International Monterrey Model United Nations Simulation

American School Foundation of Monterrey

The United States Senate

Topic: Addressing the pharmaceutical industry's legislative power in regards to the elevated prices of generic drugs
Director: Raquel Valdés
Moderator: Marcos Vedoya

I. Committee Background

The Senate of the United States is the heart of the legislative branch of the American government. It acts as the upper chamber of Congress, while the House of Representatives acts as the lower chamber. Every act and bill passes through Congress before it goes on towards the President of the U.S. for approval, or veto. Senators are familiar with having a heavy influence in the government. They play a vital role through the debates and decisions the country faces every day. First coming together in 1789, the US Senate was built to be a more elaborate and sophisticated version of the House. Having less members in the chamber helps with the bigger sense of community and unity between its members, while granting these very senators a tenure of six years in order to better discuss the issues that pertain to the nation. The Senate underwent significant modifications of procedure during Wilson's presidency, some of which provided for the election of senators by vote, instead of an appointment by the state legislatures. The title of Senate Majority Leader was also created, he or she would be the person that would guide each party through debate. The leader would be a person of seniority and great eloquence. Delegates will have the opportunity to work with peers across the aisle, hopefully supporting bipartisan agreements that will prevail and transcend beyond us. You will participate in debates on the most pressing issues that are facing the nation, trying to balance what your senator believes in, and what one has to compromise to let matters move forward in a democratic way.

II. Introduction

Description and Definition of the Topic

Over the past few years, the pharmaceutical industry has been in a constant state of extensive development. According to the Food and Drug Administration (FDA), generic drugs are medications created with the purpose of providing benefits equal to those provided by traditional branded drugs in regards to their physical form, strength, quality, safety, and overall performance. Typically, they are sold at lower prices in comparison to branded drugs, however, they have recently been affected by increased government regulation. Generic drug manufacturers have drastically increased their prices, negatively impacting businesses worldwide. Because of this, it is increasingly cheaper for pharmaceutical companies to produce a dosage instead of manufacturing a traditional branded drug. Once a generic drug is on the market, branded drugs tend to lose a vast amount of their market share with the exception of common prescriptions. If generic drug manufacturers want to endure in the marketplace, their

ultimate solution is to increase their prices which is ultimately causing prestige among the industry and imposition upon consumers.

The Problem

Generally, government regulation in modern corporations is designed to ensure that businesses are working to serve the public and not their numerous shareholders. However, when it comes to legislation regarding the pharmaceutical industry, the issue and degree of public benefit is called into question.

The most popular reason behind this claim is, without a doubt, the relationship between these corporations and the FDA. In 1992, after the scandalous discovery of several health risks in popular drugs, the passing of the Prescription Drug User Fee Act (PDUFA) made pharmaceutical companies responsible for paying the government to approve all potential drug products. While this phenomenon appears to operate towards the public's interest, some believe that the connection between both establishments leads to a shift in the intentions of government regulations. Since 1992, Big Pharma, the pharmaceutical industry, has paid the FDA $7.67 billion. This number is unnerving by itself; however, the issue becomes more present when one considers the sheer number of lobbyists paid by Big Pharma who influence decision-making in the Capitol. According to the Project on Government Oversight (POGO), "...at least 39 of 42 patient advocacy groups who participated in discussions with the FDA over agency review processes for prescription drugs received funding from pharmaceutical companies. Additionally, at least fifteen advocacy groups have representatives of drug or biotechnology companies on their governing boards." (Benishek, 2019)

The effects of elevated prices on generic drugs are immeasurable and evidently, come with many concerns. Consumers are faced with higher costs that are often unaffordable, health plans must adapt to adequately cover higher drug expenditures, and physicians must cope with alternative therapies that can be costly, ineffective, and potentially dangerous. In the words of Michelle Mello, a professor of health research and policy at Stanford Law School: "What we have, in a sense, is a system that is all engine and no brake." (Entis, 2019)

III. History of the Topic

Chronological History of the Topic

The history of Big Pharma legislation has been long and difficult, with a tumultuous pattern of health threats and the establishment of regulation only to counteract societal outrage. Regarding the FDA, there were no guidelines or any type of bookkeeping until 1820, during which eleven doctors created the US Pharmacopeia, the first list of standard drugs that had been developed and sold. More official regulations were established for drug imports and distribution in 1848 with the Drug Importation Act. In this act, the United States Congress authorized the restriction of low-quality, tainted drug importation from overseas. Twenty-two years later, in 1905, the American Medical Association (AMA) began a voluntary program that lasted 50 years. It worked towards increasing drug approval by restricting pharmaceutical companies from the

use of “advertisement” in AMA Journals if they had not yet proved that the medication they would publicize legitimately treated what they claimed it did. A small increase in drug quality and transparency was achieved only a year later, on June 30, 1906, when the first draft of the Food and Drug Act is passed, receiving support from President Theodore Roosevelt, and outlawing the sale of food, drink, and drugs that are mislabelled or simply hazardous to consume. However, shortly after, in the 1911 US v. Johnson court case, the Supreme Court clarified that false medical claims are not outlawed by the Food and Drug Act, only mislabelling when it comes to the ingredient or identity of a drug. To target this loophole, Congress passed the 1916 Sherley Amendment, illegalizing false medical claims. Major legislation was passed on drug management in 1933, during which the FDA recommended the complete rewrite of the “out-of-date” Food and Drugs Act.

However, that was not enough. Tragedy struck only 4 years later, with the 1937 Elixir Sulfanilamide Incident. Elixir Sulfanilamide was a sulfanilamide medicine whose impurities led to mass poisoning in the US and the death of 107 people. This, as well as similar incidents of improper composition in the same year, caused public outcry and anger, raising demand for drug regulation and beginning the movement for prescription-only drug assignation (something that would take until 1951 to establish). As a result, a new system of drug regulation was developed. Congress passed the Federal Food, Drug, and Cosmetic (FDC) Act of 1938, forcing drug companies to guarantee and prove safe consumption before releasing new medications. This act also limited the amount of “unavoidable poisonous matter” (FDA and Drug Regulation) in medicine and allotted officials and experts the responsibility of inspecting production factories for potentially harmful residue and byproducts. Again, this was not enough. In 1941, 300 deaths and many injuries resulted from the use of sulfathiazole tablets, an antibiotic that had been tainted with phenobarbital (a sedative). In response to this, the FDA’s procedures drastically changed which helped improve manufacturing regulations, leading to the development of good manufacturing practices (GMPs). These GMPs improved the quality of medicine across the United States and 10 years passed without another major incident. In 1951, the aforementioned prescription act was passed. Named the Durham-Humphrey Amendment, it limited the selling of certain potentially harmful drugs to medical professionals. Development of factory inspections followed in 1953 with the Factory Inspection Amendment, requiring FDA inspectors to produce written reports for pharmaceutical companies in regards to the conditions that they experienced and their analysis of the factory samples. Public support towards establishing stronger drug laws was introduced once again in 1962 when Thalidomide, a new sleeping drug, caused thousands of birth defects in Western Europe. US media reported on how Dr. Frances Kelsey, an FDA medical officer, prevented the approval and marketing of Thalidomide in the U.S, creating a wave of support and pride.

Ultimately, this approval resulted in the monumental Kefauver-Harris Drug Amendment which, for the first time, required drug makers to prove their drugs function properly before the FDA approves of them. In 1972, the Over-the-Counter Drug (OTC) Review enhanced the safety, effectiveness and appropriate labeling of non-prescription drugs. This later became irrelevant

because of the 1984 Hatch-Waxman Act, which allowed the selling of generic non-brand drugs without having to conduct the same research, further proving effectiveness and security. It also helped brand-name companies by allowing them to apply for up to five years of additional patent protection in order to "make up for the time lost while their products were going through the FDA's approval process." (FDA and Drug Regulation).

During the 1990's, the United States wasn't the outlier it is today with drug prices. Citizens of European nations such as Germany and France previously had a higher per-capita drug expenditure than the United States. This changed a few years later when Big Pharma's influence pushed for a bill that approved the introduction of several new drugs to the market. The problem with this bill was that it also provided pharmaceutical manufacturers the opportunity to pay fees in order to obtain faster FDA approval for their products. Although the goal was well-intentioned, seeking faster and more efficient development of drugs, it placed the FDA in an uncomfortable and potentially harmful relationship with Big Pharma as a considerable amount of the agency's budget now came from those companies. Eventually, the number of drugs that topped one billion dollars in sales increased from six to fifty-two. This decade also featured additional nonchalant legislation on advertisements and pricing. Legislation in 1995, 1999, and 2004 allowed propaganda from pharmaceutical companies to only require including "major" side effects. Lobbying from Big Pharma also helped eradicate President Bill Clinton's 1993 plan to regulate prices and provide universal health care to Americans.

During the first three years of the Obama administration, Big Pharma spent more than 700 million dollars lobbying to Congress vastly shadowing lobbying efforts by other industries. "By comparison, the insurance industry spent $480 million in the same period. Drug companies alone spent more than $487 million on lobbying during the three-year period; biotechnology and medical device companies spent $126 million and $86 million, respectively" (Union of Concerned scientist). The focus point of this spending was the implementation of the Affordable Healthcare Act, however, the pharmaceutical industry managed to remain unscathed from the legislations. While insurers and hospitals were forced to reduce costs and help patients pay for their treatments, pharmaceutical companies managed to avoid any regulations of drug prices and were only forced to pay for a small part of the program.

In the last decade pharmaceutical companies have spent more than 2.5 billion dollars in congress with lobbying and campaign support activities. 90% percent of the United States House of Representatives' members and 97% of the Senate's members received campaign compensations from Big Pharma. In 2018, inquiries about the high prices of drugs were called by members of Congress and President Trump promised to make generic drugs more affordable. The industry had around two lobbyists for every member of congress and that same year, they spent around twenty-eight million dollars on direct lobbying activities.

Historical Case Study

Turing Pharmaceuticals

In 2015, Turing Pharmaceuticals purchased the marketing rights to Daraprim, a drug often used for treating parasites such as malaria, AIDS patients with a weakened immune system, and patients in need of transplants. After buying its marketing rights, Turing raised the price of Daraprim overnight - from $13.50 to $750, a 5000% increase. People were outraged and quick to shun the company for price gouging, since none of the components of the pill changed, only the company managing it. This has affected patients all over the U.S. who previously received this medication for 1$ per pill - an opportunity that now only those involved in AIDS programs can participate in. While attempting to keep costs down, hospitals have begun relying on other experimental drugs with unknown side effects which could distress both patients and doctors. Daraprim is also not the only drug whose price has been spiked up. Since 2007 pharmaceutical company Mylan, for example, has increased the price of potentially life-saving EpiPens from $94 to $609 (Rapaport). These are not isolated examples, and although the focus is usually on the increase in prices of new drugs (those to treat high cholesterol, cancer, AIDS, hepatitis...), there is also a growing concern over the spiking of older, generic drugs. Some of these increases have been caused by shortages, but others are business strategy consisting of buying old neglected drugs, repackaging, and reselling as “specialty drugs” (Pollack). As for Daraprim, its CEO Martin Shkreli claimed to be a type of ‘Robin Hood,’ with the money going towards making Daraprim more efficient - a drug that has already been working efficiently for over 60 years and that some use on a daily basis (Daraprim Price Hike). Unsurprisingly, many show outrage about this being about greed.

Forest Pharmaceuticals Inc.

Through the 1990’s Forest Pharmaceuticals Inc. began promoting and selling their new antidepressant drugs, Celexa and Lexapro, without FDA approval. Although similar drugs had been in the market since the 1950s, in 1997, the FDA identified this medicine as a new drug which required approval. Despite that, they granted the company a four year grace period (until August 14 2001) to gain approval or a two year gradual decline in distribution if approval was inaccessible, as they had deemed that medically necessary.

The company never sought approval from the FDA and instead continued distributing its drugs at levels that ignored the FDA’s two year plan. Despite letters from officials, the company kept selling higher levels than allowed and did not diminish its supply. This pressured officials into forcing the company to stop selling the drugs. FDA representatives put a deadline to halt production, to which Forest Pharmaceuticals Inc. reacted by urging most of its employees to work extra hours to maximize production before the halt.

Investigators also claim that the company supplied the FDA with false information regarding the composition and distribution of the drug as well as attempting to block any investigation by officials. Officials also state that the company used aggressive, promotive approaches when introducing the drugs to minors.

In a civil liability lawsuit in 2009, the company was forced to pay 313 million dollars to the government, specifically the FDA and Department of Justice for violating multiple laws.

These laws regarded the distribution and promotion tactics that the company used in addition to violating the False Claims Act. The civil lawsuit also included a five year Corporate Integrity Agreement with the Department of Health and Human Services, which would result in a five year oversight of the company by both agencies.

Aspen Pharmacare

Aspen Pharmaceuticals is based in the South African city of Durban, which, after a 2014 dispute with the Spanish health services, began a continent-wide effort to increase the price of niche and important cancer drugs by over 4,000 percent. This started after buying the rights for these drugs from GlaxoSmithKline in 2009 for 279 million pounds sterling (Kenber). It was 5 years later that their efforts for price-gouging began. An Aspen employee even mentioned in a leaked email that, "[They've] signed new reimbursement and price agreement successfully" (Forster). This price hike could be done through a loophole that allowed companies to charge exponentially more if the medicines were no longer branded with the same name. Initially, this loophole was created to make medicine cheaper and more accessible once the patient had run out, but without competition, Aspen was free to raise the prices instead. It was three years later, in 2017, that antitrust regulators assigned by the European Commission began investigating the hefty, unjustified price increases of medicines with the potentially life-saving ingredients of chlorambucil, melphalan, mercaptopurine, thioguanine and busulfan. This marked the first time the European Commission investigated excessive pricing practices in the pharmaceutical industry, with Aspen facing fines of $284 million USD for breaking EU Competition Rules, more specifically Article 102 of the TFEU and Article 54 of the EEA Agreement (EC Investigating Aspen Pharma). The European Competition Journal, for instance, states that "pharmaceuticals are primary goods that call for protection, are entrusted to private hands which frequently try to exploit their essential nature and ensure visibility to antitrust enforcement…" (Perinetto).

In the briefest terms, generic medicine companies such as Aspen are also able to price-gouge life-saving medicines if they purchase the rights to them from other companies that invest more in Research and Development (R&D) and effectively push out the competition. Perhaps more regulations like the ones set in Europe are necessary in the U.S. in order to control the prices for not only generic drugs but also ones that provide invaluable aid.

Valeant-Philidor

In 2018, the former executive of Valeant Pharmaceuticals International, Gary Tanner, was arrested for fraud and conspiracy to commit money laundering alongside the former chief executive of Philidor Rx Services, Andrew Davenport. The relationship between both companies began in October 2015, when Valeant was given the opportunity to buy Philidor and was suspected of using it to increase sales. Over the years, Tanner maintained ties with Philidor and worked on Valeant's "alternative fulfillment", a program dedicated to finding the most efficient approach to increase prescription on the branded drugs instead of generic drugs. Many prosecutors say Tanner deliberately drove Valeant to Philidor and "helped Davenport reap more

than $40 million", so he could receive about a $10 million kickback (Silverman, 2016). According to U.S. Attorney Geoffrey Berman, Tanner was trusted to manage Valeant's ties with Davenport's company and "instead, they devised a scheme to pillage Valeant and share the proceeds" (CNBC, 2018). Both executives used this sneaky scheme to ultimately gain more money and boost their sales.

Cutter Laboratories

In 1897, Edward Ahern Cutter founded the Cutter Laboratories, a pharmaceutical company in Berkley, CA. On April 12, 1955, the polio vaccine trial was successfully created. The polio vaccine is a vaccine that helps prevent poliomyelitis. Due to its mass necessity, 200,000 midwestern US children received the polio vaccine which reported many defects. After further research, investigators found more than 40,000 cases involving the polio vaccine, resulting in 10 deaths, 70,000 ill patients, and more than 200 children with a severe degree of paralysis in their body. Since 1979, the polio vaccine has been banned from the United States of America and now the vaccine used to prevent polio is the inactivated polio vaccine (IPV). The IPV has been the only vaccine given to citizens in the US since the year 2000. Although the incident does not directly involve elevated drug prices, it inarguably serves as an example of one of the many ways in which the pharmaceutical industry suffers from a vast majority of concerns and adding money to the equation has proved to aggravate their issues even more.

Past Senate Actions

2019 has seen the largest efforts by congress members to reduce the prices of drugs in the last two decades. Apart from being a key issue in the 2018 house elections, drug price increases were announced in January by most pharmaceutical companies. Some of the most exorbitant increases were on Hepatitis C and several cancer medications so, the issue began being brought up by several congress members. Democrats, enjoying their newly found control of the lower house, launched an investigation on behalf of Elijah E. Cummings, Chairman of the Committee on Oversight and Reform, towards 12 pharmaceutical companies. Some of the companies under investigation include, Amgen Inc, Johnson & Johnson, Pfizer Inc, Celgene Corporation and Led by Rep. Made up mostly by Democratic congress members, the committee has investigated big pharma's aggressive tactics to raise prices and any illegal activity related to those them. The committee has also held hearings for most CEO's of the affected companies regarding their responsibility with the issue.

2019 has also featured highly proposed bills towards reducing high prices on generic drugs. During the first session of the 116th United States Congress, several bills were introduced. The first was launched on January 27th by Vermont Senator, Bernie Sanders, and it would allow the Secretary of Health and Human Services to negotiate drug prices under the act of Medicare. Simultaneously, House of Representatives member, Elijah Cummings, introduced a bill that would allow Americans to import generic drugs from abroad and would tie national prices to international ones. The Prescription Drug Price Relief Act of 2019 was also introduced in January and sponsored by several Democratic legislators to introduce competition towards

patented drugs that are exclusively priced. Several other bills were also introduced in July by Senator Chris Van Hollen and Senator Rick Scott seeking to give the government leverage in pricing, through sponsored research and investigation of new drugs. A bill proposed by House Speaker, Nancy Pelosi, that focuses on drug pricing, was approved by the House on October 22nd and will be voted on by the end of the month. If the bill which was discussed in 3 different Committees passes, it would allow Medicare to negotiate with drug companies and set incentives for companies to reduce their prices. It would also enforce mechanisms to prosecute companies that unnecessarily increase their prices.

Although few, several Republicans including President Trump have expressed their desire to tackle the issue and a major bill has been put into consideration. In January, the president announced that he would work with his administration to find a framework to lower the prices of drugs. Later that year, in July, it was announced that the president had considered an executive order where the US would pay the price of generic drugs in the cheapest countries such as Europe or Latin America. That same month, the president proposed allowing the importation of FDA approved drugs from countries such as Canada and the UK. Several Republicans, backed by the president, introduced the Prescription Drug Pricing Reduction Act of 2019. The bill would increase out of pocket beneficiaries for Medicare elderly as well as penalize companies for easing prices faster than inflation.

IV. Key Players and Points of View

Mitch McConnell

Kentucky's senior U.S. Senator and Senate Majority Leader, Mitch McConnell, has been spearheading the resistance towards the new bill proposed by Nancy Pelosi alongside the rest of the Democratic Party. If it passes, the government would call upon Medicare (the national health insurance program in the U.S.) to negotiate drug prices with Big Pharma companies of at least 25 generic drugs used on a daily basis - such as those to treat diabetes or arthritis. Pelosi's bill has even received support from President Donald Trump, who stated that the U.S. Senate should do this "in a bipartisan way." Despite this support, Senator McConnell was quick to call it dead on arrival, claiming that "socialist price controls will do a lot of left-wing damage to the healthcare system." (Everett). He is hesitant to begin establishing price regulations and controls that Speaker Pelosi's bill would certainly bring.

Sen. McConnell, alongside Sen. Patrick Toomey, also disagrees when it comes to the bill's second point: forcing Big Pharma to rebate if the price of drugs outpaces inflation in the U.S. Instead, he defends the private markets and price setting that is determined by societal demand. Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group that speaks for pharmaceutical companies, also claimed that the bill would siphon more than 150 billion USD from the research and the development of new and more efficient medicines. However, experts claim that most of the development for new medicine comes from private academic institutions, not Big Pharma, and it has been the same with many other threats and claims from PhRMA

(Huetteman). Still, despite these fraudulent claims, Republican Senators do voice many other doubts that Sen. McConnell has.

Many worry about price limits, since inflation caps would only delay the price increases and not actually make drugs more affordable. Democrats themselves also want to do more, bringing back Trump's proposed bill that would force Big Pharma to develop affordable health plans and discount for customers who utilize the drugs whose prices were set by the government.

Elizabeth Warren

Massachusetts Senator, Elizabeth Warren, has tried to lower the prices of generic drugs by proposing a bill that would give the federal government the power to produce affordable generic drugs. By doing so, the government would be allowed to either manufacture the drugs themselves or negotiate with external pharmaceutical companies to manage the process. According to Rachel Sachs, an expert on drug law, this bill "could be a helpful intervention for those generic drugs that have recently seen price spikes or are in shortage" (Scott, 2018). The senator's main objective is to solve the issue of pharmaceutical companies that have warped markets in efforts to increase the prices of generic drugs and authorize the manufacturing of these drugs by the public. She believes that drug companies use the free market as an opportunity to raise the prices of drugs and recognizes how the industry runs on government-provided monopolies, mainly in long-term patent protection. About 90 percent of Americans are prescribed generic drugs, yet the "generic drug market is fundamentally broken" (Warren, 2018). Nearly half of the generic drugs are produced by a single company, therefore, the competition is very limited. This evidently leads to skyrocketing drug prices, which puts individuals' health at risk by decreasing the availability of vital medication. Since Congress is not directly linked to these monopolies, Warren's purpose behind this bill is to force or entice companies to work for the consumer, instead of solely for their own benefit.

Bernie Sanders

Bernie Sanders, Vermont Senator, has been extremely public about his vehement opposition to pharmaceutical drug costs in the United States of America. The United States Senator argues that drug manufacturers are a prime example of corporate greed that must be taken down swiftly and effectively. In fact, the Senator has explicitly called for pharmaceutical prices to be cut in half.

In May of 2018, Senator Sanders called for the United States Senate to hold pharmaceutical companies accountable for the opioid epidemic that continues to plague the nation. In a letter written to Senator Lamar Alexander, Chairman of Public Health, Sanders expressed his conviction that hearings should be held on the matter. At one point, he states: "That committee had the courage to demand that the leading executives of the tobacco industry tell the American people what they knew and when they knew that tobacco was addictive ... and

had killed millions of people. Though all denied under oath believing tobacco was addictive, we now know they were lying. But the hearing eventually led to real change."

Despite praising journalism that exposed Big Pharma's role in propelling the American opioid epidemic to staggering proportions, Sanders believes there's still a long, difficult road ahead for the American people when it comes to the cost of pharmaceuticals in America. From his standpoint, legislation should be created with the purpose of condemning past corporate greed and ensuring that drugs are safe and affordable for all in the years to come.

Cory Booker

New Jersey Senator and presidential candidate for the Democratic party, Cory Booker, presented a bill on November 15 alongside fellow presidential candidate, Bernie Sanders, to establish the Bureau of Prescription Drug Affordability and Access. This new organization would aim to weigh the cost of development and research for different drugs and assist with establishing fair prices on new drugs entering the market as well as ensuring that the process of drug approval is not disrupted. Apart from establishing prices, the bill attempts to give the US government more leverage with this new regulatory department (CNN). This change is an attempt by both democratic senators to appease Republican senate members and drug investors in order to break the deadlock in congress to prevent any significant bill from passing.

Despite this new bill, Cory Booker still received significant criticism for his past funding from pharmaceutical companies. The senator has always called himself a supporter of importing drugs to lower cost and has expressed his desire to put a new bill to ensure this. However, in 2017 the representative from New Jersey voted against a bill aiming that. Although he stated he voted against the bill for its lack of guarantees that quality and safety of the imported drugs would be ensured (The Hill) and assured that he had proposed an edited version of the bill, many believe that he voted against the bill due to the heavy pharmaceutical presence in his home state. Several Big Pharma companies are based in New Jersey and in the past, the Democratic Senator received funding from some of them (The Hill). Since then, Booker has attempted to remove any funding from pharmaceutical companies and doubled his efforts to push bills aiming to reduce drug prices and swaying off critics ahead of the presidential race.

V. Possible Solutions

In order to find a solution to the issue of elevated pharmaceutical drug prices, it is imperative to consider implementing multiple elements from a broad variety of perspectives.

First and foremost, one cannot lower the price of pharmaceutical drugs without any knowledge of their current cost. In this day and age, the public listed price of drugs is altered and distorted by interested parties including pharmacy benefit managers and manufacturers. Co-pay cards are an excellent example of this phenomenon; while they provide the illusion of discounted prices, a full cost is actually included in a deductible. Increasing the transparency that surrounds pharmaceutical drugs and moving towards a more cost-based system would be

an excellent way to make pharmaceuticals more affordable for all citizens of the United States of America.

Secondly, there are those that believe that the power to lower drug prices lies in Congress. The U.S. government is the largest buyer of pharmaceutical drugs on an international scale; however, the Department of Health and Human Services is unable to negotiate drug prices with drug manufacturers. Legalizing governmental intervention in the setting of drug prices would, according to some, increase the overall affordability of pharmaceuticals.

Apart from these solutions, there are a large number of proposals that could effectively tackle this issue. From tying drug prices to their medical effectiveness, to reducing or eliminating patent exclusivity loopholes that block the evolution of a generic market, the Senate has a variety of options that would allow affordable medical care throughout the nation.

VI. Current Status

As the decade comes to an end, there is a general sense of disorientation on both sides of the political spectrum regarding drug prices in the United States of America. When compared to other first-world countries, United States drug prices are currently four times higher than the calculated average. US citizens spend over $3,337 billion US dollars annually because of the high-end prices. Alarming statistics of this nature have prompted both Democratic and Republican politicians to advocate for cost reduction, but differing stances on how to bring about these changes have created ambiguity and confusion. On one hand, President Donald J. Trump supported a bipartisan bill called the Prescription Drug Pricing Reduction Act (PDPRA) in July of 2019. This act was created with the sole purpose of forcing all pharmaceutical companies to supply documentation to the Department of Health and Human Services in order to provide justification for any increase in drug prices. While the PDPRA seems like a step in the right direction, one must understand that the effectiveness of this bill cannot be calculated before it is passed. On the other hand, Democratic House Speaker Nancy Pelosi believes federal intervention is the only way to prevent drug prices from spiraling out of control. By granting the government the authority to impose financial penalties on drug makers who do not comply with the government's demands, Pelosi believes pharmaceutical drug prices will be well within the American public's budget. It is imperative to understand that both sides of the American political spectrum believe in lowering the price of pharmaceutical drugs; however, it is the Senate's responsibility to ensure that all parties agree upon a specific method to reach this universal goal.

VII. Bibliography

Adams, B. (2019, June 11). Orkambi debate in U.K. revives the myth of a people-funded drug. Retrieved from https://www.fiercebiotech.com/biotech/orkambi-debate-u-k-revives-myth-a-people-s-funded-drug.

"A History of the FDA and Drug Regulation in the United State." *Food and Drug Administration*. Retrieved from https://www.fda.gov/media/73549/download.

"Daraprim Price Hike." *Ethics Unwrapped*, University of Texas at Austin, https://ethicsunwrapped.utexas.edu/video/daraprim-price-hike.

"EC Investigating Aspen Pharma Alleged 'Price Gouging' for Cancer Meds." *The Pharma Letter*, 16 May 2017, https://www.thepharmaletter.com/article/ec-investigating-aspen-pharma-alleged-price-gouging-for-cancer-meds.

Entis, L. (2019, April 9). Why Does Medicine Cost So Much? Here's How Drug Prices Are Set. Retrieved from https://time.com/5564547/drug-prices-medicine/.

Everett, Burgess. "McConnell Warns Pelosi's Drug-Pricing Plan Is DOA." *POLITICO*, 19 Sept. 2019, https://www.politico.com/story/2019/09/19/mcconnell-pelosi-prescription-plan-1504496.

Ex-Valeant, Philidor executives get prison for fraud. (2018, October 30). Retrieved October 25, 2019, from https://www.cnbc.com/2018/10/30/ex-valeant-philidor-executives-get-prison-for-fraud.html.

Fielding, J. (2017, December 21). The High Cost of Rising Drug Prices. Retrieved October 24, 2019, from https://www.usnews.com/opinion/policy-dose/articles/2017-12-21/the-high-cost-of-rising-drug-prices.

Forster, Katie. "Pharmaceutical Giant 'Plotted to Destroy Cancer Drugs to Drive Prices up 4000 per Cent'." *The Independent*, Independent Digital News and Media, 15 Apr. 2017, https://www.independent.co.uk/news/health/drug-giant-aspen-plot-destroy-cancer-medicine-big-pharma-times-investigation-a7683521.html

Fuentes, Fernando. "'Big Pharma' Acapara El Mercado En México." *Milenio*, Fronteras De La Ciencia, 2018, https://www.milenio.com/opinion/fernando-fuentes/fronteras-de-la-ciencia/big-pharma-acapara-el-mercado-en-mexico.

Harris, Gardiner; Walt Bogdanich (2008, March 6). "Drug Tied to China Had Contaminant, F.D.A. Says". *The New York Times,* https://www.nytimes.com/2008/03/06/health/06heparin.html

Huetteman, Emmarie (2019, July 26). "GOP Senators Distance Themselves From Grassley And Trump's Efforts To Cut Drug Prices." *Kaiser Health News*, https://khn.org/news/gop-senators-distance-themselves-from-grassley-and-trumps-efforts-to-cut-drug-pric

Jeremy Corbyn would destroy the market for specialist medicines. (2019, September 25). Retrieved from https://blogs.spectator.co.uk/2019/09/jeremy-corbyn-would-destroy-the-market-for-specialist-medicines/.

Kamal, R. (2019, February 20). What are the recent and forecasted trends in prescription drug spending? Retrieved October 24, 2019, from https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/.

Kenber, Billy. "Drug Giant's Secret Plan to Destroy Cancer Medicine." News | The Times, The Times, 14 Apr. 2017,

https://www.thetimes.co.uk/edition/news/drug-giant-s-secret-plan-to-destroy-cancer-medicine-75rg6wt2n.

Lopez, Fabiola Torres, et al. "Multinational Pharmaceutical Companies Decide on Access to Health in Latin America." *The Big Pharma Project* , OjoPúblico, https://bigpharma.ojo-publico.com/articulo/life-has-a-price-multinational-pharmaceutical-companies-decide-on-access-to-health-in-latin-america/.

Perinetto, Patrick Actis. "The Italian Pharmaceutical Antitrust (r)Evolution and Its Most Recent Example: the Aspen Case." *European Competition Journal*, vol. 13, no. 1, Feb. 2017, pp. 93–116., doi:10.1080/17441056.2017.1362864.

"Pharmaceutical Industry." *Pharmaceutical Industry | The Canadian Encyclopedia*, https://www.thecanadianencyclopedia.ca/en/article/pharmaceutical-industry.

Pollack, Andrew. "Drug Goes From $13.50 a Tablet to $750, Overnight." *The New York Times*, The New York Times, 20 Sept. 2015, https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html.

Rapaport, Lisa. "Another Look at the Surge in EpiPen Costs." *Reuters*, Thomson Reuters, 27 Mar. 2017, https://www.reuters.com/article/us-health-epipen-costs/another-look-at-the-surge-in-epipen-costs-idUSKBN16Y24O.

Scott, D. (2018, December 20). Elizabeth Warren's ambitious new bill to lower generic drug prices, explained. Retrieved October 21, 2019, from https://www.vox.com/policy-and-politics/2018/12/20/18146993/elizabeth-warren-2020-election-drug-prices-bill.

Silverman, E. (2016, December 4). Feds charge former Valeant and Philidor execs with fraud. Retrieved October 26, 2019, from https://www.statnews.com/pharmalot/2016/11/17/valeant-philidor-fraud/.

Sekerka, L. E., & Benishek, L. (n.d.). Thick as Thieves? Big Pharma Wields Its Power with the Help of Government Regulation. Retrieved from http://law.emory.edu/ecgar/content/volume-5/issue-2/essays/thieves-pharma-power-help-government-regulation.html.

Shaw, Donald. "After Record Fundraising Haul From Big Pharma, McConnell Vows to Block Drug Pricing Bill." *Sludge*, Relentlessly Uncovering Corruption, 18 Oct. 2019, https://readsludge.com/2019/10/18/after-record-fundraising-haul-from-big-pharma-mcconnell-vows-to-block-drug-pricing-bill/.

The Cutter Incident. (n.d.). Retrieved from http://paul-offit.com/booksby/the-cutter-incident/.

The Elixir Tragedy, 1937. (n.d.). Retrieved from https://www.the-scientist.com/foundations/the-elixir-tragedy-1937-39231.

Toronto, R. in. (2019, August 9). Canada announces regulations to cut price of prescription drugs. Retrieved from https://www.theguardian.com/world/2019/aug/09/canada-prescription-drugs-cut-cost.

Ubel, Peter. (2019, May 1) "The Surprising Truth About The Rising Price Of Generic Medications." *Forbes*, Forbes Magazine, Retrieved from https://www.forbes.com/sites/peterubel/2019/02/22/the-surprising-truth-about-the-rising-price-of-generic-medications/#4844eb607a09.