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# Corruption in the U.S. Pharmaceutical Industry

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## Introduction

A story that has to be told too often is that of the people who cannot afford lifesaving medications, and as a result do not survive. Doctor Nicky Mehtani says that the inability of a patient to afford their medication can be a common cause of death. This is an answer not accepted by grieving family members who have lost a loved one. It is estimated that more than a fourth of people in the United States needing medical treatment struggle with payment or simply cannot afford to pay for the lifesaving medications that they need (Mehtani, 2018). Deteriorating American business ethics today have led to both corrupt and illegal decision making by the pharmaceutical industry that leaves a lasting impact on American consumers. The Cornell Legal Information Institute defines corruption as "a dishonest, fraudulent, or even criminal act of an individual or organization, using entrusted authority or power to make a personal gain or other unethical or illegal benefits" (p. 1). Corrupt actions in the pharmaceutical industry erode trust in the business sector, weaken democracy, and hamper economic development and democracy. In addition to corrupt actions, companies within the pharmaceutical industry make illegal decisions often. This is an industry that needs reform due to human lives being at stake.

People across the globe benefit from the work of the pharmaceutical industry daily. For example, the discovery and production of insulin has saved the lives of people with diabetes. Prior to the discovery of insulin, diabetes was considered a death sentence. Discoveries such as this one are crucial to the treatment of life threatening diseases. Without modern age companies to research new drugs to bring to market to cure common health problems, the world life expectancy would be on the decline. This industry does work that saves lives of people around the globe, but in a dynamic space when considering business ethics. While the pharmaceutical industry helps create drugs that can improve life expectancy, eradicate disease, reduce pain and suffering, and boost the global economy, there is a lack of trust between the American people and the pharmaceutical industry (Burke, 2020). As an industry that is meant to help discover cures for disease and create drugs to promote public health, confidence in the industry should be high. In reality, the corrupt and illegal actions of companies in this business sector have created a low sense of confidence in big business.

While I recognize the necessity of this industry and all of the public good that comes from "big pharma," the aim of this thesis is to dive deeper into the flaws of the pharmaceutical industry. Key stakeholders of the pharmaceutical industry include patients, the government, physicians, insurance providers, "big pharma" companies, and society as a whole. Understanding the industry's flaws is important because the public knowledge of corrupt pharmaceutical industry practices is crucial to combat unethical practices and in turn promote public health for the greater good of society. I do this through understanding how the monopolistic "big pharma" operates, analyzing the relationship between big business and government, looking into regulations that are in place about drug pricing and availability, looking at past cases of how companies' actions have affected patients, and researching where the industry is headed in the future.

## Defining Ethics

Business ethics "lends itself most directly to a core set of questions about how individuals in the business world ought to behave, or what principles they might appeal to in order to negotiate moral dilemmas at work" (Norman, 2013, p. 1). Business ethics have to do with the moral principles of conduct that are set forth and expected to be followed by company leadership.

Because morals vary both within and between individuals, there is a gray area present between what is considered right and wrong. This gray area is present in the pharmaceutical industry, as there is a struggle between innovation for the promotion of public health and the desire to maximize profit. Because of the various stakeholder interest's, business ethics are often misaligned. This creates a sub-sector of the public health industry that is prone to corruption.

The fundamental problem with the pharmaceutical industry is the conflict of interest that is present between pharmaceutical companies and medical research companies. There are three levels of business ethics to consider. There is a "micro-level" that has to do with how individuals interact with a business group, a "mid-level" that includes regulatory agencies and non-governmental organizations, and finally the "macro-level" that has to do with large markets in the economy internationally (Norman, 2013). Because pharmaceutical companies have a stake in how medical research turns out, they tend to favor outcomes that help their business. This is an example of "mid-level" business ethics and raises the question of the lack of proper regulations within the internal structure of pharmaceutical companies. Lack of proper regulations creates a breeding ground for unethical decision making. Without government regulation of the industry as a whole, and even government interest in favorable results, there is a "macro-level" business ethics discussion raised. Researchers face problems because "Funding and payments to researchers create conflicts of interest, which—for conscious or unconscious reasons—affect their actions, their judgments, and their conclusions. As a result, these conflicted researchers become more likely to report outcomes friendly to their funders" (Sismondo, 2021, p. 2). This is an example of "micro-level" business ethics because of individual researchers corrupting medical science for personal gain.

Researchers began studying the effects of government versus industry funding on medical research in the 1990's (Sismondo, 2021). In a 2017 Cochrane Review, results found that industry-based funding of clinical trials consistently biased trial outcomes. There was a skew towards favorable outcomes in industry funded trial results versus no skew in government funded trial results. Because of these results, "industry funding itself should be considered a standard "risk of bias" factor in clinical trials, one that is quantifiable, and even quantified, and pushes in predictable directions. Industry funding affects the results of clinical trials" (Sismondo, 2021, p. 2). It is a norm in pharmaceutical company clinical trials for funding parties to be in control over how research is conducted and reported. This creates a conflict of interest and allows for unethical decision making for companies who are stakeholders in the results of research. Through medical science being both industry and government funded, there are various opportunities for unethical actions to take place. Bribery, kickbacks, and illegal drug marketing can lead to corrupt or illegal practices by companies within the pharmaceutical industry.

**Global Components of the Pharmaceutical Industry**

The pharmaceutical industry is composed of a handful of large companies that act monopolistic in behavior. These different companies cover the spectrum all the way from drug manufacturers to biotechnology companies, as well as distribution and wholesale companies. These industry leaders are referred to as "big pharma," and include Johnson & Johnson and Abbott Laboratories in the United States, Bayer in Germany, and GlaxoSmithKline in the United Kingdom. Other large companies include Pfizer and Merck in the United States, Novartis in Switzerland, and Sanofi in France ("Pharmaceuticals: Background"). These are companies that face no substantial competition outside of one another.

The difference between drug companies in the United States and other countries is the regulations. The United States has historically seen a large range in drug pricing compared to other developed countries due to a lack of regulations in place for drug pricing and the allowance of market exclusivity for certain drugs. Because of the lack of regulations, there have been numerous instances of price gouging in the United States for lifesaving drugs that result in the deaths of American citizens. Many European countries have put pricing regulations in place to prevent this from happening. It is expected for drug expenditures in the United States to more than triple in the next few decades, which further emphasizes the need for stronger regulations ("Pharmaceuticals: Background").

Congress has allowed pharmaceutical companies to act as monopolies ever since 1980 with the intention of excess profits leading to higher amounts of research and innovation (Engelberg, 2016). Such companies argue that monopolies are essential for the high costs of research required for new drugs to go to market. This claim can be proved inaccurate by Gilead Sciences' reports that show that between 2009 and 2014, the Gilead Sciences' spent a total of $10 billion on all research while it received over $30 billion in revenue from two drugs (Engelberg, 2016). The pharmaceutical industry has proven to be one of the most profitable business sectors due to the lack of anti-monopoly regulations. Furthermore, when asked about how pharmaceutical companies justify price points, Johnson and Johnson claimed that the high pricing on their drugs was a necessity in order to fund further research and development (Emanuel, 2019). These claims can be debunked after looking at the government provided assistance and tax breaks given to pharmaceutical companies with the purpose of encouraging research and development. It was found that out of ten of the largest pharmaceutical companies, only one spent more on research and development than it did on marketing (Emanuel, 2019). These statistics create a lack of confidence in American business ethics by consumers, and demand for the need to reform regulations to promote public health for society.

**Role of the FDA**

The Food and Drug Administration (FDA) is a federal agency that falls under the U.S. Department of Health and Human Services. This agency serves the main purpose of protecting the public's health. The FDA plays a big role in the pharmaceutical industry, as they decide which drugs are approved for consumers and how the drugs will be marketed. The Food and Drug Administration have put "Current Good Manufacturing Practices" (CGMPs) into place to promote the safety of the design process, to monitor and control manufacturing facilities and assure the composition, strength, and safety of drugs being produced ("Center for Drug Evaluation and Research 2022"). Companies in the pharmaceutical industry have to be concerned with the FDA because their products must be approved before they can be sold on the market. The main purpose of the FDA in this sector is to keep consumers safe by regulating the quality of pharmaceutical products so as to not put people's health at risk. Additionally, products that have been approved by the FDA have been deemed as effective.

The responsibility of the Food and Drug Administration to ensure the safety of American consumers is extreme. The FDA monitors over $1 trillion worth of products, and about $0.25 of every $1.00 spent annually on products by American consumers (Lipsky and Sharp, 2001) with this amount growing year to year. Because of this amount of responsibility, the process to get a drug to market is extensive. First is the "preclinical phase," where drug developers work to provide an application to the FDA called an "investigational new drug (IND)" (Lipsky and Sharp, 2001)

that includes early research and potentially animal test results. Following the IND approval, there are three phases of clinical trials. Phase 1 focuses on the safety and pharmacology of a proposed drug, Phase 2 studies examine the effectiveness of the drug, and during Phase 3 researchers try to confirm previous findings by applying research to a larger population (Lipsky and Sharp, 2001). Each of these clinical trial phases can take years, turning the FDA approval of new drugs into a lengthy process. Despite the hurdles that drug manufacturers must go through to get a new drug to market, there is still opportunity for corruption along the way.

The role of the FDA is crucial to the wellbeing of Americans because it allows for a certain level of trust to be formed between the average consumer and drug companies. Oftentimes, a consumer does not question the composition of drugs they take prescribed by doctors because with FDA approval, they are deemed safe and effective. This is a trust that can easily be broken, and this can be shown through the company Biogen's drug Aduhelm being approved by the FDA. This was a medication that sought FDA approval in 2019 by the company Biogen. The drug's purpose is to slow the effects of cognitive decline in Alzheimer's patients. After clinical trials, it was determined that with a high dose of the medication, there was a small benefit in slowing cognitive decline, and the drug was effective at removing the beta-amyloid proteins associated with Alzheimer's disease ("41% of Aduhelm Patients Had Brain Swelling or Bleeding, paragraph "Background"). However, around 40% of patients who received this high dose developed brain swelling and bleeding. An independent panel put together by the FDA decided that there was not enough evidence from the clinical trials to recommend approval of the drug by the FDA. The dangers outweighed the slight benefits, yet the FDA approved Aduhelm on June 7, 2021. Cases like this discredit the choices made by the FDA, and lead to a lack of trust in this government agency by the average American consumer.

There is speculation that the FDA has taken a more cautious approach to drug approvals after the controversy of the Aduhelm case. Since the year 2017, the FDA averaged 51 new drug approvals per year. That was up until 2022, when there were only 37 new drug approvals (Dunleavy, 2023). Since the controversial approval, the FDA typically acted more deliberately, delaying its decision on the drug Relyvrio by six months, waiting on the company to present more conclusive trial results (Dunleavy, 2023). The longer it takes a drug to pass through clinical trials and reach the market, the longer that suffering patients have to wait for potentially lifesaving treatment. This is one of the biggest criticisms of the FDA, specifically after the public was able to see the ability that the government has to accelerate the production of drugs after the start of the global pandemic, and into the creation of a mass-produced vaccination.

The federal effort called "Operation Warp Speed," had the purpose of manufacturing Covid-19 vaccines at an accelerated rate to combat the pandemic. The government department of health and human services (HHS) and the department of defense (DOD) partnered together to make this effort possible. Because of this emergency effort, typical vaccine regulations were adjusted to speed up the process of bringing a vaccine to market. For example, clinical trial phases overlapped, manufacturing began before the vaccine was fully approved, and the FDA authorized an emergency use authorization (EUA). This EUA allowed for the vaccine to be administered without a full picture of the effectiveness in the long-term. This information on vaccine effectiveness will be obtained with further follow-up participants in clinical trials already underway before the EUA was issued ("Operation Warp Speed: Accelerated Covid-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges"). The main manufacturing challenges that "Operation Warp Speed" dealt with were limited manufacturing capacity, disruptions in supply chains, and a lack of available workforce. Each of these challenges stemmed

from the effects that the global pandemic had on the country and had to be overcome in order for there to be a vaccine available to the world. This emergency effort further proved the capabilities of the FDA and government to speed up the process of bringing a new drug to market.

**Business and Government Relationship**

We see pharmaceutical companies working to influence government decisions concerning this industry. This creates a significant conflict of interest that has the potential to negatively affect the American consumer. There are several ways we see this happen with the first being lobbying, the most direct communication line to policy makers. The pharmaceutical industry's lobby is "prolific," with over $2 billion being spent on lobbying Congress in the last decade, which is larger than oil and gas, financial companies on Wall Street, telecommunications, and various defense organizations (Margetta and Duffy, 2019). The company Pharmaceutical Research and Manufacturers of America (PhRMA) is at the top of the list, and advocates for its member companies. An example about lobbying coming across negatively to the American people is when Senator Cory Booker voted against legalizing the purchase of prescription drugs from Canada (Margetta and Duffy, 2019), when it became clear that this decision was based on the pharmaceutical industry's opposition to the idea. Booker faced criticism for the decision and temporarily stopped accepting money from the pharmaceutical industry to try and remain neutral to the American people.

Next is the revolving door between specific government and pharmaceutical industry positions. When individuals "revolve" back and forth between regulatory agencies and the companies they regulate, it creates a conflict of interest in reality and perception (Margetta and Duffy, 2019). An example of this is Diana Zuckerman, a former staff member on capitol hill who now is president of a health care non-profit company. She explained the dynamic between government and private sector by saying "you'll take the call because these people are going to help you in your future career [and] get you a job making three times as much" (Margetta and Duffy, 2019, p. 4). This statement raises the question of whether or not this culture breeds the potential for improper conduct through bribery.

Next is the pharmaceutical industry's funding of medical research and how results may be biased in order to influence the FDA approval process. Research found that when comparing an industry-funded versus government-funded clinical trial for a certain drug, 85% of industry research resulted in positive outcomes, while only 50% of government research had positive outcomes (Margetta and Duffy, 2019). There are financial incentives when drugs are passed through the FDA for pharmaceutical industry companies that create a conflict of interest and a large potential to act unethically. A term called "publication bias" is when companies suppress negative results in order for their drug to gain FDA approval, which leads to "doctors prescribing medication without a complete understanding of a drug and its side effects, posing a clear risk to patient safety" (Margetta and Duffy, 2019, p. 5).

Finally, funding independent organizations is an influence tactic used by pharmaceutical companies. The main two organizations are think tanks and patient advocacy groups. The purpose of these organizations is to influence the decisions of policy makers in a certain direction. By using think tanks, pharmaceutical companies are able to determine the way that their research is framed to specific policymakers. Patient advocacy groups are funded with the intention of creating a group whose "primary mission is to combat a particular disease or disability or to work toward improving the health and well-being of a particular patient population" (Margetta and Duffy, 2019, p. 7). The

money being funneled into patient advocacy groups align with groups who are using the company's drugs.

Each of these tactics are used by "big pharma" to create policy outcomes that are favorable to their big business. Because of the "astronomical amount of money made in the global prescription drug business, the industry has inordinate power and influence over consumers' lives" (Sekerka and Benishek, p. 117). In addition to these influence tactics, pharmaceutical companies already receive tax deductions for certain drug advertising and production from the U.S. government. There have been steps taken in an attempt to reduce the amount of tax breaks these companies receive, but "big pharma" lobbyists have been able to keep deductions high. These are all examples of the conflicts of interest that are present between pharmaceutical companies and the government. There is much needed reform in regulations between the two sectors, as they are tied too closely together to have society's best interest.

**Bribery and Kickbacks**

Bribery is when "property or personal advantage is offered, without the authority of law, to a public official with the intent that the public official act favorably to the offer at any time or fashion in execution of the public officials' duties" (Turow, 1985, p. 249). Bribery occurs before an action takes place, while kickbacks occur after an action takes place. There are many methods of bribery and kickbacks used by pharmaceutical companies to influence physician and government decisions.

An example of this would be the company Novartis's antiviral drug called Remdesivir. The company is facing a $678M settlement because of the bribery and kickback schemes they engaged in as an attempt to persuade doctors to prescribe their drug that supposedly shortens the effects of the Covid-19 virus. For over a decade, "Novartis spent hundreds of millions of dollars on so-called speaker programs, including speaking fees, exorbitant meals, and top-shelf alcohol that were nothing more than bribes to get doctors across the country to prescribe Novartis's drugs" ("Novartis Pays over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians", p. 1). In addition to the front-end bribery that took place, it was found that doctors who wrote a specific number of prescriptions for Novartis drugs received "honorariums," or kickbacks in return. This is a prime example of the lengths that pharmaceutical companies will go to in order to increase the presence of their drug on the market.

Similarly, AstraZeneca created a drug called Brilinta to treat heart attacks. This drug was approved by cardiologist Jonathan Halperin and other panelists, who then began to receive compensation for "travel, consulting, research, and sitting on industry-sponsored committees" (Morgan and Duffy, 2019, p. 1), over the next several years despite having claimed no financial conflict of interest. This post-hoc gift method of bribery is an extremely common strategy used by pharmaceutical companies to get drugs passed by the FDA to then generate billions of dollars in revenue. Cases like this emphasize the different priorities of each level of stakeholders in the pharmaceutical industry. Pharmaceutical companies use bribery and kickbacks to influence both government officials and physicians in order to get certain drugs on the market and prescribed in large enough amounts to generate profit.

**Data Security Concerns**

Data breaches are becoming increasingly common in the pharmaceutical and healthcare industries. This is in part because of technologies including the internet of medical things, smart devices, various information systems, and cloud services (Hussain Seh, 2020). Although these technologies help create more accessible healthcare services, they put patient privacy in jeopardy. Data breaches have allowed for a "major lure for the misappropriation and pilferage of healthcare data" (Hussain Seh, 2020, p. 1). Electronic health records (EHRs) have replaced paper-based systems, and enhance "patient care, develop patient cooperation, enhance disease diagnosis, improve practice efficiency, and make patient health information accessible all the time" (Hussain Seh, 2020, p. 1). Electronic health data breaches create financial setbacks for healthcare organizations, reflect negatively on the image and reputations of these companies, and damage patient confidentiality.

Despite the advancements and benefits that electronic records have created for patients and doctors, vulnerabilities have arisen as well. On the dark web, a complete patient file can be sold for hundreds of dollars. Hacking incidents can be defined as "all cyber-attacks that are used to gain unauthorized access to confidential data" and unauthorized access (internal) can be defined as "attacks that lead to the exposure of confidential health data with the help of any internal source of an organization" (Hussain Seh, 2020, p. 8). While other industries face data breaches and hackers, the healthcare industry is most sensitive because "any data tampering can lead to faulty treatment, with fatal and irreversible losses to patients" (Hussain Seh, 2020, p. 2). Their records are valuable because they contain patient history of health, demographic information, and social security numbers among other important information.

Cyber-attacks on healthcare industry data are expected to continue to increase in number (Hussain Seh, 2020). Electronic health record systems have increased greatly due to the capabilities of smartphones and internet connectivity creating the potential to receive and store health information electronically. The advantages of electronic health record systems come with the disadvantage of increased vulnerability and lack of privacy. Healthcare data breaches are frequent and should be considered with caution as trends continue to move towards solely electronic data.

**Big Settlements**

Often, we hear about "big pharma" companies having to pay out billions of dollars in settlements. This is typically because of the illegal marketing of certain drugs that have ended up harming the wellbeing of patients. When a drug is approved by the FDA, it is approved for a specific illness. When a "big pharma" company advertises a drug for a different purpose than the FDA has approved and a patient undergoes adverse effects, that is when a settlement typically plays out. Companies that have been involved in some of the largest pharmaceutical drug settlement cases include Pfizer, Johnson & Johnson, and Eli Lilly & Co.

Pfizer settled their civil and criminal case with a $2.3 Billion payout. This case has to do with the drug Bextra, approved by the FDA in 2001 as a pain treatment for arthritis and menstrual cramps. Pfizer instructed sales representatives to tell doctors that the drug could be used to treat surgical pain and at doses well above what was approved by the FDA, even though the drug's dangers for kidney, skin and heart risks increased with a higher dose (Gardiner, 2009). The drug was then removed from the market in 2005 because of the posed risks to the heart and skin. The

prosecution in the case accused Pfizer of "aggressive marketing tactics," which included providing paid weekend getaways for doctors for meetings. These marketing tactics were used to bribe panelists into helping with FDA approval of the drug.

Similarly, Johnson & Johnson paid out a settlement of $2.2 Billion to settle accusations about the improper marketing of the drug Risperdal, an antipsychotic, to older dementia patients and children with developmental disabilities. These practices put the health of vulnerable populations at risk in a reckless manner (Katie, 2013). Johnson & Johnson advertised this drug to children and the elderly despite knowing the hormonal imbalances it could cause in young boys and the risk of stroke it created in older patients. The company claimed no wrongdoing on behalf of any of their individuals. The lack of responsibility taken widens the gap of the trust that citizens have in big business. In recent months, Johnson & Johnson has been working to settle an $8.9 Billion case involving the known carcinogen in their talc products such as baby powder (Hsu, 2023). The company is having to file for bankruptcy in response to this settlement.

In 2009, Eli Lilly & Co. paid $1.42 Billion to settle a case about the illegal marketing done in relation to the antipsychotic drug Zyprexa. The company marketed Zyprexa as a drug that can treat dementia and Alzheimer's despite a lack of FDA approval for this purpose. The drug was only approved for treating schizophrenia and bipolar disorder. This is what is called "off-label" marketing, when a drug maker attempts to convince healthcare providers that certain drugs are safe for uses that are not government approved ("Eli Lilly Settles Zyprexa Lawsuit for $1.42 Billion"). Eli Lilly & Co were also accused of overcharging for this drug on top of breaking marketing laws in place by the government.

An incident such as the price gouging scheme led by Martin Shkreli deteriorates American's low confidence in big business even further. Martin Shkreli abruptly raised the price of the drug Daraprim by more than 4,000 percent, raising the price from $17.50 to $750 per tablet (Mole, 2021). Daraprim is a relatively cheap, lifesaving parasitic infection fighting drug. Shkreli created agreements with drug distributors that led to his company being the sole producer and seller of the drug Daraprim. This created the possibility for Shkreli to raise the drug price due to the lack of competition on the market. Martin Shkreli is now facing a $40M settlement that will return money to the people who suffered from the consequences of the price gouging scheme (Mole, 2021). Shkreli was released from federal prison in May of 2022 and is finishing out his criminal sentence from a halfway house (Mangan, 2022).

**Drug Pricing**

As of 2020, it is estimated that over 1.1 million Medicare patients in the United States die due to overpriced drugs. Intentionally underusing drugs that are necessary to survive has cost the lives of many American citizens. A leading cause of death in the U.S., ahead of diabetes, influenza, pneumonia and kidney disease is the cost related to nonadherence to drug therapy. When patients do not follow doctors' orders because of the inability to afford medication, there are over 120,000 premature deaths a year (Lagasse, 2020). The corporate social responsibility that pharmaceutical companies have to the people of the United States proves to be nonexistent from these statistics. Big pharmaceutical companies raise drug prices on a regular basis without concerning themselves with the effects on everyday American citizens. These companies have operated under outdated patent laws, false claims, and a lack of accountability from the government for too long. Many Americans who have chronic health conditions face health care debts and other consequences for the remainder of their lives. Diabetes, heart disease, cancer,

and Alzheimer's are just a few on the long list of health problems that require expensive treatment.

Americans are paying significantly higher prices for over the counter and prescription drugs compared to other developed nations. It is stated that about 3 in 10 people report they go without prescribed medications because of cost (Ginsburg and Lieberman, 2021). The Biden Administration and Congress have made steps to start the process of reducing drug prices for American citizens. The negative impacts anticipated with the process of reducing drug prices would be a lack of innovation and slower development and time to market for new drugs. These impacts would be due to a smaller return on investment for pharmaceutical companies and less resources to allocate towards new developments. In an attempt to create more government regulation in the drug pricing sector, Congress passed a bill called "H.R.3, the Elijah E. Cummings Lower Drug Costs Now Act," but was not passed in the Senate. The bill would allow for the Secretary of Health and Human Services to set drug prices. This bill would create regulations that drug manufacturers would have to follow when pricing drugs through a process of negotiations (Ginsburg and Lieberman, 2021), and would create a penalty tax for pharmaceutical companies who do not accept the set pricing.

One of the main reasons for price gouging in the U.S. drug market is due to laws that allow for "market exclusivity" of drugs that do not have alternative treatment options. In the United States, brand drugs average nearly 3.5 times prices in other countries overall and almost twice the prices in Canada, the United Kingdom, Germany, and France (Ginsburg and Lieberman, 2021). The bill H.R.3 would create a plan to select a certain number of drugs on a set schedule and create price ceilings. The HHS would have the potential to target specific drugs that have held market exclusivity for a long time and do not currently face meaningful competition. The "market exclusivity" is due to the patent protection laws in place that have allowed large pharmaceutical companies to continue to act as a monopoly. Originally, patent laws were put into place with the intention of being short term protections that encouraged companies to research problems for society's greater good. Today, a drug patent allows one singular company to be the sole producer of a specific drug for twenty years. Competitors are unable to enter the market until that time runs out. This creates a monopolistic business structure and allows unfair business practices. Being the sole producer of a drug, these companies have no competition and are able to raise prices out of proportion.

**Drug Availability**

In the United States, availability of life saving drugs is not consistent due to price gouging schemes. Diabetes was once essentially a death sentence, but with the discovery and assistance of insulin, it is now a manageable condition to be a diabetic. Insulin was discovered by Dr. Frederick Banting and Charles Best in Canada in 1921. These doctors sold the patent for only $1.00. They intended that insulin "belong to the world" and be accessible by being reasonably priced (Randall, 2022). This is not the case now due to prices of insulin in the United States costing up to $300 for one 10mL vial. Because of these price shifts, insulin has become less accessible to people around the globe. People with inadequate health insurance who are low-income are the most at risk to a lack of insulin availability. Reasons for these gouged insulin prices are due to patents that have allowed single companies to have a monopoly over insulin delivery methods. Roughly 90% of insulin globally, and all of insulin produced in the United States, is produced by the same three multinational companies; Eli Lilly, Sanofi, and Novo Nordisk (Randall, 2022), which means these

three companies are able to charge significantly more for their products than they would be able to if there were more regulations about pharmaceutical monopolies.

While there are no patents on insulin production, there are patents on insulin pens and omnipods, two of the most popular delivery devices for insulin to diabetic patients. The issue with this is that insulin pens are made with a cartridge of insulin already inside, so the insulin cannot be bought separately from the delivery method. Therefore, these patents play a major role in increasing costs of insulin. This strategic move by the "big three" companies keeps new competitors from entering the market to lower prices for consumers.

Insufficient insurance coverage has also proved to be a challenge for diabetics needing to obtain insulin. Before the Affordable Care Act (ACA) of 2010, individuals who had pre-existing health conditions were charged premium prices for health insurance, or even denied coverage because of expensive treatments necessary (Randall, 2022, p. 8). A lack of political healthcare policies creates problems for people with preexisting health conditions still today. A term referred to as the "coverage gap," refers to people who have "a high-enough income to disqualify them for federal health insurance (Medicaid), but still cannot afford private insurance" (Randall, 2022, p. 8). Being uninsured as a diabetic creates unreasonably high insulin prices that put an individual's health in danger. Negative consequences that arise include insulin rationing, higher rates of Diabetic Ketoacidosis, and psychological distress for diabetic individuals.

Insulin for diabetics is just one example of a drug that is made extremely difficult to obtain by people who require the drug for survival. American citizens resort to either not properly taking care of themselves or leaving the country to access more affordable healthcare and prescriptions. This overpricing problem led to the death of Antavia Worsham. Antavia was diagnosed with Type 1 diabetes when she was sixteen years old. Type 1 diabetes is characterized by the pancreas no longer being able to produce insulin. Because of this, insulin treatment is vital to the body being able to properly function. When Antavia got to college, she began "rationing her insulin in 2016 when she was kicked off BCMH Bureau for Children of Medical Handicaps" (Worsham, 2019). Antavia Worsham lost her life because she was unable to afford insulin treatment in young adulthood. Rationing insulin has the potential to produce life threatening consequences and should not be a consideration for diabetics. Her mother has pleaded with the government for reform in the pharmaceutical industry but has yet to see any lasting results. Unfortunately, Antavia Worsham is not the only young adult in America to suffer like this.

**Impacts on Patients**

During the Trump administration, claims about standing up to the pharmaceutical industry were made but action was never taken. Pharmaceutical industry insiders were even placed in top administration spots, encouraging corrupt behavior because of the large conflict of interest between the industry and government that is created. A study showed that Americans spent roughly $535 billion on prescriptions in 2018, which was an increase of 50 percent since 2010 (Meller and Ahmed, 2023). These price increases surpass inflation throughout the years, even with these growth statistics, pharmaceutical companies were receiving research grants and tax breaks from the United States government. Because they were receiving additional funding, prices were wrongly expected to be cut. This is an ongoing issue that politicians are working to combat through policy implementation.

Cancer treatment is a category of struggle for the American people. While medical remedies, surgeries, and treatments have improved greatly over the last couple of decades, only

those who can afford it have benefited. It is estimated that monthly cancer treatments may reach $100,000 (Selby, 2020). The story of Robert Boseke proves that outrageous medical bills from lifesaving drug treatments can ruin people's lives. Boseke suffered from a kidney cancer diagnosis in 2013. After having his kidney removed, the cancer spread its way throughout the rest of his body. After taking a prescribed chemotherapy pill that cost $30,000 per month (Selby, 2020) Boseke was fully in debt. He had to sell his house, car, motorcycle, and lost his retirement savings as well as credit score. A story such as this is similar to many of the others who face health problems. There is no excuse for big business to be shattering the lives of the sick due to outrageously high drug prices.

**Looking to the Future**

Entrepreneur Mark Cuban has created a new online pharmacy called Cost Plus Drug. Cuban's main goal is to make profit while maximizing the impact for consumers (Reno, 2022). This online pharmacy will offer over one hundred generic medications at prices far less than what is offered at competitors such as Walgreens, CVS, etc. Cuban claims that his goal for the company is transparency, and to eliminate the middleman manager in the pharmaceutical process. The "Pharmacy benefit management (PBM) companies are the middlemen of the pharmaceutical industry, designing plans for sponsors and insurers and pushing the products of manufacturers" (Meador, 2011, p. 78). These companies create a conflict of interest in the journey from producer to consumer. Because the PBM companies push products of manufacturers, all while working with the consumer pharmacies, their interests lie with whichever decisions create the most profit. The elimination of that position will result in lower pricing on drugs for the end consumer, and a more transparent supply chain.

Cuban's online pharmacy is based in Dallas, Texas and already has a website up and running that sells over 100 medications, that include drugs to treat asthma, heart failure, mental health, allergies, and cancer (Reno, 2022). Although the pharmacy does not take insurance, drugs sold at Cost Plus Drug are cheaper than what a person would buy with insurance at a competing pharmacy. Mark Cuban is taking large steps towards making drug prices in the United States more comparable to other countries. As of this year, there are still many drugs under patent protection, meaning that Cuban cannot yet provide a complete solution to the problem but is on the way to doing so.

Through creating Cost Plus Drug and working towards transparency in drug pricing, Mark Cuban is demonstrating an understanding of his moral responsibility to behave ethically as the head of a corporation. This is the type of leadership that Mark Cuban aims to promote in his new endeavor to create a more affordable pharmacy for the people of the United States. Managers are the most significant role models in the organization setting; thus, they have a major socializing influence on lower-level employees. On the Cost Plus Drug website, Cuban writes a letter to convey his company's mission that states his belief that no American should be struggling to pay for necessary medications (Cuban, 2022). This is the ethical behavior strategy that the American people urge pharmaceutical companies to follow.

Drug pricing reform is a priority in the current political climate. There is a new drug pricing law that was passed in August of 2022 and is being implemented in 2023 called the "Inflation Reduction Act," which is meant to help limit the pricing power of drug makers (Newman, 2023). The law will allow Medicare representatives to negotiate top-selling drug prices with manufacturers who lack competition in the market. Insulin prices for Medicare patients will be

capped at $35, and prices will only be able to be raised at the same rate as inflation (Newman, 2023). Each year moving forward, there will be more drugs open for negotiation of pricing. Negotiation regulation details are being determined as the law is set into motion. These pricing regulations are a step in the right direction for drug pricing reform in the United States.

## Conclusion

Through understanding how the monopolistic "big pharma" operates, I have been able to evaluate the corruption present in the U.S. pharmaceutical industry. Big business and government have a relationship that leads to bribery, kickbacks, illegal marketing. These unethical business actions negatively impact patients across the country. This is an industry that affects the country as a whole with a multitude of stakeholders that include patients, doctors and medical service providers, insurance companies, "big pharma" employees, and government officials among others. Due to the amount of people that can be affected by the actions of pharmaceutical companies, the attention of the American people is required to keep companies held accountable for their actions.

Over the past decade, corporate responsibility has been an increasing topic of conversation. The idea that big companies have the privilege to be influential emphasizes the idea that large corporations bear the responsibility of creating change regarding social problems. It is important that influential businesses care about more than simply making a profit. In the pharmaceutical industry, the prioritized stakeholder should reflect the end consumer. Today, the corporate social responsibility standards are not being met by the large companies within the pharmaceutical industry. The United States has allowed this to happen because of outdated patent laws that allow a monopolistic structure, by not holding companies accountable in their false claims, and because of the lack of government accountability in the industry. Because pharmaceutical companies deal with the matters of life and death, the result is that ethical standards are raised. Drug company giants continue to act through corrupt decision making, but there is a light at the end of the tunnel. Entrepreneurs such as Mark Cuban have started working towards fair pharmaceutical business practices for all, leading to American citizens beginning to regain their trust in the pharmaceutical industry.

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