of high drug costs. In case studies like these, are there drawbacks to looking solely at one disease? Next, the general, most popular causes of high drug prices must be looked at, and a comprehensive plan for a solution should be created, similar to how Henry did so in this case study. Progress is already being made with the Inflation Reduction Act passed in 2024, allowing for increased coverage by Medicare on prescription drugs and capped costs for these drugs.

CONCLUSION

Costs of prescription drugs in the United States are at an all time high, which poses a significant barrier to healthcare and medication access for a multitude of individuals, especially those suffering from long-term disease/disorder or low-income individuals. The monopolistic nature of the pharmaceutical industry, long and unbelievably expensive development process, and the extreme nature of diseases all contribute to these high costs. This paper aims to highlight intrinsic issues within the government and pharmaceutical industry as it dives into specific diseases and disorders like ASD, ADHD, and Hepatitis C, and how individuals who struggle with these diseases/disorders face a plethora of issues as the prices of their much needed medications begin to rise. To combat these issues, advocating for policy reform and collaboration amongst stakeholders are the essential first steps in reducing drug pricing disparities across the United States. Accelerating the approval of generic drugs and implementing price ceilings to prevent high prices are just two of a multitude of solutions that could bring peace to those struggling financially. By addressing these disparities, we can move towards a healthcare system where necessary medications are accessible and affordable for all,

ensuring that every individual is allowed access to essential treatment without the risk of high-cost preventing that.

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