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The EFFICACY OF THE OPIOID EPIDEMIC'S PREVENTATIVE POLICY: A COMPARITIVE STUDY BETWEEEN THE FINANCIAL RELATIONSHIPS OF BIG PHARMA AND THE INTEGRITY OF PUBLIC

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ABSTRACT

As communities across the United States continue to be ravaged by the opioid epidemic, Big Pharmaceutical companies continue to evade accountability. This dual systematic review and interview process aims to compare current evidence of known "webs of influence" in the American opioid industry to the dynamic experiences and attitudes of actors within this industry. Despite knowledge and litigation of these "webs of influence," they remain. Therefore, the deterrent value of preventative policies in place, to separate Big Pharma's private interests from the sector of public health, will be analyzed through the lens of these interviewees.

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Chapter 1

Introduction

Over the past two decades, the opioid epidemic has claimed the lives of more than 400,000 individuals. Opioid addiction is a societal cost, estimating the United States trillions of dollars. Countless lives, families and communities have been destroyed while depleting social service resources, leaving much of the costs to underfunded state and local agencies. Initially related to the increased consumption and availability of pharmaceutical opioids, opioid-specific overdoses now encompass heroin and the illicit production of fentanyl and other synthetic analogs. Between 1999 and 2017, the proportion of drug-related overdoses tripled, while the rate of opioid-specific deaths increased almost sixfold during the same period (NIH, 2022). Among the 70,237 drug overdose deaths in 2017, 47,600 (67.8%) involved an opioid (CDC, 2019). Mortality rates of opioid-specific deaths have increased annually since 1999, only stabilizing between 2018 and 2019 with 46,802 losses, then continuing its annual increase after the dramatic loss of 68,630 individuals in 2020 (CDC, 2020). While the effects of opioid addiction can be devastating, many people can and do recover to achieve the full potential of their health and wellness. However, the potential for addiction is paramount, crossing socioeconomic levels to anguish entire communities.

Opioids maintain a unique role in society whose implications are both novel in effective pain management yet devastating when misapplied. This chapter is an introduction to the history of "pain" and the function of opioid medication with definitions on specific drug classes. A

discussion on the risk factors for abuse will also be included, as well as the research questions for this systematic review.

The Chronic Pain Market

Attempting to understand pain represents one of the oldest challenges in the history of medical treatment. Previously, "pain" was understood as an indicator and used as a diagnostic process to better track and identify the underlying cause of discomfort. In proper patient care, pain is the unofficial "fifth vital sign" alongside the assessment of blood pressure, temperature, respiratory rate, and heart rate. To better define a patient's pain, healthcare providers use pain scales. Pain scales generally have three categories: 1) Numerical Rating Scales which use numbers to rate pain, 2) Visual Analog Scales that ask patients to mark a place on the scale that matches their pain, and 3) Categorical Scales, typically used with children, that use words alongside color, number, and relative location to index pain. Today, the same scales are used even though "pain" has been drastically redefined.

The scientific characterization of pain took a tremendous leap forward in 1947, when English neurophysicist Sir Charles Scott Sherrington described the phenomenon as "the physical adjunct of an imperative, protective reflex," consequently confirming the existence of "abnormal pain." Discovering "abnormal pain" meant that individuals could experience pain not acting as a protective reflex (Breathnach, 2004). This development reconsidered traditional interpretations of pain as solely a protective biological tool to include the experience of pain as a pathological condition as well.

During this time, “pain” lost its identity as a symptom and became a valuable role in medical action and treatment. Consequently, laying the groundwork for the opioid epidemic in 1980, when the burden of pain became increasingly recognized as a disease. Expanding the definition of pain meant that measuring experiences of pain becomes more complicated, and even though traditional pain scales are still used, they cannot always identify whether its existence is symptomatic or a chronic condition. Still, pain scales still have tremendous value measuring responses to treatment. However, expanding pain’s definition also meant that those experiencing pain have a larger range of treatment options available to them.

Pain is Gain

The late 1980’s was a pivotal era for Big Pharma companies, the redefinition of pain meant expanding opioid prescriptions from cancer patients to the growing and more lucrative chronic nonmalignant pain market. Chronic nonmalignant pain (CNMP) is defined as: “pain which persists after healing is expected to have taken place, or which exists in the absence of tissue damage” (Hylands-White et al., 2017). The use of opioids for CNMP remains controversial, however during this shift, numerous article publications such as “The Tragedy of Needless Pain” valued opioids as a better alternative to combination pain medicine and made opioid prescriptions more widely practiced and incorporated into clinical guidelines (Melzack, 1990). Soon, opioid use “in the management of acute, severe, and chronic pain was considered the standard of care” in the United States (Zacny, et al., 2003). Subsequently**,** U.S. states began to pass obstinate pain treatment acts, removing prosecution threats for physicians who aggressively treated their patients’ pain with controlled substances.

Understanding Opioids

Opioids are a classification of drug that comes from, or are manufactured to imitate, opium from an opium poppy plant. The term opioid refers to "all compounds that bind to opiate receptors" in the central and peripheral nervous system to modulate pain (Rosenblum et al., 2008). Opiate receptors additionally maintain functions such as mood, stress, and reward mechanisms. Although they are used in various treatments, they are best known as analgesics, which are pain relieving drugs. Throughout this thesis, analgesics and opioids will be used interchangeably. There are three types:

1. Alkaloid: opiates deriving from organic sources, such as the opium poppy, to make morphine and codeine.
2. Semi-synthetic: drugs synthesized from naturally occurring opiates, such as heroin synthesized from morphine.
3. Synthetic: lab derived opioids such as fentanyl, unsynthesized heroin, buprenorphine, methadone, hydromorphone, and others.

The distinctive feature of opioid-induced analgesia is that although pain is still present, it is less intense and better tolerated. To clarify, the drug does not treat the cause of pain but decreases its perception instead. Other effects of opioid analgesia are drowsiness, euphoria, and mental clouding. All opioids are powerful painkillers and most have a high potential for dependency and abuse. However, most opioids have "relatively short half-lives, thus necessitating the development of new delivery systems designed to provide prolonged effects" and a longer dosing interval (Rosenblum et al., 2008).

Opioid Development

Pharmaceutical companies are required to show efficacy and safety of these drugs in clinical trials prior to marketing them. This includes a four-step process regulated by the United States Food and Drug Administration (FDA) that also works to identify potential side effects.

Phase one tests the safety of the drug in a small group of healthy volunteers. If the drug cannot be tolerated or produces significant side effects, testing will discontinue. The second phase determines the efficacy of the drug in treating the disease and its side effects through controlled trials with a larger group of volunteers. If found effective in controlled trials, the drug will pass into the next phase. The FDA estimates that only 33% of medications will make it into the third phase of testing (FDA, 2018). Phase 3 incorporates a substantial group of patients who will unknowingly receive the drug or a placebo pill in order to confirm the effectiveness as well as identify side effects. Trials are carried out in the fourth and final phase after approval by the FDA's post market safety monitoring. Very few medications pass the final phase to be approved by the FDA, which can take between two and seven years.

Potential for Abuse

Opioids are classified as a schedule II drug, drugs with a very high potential for abuse potentially leading to severe psychological or physical dependence. Schedule II drugs are also considered potentially dangerous but have been shown to have medical value.

Aforementioned**,** opiate receptors regulate other functions such as mood, stress, and reward mechanisms. In most individuals, when opioids are prescribed to treat pain, there is no apparent change in the receptors involved in reinforcement and reward. However, every time an

opioid is taken, it still binds to these central mechanisms. Addiction can occur in short- and long-term use of the drug, where repeating the administration and reinforcing outcomes may be associated with craving and with positive/pleasurable mood effects (Di Chiara, 2002). These outcomes are potentially serious when they transpire (driving the development of an addictive pattern of use) and can occur in the presence or absence of pain.

Risk factors for opioid addiction include youth, untreated psychiatric disorders, social settings that may encourage misuse, and a history of/current substance abuse. People who are middle aged and have substance abuse and psychiatric concurrencies are more exposed to opioid mortality (Webster, 2017). Additional effects of opioids include “respiratory depression, decreased gastrointestinal motility, sedation, nausea, vomiting, constipation and intestinal bloating” in addition to direct cardiovascular effects, such as decreased blood pressure and cardiac work (Opioids, 2020) .

Opioid Timeline

Prior to the expansion of the chronic pain market, opioid pain medications were used primarily for acute pain and cancer pain. When pharmaceutical firms get U.S. Federal Drug Administration (FDA) approval for a new product, under the auspices of health communication, the government enables them to market the drug and create demand where none previously existed (FDA, 2021) In the United States, numerous opioids have been commercialized for oral, transdermal, and intravenous administration.

In May of 1987, MS Contin was approved as the first formulation of opioid pain medicine that allowed dosing every 12 hours, instead of every 4 to 6, for moderate to severe pain (FDA, 2021).

In December of 1995, OxyContin was approved by the FDA and was also marketed as the first formulation of oxycodone controlled-release that allowed dosing every 12 hours for moderate to severe pain, yet did not disclose habit-forming properties, especially if used long-term. At the time, the FDA believed that OxyContin's controlled-release properties lacked high potential for abuse because slow absorption of the drug into the body would not elicit a "rush" or high. However, FDA labeling did acknwledge that crushing a tablet and administering it through intravenous injection may cause lethal overdose. Subsequently, the FDA released a statement that, in part, they based their "judgment of OxyContin on the prior marketing history of a similar product, MS Contin, a controlled release version of morphine from 1987 that did not have overwhelming reports of abuse and misuse" (FDA, 2021). OxyContin would soon become a focal point of opioid abuse issues that would continue to escalate into the late 2000s and beyond.

Research Questions

This systematic review will use research studies on Big Pharma marketing strategies and apply it to the interview responses of individuals working in or in relation to the American opioid market. The purpose of these interviews is to further analyze whether preventative policies in place have limited Big Pharma's private interests and relationships from the sector of public health. My goal with these interviews is to tease apart the following questions:

1. Do these preventative policies have deterrent value on pharmaceutical companies and the individuals who run them?
2. Are the enforcement mechanisms for these policies being properly exerted?
3. Over the past decade, has there been a noticeable decline in Big Pharmaceutical access to the public health sector?

Rather than coalesce with previous research studies - on Big Pharma strategies in expanding opioid prescriptions, and the relationship between new opioid medications on increased rates of abuse and clinical malpractice - these questions are unique in identifying whether simple disclosure of these "webs of influence" is enough to terminate them.

Conclusions

The past several decades in the United States have been characterized by attitudes that have "shifted repeatedly in response to clinical and epidemiological observations, and events in the legal" and regulatory communities (Marks, 2020). However, opioids remain a constant. Their use for chronic pain has increased annually since 1990. This increased use of opioids for legitimate medical purposes has been accompanied by a substantial increase in the prevalence of nonmedical use of prescription opioids (Zacny, et al., 2003). Despite prescription drug abuse being multifaceted, it does reflect the impact from "changes in available drug formulations and the prescribing practices" of opioid medication (Rosenblum et al., 2008). Previous analyses of corporate interest in the pharmaceutical sector have illustrated the main role pharmaceutical companies have played in orchestrating the epidemic, yet not enough research has been done to confirm whether preventative policies put in place have been effective in separating the private

sector from the realm of public health. This study is unique because it queries individuals who work at different levels of the opioid market whether they believe they are insulated from the corporate influence of Big Pharma.

Chapter 2

Background

The opioid epidemic of the United States is not a new phenomenon, however, its influence on the nation has never had such a palpable impact as its existence today. The socioeconomic burden of opioid abuse has ravaged communities as a result of multi-system regulatory failures. Regulatory agencies should use better remedies to promote better conduct of Big Pharma and the court system, in approving settlements, should exercise diligence in creating realistic remedies with achievable deadlines.

In this chapter, three distinct waves of the opioid epidemic will be discussed. Each wave of the opioid epidemic will be described with their respective connection to Big Pharma corporate interest. Additionally, this chapter will tease apart research of known "webs of influence" in the American opioid industry and Big Pharma strategies used to partner with physicians, public health officials and the academy. Finally, limitations to understanding the total impact of corporate pharmaceutical companies will be explained.

The Opioid Epidemic Overview

The opioid epidemic continues to pull the attention of people across all demographics, even those who do not use opioids. Throughout this crisis, stigma has been placed on addicts, yet opioid addiction is a biological reaction that can happen to anyone with or without their knowledge.

The first wave of the epidemic flared in 1990, when extended-release OxyContin and other high-potency opioids began to be prescribed to a wider range of people. Most affected were

white, rural, and middle-class individuals, unusually high compared to previous opioid abuse and overdose statistics. The second wave resurged around 2010 and rapidly increased mortality rates among African Americans typically in urban areas of the United States. The second wave is attributed to the heroin market, which rose in demand from people addicted to prescription opioids. Many people are unaware that they are dependent on opioids to perform normally until after their prescription ends. Due to the higher cost of prescription opioids, users may resort to heroin instead, which is cheaper, stronger and easier to find. In fact, about 80% of people using heroin began with an opioid prescription (Jones, 2013)

These demographic shifts continued into the third wave of the crisis in 2014, characterized by rising addiction and overdoses linked to synthetic opioids such as fentanyl. Each wave added to rather than replaced previous waves, addiction and overdoses persisting among individuals using any or all prescription opioids, heroin, or synthetic opioids. In 2020, opioid overdoses reached a record high of 70,000 in the United States, the gravity of this figure recognized when placed in comparison to Canada's record high of 6,300 opioid overdoses that same year (Belzack & Halverson, 2018).

Webs of Influence

The profit-driven spike of opioid prescriptions from inadequate regulation of the pharmaceutical and healthcare industries unfolded the opioid crisis. Departing from the long-established practice norms that persisted before the 1990s, this new prescribing pattern expanded the availability of potent opioids to chronic, non-cancer pain experiences. Immense research exists that big pharmaceutical companies created and exacerbated the modern opioid crisis

through webs of influence. Entwined in this web are health professionals, patient advocacy groups, medical professional societies, research universities, teaching hospitals, public health agencies, policymakers, and legislators.

Previous analyses of corporate influence in the public health sphere elucidate that opioid companies' strategies are neither new nor creative. Many private pharmaceuticals utilize the guidance and direction of numerous marketing entities "—public relations, management consultancy, and crisis management firms—" previously hired by tobacco companies and related industries to discredit claims of harm derived by their products or sales practices (Marks, 2019). For example, pharmaceutical manufacturers hire "medical education and communication companies (or MECCs) to shape the evidence required for the approval and promotion of new products and recruiting physicians as opinion leaders," for their product (Marks, 2019). These physicians are paid to deliver scripted presentations to their peers about a pharmaceutical brand, but also gain status in the community as well. Albeit relationships spanning across institutional levels, media attention gravitates towards the individual. Doctors and researchers are berated for not disclosing industry-related financial interests, and patients who became addicted are not portrayed as victims of an invasive marketing strategy.

The opioid epidemic has contributed to drug use being the number one cause of accidental death in the United States, and the current rate of mortality exceeds even the worst year of the HIV/AIDS epidemic. These statistics are unignorable, forcing media attention to focus on bigger names, such as Johnson & Johnson and Purdue Pharma, for accountability. In addition to the harm, they have imposed by manufacturing opioids, Big Pharma companies have also monopolized profits by selling active ingredients to create the drug. This was revealed in a recent Johnson & Johnson trial, whose company had been supplying ingredients to several other

opioid companies, including Purdue Pharma. However, it is important to note that in 2012, Purdue Pharmaceuticals only controlled about 3% of the American opioid market while three generic companies (Spec Gx, Par Pharmaceutical, and Actavis) had control over 88% of the 12.6 billion opioid pills in distribution (DEA, 2014).

Media attention has persecuted Big Pharma companies for profiting in the branded sale and promotion of generic opioids, but not the larger unbranded companies themselves, like Spec Gx, Par Pharmaceutical, and Actavis. Yet, the criminal trials of these former executives convey to us the relationships they built with public health agencies, academic institutions, and public health NGOs, as well as thousands of individual health professionals.

Influencing Physicians and Public Health Officials

Pharmaceutical companies perform the majority of their physician-targeted marketing at medical events. Clinical conferences are typically defined as "scheduled events where practicing physicians themselves present their colleagues with interesting clinical cases, share their new experiences and learn about the latest achievements of medical science and practice" (Abakumova, 2015). The value of clinical conferences is the direct communication of physicians, who analyze issues within a certain specialty in pursuit of improving quality of care. The event format varies: "workshops, highly specialized sections, round tables and seminars with participation of the leading specialists in a given field" (Abakumova, 2015). Invitation distribution ranges from text-message to mailed invites. Pharmaceutical companies can act as sponsors for the events, which are intended to bring new developments in the medical realm. Research has concluded, however, that many of these conferences are repetitive and the

discussion is pre-arranged by pharmaceutical companies. A clinical conference study done between 2012 and 2013 noted that health practitioners were invited to attend medical conferences regularly, at least 2 times a month, with November being the busiest month (Abakumova, 2015). Keynote speakers at these events, who function as the opinion leaders from local medical institutions, were speakers for 4 to 7 conferences a month and gave the same or similar speech. For physicians and public health officials, it is honorary to garner the reputation of a leading expert as a speaker for these events. Pharmaceutical corporations sponsor invited speakers by paying for their trips and paying honoraria, organizing cocktail parties and luncheons as part of medical activities. Invitation to these exclusive networking events is certain to elevate the prestige and opportunity of a physician. Pharmaceutical companies carefully target key physicians with an already established network and expand from there. The degree of expert involvement has increasingly depended on their level of influence and has strayed from the reputability of a physician's credentials. Several years ago, investigative reporters from the Wall Street Journal included the results of an internal study done by Merck & Co.. This study "calculated the 'return on investment' from doctor-led discussion groups was almost double the return on meetings led by the company's own sales force," proving clinical conferences successful (Hensley & Martinez, 2005). The pharmaceutical industry has also utilized sales representatives, or "drug reps," to influence the prescribing patterns of physicians. These drug reps are young, energetic and attractive, with the goal of increasing the sale of their medication. Drug reps are typically assigned to a geographic area to advertise a specific medication their company manufactures. Pharmaceutical companies know how well each drug rep is performing by tracking pharmaceutical sales of their drug in that location. In order to get in contact with busy physicians, drug reps offer catered lunches for the entire office in exchange for a few

minutes of the physician's time. During these crucial few minutes, reps advertise the medication and discuss research that emphasizes its superiority over other treatments. In addition, drug reps give numerous items, such as pens and notepads, covered in the brand's name to further remind the doctors, staff and clients of the medication. As the relationship between physician and representative grows, it is not uncommon for the rep to host outings, such as golf and luncheons, to further develop their connection.

Pharmaceutical companies also offer outright payments to physicians for prescribing their products. Previous studies have found that the receipt of payments from opioid companies is associated with the increase of physicians prescribing their product. Of course, this is the reason that drug companies engage in such behavior, and similar practices have been found in the prescribing of other prescription drugs.

Approximately one in seven physicians in the United States received opioid-related gifts from pharmaceutical companies between 2014 and 2015 (Hollander et al., 2020), while family physicians placed even higher at one in five (Hadland et al., 2018). 2019 court documents filed by the Attorney General of Massachusetts claim that doctors in contact with Purdue Pharma drug representatives were ten times more likely to prescribe opioids to patients who later died of an overdose than doctors who prescribed opioids without having met with the company. (Commonwealth of Massachusetts, 2019, pg. 59).

Influencing the Academy and Civil Society Groups

Clinical conferences that pharmaceutical companies sponsor are generally organized by the "Ministries and Departments of Health, by leading research and/or educational institutions in

the field or by recognized medical centers and other institutions" (Abakumova, 2015). In these partnerships, governmental institutions are responsible for organizing events and attracting audiences.

Financial relationships are also built covertly through philanthropic service. Donating large sums of money under the guise of "charitable deeds" also serves as a means to a valuable end for pharmaceutical companies. Several academic institutions and universities received donations from opioid companies, blending corporate philanthropy with individual philanthropy. For example, Purdue Pharma and members of the Sackler family afforded gifts to universities and their affiliated hospitals - the most prominent being Tufts department of science. Only three years after the launch of OxyContin, Tufts University allowed Purdue Pharma to establish a Master's of Science in Pain Research, Education, and Policy. In 2014, Purdue then partnered with the university to create two "unbranded curricula" approved for teaching Tufts students. These academic institutions provide opportunities to influence research, curriculum, speaker series, and other events, as well as elect Big Pharma officials onto faculty and advisory boards. Although philanthropic relationships between the two realms precede the release of Oxycontin, they intensified after.

Academic institutions additionally serve another angle in achieving corporate influence strategy: exposure to public health NGOs. This approach can be simplified as "killing two birds with one stone." Because leaderships of these institutions often overlap, one financial contribution to the academy can sway advocacy groups and professional associations without additional expenditure. A study published in 2018 concluded that corporations prudently gifted non-profit organizations so that they commented favorably in regulatory processes (Bertrand et al., 2018, pg.7). Many of these organizations are financially constrained. Pharmaceutical

companies exploit this stress to either promote and protect their interests by targeting these groups' influence on policy. Targeting organizations such as civil society groups or health-related NGOs is instrumental in influencing policy makers, the policy process, and future policy. Public officials place less skepticism on individuals who appear to be independent or representative of public health, than representation from the pharmaceutical companies themself. Numerous groups funded by opioid manufacturers have produced their own criteria to understate the products' risk for addiction, lobbied against legislation aiming to reduce prescribing practices, and generally supported the indirect influence of these companies.

Big Pharma additionally manipulates the efficacy and prescription patterns of opioids through relationships with tech and medical record companies. Multiple Big Pharma companies have paid technology companies to “generate prompts in electronic health record software encouraging physicians to prescribe more opioids” (Farzan, 2020).

Creating these powerful relationships at the research and regulatory level has allowed Big Pharma to stretch their influence outside of the medical realm and gain power in social and legal platforms. In the event of litigation, close contact with these institutions makes it easier to frame both doctors and patients as the problem while maintaining institutional relationships - despite prosecution and trial by media. A prime example is Purdue Pharma’s term “opiophobia,” used to describe physicians who express concern about the product’s addictive properties. Eventually, the World Health Organization came to include this term in their guidelines until 2019, after disclosure of corporate influence (Clark & Rogers, 2019, pg.7)

Influencing Legislators and Policy Makers

A study completed by the Center for Public Integrity (CIP) and the Associate Press investigated the influence opioid companies have in state and federal policymaking by analyzing campaign finance and lobbying data between the period of 2006 and 2015. Throughout this period, pharmaceutical companies spent over $880 million on political contributions, equating to "roughly 7,100 candidates for state-level offices" and an average of 1,350 lobbyists per year. Another study, focusing directly on the relationship between these companies and the U.S. Senate and House during a two-year election cycle (November 2016), found that 89% of House members and 65% of Senate members had received money from committees already under investigation for contributing to the opioid crisis (McCoy & Kanter, 2018).

In addition to collaborating with government officials, Big Pharma also builds financial relationships with government agencies. These techniques are not unique in any way and are comparable to corporate strategies in food and soda sectors who partner with government agencies in addressing health concerns such as obesity or diabetes, for example. Such is the case for the National Institutes of Health (NIH), a medical research agency part of the U.S. Department of Health and Human Services. In 2017, the NIH instituted a "public–private initiative" to acknowledge the opioid epidemic. From their first two conferences in June 2017, more than one-third of the attendees were executives of drug companies, device manufacturers, or other industry actors (NIH, 2018, pg. 9). To advertise this partnership, pharmaceutical corporations ran advertisements in various publications, such as Purdue Pharma in the *New York Times* that concluded with these words: "We want everyone engaged to know that you have a partner in Purdue Pharma. This is our fight too" (Purdue Pharma, 2018).

It is crucial to recognize that the independent actions of these companies are highly influential, despite competing with each other. When different corporations make financial contributions to patient advocacy organizations, government offices and health professionals related to pain management, these activities might be "regarded as concurrent—each company giving money with the intention of fostering a more permissive attitude towards opioid use" exemplified by policymaker representation (Marks, 2020).These activities are considered competitive when the company making the donation intends to generate more prescriptions for their product by "stealing" potential patients from competitors. Regardless of the intent, the purpose remains the same: to influence public statements and representation of opioids to slacken prescribing guidelines and downplay risks of addiction and abuse.

Limitations to Understanding the Totality of Influence

When pursuing accountability, framing corporate influence as *financial* conflicts of interest tends to have two consequences. First, while conflicts of interest can be defined broadly to include institutional conflicts, accountability is usually focused on individuals rather than institutions—for example, physicians who receive payments from drug companies, rather than academic medical centers or universities that might have equally problematic relationships with drug companies. Second, disclosing financial conflicts of interest with corporate actors is not enough to address the systemic problem of corporate influence. It is the bare minimum. Disclosure and related measures promote transparency to help reveal the extent of the problem of corporate influence. Fighting the crisis alone requires more than just mandatory disclosure of the wide array of recipients receiving payment from opioid companies. Keep in mind, many of these

corporate gifts are not a secret, which is why pursuing accountability for solely "financial" interests allows many of these corporations to settle outside of the court system, affecting the extent of public knowledge about Big Pharma "webs of influence" and the ability to measure the efficacy of preventative policies

Conclusion

Companies currently spend one third of all sales revenue on marketing their products, roughly twice what they spend on research and development. The trials and settlements of Big Pharma companies only confirms what we know about their "webs of influence," and quells further investigation about the strategies of other companies that have been more successful, thus far, at keeping evidence out of the public domain—often by settling cases before they go to trial. Shaming individuals, regardless if it is deserved or not, minimizes a structural problem: "institutional and societal cultures and practices that embrace partnership with industry and, wittingly or unwittingly, promote companies' products, increase brand loyalty, burnish corporate reputations, defuse support for the regulation of companies' products and marketing practices, and reinforce the framing of public health problems and their solutions in ways that are least threatening to the commercial interests of those companies" (Marks, 2017).

Chapter 3

Remedies

Previous analyses of corporate interest in the pharmaceutical sector have illustrated the main role pharmaceutical companies have played in orchestrating the epidemic. Nowhere is this more apparent than the inception of and responses to the opioid epidemic, where "collaborative efforts to address pain management—an important and historically neglected problem in medicine and public health—have profoundly exacerbated another major public health crisis, addiction" (Marks, 2020). On the national level, legislation addressing these concerns has been enacted.

In this chapter, numerous policies and resources intended to disclose relationships between the private pharmaceutical sector and the realm of public health will be reviewed. Additionally, a paradigm shift towards a "norm of separation" advocated by these sanctions will be analyzed considering their cultural and socioeconomic developments.

Preventative Policies

Policy solutions act as an "ethical floor" in disclosing industry-related financial conflicts of interest. Once conflicts of interest have been recognized as a problem, the most common policy solution is disclosure of said conflicts. The Physician Payments Sunshine Act (PPSA) "places the responsibility on drug and device manufacturers to disclose their payments to physicians and teaching hospitals" and is an extension of the Affordable Care act (Richardson, 2014). Enacted in 2010, the Sunshine Act publishes this data annually in a publicly searchable database. The first wave of data went live September 30, 2014, yet the full impact of this law

will not be clear for at least a few more years. However, its implications have increased transparency on physician's financial relationships as well as increased the administrative costs of pharmaceutical manufacturers and related companies as covered by the statute. Now, under Section 6111 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act of 2018—entitled "Fighting the Opioid Crisis with Sunshine"— the scope of transactions covered by the PPSA has expanded to "include payments to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives"—commencing this year of 2022 (U.S. Congress, 2010, pg. 595).

Given the evidence of the impact financial interactions have on physicians' opioid prescribing and opioid-related deaths, there is still concern that the vast majority of patients remain unaware whether or not their physician has received payments from a pharmaceutical company. In response, the Center for Medicare and Medicaid Services (CMS) developed Open Payments, a "national disclosure program that promotes a more transparent and accountable health care system," that is easier to navigate for the common patient and works in hand with the Sunshine Act (Richardson, 2014).

It is imperative to note, however, that before the data is published for the public it is compiled and then sent back to physicians and manufactures for correction and verification. In the period between the Sunshine Act's commencement on August 1, 2013, to its first wave of data published on September 30, 2014, the CMS announced that they would be holding some data pending verification - straying away from the act's initial intent to publish all data by that date.

A Norm of Separation

Creation of these preventative policies is resultitive largely in response to a wave of Big Pharma lawsuits in the early 2000s, primarily Purdue Pharma, whose settlements bore little to no repercussions. In 2007, Purdue Pharma pleaded guilty to manipulating patients and clients by minimizing the abuse and addiction properties of OxyContin, yet continued to deploy aggressive marketing strategies for at least a decade after paying some $600 million in fines (McMahon, 2021, pg.24). Since then, other Big Pharma companies such as Johnson & Johnson and Insys have pleaded guilty to the unbranded promotion of opioids and fraudulent marketing practices, which were paid in settlements. However, there are numerous procedural hurdles that impede the responsibility of harm these lawsuits aim to achieve. When litigating pharmaceutical companies, if the FDA has already approved an opioid's use, attempting to convince a jury that it is faultily manufactured is difficult (Haffajee & Mello, 2017).

Regardless, the procedural strategy of a class action suit in opioid litigation has created a paradigm shift that has worked to strengthen the aforementioned preventive policies. In class action suits, harm is assessed at the group level to focus on statistical associations between product use and injury (Haffajee & Mello, 2017). There are hundreds of thousands of individual claims against numerous Big Pharma corporations that, when combined, are more powerful in receiving restitution for individuals and social systems debilitated by opioid addiction. Outside of court, the sheer number of individuals affected by the crisis shocks the nation and the implication of pharmaceutical companies in the opioid crisis has regained media backlash from large publications. Still, many of the pharmaceutical companies in the line of fire have seen numerous trials with little to no amendments in their fraudulent and aggressive marketing - yet the public continuously grows aware. More researchers and physicians are biting back at the

legitimate purpose of opioids in chronic non-malignant pain management. The enactment of these preventative policies has championed a norm of separation between the private pharmaceutical sector and clinical outcomes, while class actions suits have highlighted the abundance of families and communities affected by this epidemic. In coalescence, the number of physicians who have had some form of interaction with drug manufacturers and related counterparts has decreased.

Conclusion

Despite literature confirming the distance between the pharmaceutical industry and the sector of public health following preventative policy implementation, a measure of their success regarding the value of disclosure has not been assessed from players working directly in or alongside the American opioid industry. The next portion of this thesis will interview these players in order to gauge their perceptions about the effectiveness of preventative policy.

Chapter 4

Methodology

Six participants were recruited for their experiences within or alongside the American opioid industry. The eligibility requirements for the study limited potential participants to two groups:

Three of the participants in this study were physicians or surgeons who have worked with, or are currently working directly with, treating and managing patient pain. The study included two doctors specializing in pain diagnosis and management after completing 4 years of medical school in addition to 4-5 years of internship and residency experience - where 20% of the patients they cared for fell into the pain regiment. To become board certified in pain medicine, both doctors achieved a satisfactory score on a three-hour, 300 question board exam, and have been recertified every 10 years since passing the original board. These individuals were contacted by the investigator via email. The original pool of participants, consisting of only pain management doctors, was selected on the basis that they specialize in orthopedic care and research. Reasoning for the selection of orthopedic specialists was that most patients who experience chronic pain tend to schedule with, or are referred to, orthopedic doctors that concentrate exclusively on the musculoskeletal system. However, this selection criteria was circumstantially expanded in the best interest of this study to include a former drug representative turned doctor. This participant completed a baccalaureate degree before working as a drug representative for ten years and subsequently, completed 4 years of medical school in addition to four years of residency and intern experience. All participants were geographically diverse across the United States and none shared the same work environment: one worked in a university affiliated multi-hospital setting, another in private orthopedic practice, and the last in a

multispecialty medical group and hospital. Collectively, the average age for this group was 53.3, with an average of 20.7 years of experience in clinical settings.

The 3 participants that constitute the second study grouphave experience working in or alongside the pharmaceutical industry. These individuals were contacted by the investigator via email. This group of participants was selected on the basis that they have direct involvement with the manufacturing or distribution of prescription analgesics. Only one participant of this study group was not directly employed by a pharmaceutical company, however, all participants were occupationally and geographically diverse across the United States. The study included a former federal agent who worked undercover, under the auspices of the Financial Crimes Enforcement Network bureau of the U.S. Department of the Treasury. Prior to retirement, they served over 30 years as an investigative consultant for the U.S. Department of Treasury and 6 years as Special Agent in Charge. This participant also achieved three certifications as a Fraud Examiner, a Forensic Interviewer, and an Anti-Money Laundering Specialist. The second participant has worked as a research fellow for six years, and is currently in their ninth year as an Associate Principal Scientist for the same company - one of the largest multinational pharmaceutical companies in the United States and Europe. To achieve this role, the participant completed a Doctor in Philosophy and a Ph.D. in Polymer Chemistry, followed by six years of research at a pharmaceutical-based material lab. The third participant in this study group also worked for one of the largest multinational pharmaceutical companies in the United States as a drug representative for fifteen years. Prior to their employment, this interviewee completed a concurrent advertising bachelor's/master's program over the course of 5 years. Collectively, the average age of this group is 59 years, with an average of 14.2 years experience in their field. The average years of experience for this participant group is dramatically lower than the first. This is

because the participating federal agent can only confidently claim that five years of work they completed was directly associated with pharmaceutical companies.

Materials

The interview templates used throughout the study by the investigator included yes/no and open-ended questions, as well as prompts to encourage further explanations. All interviews took place via Zoom or telephone, and strictly audio-data was recorded using the recorder program on a Macbook Pro laptop computer. The participants were all made aware of the purpose of the study in the recruitment email (Appendix A) as well as the consent form (Appendix B), which was read to the participant by the primary investigator prior to each interview. Participants verbally consented to take part in the study after the consent form was read aloud. After each interview, participants were subsequently sent a copy of the consent form via email.

Procedure

Participants were interviewed about their experiences in both clinical and personal settings with regard to contact they have had with, or work they have done for/alongside, pharmaceutical manufacturers. Semi-structured interviews took place via Zoom or telephone at the participant's convenience. Interviews began with a general series of questions, which gradually narrowed to build a timeline of their interaction with pharmaceutical companies before, and after, the enactment of preventative policies (Appendix C & D). Participants were asked to engage in one interview, ranging 30 minutes to an hour, and were given as much time

necessary to answer each question, with the liberty to decline as well. Interviews were audio-recorded so that the information gathered from each participant could be analyzed verbatim in retrospect. All identifying information relative to participants was removed from audio files as well as the data recording sheets used to organize the information from each interview.

Chapter 5

Interviews

Medical Specialists: All three doctors/surgeons gave similar responses when asked to describe moderate to severe pain, best defined by one as “an experience which sort of incapacitates an individual and their main focus becomes on that pain and managing it.” The reason for asking physicians to describe moderate to severe pain instead of chronic nonmalignant pain was to observe whether they viewed the duration of pain experience as an undismissable factor in treatment approach. The importance of this difference may appear minute, however, descriptions matter for a patient explaining their pain to a doctor, and to the doctor attempting to understand that pain. None of the participants included an interval for the experience of pain in their definition, despite the necessity of that pain being “prolonged” or “chronic” in order for them to prescribe analgesics under CDC guidelines. However, all participants agreed that acute pain can be cured while chronic pain can be managed.

Due to their varying specialties within the realm of pain medicine, to analyze how each is currently treating patients suffering from chronic pain, it is best to start with the orthopedic doctor, who uses a multifactorial approach. Because “medicine itself isn't gonna do it,” he recommends “physical therapy to strengthen structures and support the back” as well as “finding different ways a client can be active to naturally treat their pain via the release of endorphins from exercise to help diminish it.” The orthopedic surgeon also recommends physical therapy before surgery, however the reason most patients schedule to meet with him is because prior physical therapy did not help. This participant states that immediately before and after undergoing surgery, prescription analgesics are almost always provided to patients unless they decline. After an orthopedic surgery, painkillers are prescribed not to manage the prior injury,

but “make the pain bearable enough that they are gradually able to function after the reconstruction and participate in their own recovery, which includes mandatory ambulation during physical therapy.” In the event they are unable to pinpoint the cause of pain, they can still suggest a pain management plan for their patients, both agreeing that “95% of their patient’s pain is treatable with physical therapy, medications and injections” and still suggest the remaining 5% do things to reduce the effect of pain on the body prior to medication. In comparison, the ER doctor has a general disposition to prescribe medication to patients experiencing pain because at that point it is typically unbearable. Acknowledging their past as a drug representative, the doctor feels updated on and knows what to look for when prescribing analgesics, despite not having a medical history repertoire with his patients.

The study group acknowledged that disclosure of a patient’s history of substance abuse is largely based on the honor system. Doctors take a patient’s word at face value because abuse is quickly evident around the first or second urine screening or by asking the patient to come in for a pill count check in the middle of the month. The only true instrument in place is that almost all narcotics prescribing is now done with a contract where the patient agrees to certain conditions. One condition for dismissal would be if a physician “discovers a patient's abuse or history of abuse with the narcotic, that they were not forthcoming about” during the original signing of the contract. However, in the event substance abuse is present, all participants describe in some manner that opioids can still be prescribed and used effectively in a way that is a win-win. Someone experiencing both substance abuse and chronic pain would not be prescribed medication because it would help for maybe a week before the pain increases, but for an addict experiencing acute pain “such as a broken bone that is gonna feel a lot better in a week or two and heal in about 4 weeks - it can be done, and you can even manage the prescription so that you

give them very small quantities at a time," such as dispensing medication 3-4 days at a time to reduce the likelihood of abusing a large quantity of pills. The maximum amount of time a patient taking prescription analgesics can go before having to consult with a doctor again is 90 days if stable yet could be seen more frequently.

Ultimately, prescribing practices are at the physician's discretion yet the final decision on medication is made by the patient's insurance. When asked what systems are in place to monitor any drug a doctor prescribes, their quantity, and the frequency at which they prescribe them, the common response was that all controlled substances and prescription monitoring is controlled by the state. None of the doctors could detail what mechanisms are in place to identify if a doctor is "over-prescribing" a medication, nor the level of difficulty to prove so. Additionally, the same process is used to prescribe any medication from any schedule, regardless of their potential for abuse. One participant included that to prescribe an opioid they must " put [their] thumbprint on a biometrics to show that it's [them], but [they] have to use the biometric regardless if [they] prescribe any other schedule 2,3,4,5 drug."

In further questioning, this study group testified that they had not been in contact with a drug representative for an average of 11.7 years, yet one participant testified that they had in fact attended a meeting or event after speaking with a drug representative 13 years ago. All participants responded that they had been invited to attend an event centered around a medication or its brand at least once in their career. Interestingly enough, all doctors said that there were no outright incentives to manipulate their prescribing practices, sales representatives often bought "the office staff lunch in exchange for a few minutes of [their] time to exchange and listen to what they have to say. If it fit [their] patient or thought it could help them [they] would try it, and if it worked, [they] would prescribe it." Furthermore, each doctor agreed that trinkets left around

the office branded with a medication's name could subconsciously influence a doctors decision to prescribe, which is why each of their work settings has outlawed them. Additionally, all participants characterized drug representatives as some of the most personable, energetic, and attractive people in their pursuit, and "eager to make a connection with the physician more than [their] profession."

Specialists in the Pharmaceutical Industry: The most discussed topic from each member of this study group was the influence of insurance policies on their prescription practices, the second being each participant's academic track regarding pain treatment specifically. These themes will be analyzed later in Chapter 6's discussion.

Out of all the participants in this study group, both the chemist and former sales representative characterized their work environment as shifting and competitive. Despite their extensive job variability, each participant responded that their line of work has put them in direct contact with a drug representative or medical specialist on multiple occasions.

The manner of interaction for each participant varied considerably: the former drug representative interacted with anywhere between 1 and 12 medical specialists per day, the chemist responded between one and three times per year, while the former federal agent responded their interactions were limited to permission from federal prosecutors, but did have indirect contact when conducting surveillance.

Unsurprisingly, the nature of these interactions also varied greatly. The relationship the former sales rep had with physicians always varied, but stated that they treated each specialist with the same "persistence and resilience," regardless of being rejected or not. Because rejection is a part of the job, this participant responded that in order to be successful they had to read in between the lines of a "no" to recommend their drug in a manner that targets the potential

customer's specific set of pharmaceutical needs. Because the line of work is competitive, there needs to be continual exposure of the medication they are attempting to advertise so that physicians do not partner with a competitor, meaning they will visit a physician who rejected them numerous times. In the event that perceived product value is ignored, or the representative has "a good relationship with a physician, but that physician is committed to a competitive product," job training conditions pharmaceutical representatives to emphasize off-brand uses for the drug to illustrate brand superiority. The study's participating chemist testifies that rarely do they interact with drug representatives or medical specialists, unless explaining the chemical research techniques used to imitate or create artificial healing catalysts (opioids). Additionally, these interactions are never independent and are instead alongside a board of other chemists that collaborated on product development. The former federal agent testified that their direct interaction with sales representatives occurred when the individual felt their company was pushing illegal sales, yet has spent years indirectly observing the practices of sales executives via wire tap and other surveillance methods.

All participants agreed that drug representatives can be helpful in keeping medical specialists updated on new medicine and related developments. Inversely, all participants mentioned in some manner that drug representatives have caused increased regulations that suppress the availability of prescription analgesics for people who actually need them. When asked about the most important talking points to observe when considering the use of a new medication, the chemist responded that analyzing the proclaimed "achievements" of the brand is important to really judge effectiveness. For example, a brand may advocate that their product "achieves some high levels in the bloodstream," but "in reviewing the pamphlet, you will see that sure, the medicine does push high blood levels, but what does that achieve?" On the

contrary, our sales representative champions these generalities as a way to push more prescriptions. For this participant, how “new” the product and related research is, is the most important topic when pitching their brand. It should be noted that this participant was the only one to testify that they had advertised brand medications under false pretenses. Our final participant, the federal agent, claimed that from their work, they feel it is imperative for patients to research whether their physician is prescribing them an opioid for off-label purposes and be knowledgeable about any medical intolerances they possess.

When asked how often they work directly with opioids, the chemist possessed the highest rate of interaction, followed by the former pharmaceutical rep, then the federal agent. Our chemist further clarifies that they do extensive work with “an array of psychoactive drugs, from benzodiazepines to methamphetamines” in addition to opioids. The former drug representative rarely handled opioids directly, unless offering small samples to medical specialists, and our federal agent rarely had direct interaction handling opioids.

All participants testified that in comparison to other advancements made in the scientific community, novel developments in pain management and treatment have lulled. Insight can be gathered from this study's chemist, who states that psychoactive drugs “used to enhance or imitate natural states of consciousness share many of the same structural homologies.” The importance of this is that opium alkaloids, used almost daily in pharmaceutical manufacturing, are typically used as training molecules for students beginning synthetic education. Comfortability synthesizing these molecules later transpires in their professional role as a pharmaceutical chemist, where the power of these properties becomes overlooked. Despite being educational in face, using these specific alkaloids in academic lessons covertly fuels obliviousness and compliance in the opioid epidemic. Additionally, decades later morphine is

still the standard all prescription analgesics are compared to, despite exorbitant funding towards pain management research and developments. Interestingly, both the federal agent and chemist mention one innovation, not development, in pain medicine: abuse deterrent formulations (ADFs). These are reformulated opioids designed to reduce the ability of misuse by making it harder to manipulate the pills (via crushing, dissolving for injection, etc.), or combining them with weaker counterparts. None of the available ADFs, however, can prevent all types of misuse. These pills do little to dissuade an addict but do have the potential to prevent an individual from escalating to misuse.

Out of all participants, none believed that the supply of prescription opioids in circulation has decreased, but did believe that the overall availability of opioids has increased, whether it be prescription or illegal formulation. An interesting inclusion about opioid supply comes from the federal agent who says that pill supply has been targeted through DEA initiatives through take-back programs, where individuals are invited to return any unused medications to be properly disposed of. However, these events do not gain much traction and the use of law enforcement to oversee these events means an individual returning pills to their pharmacy on a day the event is not scheduled, is participating in illegal activity. Regardless, the review on these events proves that they are instrumental in raising awareness and do have success in reclaiming a large portion of unused pills.

The most discussed topics in this study group also centered around academic or professional qualifications and prescribing practices, as well as opioid supply. These themes will now be analyzed in Chapter 6's discussion.

Chapter 6

Discussion

Interviews in this study gauged whether actors related to the pharmaceutical industry have identified a pattern in Big Pharmaceutical access to the public health sector via preventative policies and their enforcement mechanisms. Every participant in this study acknowledged that the pharmaceutical industry's exposure to the public health sector has declined significantly in the past decade, largely due to liability regulations. However, participants additionally notioned that Big Pharma influence still exists through reciprocity, and can occur even when there are no formal ties. What was initially intended to index the deterrent power of preventative policy in financial relationships, now reveals that preventative policy does not impact former or current financial relationships in place, but dissuades future conflicts of interest. Big Pharma's lack of dependence on medical specialists to influence prescribing, does not equal independence. These policies appear to dissuade medical professionals more than pharmaceutical manufacturers. The testimonies suggest that the hardest issues to address with policy are the supply, demand, and prescribing practices of prescription opioids affected by long-standing financial relationships, whether they still exist or not.

All participants were largely unaware of the mechanisms and guidelines in place that monitor their activity with opioids, except for the former sales representative and federal agent. I believe this piece of information speaks for itself. The study's former drug rep was offered voluntary certification as a Certified National Pharmaceutical Representative, which grants benefit packages on tuition reimbursement, company vehicles, medical/life insurance and

vacations, as well as access to a job search platform called NAPRx® Career Center. Upon inspection, this platform is a government website pharmaceutical companies use to hire open positions. A potential mechanism this participant did mention was that certain states now require pharmaceutical representatives to gain licensure. After researching, I view this route of legislation as a double edged sword. If licensure means that a pharmaceutical representative's employability is at more risk, then this legislation can be instrumental in securing compliance with government regulations. Additionally, this development may force sales representatives to meet minimum educational and training requirements. Remember that this study's former drug representative only maintained a degree in advertising, and the former drug representative turned doctor also mentioned that success within their company was largely in part that his colleagues had no background in health or medicine. In this sense, licensure could better guarantee a level of scientific understanding concerning pharmaceutical products. On the contrary, licensure indirectly reveres pharmaceutical representatives with a professional title, despite lacking the extensive education and experience other "professionals" complete to be regarded as such. If one goal of this policy is to threaten the employability of a professional who practices illegal marketing at the expense of financial interest, giving them a professional title also gives them a title to act as an educator about these medicines for doctors. This has the potential to directly reconnect the pharmaceutical industry to physicians. The study's former federal agent detailed that the FDA is the overall mechanism that monitors the use, access, storage and quantity of controlled drugs, as well as the force that grants repercussions for unlawful prescriptions.

The second most discussed theme from these interviews was supply. The former federal agent included that the activity of pharmaceutical sales executives rarely gains F.D.A. attention and most intervention policies target the supply side of physician prescribing. The benefit of

preventative policies in place is their contribution to exposing pill-mills and unethical physicians. However, regulating physicians prescribing in addition to disclosure would enormously multiply the value of prescription opioids and their related forms sold on the street, and can decrease related hospitalizations and mortality. On the manufacturing side, introduction of ADFs that reduce the strength and addictive properties of analgesics helps to reduce the quantity of more potent opioids in circulation. Yet, ADFs are still brand products, and reducing their strength does nothing to stop a drug representative from selling it or building a relationship in order to do so. In effect, ADFs can potentially be a powerful tool in luring even "opiophobic" doctors with financial interests. It is still important to note however, that production of ADFs could reduce the demand for more potent opioids overtime.

An unforeseen theme that was highlighted by the medical specialist group specifically, was the role of insurance in influencing their prescribing practices and even opioid demand. Each participant discussed how Medicaid agencies or insurance companies have considered expanding policy-holder access to non-opioid pain treatment. Generally, many patients choose opioids as a treatment route because they are not as costly as regular physical therapy sessions or surgery. Increasing coverage and access to pain management means more comprehensive and layered pain management plans. In turn, reducing the number of patients in demand for opioid prescriptions and the frequency at which they are dispensed. In coalescence with preventative policy, this makes physicians who over-prescribe opioids more obvious due to expanded practice behaviors and treatment options for pain management.

Every participant in this study spent the most time discussing their educational requirements and professional certifications for their line of work. Initially intended to be a question of credibility on the topic of opioids, transformed into a review of the pharmaceutical

industry's institutional implications. This theme is best conveyed from the responses of the medical specialists and chemist. Reading in between the lines of the interviewees response, each individual sided that pain research has not experienced novel scientific expansion in over a decade. For the medical specialists, treating and measuring experiences of pain is a primary responsibility. In their education, however, each recounts in some manner that the topic of "pain" was rarely discussed of its own importance, only being taught for a few hours as a subcategory across numerous lectures. In the literature review of this thesis, Tufts University is used as an example for financial interests persuading academic institutions, and exemplifies one of the only universities with a pain-focused curriculum. Our chemist testifies that many of the principles used to teach pharmaceutical chemistry remain the same and the literature from these academic institutions and their researchers is recycled, especially from universities with Big Pharma involvement. Despite preventative policy disclosing financial relationships from these academic institutions, the interviews suggest that it has not affected the infrastructure pharmaceutical companies have already built in the pain education and research of academic institutions.

Chapter 7

Conclusion and Recommendations

It is important to keep in mind that several companies are alleged to have engaged in corporate strategies of influence. These donations, outings, and relationships formed a larger scheme to accomplish a number of correlated effects— maximizing the revenue and profit of opioid companies. However, even though their contribution to the opioid epidemic is purely profit driven, it is crucial that it is not prosecuted as solely such. The guiding principle of preventative policy is disclosure, which plays a valuable role in tracking some of the more complicated relationships that pharmaceutical companies maintain. Disclosure brings physician-industry relationships to the public record for advocacy groups, policy makers, and the media to monitor. Many legislation standards mandate that pharmaceutical representatives abstain from deceptive or misleading marketing tactics to promote a professional ethics foundation and regain social and consultative trust. However, a drug representative's main responsibility is to maximize profits by increasing prescription quantity. They are not bound to any ethical duties towards patients, and for physicians, disclosure could also be interpreted as "permission" to engage in conflicts of interest, if they are disclosed. Although norms of strong professional ethics are best equipped to respond to the complex and dynamic relationships within the pharmaceutical industry, relying on ethical guidelines and "self-regulation" has been slow to promote meaningful change.

The "ethical floor" of disclosing these relationships, as advocated by preventative policies, places the responsibility on patients and communities - the individuals who are least prepared to fight this systemic problem and who are still being harmed by it. Disclosure, rather than elimination, allows actors both inside and out of the public health sector to continue building profit-driven relationships and generating addictive pharmaceuticals - unless our

regulatory systems are dramatically reformed. Throughout this epidemic, regulations have turned perceptions of the opioid epidemic from professional to purely legal in nature, replacing the virtue of trial with compliance. Regulated parties will always find loopholes to invalidate policy and continue promoting their products. It is imperative that government regulations are attentively written to address the fundamental issue of influence, while reducing unintended repercussions. Writing and enforcing laws is no simple task, however, the threat of regulation is capable of motivating professional and industry change, as reported by our interviewees and observed over the years through press and policymakers.

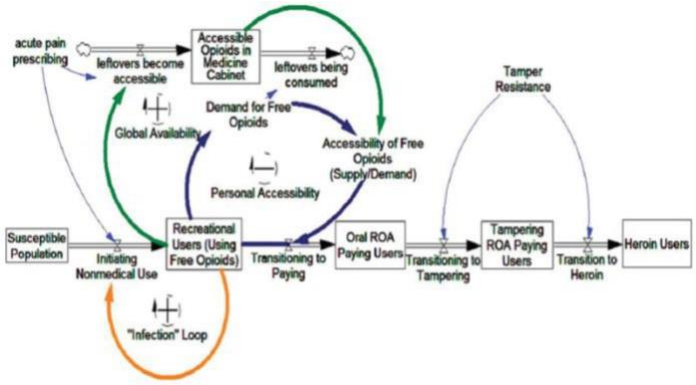
Comparing the systematic review of the known "webs of influence" pharmaceutical industries maintain within the sector of public health, to the interviews conducted from actors at each level of the American opioid industry, it transpires that preventative policy solutions in place to separate the integrity and public trust of governments, health officials, and civil society, are not isolated from corporate pharmaceutical influence. Lack of a national strategy to address the opioid epidemic is surprising despite the magnitude. Current preventative policies in place inherently assume that albeit disclosure, financial industry relationships will always be constant in the realm of public health. For that reason, this thesis will now recommend and discuss the importance of a systems model to predict what may be expected with and without the intervention of interest.

Recommendations

Because pharmaceutical manufacturers build relationships outside of their legal boundaries, a sensible response to the opioid epidemic must adjust more than prescription

policies. Sustainable and collaborative efforts to implement policy grounded in scientific research and clinical practice are needed at the national level. A systems model guides and strengthens surveillance, fosters a common policy vocabulary among all agencies with decision-making authority over opioid development, regulation, and enforcement, and demands collaboration to facilitate the exchange of information between these agencies (Library of Medicine, 2019).

Throughout my research I have encountered numerous statistics concerning different policy interventions that reduce the frequency of financial relationships yet have not seen a comparison of their effectiveness in relation to each other. Although it is a costly and time-consuming venture, the F.D.A. should consider investing in research to develop such a model to identify nonlinearities at the jurisdictional level. For example, the evolution of prescription opioid abuse is hard to pinpoint, especially after considering illegal opioid markets. However, a diagram can illustrate how a faulty prescription system increases the number of individuals with an opioid abuse problem



Systems Model from The Libraries of Medicine

The value of this system's model is that we can compare it to preventative policy to measure their efficacy. Preventative policies typically assume that opioid abuse begins with the

medical use of prescription opioids, escalates to misuse, then addiction with illegal opioids before possible overdose. Therefore, to curb the trajectory of the epidemic, policy targets the financial incentives and prescribing practices of physicians. Yet, looking at a systems model, it is realized that these policies only manage the prevalence of future prescription misuse, and do not benefit people who have current or developing opioid addiction. If the goal of preventative policy is harm reduction by disclosing industry-physician relationships, this system model conveys that most policy objectives do not alleviate harm already caused by industry, but truly aim to reduce the probability of a person at risk for abuse from receiving prescriptions from a financially ignorant physician. These little discrepancies are important when the annual mortality rate gains momentum every year. The difficulty with many of the preventative policies in place is that they are too recent to truly measure their virtue in dissuading financially motivated relationships. From this example, however, we see that a systems model is valuable in combining multiple statistics to evaluate the efficacy of current policy and predict their future outcomes.

Appendix A

RECRUITMENT EMAIL

Greetings _____,

My name is Kathryn Moyer, and I am an undergraduate student at Penn State University approaching my senior year as a Global and International Studies major. To graduate with honors recognition from the Schreyer Honors College, I am required to complete a senior thesis as the culmination of my honors experience.

For this piece, I am conducting a mobile interview study with individuals who have experience within the sector of public health, the pharmaceutical industry, or both. The title of the study is “The Efficacy of the Opioid Epidemic’s Preventative Policies: A Comparative Study Between the Financial Relationships of Big Pharma and the Integrity of Public Health." The data collected from these interviews will be used to complete my thesis paper.

Participants must have experience communicating with, or working for, pharmaceutical manufacturing companies and their related advocates. Participant interaction with the pharmaceutical manufacturing sector can be previous or current.

This study is being conducted for research purposes at the Pennsylvania State University.

Please do not hesitate to contact me via email (kjm77@psu.edu) or phone (215)-264-8772 if this proposal interests you, so that we can further discuss the scope of interview material. We can then schedule a time to conduct the interview at your convenience.

Any help or insight you could provide is greatly appreciated! Thank you for your time and I look forward to hearing from you soon.

Best Regards,
Kathryn Moyer

Appendix B

INFORMED CONSENT FORM FOR SOCIAL SCIENCE RESEARCH
The Pennsylvania State University
Title of Project: The Efficacy of the Opioid Epidemic's Preventative Policies
Principal Investigator: Kathryn J. Moyer
The Pennsylvania State University, Schreyer Honors College
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Advisor: Howard B. Smith, Ph.D.
Department of Sociology and Criminology
1013 Oswald Tower
University Park, PA 16802
(814) 863-8868
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1. **Purpose of Study:** The objective of this research study is to acquire information from dynamic actors within the American opioid industry to analyze a paradigm shift: whether federal preventative policies in place have limited Big Pharma's financial relationships from the sector of public health. This study will also examine the degree of knowledge and training each participant has in pain diagnosis and management, and controlled substances.

2. **Procedures to be Followed**: You will be interviewed about your experiences working within the American opioid industry, the sphere of public health, or both. Interviews will take place via telephone or a Zoom webinar at your own convenience. Interviews will start with a general series of questions that will be followed by subsequent questions relative to gathering the desired information. You will be permitted to completely answer each question, given as much time as necessary. You will be asked to participate in one interview, which will be approximately thirty minutes to one hour in length.

For both Zoom and telephone interviews, I will only audio-record the interview to record your answers. The purpose for the use of these recordings is to be able to transcribe the interview verbatim for further analysis. All identifying information relative to you, the participant, will be removed. Your name will not be associated with the audio recording. Each participant will be assigned a random alpha-numeric code which will be used in reference to the audio-recordings of each interview, respectively. Each interview will be recorded on the primary investigators laptop, and permanently deleted after it is immediately transferred to an external hard drive which will be kept in a locked laboratory in a locked corridor.

3. **Benefits:** The benefits to you for participating in this interview may include the ability to reflect on the work you have performed in the professional setting and its impact on public health. Your insight will be used to help expand the scope of knowledge about this relatively under-studied area of the opioid epidemic. Increased knowledge in these areas may help identify the effectiveness of preventative policies in intervening the financial relationships between healthcare providers and pharmaceutical manufacturers.

4. **Duration/Time**: Approximately thirty minutes to one hour of your time will be necessary to complete the interview. Times will be dependent upon the length and insightfulness of the answers given.

5. **Statement of Confidentiality**: Your identity will be kept strictly confidential and be known only to the principal investigator and advisor. All of the data (on the external hard drive) and information related to the data (identifying you, the participant, with the alpha-numeric code) that has been collected and analyzed will be stored in a locking filing cabinet in a locked room that only the primary investigator and advisor will be able to access.

The Pennsylvania State University's Office for Research Protections and Institutional Review Board, and the Office for Human Research Protections in the Department of Health and Human Services may review records related to this project.

6. **Right to Ask Questions**: Please contact Kathryn J. Moyer at (kjm77@psu.edu) or (215) 264-8772 with questions, complaints or concerns about this research. You can also call this number if you feel this study has harmed you. If you have any questions, concerns, problems about your rights as a research participant or would like to offer input, please contact The Pennsylvania State University's Office for Research Protections (ORP) at (814) 865-1775. The ORP cannot answer questions about research procedures. Questions about research procedures can be answered by the research team.

7. **Risks and Discomforts**: The greatest possible risk to you by participating in this study is loss of confidentiality. The potential for this risk will be minimized by keeping all records that link your identity to your interview in a locked file cabinet, in a locked room, in a locked corridor. Only the primary investigator (Kathryn J. Moyer) and adviser (Dr. Howard B. Smith) of the study will know the location of the participant identifier sheets and how to access them.

8. **Voluntary Participation**: Your decision to be in this research investigation is voluntary. You can stop at any time. You do not have to answer any questions you do not want to answer.

You must be 18 years or age or older to consent to take part in this research investigation. Your voluntary participation in the research would imply your informed consent to participate. Are you still willing to participate?

YES
NO

If you agree, may we audio-record the interview?

_____Yes, I give my permission to be audio-recorded

_____No, I do not wish to be audio-recorded

You will receive a copy of this consent form via e-mail to keep for your personal records.

Appendix C

INTERVIEW QUESTIONS GROUP 1

1

-In your own words, how would you describe moderate to severe pain?

-What kind of training do you have in pain diagnosis and management?

-How are you currently treating patients suffering from chronic pain?

-If unable to pinpoint the cause of pain, can you still suggest a pain management plan?

-What are the next steps if the recommended treatment does not work?

2

-Have you ever been in contact with a drug representative, more specifically, a drug representative for opioids?

-Besides drug representatives, what other ways are there that doctors are contacted to help promote a pharmaceutical company's drug.

-To your knowledge, how do drug representatives find/choose a doctor to promote their product (drugs/medical equipment)?

-Have you ever attended a meeting or event after speaking with a drug representative? If so, please explain.

-Has another physician, doctor, administrator, etc., invited you to attend an event centered around a medication or its brand?

-What incentives are there for physicians to prescribe more or start prescribing a drug advertised to them by a sales rep?

-Personally, what talking points or information would you look or ask for from a drug representative to consider prescribing the drug that they are advertising?

-In their pursuit, how would you characterize a drug representative's behavior when attempting to or actually networking with physicians?

-Do you believe that drug representatives are helpful in keeping you updated on new medicine or any other news related to medicinal developments?

- How do you stay updated on medicinal innovations and what do you believe is the most reliable source to stay updated?

-Drug reps utilize catering, hosted events, telephone calls and even choose to leave items with the medicine's name on it to remind doctors of their product - do you believe that doctors may feel more incentivized to prescribe that medication because of the amicable behavior and initiative a sales representative bestowed upon them and their staff?

- Do you think that trinkets or office supplies left around the office and branded with a medications name could subconsciously influence a doctor's decision to prescribe said drug?

-What systems are in place to monitor any drug a doctor prescribes, their quantity, and the frequency at which they prescribe them?

-Is there a way to identify when a doctor is "over-prescribing" a medication and what is the level of difficulty to prove that they may be overprescribing?

-When prescribing an opioid, are there any extra steps you have to take to prescribe that opioid or would it be the same as prescribing another schedule 2 drug, such as the stimulant Adderall, for example?

- Is prescribing a drug in a different schedule easier, harder or the same level of difficulty as writing an opioid prescription?

3

-Do you believe that in some instances pain can be fully eliminated?

-When prescribing opioids, what is the longest a patient can go before having to consult with a doctor again?

-Are patients required to try other forms of pain relief medication before opioids?

-How do you choose which opioid medicine to prescribe a patient? Who has more say in choosing the brand - the doctor or insurance?

-Is there any way to tell if a patient experiencing moderate to severe pain has or had a history of substance addiction and/or abuse? Are there any repercussions for patients who choose not to disclose current or prior drug abuse?

-If a patient with a history of drug abuse and addiction is experiencing moderate to severe pain following an injury, surgery, etc., are painkillers still a viable treatment option?

-Has there been an experience where you have observed a patient beginning to rely on opioids for their pain management? If so, what signs led you to notice the dependence?

Appendix D

INTERVIEW QUESTIONS GROUP 2

1

-What line of work are you in? (in relation to the pharmaceutical industry)

-What kind of training have you completed to achieve this role?

-How often are you working directly with opioids?

2

-Have you ever been in contact with a drug representative, more specifically, a drug representative for opioids? What were these interactions like?

- Or, as a drug representative, how often were you in contact with a medical specialist?

-Do you believe that drug representatives are helpful in keeping medical specialists updated on new medicine or any other news related to medicinal developments?

-What talking points or information do you consider the most important when considering the use of a new medication?

-Throughout your work related to the pharmaceutical industry, have you seen any advancements or new developments in pain management and treatment?

-Have you ever knowingly promoted a medication under false pretenses? Unknowingly?

- Have you promoted or endorsed a prescription opioid's off-label use?

3

-Are there any regulating authorities that govern your work/interaction with controlled substances?

- Are there mechanisms in place to identify, or consequences for unlawful engagement in regard to these substances?

-Do you believe the supply of prescription opioids has increased or decreased over time?

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ACADEMIC VITA

KATHRYN J MOYER

EDUCATION

THE PENNSYLVANIA STATE UNIVERSITY, Schreyer Honors College **Class of Spring 2022**

Major in Global and International Studies; minor in Spanish

- Dean's List honoree
- Phi Eta Sigma Honor Society member, inducted as freshman
- Schreyer Honors College Scholar
- Paterno Fellow

EXPERIENCE

Homewatch CareGivers Inc., Personal Caregiver, Bucks County, PA **May 2020 - Present**

- Supervised medication administration, personal hygiene and other activities of daily living.
- Monitored vital signs and medication use, documenting variances and concerning responses.

International Institute of Restorative Practices, Intern, Philadelphia, PA **June - Aug. 2020**

- Planned and documented progress made in individual youth's parole plan, such as community service, rehabilitation, education and skills training as well as co-facilitated in acquiring daily urine tests.
- Queried International Institute of Restorative Practice delegates from Hungary, Brazil, Costa Rica and Canada about Institutional intersections of government and prison.

LEADERSHIP

Pi Beta Phi Fraternity, Vice President of Community Relations, University Park, PA **Oct. 2020 - Oct. 2021**

- Ensures the chapter's service and philanthropy requirements are met through charting volunteer hours and coordinating fundraising benefits with the Vice President of Recruitment and Director of Recruitment.
- Collaborates with the Vice President Finance and Housing to ensure the chapter's required and optional contributions to Pi Beta Phi philanthropies have been made.

THON, Talent Specialist, University Park, PA **Oct. 2019 - Feb. 2020**

- Collaborated the minute-to-minute timeline of the event in order to streamline program efficiency.
- Prepared communication deliverables for internal and external THON audiences to be presented on stage in front of a capacity of more than 13,000.

Gender Equity Center, Gender Equity Staff, University Park, PA **Feb. 2019 - Feb. 2020**

- Produced and administered a student-created curriculum on issues relating to emotional and sexual relationships.
- Cooperatively employed biweekly seminars around campus for over 200 first year students to effectively advise and engage them in equity learning resources.
- Valued teamwork and reflected on staff presentation performance monthly.

THON, Family Relations Chair, University Park, PA **Oct. 2018 - Feb. 2019**

- Liaised between THON and the Four Diamonds Fund monthly to ensure family requirements and philanthropy obligations are met.
- Organized, developed and presented programs and events for families as well as provided any support or assistance needed.
- Responded timely to family information requests and health concerns regarding the THON marathon.

ADDITIONAL SKILLS

- Proficiency with Adobe Photoshop; MS Office; Windows; macOS
- Strong interpersonal and interviewing skills
- Spanish - Business Level Speaking and Writing