Big Pharma, 2018

Thomas Jefferson Model United Nations Conference

TechMUN XXVI

High School Crisis

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Director's Note

Mr./Ms. Reader, congratulations on completing one of the most important first steps by opening this background guide. If you're doing this anytime ahead of the night before committee, you're probably miles in front of your peers.

I hope that this note will be useful for putting Big Pharma into context. First and foremost, our committee is operating in the *present day*, meaning that any events that occur prior to Friday evening's opening committee session are completely relevant. If, for instance, a major development related to one or more of the topics occurs a few days before committee, we expect everyone to know about it. So I'd suggest that everyone keep up with the news at least enough to be prepared for committee.

Your chairs and I have also tried to create a diverse group of delegations that we hope will make your time in Big Pharma fun and interesting. When you receive your position, look up their position, relationships, wealth, etc. to get a sense of what advantages and disadvantages you'll have in committee. Try to understand what that position's goals are and make a plan to achieve them. If there isn't too much information available, extrapolate within reason or send us an email with any questions if you're having trouble. The three of us are here to make sure that your experience at TechMUN is the best it can be. We will never look down on any delegate asking for help. Asking questions demonstrates thoughtfulness and preparedness, two qualities which are always good to see.

Finally, a quick description of the "committee" that you will be a part of. This event takes place during the first annual American Pharmaceuticals Conference, a (fictitious) convention assembled by request of the Trump administration. Consequently, assume that your fellow conference members are a mix of high-ranking government officials, head business

leaders within pharmaceutical and medical firms, and persuasive lobbyists. As a group, this conference will work to solve (or exacerbate) the problems below, while each individual will attempt to further his or her personal agenda. And, there might be an unprecedented number of crisis events along the way. Nearby will be the meeting of the U.S. Department of Health and Human Services. That meeting will be comprised of Senators, Department Heads, and official Government figures working on the issues of Healthcare and the Opioid Crisis. Both of these groups may influence one another so be prepared!

Best of Luck,

Ian Moritz (12), Crisis Director

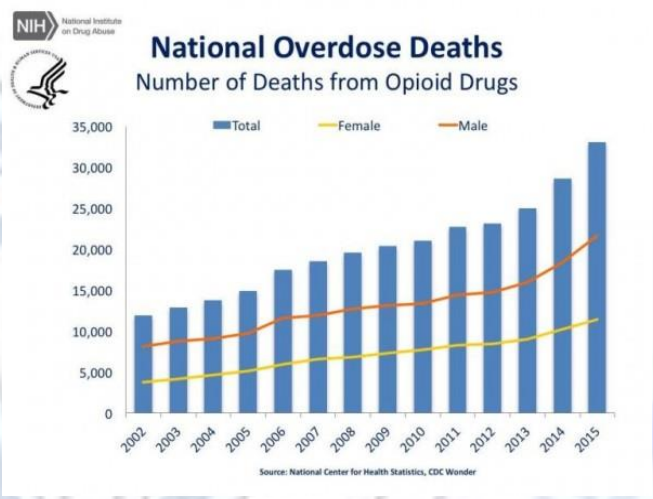
Shivani Mullapudi (12), Chair

Abhishek Bazaz (11), Chair

Topic 1: The Opioid Crisis

Introduction

The growing opioid epidemic is pervasive throughout the U.S., devastating various communities regardless of demographic.



Deaths resulting from drug overdose, the majority due to heroin and opioid use, are now the leading injury cause of death in the United States, a phenomenon highlighted by the staggering 406% increase in heroin and opioid overdose deaths from 2006 to 2014 (Department of Justice). Occuring in tandem has been the near quadrupling of the amount of prescription opioids, such as oxycodone, hydrocodone, and methadone, sold to pharmacies, hospitals, and doctors' offices between 1999 and 2010 (Center of Disease Control and Prevention). Known today as the biggest public health epidemic in American history, the opioid crisis continues to claim an average of 115 American lives everyday (CDC), one reason why this epidemic is among the most pressing challenges today facing the pharmaceutical industry as well as its consumers.

Extensive distribution and misuse of prescription opioid medications began towards the late 1990s, before the highly addictive power of these substances was made apparent (Department of Justice). Major pharmaceutical companies, or "Big Pharma" as they are known today, claimed addiction to prescribed pain relievers would not occur in patients, thus healthcare providers began to prescribe them at greater rates. Since its conception, the opioid crisis has been correlated with increasing incidence of neonatal abstinence syndrome in newborns,

specifically due to opioid misuse during pregnancy, and with the increasing spread of infectious diseases, such as HIV and Hepatitis C, as a result of injection drug use (National Institute on Drug Abuse). Historical evidence and studies indicate a link between opioid prescriptions and substance use disorders; a Blues report found that people who received high doses of prescription pain relievers were more likely to end up addicted, even when the prescription lasted for less than 90 days (Sapatkin, 2017).

Unprescribed Usage of Opioids

After becoming addicted to these often recklessly prescribed opioids, many Americans find themselves unable to find a source of opiates at the eventual end of their prescription. As a consequence, addicted Americans often turn to the black market to acquire cheaper opiates, like heroin. This is supported by polling evidence, which shows that prescription opiate users are 19 times more likely to eventually turn to heroin and other cheap street opiates (National Institute on Drug Abuse). The increased demand for these drugs has led to a flourishing criminal drug trade and the breakdown of many American neighborhoods and communities, especially concentrated in the American midwest (Frostenson and Lopez, 2017). This collapse of many American homes has increased anger against Big Pharma and has led many to call for new punishments for Big Pharma' mistakes.

Role of Pharmaceutical Companies

The ever-increasing spread of prescription opioids can partly be attributed to the pharmaceutical industry's fervent drug distribution efforts, resulting in recent backlash against Big Pharma across the nation. More than 60 federal lawsuits filed by U.S. cities and counties are currently awaiting litigation, one of which was filed by this past January 23rd by New York City Mayor Bill de Blasio against a coalition of companies led by Purdue Pharma, the creator of

OxyContin (Walters, 2018). Across the board are claims that the pharmaceutical industry is responsible for the commencement of the opioid crisis 20 years ago with their aggressive marketing initiatives and inadequate warnings about drug addiction and abuse (Walters, 2018).

Accused of engaging in greedy and reckless tactics and tearing families apart, pharmaceutical companies, such as Endo Health Solutions, Teva Pharmaceuticals, and Allergan, now face the daunting task of responding to the opioid crisis appropriately while maintaining company image and wellbeing in the industry (Lopez, 2018). Aside from the efforts of the Department of Human and Health Services, Department of Justice, and various other government bodies, pharmaceutical companies are being called upon now more than ever to develop safe and non-addictive strategies to manage chronic pain, innovative medications and treatments for opioid use disorders, and better overdose prevention in order to support recovery efforts.

Government Action and Targets

According to the Washington Post, no immediate suspension order has targeted a pharmaceutical distributor or manufacturer since late 2015 (The Washington Post, 2017), an alarming statistic considering the skyrocketing nature of drug overdose deaths since then. Federal officials have been accused of weak enforcement of drug distribution control, perhaps a byproduct of persistent and large-scale industry lobbying that cripples such enforcement and essentially protects the monopolies of pharmaceutical companies. At the local level, cities and states have attempted a myriad of solutions (The Washington Post, 2017), but the crisis continues to grow, implying the necessity of federal action.

For example, providing Naloxone, an overdose-reversal drug, in readily available locations does not reduce addiction rates. Similarly, limiting the supply of prescription opioids,

such as Oxycontin, to local distributors has led to a surge in fentanyl use, a drug that is 50 times stronger than heroin (Quinn, 2017). Public health officials face a challenge that is, more or less, twofold: fighting the increased use of heroin and other illicit drugs in young adults while combating the abuse of prescription drugs by older adults. New and increasingly potent substances make the opioid crisis a growing issue, worsening its effect on U.S. jobs, housing, and mental health (Quinn, 2017). Addressing the broader issues of the opioid crisis is vastly difficult and will require a cohesive and coordinated approach.

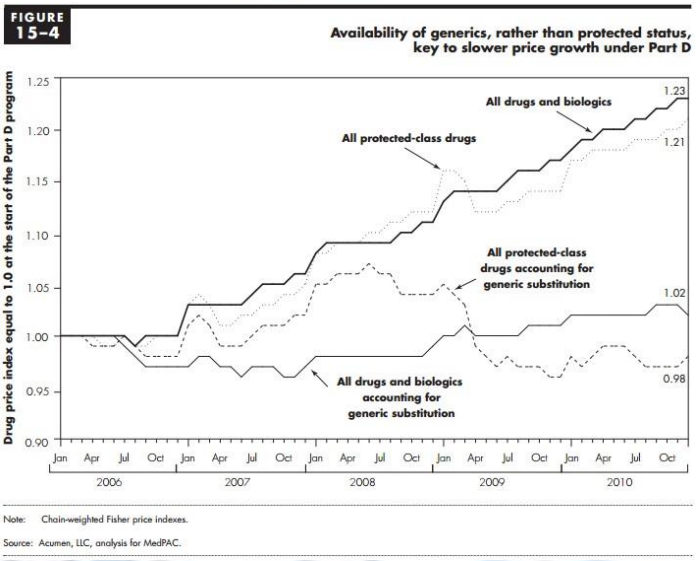
Questions to Consider

1. How should pharmaceutical companies respond to recent calls for negotiation over the exorbitant price of the opioid overdose antidote naloxone?
2. What steps must be taken to develop more effective addiction treatment strategies alongside other parties? Governmental bodies?
3. What strategies or changes by pharmaceutical companies can reduce overprescription of opioid medications?

Topic 2: Rising Pharmaceutical Drug Prices

Introduction

Over the past decade, medical innovations have added nearly three years onto the average American life expectancy (World Bank). Previously incurable disease have turned into manageable ailments or eradicated all together. Despite such progress, the benefits of advancements in medicine have been dampened by soaring drug prices controlled by Big Pharma. According to a study done by AARP, specialty drug prices have increased, on average, by 10% (Strauss, 2017). Such price increases have prevented people suffering from life threatening diseases from getting the medication they need. However, the problem is not solely astronomically high drug prices. What makes these companies' actions so problematic is that the high prices spill over into other healthcare related products and services. Periodic spikes in drug prices contribute to low patient confidence and unstable healthcare costs in the United States (Waxman, 2017). These factors make it hard for patients who require long term medications to easily purchase them, especially when on a budget. Despite generally having a lower price, generic medicine has a hard time competing with specialized medicine due to state and federal legislation along with long FDA approval times (Lupkin, 2017). Big Pharma have drawn ire from the general public as well as politicians for being apathetic in regards to how their prices affect



families and patients in need. While there have been efforts to reduce the control big pharma companies have on drug prices, none have resulted in much success.

Effective Monopolies

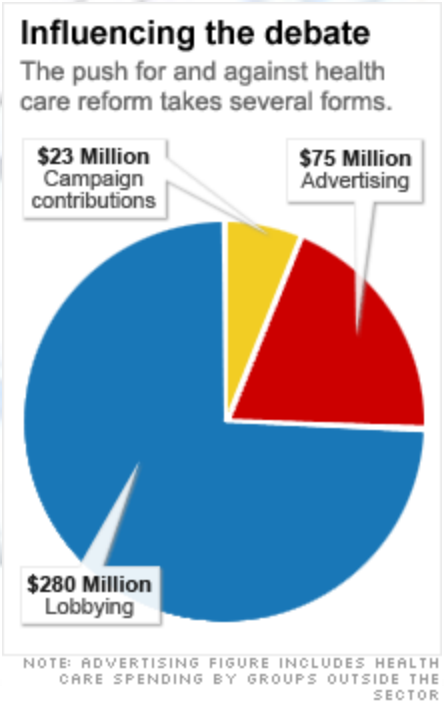
One of the principle reasons Big Pharma have the ability to manipulate drug prices is due to the government protected monopolies on certain drugs. In the United States, the Drug Price Competition and Patent Term Restoration Act allows drug companies to be the sole producer of certain drugs for over 20 years (Fox 2017 & Lupkin 2016). These patents include companies that produce medicine for rare diseases. Such patents allow for providers to control the market surrounding a particular drug. Due to the mere nature of patents and patent laws, there is little the government or other smaller drug companies can do to regulate the prices or compete with the larger companies.

Theoretically, after 20 or less years, the patent on many of these drugs will expire and other companies can begin producing them, normalizing the prices. However, this is usually not the case as companies attempt to extend their monopoly on the drug by making minor changes in the nontherapeutic parts. This way they can extend their patents and continue being the sole provider of these specialized drugs. This severely harms generic drug producers and patients who count on such patents running out to making money and normalize the price respectively. Often times smaller businesses will sue Big Pharma for employing this tactic, but they are usually not successful since large companies can use "pay to delay" legal tactics to delay the lawsuit for years. Pfizer, the pharmaceutical company that produces the breast cancer medication Lipitor, used "pay to delay" tactics to make a generic drug brand wait 9 years before they could sell the generic version (Wisperg, 2013). Once the patent had expired, the price of a 30-day sample of

Lipitor decreased from $205 to $18. While the FTC has condemned such actions, regulating such tactics is easier said than done.

Lobbying Efforts

With laws in place to protect numerous Big Pharma monopolies, only politicians can influence drug prices on a universal scale. However, this is made increasingly difficult with Big Pharma lobbying campaigns and political donations. For instance, nearly 300 million dollars were spent by pharmaceutical and healthcare lobbyists in 2017. Receiving such hefty campaign donations sways politicians to vote in favor of such companies and laws that benefit them. One of the biggest representatives of these companies is the Pharmaceutical Research and Manufacturers of America (PhRMA), which donated over 25 millions dollars last year to politicians (Open Secrets). Such contributions have led to favorable laws and regulations passed which, to quote President Trump, have allowed them to "get away with murder." These bills include regulations that require generic brands to pay a fee to release their medications and others that delay the release of generic medications (Stat News, 2017). Unfortunately, this pattern of Big Pharma lobbying and donations target both Republicans and Democrats, often creating bipartisan support for these companies in government (Liberto, 2009).



Public Opinion and Initiatives

This systemic problem of high drug prices has encouraged many to craft new possible solutions. Perhaps as the simplest solution, many government bodies and groups have simply called for a greater embrace of generic drugs

(medicare.gov). Unlike the brand-name drugs that Big Pharma traditionally develop, generic drugs have similar/the same efficacy at reduced prices. However, because of patent protections, many drugs receive no generic product until years after their release.

Other strategies largely require the government to act an an intermediary to lower drug prices. They include increasing foreign drug imports, "pay-for-delay" prohibitions, and a more easily terminatable monopoly period for recently developed drugs (Bernie Sanders). But, it will also be extremely important to balance these government regulations and still encourage medicinal innovation. As members of this conference, Big Pharma and government officials will have to work together to find the best solution.

Questions to Consider:

1. Should Big Pharma prioritize public relations and prepare for potential government regulation, or maximize profits in the present with the consequences of major backlash?
2. How can pharmaceutical companies work with either generic brands or government officials to benefit both parties?
3. Are there other, less discrete, routes to control supply rather than lobbying and lawsuits?

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Committee Dossier

Note: This committee list represents members of not only Big Pharma companies, but healthcare providers, lobbyists, and top govnerment officials as well. Each position comes with their own set of portfolio powers. While this may seem like a contradictory or diverse list, we created it to ensure multiple perspectives to the issue. Above all, research not only your position's policy on the issue, but their own private agendas as well.

Pharmaceutical Representatives

1. Alex Gorsky, Chairman of the Board and Chief Executive Officer of Johnson & Johnson
2. Kare Schultz, President and Chief Executive Officer of Teva Pharmaceuticals
3. Craig Landau, Chief Executive Officer of Purdue Pharma
4. John Castellani, Chief Executive Office of Pharmaceutical Research and Manufacturers of America
5. Ian Read, Chairman of the Board and Chief Executive Officer of Pfizer
6. John C. Reed, Head of Roche Pharma Early Research and Development
7. Vasant Narasimhan, Chief Executive Officer of Novartis International
8. John F. Milligan, Chief Executive Officer of Gilead Sciences
9. Jack Y. Zhang, CEO, Director, and Chief Science Officer of Amphastar Pharmaceuticals

Government Officials

10. Lawrence A. Tabak, Principal Deputy Director for National Institute of Health (NIH)
11. Robert Patterson, Acting Administrator of the DEA
12. Stephen C. Redd, Principal Deputy Director for Center for Disease Control and Prevention (CDC)

Health Care Companies

13. Larry J. Merlo, Chief Executive Officer of CVS Health
14. Mark Bertolini, Chief Executive Officer of Aetna
15. David Stack, Chief Executive Officer of Pacira Pharmaceuticals
16. Tim Wentworth, Chief Executive Officer of Express Scripts Holdings

Lobbyist Groups

17. James L. Madara, CEO of American Medical Association
18. Robert A. Bradway, Chairman of PhRMA Board of Directors

Health Insurance Companies

19. David S. Wichmann, CEO UnitedHealth Group
20. Gail Koziara Boudreaux, CEO and President of Anthem, Inc.
21. Scott Serota, CEO of the Blue Cross Blue Shield Association