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Social Entrepreneurs in the Pharmaceutical Industry: The Catalyst That Finally Drives Down Price?

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ABSTRACT

The cost of healthcare in the United States is notoriously expensive. In recent years, social enterprises and nonprofit organisations have begun flooding into the market to try and stem the rising costs. I perform a case study on two prominent social enterprises and analyse the challenges they're facing and the implications of their work. I requested an interview from a key figure within each respective organisation to gain a better understanding of their perspective. The companies are at polar ends when it comes to company growth, with one being a startup company that is just beginning to grow into its name and the other an already well-established firm. I provide overviews on each respective firm and compare their challenges and company goals. A better understanding of the pharmaceutical market led to suggestions of potential solutions to the problem of high healthcare prices in the form of patent reform and negotiation committees.

Introduction

Healthcare in the United States is considered to be one of the most expensive in the world. The average wealthy country spends half what the United States spends on healthcare per capita, at $5,000 compared to $11,000 (Wager, 2022). Major media sites and healthcare professionals have clamoured for a reduction in prices, claiming an inability to afford medicine has drastically altered the reputation of pharmaceutical companies within the medical landscape (Kessel, 2014). These high prices have markedly affected the average consumer/patient. Many lower income families are unable to afford to pay hundreds of thousands out of pocket in addition to basic living expenses. As such, many Americans are having to look elsewhere for potential (and perhaps not as effective) alternatives. Some have even taken to crossing the border for more affordable medication. For instance, the Minnesota 'Caravan' of Americans drove a couple hundred miles to Ontario for more affordable medicine (Da Silva, 2019).

Due to the soaring prices of medicine, nonprofit organisations and social entrepreneurs alike have entered the market to try and find a way to bring costs down. Companies such as NP2 and Civica Rx have managed to think of ways to integrate themselves into the market in a way that could effectively bring about institutional change. By providing lower cost drugs that are in greater demand to an already predetermined list of buyers, these social enterprises can compete with some of the for-profit organisations to lower prices nationwide.

In an effort to delve into the heart of the issue, I decided to conduct a comparative analysis of two organisations that are trying to solve the problem. This paper will provide case studies for the social enterprises and then contrast the circumstances they find themselves in. I will go over the challenges they might be facing and the ways in which they might both be able to contribute towards solving the issue of overpriced medication. The paper is structured in the following manner: I first provide a literature review to introduce the context surrounding the high costs of medicine as well as what social enterprises are and what their role is in this particular market. I will then go into individual case studies for each company and then begin comparing the similarities and differences of the two organisations. The paper will end with a discussion of potential solutions (possible government-implemented strategies and commercial contributions), and then I will conclude by summarising the paper and emphasising the impact the companies have on the market.

Healthcare in the United States

The United States is renowned for their expensive prescription medications, seeing that patients in the United States pay 2.5 times more than any other Western country (Goldman, 2018, Lowe, 2010, Mulcahy, 2021). The United States spends about $350 billion of the world's annual $1.3 trillion on healthcare (around 27%) while only purchasing slightly over one twentieth of the volume (Mulcahy, 2021). The US is forced to compensate by diverting funds from places where it might be needed more. In 2020, they spent 19% of their national GDP on healthcare (Ortaliza, 2022). A recent report came out by the RAND Corporation, a nonprofit research organisation, stating that generic unbranded prescription drugs account for nearly 85% of the USA's purchased medication but only make up 12% of its total spending (Mulcahy, 2021). Surprisingly enough, this number is lower in the US than in various other countries (Mulcahy, 2021). It is largely the brand-name drugs that drive the high prescription prices in the US, leading to a number of questions being directed towards the large drug brands (Mulcahy, 2021).

Pharmaceutical companies have come forward to say that the Research & Development (R&D) costs for the production of new drugs is extremely high, and the prices of the marketed drugs will help cover that. They stated that the US leads the world in drugs discovered (40-50% of drugs discovered every year come out of the US) (Emmanuel, 2019). They explained that the profits from over-the-counter drugs they sell goes into making more innovative and effective medicine that would garner huge social benefits (Emmanuel), 2019. Another factor that goes into their pricing plans is the cost of development for these new drugs. On average, development is carried out over a minimum of a 2-year period, costing over $2 billion for every new drug brought to the market (Emmanuel, 2019). The drug production market is also extremely competitive, success rates are between 6-9% through the five stages of development (Emmanuel, 2019). With the miniscule number of success cases, the high prices help compensate pharmaceutical companies for their losses. Without this type of compensation, companies would have no incentive to innovate.

Reporters and analysts who have expressed scepticism of how transparent pharmaceutical companies are with what goes into the high prices of their drugs have performed research of their own. Some reports show that pharmaceutical companies only spend around 17% of their profits on the R&D of new drugs (Emmanuel, 2019, Blumberg, 2019). Medical experts have claimed that a large majority of the drugs that come out of the US are only made for 'profiteering.' The drugs are merely slight alterations of previous success cases to maintain patent ownership and increase prices. Reporters have also claimed that the figure pharmaceutical companies use for the cost of development is greatly exaggerated; that is, several experiments show that the number is closer to about $600 million compared to the stated $2 billion. Of the drugs that do fail, 40% do so in the first stage and another 40% fail in the second, costing under $25 million and $60 million respectively (Emmanuel, 2019). While this means that very few drugs make it to the market, a large majority of them fail at relatively cheaper stages.

A lack of governmental regulations has been acknowledged as one of the primary reasons for the constant price hikes (Kliff, 2016, Rajkumar, 2020). Other countries have specific agencies or committees dedicated to making sure that the drugs that enter the market are worthwhile (whether or not they can be objectively considered a distinct mark up from the previous iteration) and make sure that the price is not set too high. The United States government does not regulate or negotiate over the prices of newly manufactured prescription drugs, allowing drugmakers to set the price as high as they want so long as the drug proves safe and effective. Other countries see medication and healthcare as a public utility, a necessity. So what has the US government done?

The oldest acts are the Medicare and Medicaid programs, created fifty or so years ago to help provide medical insurances to lower-income families, senior citizens and the disabled. Yet the programs have not been as effective as they used to. Issues like medical cost sharing and expensive medical insurance have crippled the programs to the point of deficiency. They created the Affordable Care Act (ACA, colloquially referred to as ObamaCare) in 2017 to help Americans gain better access to and be able to better afford medical insurance. It provided the lower-income families with subsidies and expanded the Medicare/Medicaid programs ("Affordable Care"). One of the provisions in Biden's 2022 Build Back Better Act would attempt to allow the government to negotiate prices with some pharmaceutical companies and expand the Medicare programs to try and eliminate cost-sharing for the drugs in higher demand.

The expensive nature of prescription drugs is detrimental to the medical welfare of many patients. Families are forced to choose between purchasing the prescribed drugs and other essential human needs. People taking prescription drugs found that they were being forced to "cut back on groceries, delay retirement, […] take on a second job, […] even rationing or stopping their meds" (Gill, 2018, Sanchez, 2019). A recent study showed that around 30-42% of American adults have been unable to take the prescribed medicine due to an inability to afford the drug (Hamm, 2020, Kirzinger, 2019, Sanchez, 2019). Professor William Stauffer said, "dramatic drug price increases lead to much higher outpatient costs and decrease appropriate drug treatment due to access issues and healthcare professionals switching to a substandard drug" ("New Evidence", 2021). A study in 2016 showed that even insured patients have been shown to skip prescriptions, a startling 14% (Blumberg, 2019). Uninsured Americans were worse, almost three times the percentage having to skip treatment (Blumberg, 2019). Over a fifth of the average American's insurance bill is dedicated towards coverage of prescription drugs. All of this means that patients are unable to take the medicine they're prescribed or receive the healthcare they might desperately need.

These issues have attracted global controversy, and organisations in different sectors have endeavoured to seek solutions or ways to root out the problems. Patients and consumers have sought to appeal to the pharmaceutical companies and even petition their respective governments. In an effort to take the matter into their own hands, social entrepreneurs have injected themselves into the market to try and do what they can for this industry.

Social Entrepreneurships

The word 'entrepreneur' is tied to words like 'corporation' and 'commercial,' bound to a narrative of profit and ambition in the business world. The media has begun to shine a light on the pursuit of profit over social welfare in a variety of industries, and such behaviour has turned many off towards the concept of entrepreneurship. The upsurge in social problems that society is facing today has made inventing innovative and effective solutions extremely valuable. A niche for those dedicated to bettering the welfare of society has thus been crafted in the business world, a way for the 'Steve Jobs' of the world to work towards more sustainable solutions. As a result, the field of nonprofit organisations and social entrepreneurs is blooming, attracting no small amount of attention.

The definition of social entrepreneurship is somewhat elusive, especially considering the prominence of nonprofit organisations in the business world today (Tamara). A common misconception is that nonprofits and social enterprises are one and the same. But being that the definition is not something objective, but rather irrespective of how an individual perceives their targeted industry, the numerous businesses under this umbrella have interpreted the concept in their own respective ways.

Some say that social entrepreneurship is the marriage of commercial corporations with social values. Companies that would straddle the fence, using their business know-how to run a commercial business that still accomplishes social goals. For instance, renowned sneaker company TOMS has famously operated their one-for-one program to donate a pair of shoes to a child in need for every pair that they sell (Holman, 2021). The company dedicates a third of their profits towards causes like anti-gun-violence (Holman, 2021). TOMS isn't a nonprofit organisation but a large portion of their identity is dedicated to working towards social values. Another example is the Mozilla Foundation, a non-profit organisation that wants to ensure the internet stays a 'global public resource that must remain open and accessible,' formed a for-profit subsidiary: Mozilla Corporation (Mozilla Foundation, 2005). The Corporation would market their goods (FireFox and Thunderbird) as a taxable entity but all the profits would be infused back into the Mozilla Foundation, improving upon their ability to provide social benefits. The Mozilla Foundation is essentially a nonprofit organisation that utilises a for-profit to advance towards their socially responsible goals (Mozilla Foundation, 2005). These types of companies employ a slightly different approach to endeavour towards their socially beneficial objectives. This type of social enterprise is the most popular, allowing commercial companies to make money while still allowing them to advocate for a better world.

Social entrepreneurship has been perceived to be many different things. Some define social entrepreneurship as the ability to find solutions for social problems through more unconventional methods. This particular definition is

based primarily on the idea that social entrepreneurs innovate for the sake of the betterment of society, that they exist outside the realm of a normal market (Dees, 1998). Others see social enterprises as a catalyst for change. Companies that look at the way the market operates and identify the best way that injecting themselves into the system could induce positive change. These types of organisations seek to completely shift the social context surrounding the industry, resulting in large-scale sustainable social transformations (Ashoka).

Regardless of how an individual defines social entrepreneurship, the focus of a social enterprise is always on the betterment of the industry through an emphasis on social values. Any organisation that applies business-like principles towards maximising improvement for the well-being of any industry, be they for-profit or not, can be considered a social enterprise. Social entrepreneurs help to introduce newer and more innovative ways of thinking into the business world, opening up additional avenues of opportunity.

The wave of nonprofit organisations in the pharmaceutical industry started prior to the Second World War, in the late 19th century (Fox, 2015). Voluntary hospitals, or nonprofit/charity hospitals, were incorporated to admit those who could not afford to be admitted into public or private medical institutions (Fox, 2015). The demand for treatment from the voluntary hospitals began to eclipse their ability to supply quality healthcare, and so they turned to the federal government (Fox, 2015). Their petition for subsidies with minimal governmental oversight was granted (Fox, 2015). During and after the Second World War, the government began funding nonprofit medical academic institutions, in order to train doctors and physicians quicker (Fox, 2015). Eventually, around the implementation of Obamacare, nonprofit drug manufacturing firms began entering the market, seeking to drive prices down (Fox, 2015). The firms would enter the market and offer up lower priced alternatives, being utterly transparent with what went into pricing their product. It would provide competition for the other for-profit pharmaceutical companies, forcing them to lower prices to compete with the nonprofits.

In an effort to learn more about social entrepreneurs in the pharmaceutical industry, I conducted research to examine the impact of their role in this particular market. I thoroughly researched the pharmaceutical industry to identify the major nonprofit and social enterprises. In trying to conduct case studies of several of the key players, I requested interviews with the companies that responded to my inquiries.

Methodology

The research for this paper majorly consists of two parts: a literature review and interviews with an accompanying analysis. The former entails a deep web search of various academic journals and popular news websites in order to compile a list of numerous contrasting opinions of which to write a literature review. The other is more of a qualitative research collection where I reached out to people of interest to interview for more information.

In order to get to the interviewing stage, I had to first identify who I would like to interview. I sought to identify ten organisations that would best be able to provide answers to questions that support my research question. I researched companies in different geographic locations, with different ways of achieving similar goals and at different stages of development to ensure a broad array of answers that I might receive. So long as they were a non-profit organisation in the pharmaceutical industry seeking to target the high costs of medicine, I decided to reach out to them. I emailed all ten organisations. After two follow-ups and a month of waiting, two of the ten organisations got back to me, willing to talk to me on a Zoom call. Before each interview I conducted some background research and made sure to have at least a page of notes on the organisation and the person I was interviewing. I drafted an interview protocol, focusing on topics like their recent growth, the challenges they'd faced and what solutions they'd used.

I first contacted Civica's senior vice president and leader of public policy, Allan Coukell. He joined Civica in the beginning of 2020 after acting as a senior director of the health program at Pew Charitable Trusts, a nonprofit policy and advocacy organisation, for 11 years in Washington DC. I spoke with him for about a half hour, delving into the topics that might not be easily available on their company's page and popular media sites.

I then interviewed NP2's CEO, William Buhles, PhD. In that interview, he detailed his medical background, "I spent my career running clinical trials and doing late-stage drug development for several pharmaceutical firms

primarily in the clinical area of cancer and infectious disease…I was in the pharmaceutical industry from 1978 through the early 2000s and then I retired until 2013, working until 2016 before retiring a second time. In 2019 I became the co-founder of NP2." He worked as a pharmaceutical R&D scientist for around 25 years, for big names like the FDA and European Union. I interviewed him for around 45 minutes, trying to best understand what was going on in his company and to listen to some of his personal insights.

After asking for their consent, I recorded the interview, took notes, and remained an active listener and engaged interviewer throughout the duration of the interview. When I finished conducting the interviews, I spent a few hours transcribing each interview so that I would have the full script to analyse the data (interviews and notes). I used this data to support my analysis in the case studies of the two companies.

Overview of Civica Rx

Civica Rx was founded in 2018 to combat nationwide mass drug shortages. Former Parenteral Drug Association chairman on the board of directors Martin Van Trieste partnered with a consortium of US hospitals to form a nonprofit organisation that would supply a steady stream of accessible and affordable drugs directly to the hospitals (Person, 2019). The drugs would be produced on a need-to-make basis, preventing wastage of resources while simultaneously competing with some of the more highly-priced drugs that served similar purposes. In an interview with the Senior Vice President, Allan Coukell, he said "Civica was created to solve a specific problem, which was drug shortages. There are drug shortages in multiple settings, but the biggest ongoing problem has been sterile injectable drugs, which are mainly used in hospitals." Additionally, with many previous nonprofits failing due to their inability to keep the drugs out of their competitors hands (nonprofits would sell their goods at a lower price and other companies would buy it and resell it with large profit margins), Civica's method would maximise efficiency.

Over the past few years, Civica has grown into a respectable competitor in the pharmaceutical market. They initially sought to produce 14 of the drugs in highest demand in their first year, yet managed to finish the year with 18 different types of drugs in circulation (Person, 2019). Coukell was especially proud of their growth in recent years, stating "we went from a single product in early 2019 to 55 today."

They've currently managed to partner with over 55 hospital systems, accounting for nearly 1500 hospitals and around 33% of all licensed hospital beds in the United States (Civica Rx, 2022). Civica Rx's outreach is extensive, being able to make medical care more efficient and affordable for many patients. All in all, they've treated over 24 million patients to date, more than 55 million vials of the 55 sterile injectable drugs they've produced available in the market (Civica Rx, 2022). Civica Rx has also recently created a new operating branch: CivicaScript. Where Civica Rx would deal exclusively in providing injectables to hospitals, CivicaScript would focus on lowering the prices of prescription drugs dealt in pharmacies. They'd both be contributing towards lowering the cost of drugs in the healthcare system but on different fronts. CivicaScript would hopefully be able to develop and produce 6-14 new prescription drugs by 2022 (Civica Rx, 2022, "CivicaScript", 2021). Coukell stated that, 'We are specifically focused on getting all those savings to the patient and bringing prices down'.

Civica Rx found that they were well suited to deal with all that the pandemic brought. Being a company that dealt with drug shortages, the pandemic did exactly that. Drugs that specifically alleviated lung problems or drugs that were used in unison with ventilators found demand skyrocketing by 300% overnight. However, Civica kept a physical stockpile of several month's supply of all their drugs, and could easily accommodate the excess demand. Coukell voiced that they prided themselves on their ability to respond to the crisis, saying, "That was a good validation of the Civica model […] We have tracked ahead of initial projections since the beginning. We've been able to produce more drugs at a faster rate, recording more sales faster than even the most optimistic projection when we first announced."

A majority of the challenges that Civica faced were in the administration department. Seeing that they've managed to get to a point of consistent production, a majority of their work consisted of making sure that the manufacturing procedure ran smoothly, that the transportation ran without a hitch, and that all the workers knew what their

roles were. Coukell listed, “supply chains and a model of a lack of transparency in prices in the retail sector” as some of the challenges that they faced on a daily basis but wasn’t something that worried them overly much.

Civica Rx is a company with ambitious goals that has managed to exceed expectations on many fronts. They are in the process of building a multi-million dollar manufacturing facility in Utah to speed up the process and cut down on the per-unit costs of each drug. Coukell spoke to the benefits of building such a facility, “As our new manufacturing facility comes online, we'll have the ability to be more nimble in the drugs we make and also more cost effective in the drugs we supply.” Civica Rx hopes to continue to build upon their success by improving on their existing products and developing additional quality products while CivicaScript looks at getting their first products into the market soon. As Coukell said, ‘the trajectory is upwards’.

Civica is one of the most successful nonprofits/social enterprises in the pharmaceutical industry. They have garnered attention from all around the nation and developed a broad consumer base. Contrarily, there are some firms that have only just begun to enter the market, a vast contrast to a well-established firm like Civica. NP2 is one such startup company that is looking to entrench themselves in the biotechnological industry.

Overview of NP2

In late 2018, Dr. William C. Buhles, PhD came out of retirement for the second time to head a nonprofit organisation with former coworker and friend, Dr. Jacob P. Lalezari, MD. Dr. William Buhles worked as a pharmaceutical scientist for over 25 years, running clinical trials and late-stage drug development procedures to treat diseases like cancer from 1978 to the early 2000s. Dr. Buhles mentioned that being able to work as a scientist developing drugs/cures for life-threatening diseases was a huge honour, an immensely gratifying profession. He found himself doing the same work at the behest of various different companies, and wondered if he could turn that same work towards a more socially responsible cause. ‘Something as important as life-saving drugs shouldn’t be left up to for-profits,’ he remarked.

The two of them found that the high prices of drugs in the United States dramatically impacting the populace combined with the fact that drug prices were much more reasonable all throughout the globe made them want to form a nonprofit organisation that would help remedy this issue. They decided to favour injectable generic drugs, since “to develop generic solid oral dosage forms, tablets or capsules, you need to do a human pharma kinetic study to show that your generic drug is equivalent to the reference drug. In terms of an injectable, intravenous infusion type drug, you don't have to show that.” Dr. Buhles and Lalezari’s expertise in cancer treatment turned their attention towards anti-cancer specific prescription drugs to start off with. And thus, NP2 was formed.

NP2 is a startup nonprofit organisation that plans on developing, manufacturing and selling life-saving generic drugs at a constant rate below the market price. They were founded in 2019 specifically to treat people suffering from cancer. The profit from their sales would go directly into providing more research & development for safer/more effective treatments and manufacturing cheaper (but still quality) drugs. As a startup company, their growth has been limited, especially with the emergence of COVID-19. NP2 is still in the manufacturing and developmental phases, still trying to grow the organisation and develop relationships with working partners. According to Dr. Buhles, “we’re not gonna grow significantly until we get a drug on the market”, after which funding will be able to orbit primarily around revenue from drug sales. Over time, they hope to be able to develop and produce one drug every year over the next four to six years. They intend to collaborate with other nonprofits and for-profits to develop drugs and provide them to cancer treatment facilities. Potential partnerships have already been in the works, looking at oversight committees and purchasing licensing rights for some drugs from several for-profits. Their goal is to eventually be able to grow to the point that they’re a fully functional pharmaceutical company that is able to produce consumable forms of a variety of medicine and also develop a unique (specialist) drug.

Dr. William Buhles came forward to say, “The biggest problem has been raising funds. For profit biotech companies can go out and get investor money through a venture capital firm or get loans with the promise of a high return. And we can't do that.” Their competition, for-profits, can make a lot of money simply based on their large

profit margins, luring in many investors. Thus far, the company has managed to survive on donations and gifts from foundations but the emergence of the coronavirus a mere 7-8 months after their initiation confronted the company with another roadblock. Nonprofits have to work very hard to get the proper funding that is needed to run the company, and people who used to donate sizable chunks of money were now donating it to COVID related endeavours. Fund-raising became even more difficult because meeting someone remotely made the meeting a little bit more impersonal, preventing the company from making a deep connection with donors. Additionally, the imposition of the coronavirus took both resources and time away from medical institutions, preventing NP2 from getting the backing they had been hoping for from that sector. Dr.Buhles also pointed to the fact that "tax laws / IRS laws are not particularly friendly to nonprofit pharma companies as we operate". Their unique mission and methodology meant that they lacked the necessary surrounding policies to maximise their company's efficiency. The issue of transparency, especially when taking into consideration the risk of manufacturing high risk drugs, is also one that NP2 has found itself deliberating over. To get the necessary proprietary coverage would mean sacrificing the transparency of their prices, which would run contradictory against their mission. As a whole, there are a few problems that are hindering the rapid growth of NP2 as a company, but their status as a startup provides them with some time to talk things over.

NP2 hopes to grow their financial resources as time goes on, but the imposition of tax laws and regulations that limit how much a nonprofit can receive is the major roadblock in their fast track to success. With the virus setting them a year back in their two year process of drug development, NP2 hopes to be able to get their first drug out into the market within the next year, a sure marker for optimistic growth. Dr.Buhles said in his interview, "It's crazy, this has been my dream for so many years and what's interesting is that so many other people have had the same dream."

NP2 is considered a startup in the industry and is still in their developmental stages, hoping to quickly get to the point where they can truly begin contributing towards their goals. They are well on their way to producing their first injectable. In relation to the other firms within the industry, NP2 is much less established, especially compared to Civica. Due to the disparity in their growth, the two companies face different circumstances and challenges.

A Comparison of the Two Organisations

The disparity between startups and the more well-established firms is substantial; the startups are unable to generate revenue through sales or contribute goods to the market while the more established firms can actively compete with the other for-profit organisations in the industry. Within the social entrepreneurship sector of the pharmaceutical industry, NP2 and Civica Rx exist at opposite ends of the spectrum. As a trailblazing leader, Civica quickly gained funds and established itself as a dominant competitor in the market. Contrarily, NP2 is a startup company that is still near the beginning of their developmental stages. As such, while the two companies may boast some similarities, the circumstances and challenges they find themselves faced off against are completely different.

NP2 and Civica Rx were both created with the idea of curbing high drug prices and mitigating the effects of massive drug shortages across the nation. Especially when compared to the prices of drugs in other nations, where the government has the ability to negotiate prices down. And thus, when this particular free market system in the U.S. did not correct itself, social entrepreneurs got together to make sure that hospitals and treatment centers got the steady supply of essential drugs that they needed for a low price. NP2's mission then branches a little from Civica, in that NP2 decided to focus on manufacturing drugs for cancer patients. The CEO of NP2, Dr. William Buhles, said in a recent interview, "We've decided to target the cancer area because we want to work in an area where we are developing drugs that are life changing, life extending and life saving." NP2 has since partnered with 63 national cancer institute-funded treatment centers, hoping to soon be able to begin supplying them with cheaper alternatives that are just as effective (NP2, 2022). On the other hand, Civica Rx focussed more on the general supply of sterile injectable drugs to hospitals as a buffer against future drug shortages. Senior Vice President of Civica Rx, Allan Coukell, classified Civica Rx as being "created by hospitals for hospitals." They've also recently formed a new operating branch named CivicaScript, designed specifically to counteract the cost of generic drugs in pharmacies, targeting health plans. Coukell explained how CivicaScript came to be, "A number of health insurers came to us and said, can you help solve

the cost problem in retail pharmacy? We're focused on cost, still looking at generic drugs, but looking at products where the prices have not come down the way they should in a competitive market." Thus, in terms of their individual missions, NP2 prioritises the treatment of cancer patients through treatment facilities by developing life-saving drugs at a lower price. Civica Rx seeks to prevent drug shortages and ensure that generic drug medications are accessible and affordable to all patients in need.

The largest contrast between the two companies is in relation to their company growth and the challenges that each company has needed to face thus far. Civica Rx was founded nearly two years before NP2, which allowed them to get their drugs out into the market prior to the emergence of the global pandemic. NP2 came to in late 2019, which was just around the corner from the pandemic. In the year since their founding, NP2 has continued to progress in their manufacturing process, made partnerships with other companies and managed to establish their legal credibility as a nonprofit in the US. Dr.William Buhles commented on their growth in his interview, "It's been limited because we've mostly been in the pre manufacturing, pre-development phase. And I would say we're not gonna grow significantly until we get a drug into the market." Civica Rx is one of the most prominent social enterprises in America, having treated over 24 million patients and occupying 33% of USA's hospital beds, circulating 50 types of medication. They've partnered with over 50 healthcare systems, grown their personnel by 2000% and even built their own state of the art manufacturing facility in Utah. In his interview, Coukell was extremely positive about their future growth, stating 'the trajectory is upward."

The circumstances that each firm faced bred different challenges. As a startup, NP2 found that their largest challenge was their revenue. Both tax laws and COVID made fundraising extremely difficult for them, which severely hindered the developmental process of their drugs. Since the production of the drugs would be the catalyst for their growth, a lack of funding in such a critical stage could be extremely detrimental. NP2 stressed the impact of the coronavirus on their growth, Buhles stating, "The COVID epidemic probably put us back a year from where we would've been." While NP2 seemed to have taken a hit from the epidemic, Civica was remarkably unphased by the emergence of COVID-19. Being that Civica's mission was to prepare for drug shortages, ensuring that hospitals were well-stocked in cases of emergency was something Civica was well-prepared for. "We had an overnight surge of demand of about 300%, but because we had a physical stockpile of about several months' worth of drugs, we were able to supply the hospitals without interruption," Coukell explained. Coukell pointed to the fact that the majority of the problems that Civica faces comes from how well-oiled the machine runs (transporting drugs, dealing with the manufacturing equipment and so on) and competing with the lack of transparency on the for-profit front. Another thing was making sure that the prices of the drugs remained relatively constant along the supply chain, preventing the middle-men from raising prices along the supply chain. The challenges that NP2 and Civica face are problems that companies confront at two different stages in their development. NP2 is facing problems with getting sufficient funding to start up their company while Civica is primarily concerned with ensuring that their operation runs smoothly and efficiently.

The two organisations are at vastly different stages of development while still working in unison to better the social landscape in the industry. NP2 is focussed on improving treatment for cancer and Civica on combating drug shortages and high prescription/injectable drug prices. With NP2 being near the genesis of their organisation, the concerns and circumstances they're faced with are extensively different from that of Civica, who is more concerned with oversight of the drug distribution process. Therefore, how do these challenges differ or coincide?

Challenges Facing these Organisations

Most social enterprises in this sector of the pharmaceutical industry start off as nonprofit organisations. One of their biggest concerns are issues with fundraising. Dr. Buhles spoke to the process of developing and producing any drug, "[the process] takes two years and costs about 3 million to make an injectable generic drug." The manufacturers/scientists perform preliminary research, preclinical studies and clinical trials for over a year, attempting to make the drug as safe and effective as possible. After this period, the drug is submitted to the FDA for approval, during which the

FDA spends a year turning everything upside down in an effort to protect humanity's well-being. Over this period of time, the social enterprises are physically unable to contribute goods to the market. This means that the companies would be unable to grow significantly until they produce their first drug. Being that the developmental stages would occupy all of the firm's resources, most other avenues they'd pursue would not gain any traction until they complete the developmental process. As such, they request monetary aid from donors and healthcare institutions to help fuel their developmental process.

For many startups in this field, generating a steady flow of income would be difficult. As with every nonprofit organisation, raising funds is something that provides a major challenge. Investors buy stakes or invest in a company to rake in some form of return. For for-profit organisations, their very nature allows them to provide a decent return on their investments with interest, due to their ability to generate profits at the margin. I asked Dr. Buhles to comment on this in my interview with him. He said, "For-profit biotech companies can go out and get investor money through a venture capital firm or get loans with the promise of a high return. We can't." For nonprofit organisations, funds that go into their cause are only returned to the market in the form of a drug. With a lack of an expectation of a sizable return on their investments, the donors that nonprofit organisations seek to appeal to are the saints and the kindred spirits. Therefore, the companies have to survive on donations and gifts from foundations in order to remain adrift. Being that the startups are still in the manufacturing process, they cannot yet receive income from drug revenue. An inability to generate substantial donations would lead to stagnation or a deceleration in manufacturing the drugs, slowing company growth. A lack of monetary funding is a critical issue that many nonprofit firms in this sector face, and the emergence of the coronavirus only exacerbated that.

The coronavirus impacted both the startup and established firms in this sector. On the startups front, the fundraising process also took a hit. Dr. Buhles spoke to the challenges of raising money in the midst of a pandemic, "People who were able to make donations of a sizable amount were giving their money to COVID related endeavours." The coronavirus also shifted near every meeting to online platforms. The effect of only seeing someone through a screen meant that the potential for the two to strike up an interpersonal connection would have diminished. It made fundraising, which is primarily about appealing to the donor's personal side, a little more difficult. These combined effects resulted in a plunge in funds, correlating to a reduction in personnel. As such, the manufacturing process would slow down, meaning that patenting their first drug would have to fall later than their original plans. Company growth would slow and the time they could contribute to the industry would be pushed further down the schedule. For the more established firms, the effect of the coronavirus on the healthcare industry was a varying shift in demand. Some drugs experienced drastic spikes in demand while others fell to all-time lows. Established social enterprises that did not have a reliable stockpile of extra drugs sold out all too quickly. Coukell pointed out how some of the other pharmaceutical companies may not have been as prepared, "We do some things that are really different from a traditional manufacturer. For instance, we keep a physical stockpile (several month's supply's worth) of all our drugs." Mass inventory sellouts can lead to rushed delivery and negative perceptions of the company. Overall, be they a startup or an established company, most firms within this industry were impacted by the emergence of the coronavirus.

Issues with the supply chain is one such thing that has brought up some concern within several companies. Due to the many hands that touch the drug in order to get to the hands of the patients, the price may get progressively higher as the middle men try to garner some profit. Coukell mentioned that this is something that impacts a majority of the firms trying to succeed in this industry, "It's not in any way specific or special for Civica, but certainly part of the context that we're operating in now." Potential oversights and errors in the supply chain could lead to devastating ramifications, drugs being delivered or administered to the wrong patient or being lost in delivery. Being able to oversee the entire supply chain and ensure that everyone works towards furthering the cause is very important.

With all the challenges that these firms are facing, they are still resolute in their desire to work towards bettering the pharmaceutical landscape. Startups have had to face issues with generating steady flows of income, especially in the face of the coronavirus whereas the more established companies are primarily concerned with ensuring stability within the supply chain. In trying to restore equity to a crucial industry, they have been faced with a

variety of challenges. Yet they are not alone in their mission, for there are many other potential solutions that have been proposed.

Possible Solutions

Possible solutions that could help mitigate the issue of high drug prices in the United States include governmental and nonprofit action. To begin, comparatively, the United States' healthcare sector is suffering much more than other countries that have decided to allow their government some role in regulating drug prices; the prices of drugs in other countries appear (relatively) to be priced at a lower rate compared to drugs in the United States. Due to this fact, many have pointed to this issue being an easy fix so long as the government is willing to intervene (Feldman, 2021, Quigley).

One solution is governmental involvement through patent reform, which entails reducing the term of patents and discouraging companies from over-patenting by making minor modifications to existing drugs. Currently, in the medical industry, drug manufacturers file patents to protect their ability to innovate. It rewards successful inventions by allowing the manufacturers exclusivity in their selling rights for extended periods of time, essentially incentivising innovation through granting legal monopolies to enhance selling power. These patents typically grant drugs a monopoly over a couple decades, allowing the manufacturers to extend ownerships of their drug. Pharmaceutical companies have rebuffed any attempts at patent reform by stating that the patents act as reimbursement for the billions they lose in the innovation process. Some say that this is highly logical, that these patents incentivise pharmaceutical companies to continue to innovate while still making profits ("Why Patents", 2017). Yet others say that this goes against the nature of a patent– if you reward a company for their loss, does that not incentivise them to lose more (Feldman, 2021)? Patents also highly reward drugs that generate high profit margins. Patents disincentives companies from producing more generic drugs since they are typically cheaper even if the demand is higher. Therefore, pharmaceutical companies might prioritise developing expensive treatments for male-pattern baldness or erectile dysfunction, rather than addressing more widespread and dangerous diseases (cite). As it is now, the patent system is not without flaws. Introducing effective patent reform that promotes innovation while simultaneously fostering competition could help appease both opponents and proponents.

To prevent or mitigate this kind of patent abuse, the US government might institute a variety of measures, including strict penalties for those that openly guard their territory and prevent other companies from developing (potentially) more effective alternatives. For example, laws and legislation to prevent over-patenting, the practice of producing drugs with minute modifications to act as another buffer against competing firms, is one viable option. A lack of competition within the pharmaceutical industry is primarily accredited to the grants that companies have over certain treatments. Smaller pharmaceutical companies can rarely compete with the exclusivity over extended periods of time. By lengthening their patents, companies can extend the length of their monopoly over a certain drug and treatment. On a similar note, the time that manufacturers are granted to successfully launch a drug could be reduced, encouraging additional competition. In order to counteract the overproduction of highly profitable drugs in place of life-saving drugs, medicinal research and development oversight might be implemented (Quigley, 2015). This could help prevent companies from spending unnecessary time developing a drug with a higher cost that might not help as many people. The direction companies' trend towards could be redirected to manufacturing drugs that benefit those who don't have treatment for their ailments. For instance, incentives could be given to companies that push in the direction of life-saving research. Government funding, subsidies or awards could be given to those who give up their monopoly rights and work towards goals that are not profit-driven. Per this perspective, patent reform should prevent unnecessary monopoly rights to life-saving drugs and increase innovation that services public welfare over profit margins.

One of the most popular forms of resolution amongst the medical community is extensive government intervention in the form of a drug price negotiation committee (Feldman, 2021, Quigley, 2015). Governments across the globe, particularly those in the European Union, have demonstrated the point that the creation of ethics and negotiation committees would dramatically lower the prices of the drugs and increase the effectiveness of the drugs that do get

approved (Mulcahy, 2021). The creation of the program Medicare also introduced the non-interference clause, which prevents the government from negotiating with private parties in any form or fashion. However, nearly 90% of Americans oppose the non-interference clause and would wholeheartedly support government negotiations (Hamel, 2021, Kirzinger, 2019). Many different presidents have sought to fight against the clause, and to no avail. For example, U.S. President Donald Trump tried to introduce a Medicare negotiation bill that failed to pass, and U.S. President Joe Biden has been arguing the case for even a relatively limited amendment only to be rebuffed (Gazette Fact Checker team, 2021). A report showed that even with a small role in negotiating for lower prices, the government could save $117 billion over the next nine years (Gazette Fact Checker team, 2021). Looking at the results of such legislation in other countries, such as France and Germany, an introduction of similar legislation in the United States could also see similar results in a timely manner (Gross, Robinson).

However, government intervention through patent reform comes with several disadvantages. In 2019, according to the Pharmaceutical Research and Manufacturers of America, the United States spent over $80 billion on research and development (Austin, 2021). Just under 50 novel drugs were approved by the FDA in 2019, meaning that, on average, each successful drug costs an astronomical $1.5 billion to develop (Center, 2020). In order to make these large investments worthwhile, companies would endeavour to maximise their profits. Without functional patents in place, other companies could effectively swoop in and steal the finished product. A company would not feel such a large investment necessary if they could shuffle some revenue away from other companies. An industry that operates in this way would practically cripple innovation. In terms of the institution of a government negotiation committee, that would add even more time to an already extensive drug production timeline. The manufacturing of a drug takes two years at minimum, factoring in the year-long FDA approval process. Having to go through another regulatory procedure in a country that leads the world in drugs produced would add to painstakingly long wait times. In justifying the lack of drug-related regulations in the United States, FDA counsel Thomas Miller reasoned, “There are three reasons that prescription drug costs are higher in the U.S. than in other countries. One, we have a multi-payer insurance system with several intervening entities each taking a margin; two, the government does not set ceiling prices in the U.S. like they do in other countries; and three, marketing exclusivity periods for patented innovator drugs” (Curley, 2021). As per FDA counsel Miller’s statement, the United States government recognises what keeps the prices high. Implementing patent reform to reduce the impact of the marketing exclusivity periods would be a major factor in driving prices down.

Within the business world, nonprofits and social enterprises have introduced reduced drug prices into the market, causing larger pharmaceutical companies to have to lower their prices to compete; however, more like-minded nonprofits would need to be involved to introduce a sufficient level of competition into the market that substantially drives prices down. Prior to the rise of popularity of nonprofit organisations and social entrepreneurs, for-profit organisations had extensive bargaining power. The for-profit organisations were able to monopolise on their goods, preventing new entrants or ambitious competitors from encroaching upon their territory. However, the rise of nonprofits and social enterprises began to nullify that. Hospitals, medical clinics and treatment centres strongly disliked having to depend on the for-profit organisations to supply them with drugs. Being a profit-driven firm, the emphasis is on reaping large sums of revenue, not so much on making sure that everyone gets the treatment that they need. As such, drug shortages and unaffordable prices were abundant. The medical institutions were eager to make a deal with nonprofits who were devoted to the same goals they were. The social enterprises gained near exclusive access to the medical institutions, and the for-profit organisations suddenly gained competition. As of now, the nonprofits and social enterprises are not in large abundance. With the type of radical change these nonprofits are trying to achieve, a large number of like-minded individuals would be needed.

There are many ways in which the problem that has been so prevalent in the United States for so long can be resolved. Through patent reform, government intervention and the introduction of social enterprises, the problem could be mitigated. The introduction of firms like NP2 and Civica Rx could greatly help lower the prices of healthcare nationwide.

Conclusion

The United States utilises a different medical system than many other countries, opting for a more laissez faire approach to prescription drug development and nation-wide availability. This approach has given pharmaceutical companies free reign of the drug industry and the ability to monopolise drug sales. A study conducted by the Commonwealth Fund in 2017 found that of the four factors that determine a country's pharmaceutical spending (i.e., population size/volume of drugs consumed, drug utilisation per person, type of drug consumed, and price of drugs), the United States was only a true outlier in terms of the price of their drugs (Sarnak, 2017). In fact, the United States lists drugs at a price that is 256% higher than that of other countries (Garver, 2021). Unhampered by government regulations, pharmaceutical companies can run amok within the industry and raise prices without considering the effect on the livelihood of many citizens. In 2017, paying for a prescription drug would cost, on average, more than the median American's annual Social Security retirement benefit, at around $20,000 (Jenkins, 2019).

Civica Rx and NP2 are among the nonprofits and social enterprises in this industry that are trying to supply cheaper, generic drug alternatives to consumers. Both Civica Rx and NP2 Rx aspire to lower the prices of various types of medication within the healthcare industry. Civica Rx has made a large splash within their first few years as a contributor in the industry, becoming a large name and competitor to some of the other for-profit organisations that are responsible for the higher price tags. Civica Rx has created a system where hospitals and medical systems do not have to rely on companies that are not as well-prepared or whose first priority is revenue. Civica Rx is now well-equipped to handle many problems thrown their way and will be a staple in the business for years to come. While Civica is a lot further along in the developmental process of their company, NP2 is a name that is also beginning to grow in prominence. NP2 is still manufacturing their drugs and obtaining patents for previously manufactured drugs in order to make their mark in the cancer treatment industry. They are in the second year of their manufacturing process and going strong despite the many roadblocks put up by the emergence of the COVID-19 pandemic. These two companies are two prime examples of social enterprises that have established themselves in the market as key players in keeping quality healthcare affordable for years to come.

Nonprofits and social enterprises are split down the line between the startups and the more established firms, each dealing with their respective problems in contending with larger pharmaceutical companies and growing into their own. The startups have had to face issues like generating substantial income, especially considering the two years of development that is needed for the production of any drug. Struggling to cover the costs amidst the pandemic dealt a huge blow to those companies that have been trying to reach a point where they can actively contribute. For the well-established firms, the emergence of the pandemic meant having to shift supply lines to deal with an upsurge of demand. Their biggest issue of recent was simply making sure that the supply chain runs smoothly.

As a whole, the high prices in the pharmaceutical industry may not be something that the nonprofits and social enterprises can solve alone. Proposals of patent reform and government instituted negotiation committees are the most popular solutions amongst analysts, who state that these proposals have worked in other nations (Wager, 2022). Yet, critics have pointed to incentives to innovate and extensive waiting times as reasons for governments to refrain from reforming the patent system. The nonprofit sector is one of the solutions that has already been introduced into the market. Nonprofits have sought to provide lower prices to consumers in an effort to drive down the market price through competition.

The impact of social enterprises on such a sensitive issue is not to be understated. While simply introducing a nonprofit organisation into the market may not seem like an unprecedented radical change, the autonomy and power such an organisation has in a less balanced business market is not insignificant. Being able to market their goods at a lower price means that the consumers will likely flock to the nonprofits, forcing the for-profit organisations to lower their prices, even marginally, to try and maintain higher profit margins. This small change could help spark large-scale change, catalysing the market into correcting itself. As such, companies like NP2 and Civica Rx can help pave a more bearable path for the Americans most heavily affected.

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