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## Opioid use and abuse in the United States

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Opioid Use and Abuse in the United States

by

James Pellerin

Thesis

Submitted to the School of Sociology, Anthropology, and Criminology

Eastern Michigan University

in partial fulfilment of the requirements

for the degree of

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in

Criminology and Criminal Justice

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November 15, 2018

Ypsilanti, Michigan

Dedication

For my wife, Jessica, who has tirelessly exhibited patience and kindness with me while I researched and wrote this thesis. Your encouragement has made a tremendous impact on my life and my work. I love you.

### Acknowledgments

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### Abstract

Opioids have quadrupled the number of unintentional drug overdose deaths since 1999 and are now among the leading causes of death in the United States. Though some reform has recently occurred, the United States continues to operate largely under a punitive criminal justice model despite unsuccessful legislative schemes and voluminous research stemming from a previous war on drugs. This thesis serves to explore the history and extent of opioids in the United States and to analyze salient catalysts responsible for creating an epidemic of abuse. While private and governmental coalitions have formed to develop successful interventions and treatments, they are drastically underfunded. Beginning in the early 2000s, there have been a number of civil and criminal lawsuits against manufacturers, distributors, and prescribers of opioids, with the hope of curbing overdose deaths and disrupt the illicit opioid market.

*Keywords:* opioid, epidemic, Sackler family, Perdue Pharma, OxyContin®, pain scale, opioid intervention, opioid treatment, opioid legislation, opioid litigation

## Table of Contents

Dedication.....	ii
Acknowledgments .....	iii
Abstract.....	iv
Chapter 1: Introduction.....	1
Opioid Etiology in the US .....	2
Opioids and Pain.....	5
Mass Imprisonment and Racial Disparity .....	10
Chapter 2: Legislation and Public Policy .....	13
Legislation .....	13
Public Policy.....	16
Chapter 3: Litigation.....	19
Criminal Lawsuits .....	20
Civil Lawsuits.....	32
Chapter 4: Treatment and Intervention.....	45
Medication-Assisted Therapies .....	47
Treating Inmates .....	52
Social Support .....	56
Sober Living Houses .....	59
Opioid Interventions.....	62
Chapter 5: Conclusion and Discussion.....	69
References .....	74

## Chapter 1: Introduction

Opioid use and abuse in the United States (U.S.) has become a major issue, and as governmental and non-governmental organizations survey the problem in search of solutions, the death toll continues to rise. The number of deaths attributed to drug overdoses in the U.S. has almost quadrupled from 17,000 (6:100,000) deaths in 1999 to a staggering 70,000 in 2017 (22:100,000); (Hedegaard, Miniño, & Warner, 2018). In the year 2017 alone, over 47,000 deaths involved opioids (Center for Behavioral Health Statistics and Quality, 2018), which is a stark contrast from the 4,000 that died by way of opioids in 1999 (Warner, Chen, Makuc, Anderson, & Miniño, 2011). Opioids are a specific type of drug, such as hydrocodone and fentanyl, that work to inhibit and control pain levels. Opiates are natural compounds derived from the poppy plant, while opioids are considered to be drugs (i.e., synthetics) that come from opium poppy, and both forms target opioid receptors in the brain. Heroin also falls under the opioid umbrella, although it is completely illicit in the U.S.

The Substance Abuse and Mental Health Services Administration (SAMHSA) reported that in 2016, an estimated 3.8 million Americans age 12 and older abused prescription pain relievers and that approximately 11.8 million people abused an opioid in the last 12 months (“Opioid Abuse and Sources of Supply,” 2018). The National Institute on Drug Abuse (NIDA, 2019) cites that fentanyl, an intensified form of opioid, is mainly to blame for the high increases in overdose deaths over the last decade, killing 28,466 in 2017 alone. Medical examiners (ME) have been overwhelmed with the increased number of overdose deaths that have stemmed from opioids, and many feel that the influx of cases could cause MEs to rush to get through all of them, which might potentially jeopardize accuracy (Vestal, 2017). What’s more, morgues have run out of space and have had to rent refrigerated trucks to house the bodies as well as rent space in funeral homes and at hospitals (Vestal, 2017).

According to data collected by The Sentencing Project (2017), in 2016, “2.1 million people met the criteria for an opioid use disorder (OUD): 1.8 million related to an [opioid] prescription pain reliever and 600,000 related to heroin (for some the disorder involved both drugs),” which was “35% higher than those abusing cocaine and methamphetamine” (p. 7). In the same year, 11.5 million people reported that they had abused opioid pain relievers, while another 948,000 said that they used heroin (The Sentencing Project, 2017). The U.S. consumes 80% of the world’s supply of opioids; however, it should be noted that access to these drugs is virtually nonexistent for the vast majority of countries around the world (Rose, 2017). The American opioid epidemic is an issue that deserves a brighter spotlight, not only to highlight the ethical issues surrounding supply and demand, but to also understand who the users of this drug are and how we, as a country, have treated them. Additionally, it is important to review this issue through the eyes of the criminal justice system and U.S. lawmakers since this has affected how the U.S. carries out its mission to stop drug use by special tactics in a new war on drugs.

### **Opioid Etiology in the US**

Opioids have been available in the U.S. going back as far as the 1800s, but they were not used in large numbers until more than a hundred years later. For over a century, opioids were used by many agencies (mostly medical) to treat a number of ailments such as toothaches and diarrhea, but after the Harrison Narcotics Tax Act in 1914 passed, the drug became regulated (Vadivelu, Kai, Kodumudi, Sramcik, & Kaye, 2018).

Prescription medications were also surged in the 1990s, and when Oxycontin hit the market in 1996, the number of opioid prescriptions tripled (“Opioid Abuse and Sources of Supply,” 2018). People quickly became addicted to these types of medications, and when their doctors cut them off, abusers were determined to obtain these drugs through a myriad of schemes, including doctor shopping, prescription fraud, pill mills, and eventually the internet.

Authors Vadivelu et al. (2018), cite that “Purdue Pharma, the manufacturer of Oxycontin, expended \$200 million to promote the drug in 2001, which resulted in an increase in the prescription of Oxycontin by almost 10-fold to nearly 6.2 million annual prescriptions the following year” (p. 16). The over prescription of opioids caused a surplus in the homes of millions of Americans, which gave access to a younger generation seeking out a more intense drug that came without the risks associated with buying from a street dealer. High schools and college universities experienced overdoses in teens and young adults who attended what was known as “pharm parties,” where handfuls of mixed pills, contributed by party goers, are ingested with beer or liquor. This particularly lethal game of prescription Russian roulette can cause serious illness and/or death from seizures, stroke, or cardiac arrest.

As the U.S. entered the 2010s, millions of people had become addicted to opioids, and the cost of a purer form of street heroin was very low since the major source of import had shifted from South America to Mexico (over 90%); in 2013, the nation experienced a massive flow of both legal and illegal fentanyl, an opioid which is much more severe and potent than heroin (“Opioid Abuse and Sources of Supply,” 2018). While U.S. pharmaceutical grade prescription opioids are developed in specialty labs, tracked carefully, and scrutinized by the Food and Drug Administration (FDA) for the purpose of quality control, non-pharmaceutical fentanyl is smuggled into the U.S. from Mexico, which originates in China. Once in the country, dealers will often mix fentanyl with heroin to increase the potency of their product to get as many clients addicted to their specific product as possible in order to ensure repeat business.

Since fentanyl is roughly 50 to 100 times more potent than heroin, dealers walk a fine line between securing future business and death of the customer. As popularity of fentanyl has risen to an all-time high in the U.S., so have the prices. The cost per kilogram has risen over the last two years to between \$30,000 and \$38,000 (“Opioid Abuse and Sources of Supply,” 2018).

Law enforcement officers anticipate that the market for fentanyl will expand greatly as more advanced and potent syntheses are introduced. Due to the increased problems associated with these enhanced drugs, the U.S. government has ranked legal and illicit forms of fentanyl, as well as heroin, the most significant drug threat to the country (“Opioid Abuse and Sources of Supply,” 2018). In a 2017 survey on drugs and drug abuse in the U.S., 76% of Americans recognized that “prescription drug abuse is an extremely or very serious public health problem in America, compared to 63% who said the same in 2013” (James et al., 2018, p. 412).

According to the Center for Disease Control (CDC), there are two related trends that have driven the opioid overdose crisis. The first is that over the last 16 years, there has been a steady increase in prescription opioid overdose deaths, and the second is the current rise in lethal overdoses that are attributed to synthetic opioids and heroin (The Sentencing Project, 2017). Unfortunately, due to the rapid growth of prescription popularity in the medical profession and the simultaneous distribution on the illegal street market, researchers cite that there was no central coordinating entity monitoring the effects of what the U.S. had experienced (Aron, 2016).

Ultimately, there were many unintended consequences in allowing prescription medications to increase as rapidly as they did, especially since these drugs have a high potential for abuse and addiction. In 2015, California recorded the highest number of drug overdose deaths in the nation at 4,659 people, while Ohio came in second with 3,310 people (“Opioid Abuse and Sources of Supply,” 2018). That same year, the NIDA conducted a study in which they discovered that New Hampshire had more opioid overdoses per capita than any other state, with 293 of the 439 deaths in the state that were fentanyl related (“Opioid Abuse and Sources of Supply,” 2018). Interestingly, in a 2016 study among people aged 12 or older, respondents were asked why they had abused opioids, and the majority (62%) revealed that the salient cause was pain management (The Sentencing Project, 2017). Thirteen percent reported that they wanted to

get high, and 11% took opioids to relieve tension and relax (The Sentencing Project, 2017).

Socioeconomic status also seemed to play a role in opioid abuse. In 2015, the National Survey on Drug Use and Health (NSDUH) disclosed that Americans aged 18 to 64 with incomes below the federal poverty level (FPL) were 47% more likely to abuse opioids than those with incomes 200% above the FPL (The Sentencing Project, 2017).

Another interesting opioid abuse development concerns what researchers have discovered about the gender differences of abuse. During the 1960s, the vast majority (80%) of opioid abuse treatment program enrollees were heroin-abusing males that lived in urban, inner city regions; however, in 2010, the majority of patients in the same treatment programs were middle-class women from rural regions, and 90% of them were White (Vadivelu et al., 2018). As previously mentioned, youths are affected by this epidemic. In 2016, the FDA reported that of children who were under the age of 18, roughly 85% had obtained opioids from family members who have not secured their own prescribed medications (Vadivelu et al., 2018).

### **Opioids and Pain**

Treatment for injuries related to pain is one of the most common reasons that people visit the hospital or their doctor, and acute pain is reported in over 80% of hospital visits according to a study that examined medical charts from the Department of Veterans Affairs (Mularski et al., 2006). How hospitals and private physicians deal with pain has come under greater scrutiny as a result of the opioid epidemic. During the early 1970s, Knezevic (2019) identified that the International Association for the Study of Pain (IASP) defined pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage” (p. 15). Medical professionals often find it difficult to understand their patient’s pain unless its cause can be quantified.

When it is left exclusively to the patient to qualify their pain, a doctor or nurse must accept their complaint as truth. The management of pain, both acute and chronic, has had a tumultuous journey over the years as medical associations and doctors find themselves on either side of a line that separates overprescribing and under prescribing to their patients; however, on November 12, 1995, a new perspective changed the way the U.S. medical community dealt with pain, which opened the door for the subsequent opioid abuse epidemic.

During the 14<sup>th</sup> Annual Scientific Meeting of the American Pain Society, President Dr. James N. Campbell, MD, likened his innovative declaration of pain as the fifth vital sign (P5VS) to the Wright brothers who made it possible for man to fly (Campbell, 1996). Soon after, two of the largest medical oversight organizations in the country, the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) and the Veterans Health Administration, backed Dr. Campbell's remarks and urged the entire U.S. medical community to adopt P5VS (Morone & Weiner, 2013). As opioids (primarily morphine) became standard issue in hospitals, doctors' offices, and dental offices around the country, some questioned whether pain as a vital sign would cause issues with overprescribing. In 1999, an article entitled "Opioids in Pain Management" was distributed by Dr. Henry McQuay, formerly a professor of anesthetics at the University of Oxford, in which he made clear the delineation between analgesic use and abuse of opioids by stating the following: "The drug-seeking behaviour synonymous with drug addiction does not occur in patients after pain relief with opioids in childbirth, operations, or after myocardial infarction. Drug addicts are not in pain" (p. 2229). His message indicated that use of opioids for pain relief in medicine would not create drug addicts.

Dr. McQuay based his erroneous theology on a study conducted by two doctors in 1980. Those doctors reviewed the medical files of 39,946 hospitalized patients in order to analyze any notes left by staff indicating abuse (Porter & Jick, 1980). They cite only four "reasonably well

documented” cases of narcotic abuse where the patient had not previously admitted to drug abuse (p. 123). In addition to the numerous scientific issues with this statement, the study had not been published, was not peer-reviewed, and, since its existence, appeared only as a letter to the editor of the *New England Journal of Medicine*, no additional information was provided about the study. The medical community became fixated on the alleviation of pain to the point of jeopardizing their Hippocratic Oath to do no harm.

A number of qualitative scales were developed to help physicians measure sensory pain as reported by their patients, and the two most widely used were the Numeric Rating Scale (NRS) and the Faces Pain Rating Scale (FPRS). These scales were derived from the original pain scale developed in the 1970s, known as the Brief Pain Inventory (BPI), which identified pain as one of the following: worst, least, average, and current (Knezevic, 2019). Almost a decade later, a lengthier pain questionnaire called Pain Catastrophizing (PC) allowed doctors and nurses to dig deeper into what pain their patients experienced. This test also served as a safety measure to limit the number of errors connected with the under- or overestimation of pain by doctors. These scales have evolved into even lengthier questionnaires, and ones that are specific to each medical department and procedure (Knezevic, 2019).

Medicine has modernized and so has the way in which the medical community measures pain. In part, this is done to more accurately treat the patient since not all pain should or can be assuaged. With the rise of use, abuse, and deaths has stemmed from the opioid epidemic, doctors and nurses are much more formal and adhere to rigid prescription standards. Such evolved standards have been supported by research which indicated that sole use of qualitative unidimensional pain management tools have not improved the results of effectively decreased pain (Scher, Meador, Van Cleave, & Reid, 2018). A new body of evidence finds that emotions such as anxiety and anger are factors involved in the patient’s pain rating score. The concern

with using pain as a vital sign is that it is not only ineffective, but it has caused more harm than its intended benefits (Scher et al., 2018).

Another negative consequence of P5VS is that doctors and hospitals are frequently penalized financially. One component of Obamacare's 2010 Patient Protection Act connected Medicare reimbursements to the results of patient surveys. For example, if a Medicare or Medicaid patient persists that their pain is at an eight or a nine on the NRS and the medical staff has chosen a less potent narcotic or an opioid at a lower dose, that patient is likely to complain on the satisfaction survey, which is required to be distributed to each patient. The Center for Medicare and Medicaid Services (CMS) is the government entity that developed the United States Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, a requirement for all medical facilities that operate under the Medicare and Medicaid umbrella (Levy, Sturgess, & Mills, 2018).

As a result, Medicare/Medicaid can cut the reimbursement by up to five percent (Scher et al., 2018). Doctors feel it necessary to ingratiate their patients in order to achieve satisfactory survey results and, in doing so, lose sight of what is best for the patient. It is a situation of the tail wagging the dog. Perhaps the most significant change to pain management in the last 20 years came in 2016 when the American Medical Association voted to remove all content that endorsed P5VS during their annual conference and encouraged everyone in the profession to do the same; however, the medical community continues to struggle with how best to treat pain without creating addicts (Ahluwalia, Giannitrapani, Dobscha, Cromer, & Lorenz, 2018).

Researchers point out that it is difficult for medical staff to properly address pain management issues since a typical doctor's office visit lasts only around 15 to 20 minutes, and even less in a hospital's emergency room (Morone & Weiner, 2013). During that time, the doctors and nurses are not solely focused on the patient's pain but treating that which caused it.

Also, medical staff report the frustration of lengthy pain evaluations for every client. In one study of pain management clinics, the staff admitted that talk of pain distracted the patient from other issues and during numerous visits with elderly patients, pain was not the chief complaint (Ahluwalia et al., 2018).

When staff members were asked how they felt pain management should be handled at their clinics, they reported that it should be targeted towards specific patients in specific circumstances. In many cases, the staff members, including nurses and physicians, complained that routine pain screening can often achieve false positives and force providers into a course of treatment that might not be salient (Ahluwalia et al., 2018). Additionally, routine screenings specifically for pain were found to bring on an expectation of never having to experience pain, which is widely regarded as unrealistic. It sets the patient up for poor self-management when they know they can get an opioid prescription with several refills.

With the risk of opioid addiction following surgery as high as 1 out of every 16 patients, the medical community at large reviewed options for the development of a pain management scale that is more accurate and has long-term benefits for the patient (Levy et al., 2018). In 2016, the American Pain Society (APS), set forth a list of seven modernized guidelines for how to best score and treat pain which includes: onset and pattern, location and quality of the pain, aggravating and relieving factors, and how the pain affects/hinders the patient. The hope is that with these new guidelines in place, the rate at which opioids are prescribed for the management of pain will reduce substantially over time.

The overuse of opioids in hospitals not only leads to later misuse and abuse by patients, but in the short term, it leads to longer hospital stays (7.6 vs. 4.2 days), larger costs (\$22,000 vs. \$17,000), readmission within 30 days of release from the hospital (36% higher), and a higher risk of inpatient mortality (by 3.4 fold); (Vadivelu et al., 2018). One researcher found that of 250

patients who experienced surgery of their upper extremity, 98% were given a prescription of opioids (30 tablets on average). These patients reported that they used an average of 10 pills, which left them with an extra 20 pills that were unused (Vadivelu et al., 2018). Consider that 20 unused pills multiplied by 245 patients equals 4,655 opioid pills overprescribed. The federal government, along with state and local governments, worked tirelessly to control this epidemic, while also contemplating how best to punish offenders of drug use as well as prosecute distributors. Many agree that there needs to be better oversight and accountability, not only for public-sector agencies, but also in private industry.

### **Mass Imprisonment and Racial Disparity**

Mass imprisonment can be identified by two distinct characteristics: (a) The number of prisoners held and (b) the effects, on a macro scale, of imprisonment on the members of society (Garland, 2001). This second point is more clearly defined by explaining that mass imprisonment includes the incarceration of “whole groups of the population,” which becomes “one of the “social institutions that structures this group’s experience” (Garland, 2001, p. 6). As of 2018, the U.S. held nearly 2.3 million people in a total of almost 7 thousand correction institutions, and this number of people is most certainly higher given the fact that it does not include inmate counts from immigration detention centers, state psychiatric hospitals, or military prisons (Wagner & Sawyer, 2018). This equates to 1 out of every 100 people in the U.S. behind bars, and 1 in nearly 31 adults under the control of a correctional institution (Pew Center on the States, 2009).

During the 1950s and 1960s, the U.S. experienced an influx of narcotics distributed in the Black ghettos. One of the areas hit hardest was New York City, and the governor at the time, Nelson Rockefeller, enacted what was known as the “Rockefeller Drug Laws” in 1973 to combat the further spread of drugs and crime. The legislation was extremely tough on offenders and

often called for mandatory life sentences for even a small amount of opioids (> 1 oz) possessed or sold. Opiates spread and synthesized into an even greater threat to Americans by way of crack-cocaine during the 1980s and 1990s. By this time in U.S. history, there was an ethnic divide in opioid consumption, which was based in some respect on the costs of the drug.

Crack-cocaine was a cheaper and much more powerful and addictive opioid that wreaked havoc in the Black ghettos, while powder cocaine was propagated in middle and upper-class White populations as a party drug (James et al., 2018). Despite many states following suit with Rockefeller drug legislation, the federal government decided that these laws did not solve the problem, so in 1986, it declared a war on drugs and passed the Anti-Drug Abuse Act (James et al., 2018). The penalties with this act made it 100 times more severe for crack than for powder cocaine, which created a distinct difference in incarceration rates between Blacks and Whites. It was also during this time that a purer form of the opiate heroin, which was cheaper than ever before, was smuggled in from South America in record quantities, and flooded the U.S. illicit drug market.

Between 1925 and 1975, the rate of imprisonment plateaued around 100 per 100,000 people in the U.S. By 2001, that number had increased more than fourfold to 472 per 100,000 people (Pettit et al., 2004). In 1997, 60% of inmates in Federal prisons served time for a drug offense, thanks to the U.S. drug wars of the 1980s and 1990s (Pettit et al., 2004); the number of drug arrests rose almost threefold from 581,000 in 1980 to over 1.6 million by 2009 (Mauer, 2011). In 1980, there were approximately 41,000 people incarcerated for drug offenses involving opioids; by 2003, that number rose to 500,000 (Mauer, 2011). Of those arrested in the drug wars from the 1980s, 21% were African American; that number rose to 36% by 1992 (Mauer, 2011).

Researchers suggest that crime control policies, which stem from the illicit opioid market, such as mandatory minimum sentencing, truth-in-sentencing, “three strikes” law, and stop-frisk-

question, led to further racial discrepancies that occurred at the prosecutorial level (Grawert & Kimble, 2018). These policies, coupled with the fact that the majority of guilty verdicts are a result of a plea bargain that takes place behind closed doors and cannot be evaluated for fairness, are largely what has contributed to mass imprisonment (Mauer, 2011). As of 2011, national data cited that drug arrest rates were responsible for 89.5% of racial disparities in U.S. imprisonment (Mauer, 2011). In 2016, state prisons held African Americans at a rate five times higher than Whites, and “in five states (Iowa, Minnesota, New Jersey, Vermont, and Wisconsin), the disparity is more than 10 to 1” (The Sentencing Project, 2017).

Twelve states have prison populations that are more than 50% Black, and Maryland led the nation in 2016 with a prison population that was 72% African American (The Sentencing Project, 2017). Blacks are incarcerated at a rate of 1,408 per 100,000 people as of 2016, compared with Whites who were at a rate of 275 per 100,000 people (The Sentencing Project, 2017). According to current research, if these rates of incarceration for African Americans continue, “1 of every 3 African American males born today can expect to go to prison in his lifetime, as can 1 of every 6 Latino males, compared to 1 in 17 White males” (Mauer, 2011, p. 88S). As will be discussed in depth in a later chapter, alternatives to incarceration have been developed to address offenses motivated by OUD including drug courts and alternative sentencing, which have shown to be successful.

## Chapter 2: Legislation and Public Policy

### Legislation

The Violent Crime and Law Enforcement Act of 1994 was an attempt at crime control by expanding the police department in the U.S. Researchers Roeder, Eisen, Bowling, Stiglitz, & Chettiar (2015) state that “the \$30 billion Congressional package, which funded both law enforcement and incarceration, provided funds for 100,000 new local police officers” (p. 42). Over the course of 10 years, the nation saw a 28% increase in the number of police officers hired that equated to a total number slightly under 900,000 and accounted for approximately 0 to 10% of the reduction in crime. This is not surprising since one common reaction to a steady increase in crime would be to hire more police officers. Interestingly, as the rate of hired officers declined in the 2000s to just 3%, the overall crime rate continued to decline (Roeder et al., 2015).

There was an initial impact on decreasing crime as a result of these initiatives in the 1990s, but soon prisons became filled, which ushered in what researchers identify as the effect of diminishing returns, which essentially rendered crime prevention ineffective (Raphael, Stoll, Duggan, & Piehl, 2004). The most obvious example of the diminishing returns theory occurred in California’s penal system. In 2011, the state enacted the Public Safety Realignment Act after being ordered by the U.S. Supreme Court to reduce their number of inmates due to massive overcrowding (Goode, 2013). The Brennan Center reported that since 2000, the crime rate has not been affected at all by the increased rates of incarceration (Roeder et al., 2015).

It is now understood that increases in crime are only moderately responsible for such mass incarceration when compared with other factors such as policy changes and sentencing enhancements (PEW Center on the States, 2008). One example of this occurred in 1973 when Governor Rockefeller’s hardline mandatory minimum sentencing guidelines for drug offenses in the state of New York made possession of four ounces and sales of just two ounces a Class A

felony, which drove the prison population from 470 in 1970 to 8,521 in 1999 (Greene & Mauer, 2010). Additionally, a series of “get tough” laws were passed in the 1980s and 1990s that sent even more people to prison for longer sentences (Greene & Mauer, 2010). Initiatives such as the Drug Treatment Alternative-to-Prison Program (DTAP) helped NY foster a 67% drop in recidivism; additionally, the state invested in education for prisoners as well as instituting the “Earned Eligibility Program” and “Merit Time Program” to shorten prison sentences (Greene & Mauer, 2010). These programs helped to drastically reduce the state’s inmate population and save the taxpayers hundreds of millions of dollars.

A second example of a state that underwent reform is the state of New Jersey, which led to a drop of 19% in the prison population from 31,493 in 1999 to 25,436 in 2009 (Greene & Mauer, 2010). In 2000, three inmates filed a lawsuit against the NJ State Parole Board, stating that the state was massively behind on processing pre-parole reports, which were needed for parole hearings, thus causing the whole system to be backlogged in approximately 5,800 instances (Greene & Mauer, 2010). The state brought in a new chair of the parole board that same year, and he revamped the system. First, he streamlined parole hearings by teleconferencing those meetings, then he changed the “zero tolerance” drug rules for parolees to electronic monitoring and day reporting, and he also introduced a risk assessment instrument meant to analyze which offenders were most likely to succeed out in society (Greene & Mauer, 2010). These tactics increased the rate of people who were granted parole by more than 350% between 1999 (3,099) and 2001 (10,897), with “far fewer [prisoners] being sent back to prison for parole violations” (Greene & Mauer, 2010, p. 44). New Jersey also developed Regional Assessment Centers (RAC) to hold 45 parole violators for up to 30 days in order to run a battery of tests with the goal of assisting the parole board in assessing whether the violator should return to prison, ultimately cutting returners by 35% as of 2009 (Greene & Mauer, 2010).

New Jersey then revamped the Comprehensive Drug Reform Act (CDRA) of 1986, which instituted strict “drug free zone laws” that included mandatory minimum sentences (Greene & Mauer, 2010). The state discovered that 96% of those imprisoned under CDRA were people of color, and the New Jersey Office of the Attorney General elected to change the way offenders were being charged by instituting “open pleas,” which meant that judges were allowed discretion in sentencing drug offenders to treatment programs instead of prison (Greene & Mauer, 2010). In 2009, the number of drug offenders serving time in NJ prisons dropped to 7,377, which makes up 29% of the entire prison population in the state (Greene & Mauer, 2010).

Michigan, which operates the seventh largest prison system in the nation and has the second highest rate of incarceration in the Midwest, has changed the way in which it processes drug offenses, grants paroles, and conducts community corrections (Greene & Mauer, 2010). One cause for the drastic increase of inmates was a result of a late 1970s decision to eliminate “good time” credits used for early release (Greene & Mauer, 2010). Additionally, Governor John Engler replaced parole board experts in 1992 with political appointees, driving the prison population from 10,855 in 1970 to 51,577 in 2006, a 475% increase (Greene & Mauer, 2010). Michigan was also known for some of the toughest mandatory minimum laws in the nation; as a result, in 2010, Michigan spent one-fifth of its entire budget on corrections (Greene & Mauer, 2010).

In 2002, state legislatures gave wide discretion to judges to sentence drug offenders to treatment instead of lengthy prison sentences, driving down “people convicted of drug crimes to one of the lowest levels in the nation” (Greene et al., 2010, p. 28). That same year, Governor Engler threw out almost all of the state’s mandatory minimum sentencing policies, which dropped the rate at which offenders were sent to prison for these crimes from 18% in 2002 to 11% in 2008. The state’s department of corrections managers created the Michigan Prisoner

Reentry Initiative (MPRI) in 2005, and five years later, there were 33% fewer parole violators who had returned to prison (Michigan Department of Corrections [MDOC], 2010). A major focus for MPRI has been to institute better training and modernization of parole assessment tools, which enabled better decision-making, and thus, higher parole approval rates (Greene & Mauer, 2010, p. 28).

The federal government has recognized that a call for action is warranted. Additionally, the attorney general would be given broader authority to ban synthetic drugs. In 2018, Under President Trump, the 115<sup>th</sup> Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act on October 24<sup>th</sup> and procured \$6 billion over a two-year period. According to the WhiteHouse.Gov website, this money is meant to curb over prescription by implementing a safer prescribing plan, which Trump claims will “cut opioid prescription fills by one-third within three years” (The White House, 2019). The president also claims that by securing our borders, the flow of illegal opioids coming in from Mexico will diminish exponentially.

### **Public Policy**

There are clear racial differences between Whites and minorities (mainly Blacks and Hispanics) when it comes to addiction and incarceration. The rates at which Blacks have abused opioids have steadily increased over the last decade, but those numbers pale in comparison to the much higher rates in which Whites are affected by opioid use and abuse (Bebinger, 2019). Researcher discuss in their 2017 article concerning implication for the racial disparity with drugs and the criminal justice system, minorities are certainly affected by opioids but in a different way. Blacks are significantly more likely to be contacted by the police than Whites, and during that contact, there are more Blacks arrested for the possession (20% vs. 15%) and sale (27% vs. 4%) of drugs than Whites, respectively (Rosenberg, Groves, & Blankenship, 2017).

This research was conducted in New Haven, Connecticut, where 924 opioid overdose deaths occurred between 2015 and 2018, and where accidental drug overdoses increased 40% during that same time period (Stannard, 2019). The adjoining counties of Hartford and Fairfield had the first and third highest death during that four-year period, respectively. According to the CDC (2019), the state of Connecticut had the eleventh highest death rate total for deaths caused by opioid overdoses.

Creating criminal justice reform is a necessary element that must coincide with successful treatment methods. Decades of data have proven that America's tough-on-crime approach has backfired. Prisons and jails are grossly overcrowded, and the rate of diminishing returns is in effect because the disparity gap between fears surrounding incarceration and the reality of correctional facility desensitization is wider than ever before. Congress needs to reduce drug standards that trigger mandatory minimum sentencing, such as increasing the minimum amount of opioids (e.g., fentanyl, carfentanil, heroin) required to trigger federal mandatory minimum sentencing. Researchers strongly believe that at the current rate of growth for opioid potency, dealers will continue to increase concentrations in order to draw in more customers and be able to increase the cost of their product since the fear of being caught is negligent in the eyes of many dealers (Saloner et al., 2018).

Courts should also increase access to treatment and harm-reduction programs for both first-time abusers and dealers, as well as for repeat offenders (Saloner et al., 2018). As briefly discussed earlier, all law enforcement should be trained and given access to naloxone in order to reduce overdose deaths, and all departments should implement Good Samaritan laws, fostering a sentiment of trust for those people who call on police and other first-responders (Saloner et al., 2018). Aligning law enforcement policies with public health policies would be a great improvement on how officers are trained and held accountable by their departments. For

example, Seattle has adopted the Law Enforcement Assisted Diversion (LEAD) program, which has reduced their number of drug arrests and increased the number of opioid addicts in treatment and those engaged in harm-reduction services (Saloner et al., 2018).

In 2015, West Virginia permitted first responders, as well as friends and family of opioid abusers, to administer naloxone, while Pennsylvania allocated \$5 million from their FY2018 budget to do the same (The Sentencing Project, 2017). This is a trend that has quickly been adopted by states. As of 2015, there were 38 states that, through legislations, allowed friends and family members to be prescribed naloxone for use with opioid addicts (The Sentencing Project, 2017). Kentucky, which is one of the states referenced above, also recently passed legislation (HB 333) in 2017 that reduced the number of pills to only a three-day supply of prescription opioids for patients (The Sentencing Project, 2017). Also, in 2017, New Jersey passed legislation (SB 3) that cut a patient's opioid prescription supply from 30 days to 5 days; Arizona and Massachusetts reduced their states' maximum supply to just 7 days (The Sentencing Project, 2017).

### Chapter 3: Litigation

Jillian Sackler, President and CEO of the Dame Jillian and Dr. Arthur M. Sackler Foundation for the Arts, Sciences, and Humanities, penned an op-ed article for *The Washington Post* in April 2019 and pleaded for people not to associate her late husband and their foundation with the rise of the opioid crisis (Sackler, 2019). Mrs. Sackler contests that since her late husband passed away in 1987, before the U.S. recognized that it had entered into an opioid epidemic, her family and their philanthropic benevolence must be exempt from criminal and/or civil responsibility. Instead, she shifted the blame to Arthur's younger brothers, Mortimer and Raymond, and claimed that what we know of Purdue Pharma today had not been formed until 1997, four years after Arthur's death.

In truth, even if we concede Jillian's admonishment of her in-laws' moral apathy and predatory marketing practices, one must, at the very least, hold Arthur as suspect in the wake of Purdue Pharma's early success. Records indicate that Dr. Raymond Sackler, a Board-certified psychiatrist and neurologist, and Dr. Mortimer Sackler, an expatriate British psychiatrist, purchased Purdue Frederick in 1952 (Belmonte, 2019). Prior to this acquisition, the brothers, along with help from Dr. Arthur Sackler, ran a successful New York City pharmaceutical firm. Sackler, a graduate of New York University's School of Medicine, focused on research in biological psychiatry, specifically in the field of neuroendocrinology. Arthur paid his way through school by working as a copywriter for the NYC-based marketing agency, William Douglas McAdams (WDM), a company he would eventually purchase in 1947 (Keefe, 2019).

During the 1940s and 1950s, pharmaceutical companies did not believe in the direct-marketing of their products to doctors or the public at large; instead, most companies depended on word-of-mouth from one doctor or hospital to another. According to the Medical Advertising Hall of Fame (MAHF, 2019), "Dr. Sackler saw the important role nonpersonal selling could play

in this environment and became an advocate for the full-blown marketing programs (field force plus multimedia promotional activities) employed today.” Arthur worked feverishly to promote Pfizer’s new antibiotic, which included a number of full-length print advertisements in the *Journal of the American Medical Association (JAMA)*, for which Arthur negotiated a deal to have *JAMA* allow ads only for Pfizer (MAHF, 2019). He then began to experiment with radio and television advertisements in the 1950s and found great success. It was during this time that Arthur joined forces with his brothers and brought highly effective marketing tactics, which included the development of personal relationships with doctors and hospitals to Sackler pharmaceuticals.

Although none of the lawsuits currently filed in state or federal courts include Arthur Sackler or his heirs, it is not a great leap to conclude that the man who, in 1960, published one of the most widely read newspapers exclusively for doctors (distributed to 20 countries and in eight different languages), played a key role in creating *the* marketing blueprint for the pharmaceutical weapon of mass destruction known as the current U.S. opioid crisis. Arthur’s bereaved, Jillian Sackler, likens his contribution of the opioid crisis to “blaming the inventor of the mimeograph for email spam,” and she cautions that vilifying such a great man will cause irreparable damage to the many organizations that have benefited from their financial contributions; however, numerous critics of the Sackler family have aptly cited the hundreds of thousands of people that have been negatively impacted by the doctor’s alleged good business deeds (Keefe, 2019).

### **Criminal Lawsuits**

During a press conference in the fall of 2016, Deputy Attorney General Sally Quillian Yates stated that the Department of Justice (DOJ) would expend a large part of its resources to combatting the heroin and opioid crises in the U.S. (Rothberg & Stith, 2018). This directive spurred on a partnership between the Drug Enforcement Administration (DEA), the Organized

Crime Drug Enforcement Task Force Program, and the Bureau of Justice Assistance's Prescription Drug Monitoring Grant Programs to identify, target, and disassemble national and international illegal opioid trafficking organizations. In addition to this task, this consortium sought to gather and analyze various opioid data used for tracking both legal and illegal drug activity and to coordinate and provide operational case assistance for criminal prosecutions (Rothberg et al., 2018). Organizations that had previously been established to monitor healthcare fraud, such as the 2007 Medicare Fraud Strike Force (MFSF), saw increases in funds, which extended the effectiveness of the program.

In 2017, the MFSF worked with local, state, and federal law enforcement towards the dismantling of numerous fraudulent healthcare agencies that involved with opioid waste and abuse that totaled \$1.3 billion (Spivey, 2017). Attorney General Jeff Sessions and the U.S. Department of Health and Human Services Secretary Tom Price jointly announced that this national, multi-agency investigation spanned 41 federal districts, resulted in 400 individuals charged. Among those charged were doctors, nurses, pharmacists, and other medical professionals. They allegedly participated in the fraudulent billing of Medicare and Medicaid, as well as a military health insurance program known as TRICARE. Charged healthcare professionals reportedly received kickbacks by submitting false information to medical providers, and in turn, those providers fraudulently billed federal healthcare programs exorbitant sums.

Doctors were said to have knowingly contributed to the opioid epidemic based on illegal practices in the distribution of opioid medications and other federally scheduled narcotics. Sessions and Price noted that to date, this was by far the largest take-down of its kind. They also stressed the need for more funding to investigate fraudulent activity. Based on the findings in this investigation, the DOJ believes that the fraud associated with the opioid epidemic reaches farther

than has been covered by these charges alone. Over the decade that the MFSF has been established, they have charged more than 3,500 individuals who collectively have accounted for over \$12.5 Billion in Medicare fraud (Spivey, 2017). Some of the largest offenders include Florida, Michigan, Texas, California, Illinois, New York, and Louisiana.

In the Southern District of Florida, 77 offenders were charged for billing schemes that resulted in over \$141 million from home healthcare, pharmacies, and mental health services. The owner of a popular drug addiction treatment center was charged with fraudulently billing almost \$60 million on treatment services (DOJ, 2017). The scam involved the owner bribing addicts to move to South Florida, and in return, he furnished them with incentives such as free airline tickets, gift cards, trips to strip clubs, and drugs. In the Eastern District of Michigan, 32 offenders were responsible for \$218 million in false healthcare claims. Additionally, the co-conspirators were involved in money laundering, as well as receiving and distributing kickbacks from healthcare providers (Wingblad, 2017). In one case alone, nine defendants, of which six were doctors, frequently billed Medicare for over \$164 million (DOJ, 2017).

In the Southern District of Texas, 26 offenders, including physicians and clinic owners, were indicted on conspiracy charges for their actions resulting in a sting operation of the pain clinic they ran together, which billed more than \$66 million in bogus patients (DEA, 2017). The clinic in question was by far the largest supplier of opioids in the Houston area, prescribing medications illegally to roughly 65 patients every day (Spivey, 2017). The criminal complaint describes how alleged patients would enter the facility under false pretenses in order to obtain hydrocodone at a cash payment of \$300 per prescription. In the Central District of California, 17 defendants allegedly placed fraudulent claims for prescription opioids on behalf of patients that never existed (Department of Health and Human Services, 2017).

In the Northern District of Illinois, 15 offenders were indicted on a number of fraudulent activities that included kickbacks, physical therapy fraud, and wire fraud, which totaled over \$12.7 million dollars that was charged to Medicare (Baxter, 2016). A number of these alleged charges stem from false services that were billed when no patient received said services. In the Middle district of Florida, 10 offenders were indicted on felony fraud charges that stemmed from a 2017 sting operation of healthcare providers and workers. The most notable offense comes from an individual worker that defrauded TRICARE, a military healthcare program backed by the federal government, for \$4 million dollars who claimed that he was a retired Lieutenant Commander of the U.S. Navy in order to gain access to a beneficiary's information (DOJ, 2017).

In the Eastern District of New York, 10 defendants were charged with defrauding Medicare over \$151 million (Spivey, 2017). Most significantly, \$100 million of that sum was paid to numerous individuals as part of a kickback scheme for the recruitment of a steady flow of patients, some of whom never received any of the copious amount of treatments attached to their patient files and submitted to the government. Finally, in Southern Louisiana, seven individuals were indicted on healthcare and wire fraud (among a number of other charges) for scams that, in total, cost the federal government \$207 million (Kieler, 2017). One pharmacist in particular was found to have charged TRICARE over \$107 million dollars on false and fraudulent insurance claims. Additionally, this individual was involved in running a pill-mill, whereby he either overprescribed opioids or provided lethal combinations of opiate-based meds that were not medically necessary for the patient and in return, he received payments in the form of cash.

As a result of these major cases, Sessions has launched a new initiative out of the DOJ called the Opioid Fraud Abuse and Detection Unit (OFADU), the primary objective of which is to detect and investigate opioid-related healthcare fraud (Rothberg et al., 2018). The targets are most often doctors that overprescribe opioids and other narcotics, pharmacies that do the same,

and other pill-mill locations that sell medications for cash and other assets. More and more, these cases are ending up at the federal level for prosecution, which means that as the various arms of the DOJ investigate, they indict defendants and prosecute through one of the designated Attorney Generals' (AG) offices around the country. During the latter part of 2017, there were 12 participating AG offices, but that number has grown. The first was prosecuted out of Pennsylvania's Western District in October 2017 on the same day that President Trump publicly identified the opioid crisis as a national health emergency for the U.S.

On December 5, 2017, the U.S. Sentencing Commission (USSC) held a meeting to discuss sentencing guidelines for opioids and their analogues (e.g., fentanyl, carfentanil) based on Trump's directive to reevaluate prison terms for drug offenses (United States Sentencing Commission, 2018a). As a result of this meeting and other lobbying efforts, the commission made a number of sentencing changes regarding synthetic drugs, acceptance of responsibility for offenders, and alternatives to incarceration for non-violent first offenders (United States Sentencing Commission, 2018b).

A non-exhaustive attendance list included Matthew Barber, a detective for the Lubbock Police Department in Lubbock, Texas; Dr. Brian Browne, Department of Emergency Medicine at the University of Maryland's School of Medicine; Major Juan Colon, New Jersey State Police, Office of Drug Addiction and Control; Dr. Michael Gatch, a biomedical sciences professor for the University of North Texas; Dr. Howard Haft, Deputy Secretary for Public Health in Maryland's Department of Health and Mental Hygiene; Dr. Roger A. Mitchell, Chief Medical Examiner, Office of Chief Medical Examiner, Washington, DC; Robert Perez, Commissioner and Operations Support for the U.S. Customs and Border Protection; Joe Schleigh, Synthetic Drugs and Chemicals Section, Diversion Control (special agent), U.S. DEA; and a number of

other pharmacologists and drug control and treatment experts from academia and the medical community (United States Sentencing Commission, 2018a).

During the spring of 2018, the USSC laid out their amendments to a number of sentencing guideline issues, including those discussed previously. The effective date listed for the following amendments occurred on November 1, 2018. The most notable amendment concerning sentencing for opioids included a four-level increase when a defendant knowingly caused the death or serious harm of an individual by providing them with a mixture of drugs the victim knew they had acquired but also included other drugs such as fentanyl or carfentanyl, which the victim did not know was mixed in (United States Sentencing Commission, 2018b). This decision was based in part by statistics provided by the CDC, which outlined a 72.2% increase in deaths between 2014 and 2015 in the U.S. due to synthetic opioids. Additionally, those in attendance for the sentencing meeting stated that a large number of opioids had been trafficked into the U.S. by way of Mexico and Canada and many of the lethal doses of synthetics had already been mixed into cocaine and heroin. The traffickers combine a mixture of the drugs into pill capsule form and then sell these in large quantity on the streets to unsuspecting buyers.

Experts pointed out that those who did not have a high tolerance for street drugs would be the most susceptible, since they believed that they merely purchased a ramped-up version of what their doctor would no longer prescribe them. This amendment serves to more severely punish those that knowingly deceive buyers in the effort to reduce the number of overdoses in the U.S. The caveat to this amendment resides in the judicial issue of a mens rea requirement, which may be difficult to prove for prosecutors. If this level of culpability cannot be obtained, the four-level enhancement cannot be imposed. To better understand the practical implications of this amendment, the following example is provided. An offender that has been arrested for carrying between four and eight grams of fentanyl with no criminal history, or one whose history

is diminutive, would be allocated for sentencing at a predetermined guideline level of 15. The prosecutor would routinely recommend a length of sentence between 18 and 24 months.

However, with this new amendment, the recommended sentence length jumps to between 30 and 37 months, since the defendant would now be a sentencing guideline level of 19 because of the enhancement.

A second opioid sentencing amendment concerned the labeling of opioid analogues in court so as to better understand the actual drug in question and its degree of lethality to the community. Due to evolved analogues, the courts have had a difficult time comprehending the drug which is set before them in any given case, and often leads them to set sentencing levels based on the lower end of the opioid analogue scale, when in fact, it deserves to be much higher based on the specific drug involved. In an effort to assist judges, a new and more comprehensive sentencing dialogue revised the previous, which was open to far too much assumption and interpretation. The new verbiage lists fentanyl analogue as “any substance (including any salt, isomer, or salt of isomer) whether a controlled substance or not, that has a chemical structure that is similar to fentanyl” (United States Sentencing Commission, 2018b, p. 21).

The acceptance of responsibility rule for sentencing in drug charges was amended by the USSC. Previous to this amendment, if a defendant made a successful good-faith acceptance of responsibility to the court that was not recognized as frivolous, the court would reduce the defendant’s sentencing level by two points. Additionally, if the offender assisted the court in his/her own case and was at a sentencing level of 16 or greater, the court was permitted to reduce the defendant’s level by one point. The amendment to this sentencing rule added the note that in cases where the defendant was found to be unsuccessful in their petition of acceptance of responsibility, it would now be acknowledged that the unsuccessful challenge would not

definitively establish that the challenge was either a false denial or frivolous (United States Sentencing Commission, 2018b).

Lastly, amendments affecting the alternatives to incarceration for non-violent first offenders were dealt with during the USSC's meeting in 2017 and decided upon during the spring session of 2018. The commission ruled that if a defendant was a first-time, non-violent offender and their offense fell within the specific sentencing guidelines of Zone A (0-6 month[s] max sentence) or Zone B (6-15 months max sentence), then the court should avoid a sentence of incarceration and instead seek to impose probation (United States Sentencing Commission, 2018b). The commission based the ruling of this amendment on previous studies which outline recidivism rates for non-violent offenders. One article in particular, which was commissioned by the USSC, found that "offenders with zero criminal history points have a lower recidivism rate than offenders with one criminal history point, and that offenders with zero criminal history points and no prior contact with the criminal justice system have an even lower recidivism rate" (Kyckelhahn & Cooper, 2017, p. 6).

The USSC explains that a non-violent offender is one that has no prior convictions, nor used violence or threat of violence in the commission of the offense (United States Sentencing Commission, 2018b). The committee advocated for such non-violent offenders to receive diversion, which would include home detention; however, these guidelines have also been altered to promote lighter restrictions on the defendant. The USSC describes a myriad of location monitoring services that a court may impose on an offender, but it goes so far as to recommend that, for non-violent offenders, the court should utilize "less intensive surveillance methods (e.g., telephonic contact, video conference, unannounced home visits by probation officers) [which] are sufficient to enforce home detention" (United States Sentencing Commission, 2018b, p. 74). This amendment would afford probation officers the discretion on whether or not to use an

appropriate surveillance method. The commission has been convinced that handing out mandatory location monitoring by default is a counterproductive measure of supervision for low-risk offenders based on the highly utilized risk-needs-responsivity (RNR) model, which has been a sentencing benchmark since the 1990s (Polaschek, 2012).

On August 27, 2018, The Sentencing Project co-authored a memo with the American Civil Liberties Union (ACLU), Human Rights Watch, and the Drug Policy Alliance, in which some of the USSC's amendments are discussed. Their concerns are highlighted by a statistic cited whereby 80% of people in federal prisons and 60% of people in state prisons for drug charges are Black or Latino (The Sentencing Project, 2018b). The thesis of their report is based on what they recognize as a biased criminal justice system, and in turn, they have sought to petition further changes on sentencing guidelines by the commission. Regarding the section that deals with amendments to acceptance of responsibility, the memo seeks clarification on the distinction between charged conduct and relevant conduct.

Relevant conduct, as described by the USSC, are "actions of the defendant performed in preparation for the offense, during the offense, and following the offense to avoid detection. Relevant conduct always includes acts the defendant counseled, commanded, induced, procured, or willfully caused)" (United States Sentencing Commission, 2019a, p. 2). An enhanced or expanded relevant conduct is in effect for drug trafficking offenses, which affords the court broader discretion where the judge must rely on magnitude to determine the level of guilt. The ACLU et al. memo points out the inherent flaws with which these guidelines erroneously dispense drug sentences. Primarily, the memo states that acceptance of responsibility should consider whether or not the offender admits charged conduct rather than relevant conduct, since sentencing courts involve a lower burden of proof, and in turn muddies the normal rules for evidence found in trial courts. For example, under relevant conduct standards in the sentencing

phase of trial, hearsay is admitted where it would be considered inadmissible elsewhere in other phases (The Sentencing Project, 2018b). The memo states that they believe relevant conduct to be coercive for defendants and in violation of the Fifth Amendment rights concerning self-incrimination. The coercive nature exists in getting a defendant to admit to conduct for which they were not charged in order to enter them into a sentence-reduced plea deal.

The memo consortium also takes issue with drug sentences from these amendments that do not include treatment for offenders. They state that the opioid crisis is a public health crisis and should be treated as such. They advocate heavily for diversion in place of retributive policies backed by the USSC. Although the USSC believes that it is leaning slightly this way based on some of their amendments, it is a far cry from prioritizing restorative measures over mandatory minimum sentences, which is the heavy hand filling state and federal prisons with drug offenders.

Additionally, the memo expresses serious concern over the USSC amendment to increase a defendant four additional sentencing levels because their drug sales caused the user to die as a result. Their reasoning for this lies in their evidence that only 15% of dealers admit to knowing the combination of drugs that were in the supply they had sold, and even when they do, they do not know in what quantity (The Sentencing Project, 2018b). Their position is that regardless of any enhancement, dealers will not be deterred for one of two reasons: (a) They simply do not care about the repercussions and believe that the risk is worth the reward, and (b) they are not concerned with the enhancement because they genuinely believe that they are selling product void of lethal analogues. This is viewed by many as a throwback to the war-on-drug era where stiff penalties were thought to deter drug crimes. Though much of the memo contests the amendments, one part dealt with non-violent offenders received praise. The consortium agreed with the commission's efforts to reevaluate how low-level drug crimes are prosecuted and

lighten sentences on, including home monitoring, for non-violent first offenders (The Sentencing Project, 2018a).

For decades, the efforts of the USSC have been strictly guided by all three branches of U.S. government due to the sensitive nature of this opioid crisis. President Trump merely inherited an evolved crisis which has plagued the U.S. since the 1950s, and just like his predecessors have worked to properly control the spread of devastation, the president, congress, and the U.S. courts struggle to find an effective course of action that can withstand future political and social opposition. Though each leader has a plan for what will curb opioid use and abuse, the results speak for themselves; we are continually losing this war on opioids.

For example, the 114th Congress under President Obama passed the Comprehensive Addiction and Recovery Act (CARA), which mandated that physicians needed to follow prescribing guidelines set forth by the CDC (The Sentencing Project, 2017). In 2017, Senators Chuck Grassley (R-IA) and Dianne Feinstein (D-CA) established “Schedule A,” a new category of controlled substances through the Importation and Trafficking of Synthetic Analogues (SITSA) Act (S1327), and in similar fashion, the House Judiciary Committee passed bill H.R.2851 that same year (The Sentencing Project, 2017). Under these two pieces of legislation, sellers and manufacturers of Schedule A substances would be charged with the same criminal penalties that the sellers and manufacturers of Schedule III substances are currently charged (The Sentencing Project, 2017). Additionally, the attorney general would be given broader authority to ban synthetic drugs. Another example of heavy handedness that did not substantially reduce opioid abuse.

On the state level, policymakers have also worked towards a solution to the opioid epidemic in the U.S. In 2014, Louisiana passed legislation that increased penalties for repeat offenders, specifically targeted opioid dealers, and increased the prison sentence from 50 to 99

years (The Sentencing Project, 2017). Additionally, the mandatory minimum for first-time opioid drug offenders went from 5 to 10 years. In 2017, Kentucky passed legislation (HB 333) increasing the penalty for dealers of illicit opioids, and it caused the prison sentence for first-time offenders of dealing to go from a range of 1-5 years to the increased range of 5-10 years, while sharing any amount of an opioid with another person guaranteed a sentence of at least 5 years but could also be up to 10 years in prison (The Sentencing Project, 2017). This new law delayed an inmate's possibility for parole. Florida, which has some of the strictest drug laws in the country, set a mandatory sentence of three years for the possession of four grams or more of fentanyl and a mandatory 15 years for 14 grams or more. Florida legislators then passed laws in 2017 (CS/HB 477) that gave prosecutors discretion to charge opioid dealers with first-degree murder if any of their customers experienced a fatal overdose (The Sentencing Project, 2017). It should be noted that as of 2019, Florida still allows use of the death penalty for certain cases, though it is uncertain if these cases would warrant such a sentence.

Being tough on drug crimes is certainly not an original solution, and critics are concerned that with the current massive overcrowding of drug convicts from the 1980s, 1990s, and 2000s, tightening an already punitive grip is not conducive for combating a modern drug war: "Between 1980 and 2006, the number of people incarcerated for drug offenses in state and federal prisons increased 1,412% from 23,900 to 361,276" (Petteruti & Fenster, 2011, p. 1). The National Center on Addiction and Substance Abuse at Columbia University conducted a study which focused on the actual costs of substance abuse in the U.S. and found that in 2005, abuse and addiction cost localities, states, and the federal government \$467.7 billion. Less than 2% of that money was for prevention treatment; instead, it went towards managing the consequences of substance addiction (e.g., crime and punishment, domestic violence, homelessness, and child abuse); (Petteruti et al., 2011). The federal government understood that old and outdated drug laws needed to be

changed, and in 2010, U.S. legislatures reduced the gap in sentencing for cocaine versus crack down to 18:1 from 100:1 (Petteruti et al., 2011).

### **Civil Lawsuits**

When the Rhode Island native Reverend Perry Davis developed an elixir in 1839 that consisted of 90% ethanol, 1% opium, and a 9% mixture of assorted vegetables including pepper and myrrh, he could only imagine the implications his homemade remedy would have on his future customers (Petty, 2019). He named it Pain Killer, and when doctors refused to prescribe it to their patients, Davis set out on foot and walked over 50 miles from Providence to Boston, selling his pain medicine door-to-door along the way. This direct-to-consumer marketing strategy was highly successful for Davis in the 19<sup>th</sup> century, just as it was for the Sackler family in the 20<sup>th</sup> century.

The Food and Drug Administration (FDA) granted approval for the opioid pain reliever OxyContin<sup>®</sup> in 1995 as the first extended-release version of oxycodone, and Dr. Richard Sackler, Purdue Pharma board member and son of the company's co-founder Raymond Sackler, wasted no time in promoting the drug at a launch party the following year. Sackler predicted in his keynote address that their "prescription blizzard would be so deep, dense, and White..." that it would "bury the competition" (Belmonte, 2019). This reference was derived from the blizzard of 1996 that primarily affected New York City, which is where the launch party was held. Many contend that Sackler should have known that his miracle pill would bury its recipients as well as its competition, and they sought justice in civil court.

Big Pharma (BP) has experienced multiple waves of civil litigation from numerous entities since the early 2000s in an effort to monetarily hold those who are responsible for creating the opioid epidemic accountable, as well as to force the reform of predatory prescribing practices. One example came in 2007, when Purdue Pharma was ordered to pay \$214.6 million

dollars to 26 states and the District of Columbia, and \$100 million to the federal government after pleading guilty in a federal suit (Gluck et al., 2018). Members of the Sackler family pled guilty to violating the Unfair and Deceptive Acts and Practices (UDAP) statute by fraudulently marketing OxyContin® from 1995 through 2001 (Belmonte, 2019). The UDAP statute functions similarly to the Federal Trade Commission Act, which states that it is unlawful for a company to engage in deceptive acts and/or practices, as well as unfair methods of competition (Childers, 2018). Purdue Pharma claimed that they did not have knowledge or intent of any wrongdoing since their drug was approved by the FDA.

This is similar to the Big Tobacco (BT) lawsuits of the 1980s and 1990s. BT claimed ignorance in knowing that tobacco use was linked to cancer, and they said that there was no intent on causing such cancer in their customers. After two decades of litigation, the courts uncovered hidden documents showing BT moderated the risk of using their products and participated in unlawful marketing acts, and they were forced to compensate the U.S. government a total of \$250 billion (Gluck et al., 2018). Many state and federal agencies were upset in the financial disparity between BT's and BP's judgments, stating that the predatory acts of BP were far more egregious. Their evidence of this complaint primarily concerns the veracity of how they exploited loopholes and took advantage of a broken system.

A 2018 study was conducted to investigate the connection between incentives given to doctors by BP and the rate at which those doctors prescribed opioids including, but not limited to: oxycodone, hydrocodone, fentanyl, tapentadol, and morphine (Gluck et al., 2018). The opioids Buprenorphine and Methadone were excluded from the analysis since they are used in the treatment of OUD. The database analyzed in this research was a congressionally mandated transparency program titled the Sunshine Open Payments Act that was born out of the Affordable Care Act of 2010 (section 6002), which requires physicians to report any and all

payments (including transfers of value) to the Centers for Medicare and Medicaid Services (CMS) (Health Affairs, 2014). It should be noted that the CMS, previously known as the Health Care Financing Administration (HCFA), is the arm of the U.S. Department of Health and Human Services (DHHS) that oversees all Medicare/Medicaid related issues. The Sunshine Act gave doctors and hospitals until March 2014 to submit all of their records.

A total of 865,347 U.S. physicians were examined between the years 2014 and 2016. The records indicate \$50.3 million were distributed to 77,085 doctors during those three years; regarding individual years, there was an increase from \$15.1 million in 2014 to \$20.5 million in 2015 (Nguyen, Bradford, & Simon, 2019). Researchers found that physicians who were incentivized by opioid manufactures prescribed 8,784 daily doses per year more than their non-incentivized peers. Payments to promote Hydrocodone saw the largest increase during that time period with 5,161 additional daily doses, followed by oxycodone with 3,624 additional daily doses. It is now clear that these incentivized direct-to-doctor marketing programs were largely responsible for the most dramatic increase in prescribed opioids in U.S. history during the years 2005 to 2012, when opioid prescriptions rose from 148 million to over 255 million, respectively (CDC, 2018).

These prescribing practices occurred out of the Medicare Part D program, which is the largest accepted prescription-based insurance program in the country, encompassing 30% of all prescriptions filled. According to a survey distributed by the Kaiser Family Foundation, 93% of all U.S. primary care doctors participate in this program. Subsequently, Medicare has the fastest growing OUD population (Lembke & Chen, 2016). As of 2014, that equated to 300,000 patients out of the 55 million on Medicare, or 6 out of every 1,000 patients. Since the rates of prescribing opioids have increased because of payments to physicians by opioid manufactures, and the rates of opioid overdoses have increased during that same general time period, it is plausible to

suspect a correlation between counties with high rates of prescribed opioids and high rates of opioid deaths.

A 2019 study conducted a county-level analysis that cross-referenced opioid marketing payments to physicians with the CDC's mortality rates from unintentional opioid overdose deaths during a three-year period, from 2014 to 2016. Their results concluded that counties that had aggressive opioid marketing campaigns also had the highest number of deaths from opioids (Hadland, Rivera-Aguirre, Marshall, & Cerdá, 2019). Their research held for numerous different marketing measures such as the number of physicians that received any marketing per capita, the total dollar amount of received marketing, and the number of payments made to physicians per capita. Given this data, these researchers presume the chain of events as follows: opioid manufacturers such as Purdue Pharma target specific geographical areas to market their product based on numerous factors; they launch aggressive direct-to-doctor marketing campaigns to increase prescriptions; doctors immediately begin to prescribe for a myriad of on- and off-label analgesic situations; and as a result, OUDs increase along with unintended overdose deaths from opioid use. It should be noted that off-label use pertains to the judgment of any medical provider to prescribe a specific medication to their patient for anything recognized to be medically appropriate once the FDA approves that medication (US Food and Drug Administration, 2017).

Interestingly, they also provide the context for a reverse-causality regarding marketing and distribution. Hadland et al. (2019) propose a scheme whereby BP markets in areas where opioid use and abuse is well-established, which ensured that the supply of their product meets the demand of prescribing physicians. It may actually be a combination of these two theories and others not yet discovered. What is known is that BP would not continually spend tens of millions on marketing to physicians and hospitals if they did not see the results in terms of prescription increases. One of the most effective marketing strategies highlighted in this article discusses trust

visits. These are the one-on-one sales visits made to physicians and hospitals by BP's drug representatives to push certain drugs for on- or off-label use. Research shows that trust visits were far more persuasive in getting doctors to prescribe opioids than high dollar payments (Bernstein, 2019). The totality of these findings suggests that direct-to-doctor marketing of opioids drastically contrasts the efforts made at the state and federal levels to combat this epidemic.

According to a study conducted by BlueCross BlueShield, opioid addictions increased 493% between 2010 and 2016 (Haffajee & Mello, 2017). The rates at which OUDs are increasing has states scrambling to find traction in the new war on drugs that has slipped further out of control. States have targeted BP and others in the medical industry over the last two decades with the intent of reducing the opioid stream and shutting down illegal commercial enterprises. Summit County, in the state of Ohio, brought a lawsuit alleging that since 2012 it spent \$66 million on fallout stemming from the opioid crisis.

New York City filed suit, alleging hundreds of millions of dollars in damages: "Claims are brought on the theory that defendants are fraudulently profiting from illegal activity," and the "causes of action include public nuisance, negligence, unjust enrichment, violations of state consumer protection, Medicaid fraud, and racketeering violations of both state and federal law" (Gluck et al., 2018, p. 355). In 2019, New York state's AG filed civil suits against members of the Sackler family and six national opioid manufacturers including Teva Pharmaceuticals USA Inc.; Janssen Pharmaceuticals, whose parent company is Johnson & Johnson; Allergan Finance LLC; Endo Health Solutions; and Mallinckrodt LLC. There were also four national distribution centers that were added to the complaint, including Cardinal Health Incorporated, Rochester Drug Corporation, McKesson Corporation, and Amerisource Bergan Drug Corporation.

The state claims false and deceptive marketing practices, as well as failing to prevent use and abuse diversion (Knopf, 2019a). This suit was amended from the earlier complaint and provides additional evidence that had recently been discovered that reveals UDAP violations. In addition to these claims, NY state's AG Letitia James alleges predatory sales practices (Knopf, 2019a). James has evidence that BP trained sales teams to inform doctors that opioids would improve the patient's cognitive functioning, leading to a better quality of life (Knopf, 2019a). Additionally, James states that BP sales members were falsely promoting the concept of pseudoaddiction as the explanation for addictive behavior exhibited by patients. This concept of pseudoaddiction has surfaced in previous civil suits concerned with opioid use and abuse, and therefore, will briefly be defined and discussed.

According to the Massachusetts AG Maura Healey the term pseudoaddiction was first identified in medical context in 1989 when Purdue Pharma President, Dr. Richard Sackler, created the term to identify when physicians were underprescribing pain medications for their patients (Commonwealth of Massachusetts, 2018). In November 2007, Purdue Pharma held a presentation on pain management for an audience of doctors which was titled Medication Therapy Management. In that presentation, Purdue speakers assured doctors that the symptoms of addiction experienced by their patients after only a short time of receiving opioid medication was simply the result of the patient not receiving a high enough dose to achieve the end result of analgesia (Commonwealth of Massachusetts, 2018). Doctors were instructed to administer higher doses for a longer period of time and to disregard any symptoms of addiction, especially in patients that did not have a prior history of drug abuse, since it was clear that they were experiencing pseudoaddiction.

This message was reinforced when Purdue distributed pamphlets to doctors and hospitals in 2008, citing that physicians were still underprescribing opioids to their patients, which was a

serious problem that should be rectified aggressively (Commonwealth of Massachusetts, 2018). In 2009, the *Opioid Clinical Management Guide* that was written and distributed by Purdue Pharma stated that “the greatest risk of addiction was giving patients too little of its [drugs]” (Commonwealth of Massachusetts, 2018, p. 21). In 2011, Purdue released an updated pamphlet titled *Providing Relief, Preventing Abuse* as well as a book titled *Responsible Opioid Prescribing*, which continued to push the concept of pseudoaddiction and again reconfirmed that opioids were to be administered in even higher doses as previously stated (Commonwealth of Massachusetts, 2018).

Researchers Weissman and Haddox (1989) reviewed the concept of pseudoaddiction concerning a 17-year-old cancer patient. They begin their introduction by declaring, “It is well recognized that patients with cancer and those with other painful medical conditions rarely develop psychologic dependence (addiction) during a course of opioid analgesic administration” (p. 363). They proceed to educate the reader on the progression into pseudoaddiction by way of three distinct and recognizable steps.

First, an inadequate amount of prescription opioids is given to the patient, causing that patient to continue to suffer in their pain. Second, the patient will voice their need for an escalation of pain medication coupled with aggressive behavioral changes towards hospital staff. Third, a breakdown in trust occurs between the patient and medical staff, which led the staff to make assumptions that the patient has become addicted to the opioids, when in reality, they have simply not received a high enough dosage (Weissman & Haddox, 1989). Research such as this served to aid BP in their efforts to reinforce their message of medical neglect on the part of physicians. It should also be noted that as of 2019, a number of peer-reviewed research articles identify and discuss the concept of pseudoaddiction; however, there has never been any empirical evidence to support this theory (Origins, 2019).

In 2014, Chicago filed a civil suit against Purdue Pharma in the Northern District Court of Illinois, alleging that BP has deceived the medical community and the public in general as to the results of using OxyContin® and other opioids (Childers, 2018). Four years later, Judge Jorge Alonso dismissed the case against all defendants, citing that the city failed to meet the burden of proof for a successful court case (Sullivan, 2018). California along with a number of other states have brought civil suits against the same manufacturers, distributors, and even some individual doctors with the same dismissal results. One of the most damaging dismissals occurred in North Dakota. Burleigh County District Court Judge James Hill's July 2019 decision to dismiss was based on his view that Purdue Pharma could not have controlled how physicians would prescribe their drugs and, furthermore, was not responsible for how patients used those drugs “regardless of any warning or instruction Purdue may give” (Belmonte, 2019:4). There is an issue of evidence that prevents these cases from moving forward; however, there are some instances where states are gaining traction.

The previously highlighted Massachusetts civil suit, which is being heard by Judge Janet Sanders in the Suffolk County Superior Court, recently received the decision that the motion to dismiss all claims of wrongdoing, brought by attorneys for BP, was denied on all counts (Becker & Bebinger, 2019). As of September 2019, the case will continue as attorneys on both sides have worked through the discovery phase of litigation. Oklahoma was also successful in suing BP and its distributors. Oklahoma AG Mike Hunter claimed that BP and its distributors directly caused the deaths of 4,653 individuals in the state between 2007 and 2017 (Cooper, 2019). Hunter has focused the state’s efforts on drug manufacturer Johnson & Johnson (J&J), stating that along with Janssen Pharmaceuticals, it acted as a public nuisance that killed thousands of people in the state of Oklahoma. Attorneys for the defendants’ state that they have not done anything wrong and acted in accordance with the rules and regulations set forth by the FDA. Their argument is

rooted in the notion that since the FDA has approved the labels for these opioids, their clients are void of responsibility stemming from the consequences of its use.

Hunter also argued the excessive nature of BP's marketing strategies in his state, citing 149,183 visits by BP sales representatives during the years 1999 to 2005 (Cooper, 2019). He also stated that there were 135 opioid pills for every adult in Cleveland County, which is where the trial was held. Hunter also pointed out that Johnson & Johnson was in heated competition with drug maker Purdue Pharma, and that in the pursuit of a greater piece of market share for stockholders, the company took unlawful risks that violated UDAP and other statutes. Michael Ullmann, general counsel for J&J, argued as he had in numerous other cases, that this epidemic is a complicated situation. They highlighted the fact that acute pain can be difficult to alleviate, and chronic pain is a "soul stealing, life robbing thief" (Cooper, 2019, p. 6). They added that their companies produce a product that helps these people through their pain if prescribed and taken correctly.

On August 26, 2019, Judge Thad Balkman ruled in favor of the state of Oklahoma, citing that BP created a provisional public nuisance by manipulating physicians into prescribing their opioid drugs. The judge awarded the state \$572 million, which BP states they intend to appeal (Feeley & Griffin, 2019). J&J's stock prices actually rose more than 5% after the ruling since many investors believed that the company faced losses as much as \$2 billion. All other co-defendants watched their stock prices rise following the judge's decision after an eight-week bench trial. While some believe that this sets a judicial precedent in future civil matters concerning BP and other similar litigation, others believe that this was a very low financial penalty and BP will consider this as the cost of doing business (Feeley et al., 2019). J&J believes that they have a solid argument with which to appeal the ruling, citing a lack of culpability under the Supremacy Clause.

The Supremacy Clause states that federal law supersedes all other state laws and state constitutions, since federal law is made pursuant to the U.S. Constitution (Jurkowski, 2017). Opioid manufacturers and distributors are seeking to justify their actions by exercising federal regulatory preemption against state civil suits, which posits that states are not legally able to argue that which has been decided upon by the federal government (Pace, 2006). This is called the FDA compliance defense, and it works to counter product liability allegations surrounding BP's failure to warn of impending harm stemming from the use and overuse of their drugs (Childers, 2018). The FDA is the U.S. governing body which serves to approve or remove new and altered drugs as well as to maintain the ongoing scrutiny of drugs. Drug companies operating under this umbrella contest that if the FDA has approved their label, then it stands to reason that they are free from product liability. Additionally, any drug manufacturer and/or distributor is subject to criminal and/or civil prosecution by the FDA if the agency decides to bring charges. The supremacy clause is the primary reason that states have historically failed at prosecuting BP.

In 2005, Federal judges in *Cartwright v. Pfizer* and *Zikis v. Pfizer* caused a major change to this federal regulation by ruling on a tangential and semantic position concerning suicide warnings for the medication Zolofit<sup>®</sup>. While the state wanted to mandate suicide warnings, the FDA had previously approved this medication's label without the need to include such a warning. In *Dusek v. Pfizer* (2004), the courts ruled against Dusek on the basis of the supremacy clause; however, in the following year, both judges in the 2005 court cases listed previously, ruled in favor of the states. They ruled that since the states had not declared a causal connection between Zolofit<sup>®</sup> and suicide, but instead identified an association, the states had the right to force Pfizer to change the label accordingly (Childers, 2018). Both states in the 2005 suits also argued successfully that because they held drug manufacturers and distributors to higher product liability standards for the protection of the people, the changes in this case were warranted.

Future cases at the state level that dealt with similar issues found that tort suits could also be used as the catalyst to change warning labels on medications as deemed necessary by the state since the manufacturer's culpability exists in the fact that they have the greatest first-hand knowledge of what long-term effects their products will have on society (Childers, 2018).

As a result of these recent civil litigation rulings at the state level, there have been thousands of lawsuits filed by numerous corporations, city and county agencies, 41 state Attorneys General offices, and Native American tribes that target opioid manufacturers, doctors, distribution companies, major pharmacies, and health-accrediting organizations that have lobbied for liberal pain treatment (Gluck, Hall, & Curfman, 2018). This unprecedented new wave of civil litigations has forced the federal government to initiate a multidistrict litigation (MDL). An MDL consists of a panel of federal judges that consolidate a multitude of plaintiffs into one, similar to how class action suits are prosecuted. One important difference between an MDL and class action suits are that the standards in class actions are far stricter for acceptance (Gluck et al., 2018). Once the list of plaintiffs is selected, there is one federal judge that conducts pre-trial management, including motions and discovery. Although an MDL judge cannot try these cases, historically, 97% of all MDLs end in settlement (Gluck et al., 2018).

It was decided in 2018 that Judge Dan Polster of the Northern District of Ohio preside over this MDL. Judge Polster had initially vowed to see this MDL settled by the end of 2018, but thanks to voluminous motions hearings to suppress evidence, petitions for summary judgments, and outright dismissal petitions by defendants, this case has flowed into 2019. As of September 2019, Judge Polster handed down a number of groundbreaking decisions that will most assuredly affect subsequent civil litigation. The most prominent ruling concerned the issue of the defendant's general culpability. Judge Polster ruled that "based on this evidence, a jury could reasonably conclude that the increases in prescription opioids proximately caused harm to

plaintiffs” (Bronstad, 2019, p. 2). He indicated that the plaintiffs in this matter have presented sufficient evidence that they have suffered injury to the point that summary judgment would be denied. Summary judgment pertains to the ruling of a case void of a trial and when ruled that the evidence is such that the trial is not needed, a judgment may be issued. The judge in this case indicated that there has been enough evidence provided that would require a jury trial. This also meant that an outright dismissal in favor of the defendant’s motion would not be justified.

Judge Polster ruled that the motion for Supremacy Clause related to federal preemption was denied, as was the motion for civil conspiracy (Bronstad, 2019). Motions on public nuisance and U.S. Racketeer Influenced and Corrupt Organizations (RICO) have not yet been decided. General counsel for Johnson & Johnson and Janssen Pharmaceuticals, Sabrina Strong of O’Melveny & Myers, downplayed her client’s role in the opioid epidemic, stating that J&J plays a crucial role in the medical industry and that only 1% of her client’s products contributed to the opioid crisis. The judge further stated that “a factfinder could easily conclude the manufacturer’s misleading marketing activities resulted in a substantial increase in the supply of prescription opioids” and that enormous increases in prescriptions constituted “a complete failure by the distributors and pharmacies to maintain effective controls against diversion” (Bronstad, 2019, p. 3).

The judge refused to issue a dismissal concerning the charge of conspiracy, citing that it would be prudent for a jury to review involvement in trade organizations and marketing strategies, as well as the involvement and timing of the plaintiff’s opioid orders to physicians and hospitals. More specifically, Judge Polster remarked that “a reasonable jury could review the record evidence and find that distributor defendants shared a general conspiratorial objective, with themselves and with other defendants, to expand the opioid market and disregard regulatory obligations in order to achieve that goal” (Bronstad, 2019, p. 5). Any one of these rulings would

be considered a win for the plaintiffs; however, as a whole, they are considered by some to be heavily weighted on the side of retributive justice. As there are a number of ongoing individual civil litigations in the fall of 2019, the rulings of this MDL will either set a new precedent, paving the way for large monetary judgments against BP or tie these cases up in the appellate courts for decades.

### **Chapter 4: Treatment and Intervention**

For many reasons, including financial, it is advantageous for policymakers and coalitions to invest in treatment programs for opioid abusers. From 1999 to 2007, opioid use and abuse cost the U.S. an estimated \$55.7 billion, a total that was calculated across three main criteria: workplace costs (\$25.6 billion, 46%), healthcare costs (\$25 billion, 45%), and criminal justice costs (5.1 billion, 9%); (Birnbaum, White, Schiller, Waldman, Cleveland, & Roland, 2011). Workplace costs, which included employment lost by OUD, subsequently caused reduced financial support to both the individual and the state/federal government in tax revenue. Healthcare costs were associated with the total amount of opioid prescription costs and medical attention required by the individual. Criminal justice costs were related to the cost of additional police officers, as well as the direct and indirect expenses connected to correctional facilities.

By 2013, it was estimated that opioid abuse was costing the U.S. \$78.5 billion per year across the same three main criteria previously listed (Cornaggia, Hund, Nguyen, & Ye, 2019). The largest share of total costs, accounting for \$28.9 billion (38%), came from substance abuse treatment and medical care for opioid abusers (Zhou, Florence, & Dowell, 2016). Patients with an OUD had annual health care costs \$13,000 greater than patients that were not abusing opioids and accounted for 70% of fatal overdoses that year (Florence, Zhou, Luo, & Xu, 2016). According to recent estimates, from 2007 to 2013, over 200,000 people in the U.S. have become dependent on and abusers of opioids (Cornaggia et al., 2019).

A large number of states have also been negatively affected financially by this epidemic. Researchers estimate that from 2000 to 2016, states lost \$11.8 billion on their labor market alone (Segel, Shi, Moran, & Scanlon, 2019). This estimate does not include the money spent on healthcare and criminal justice costs such as incarceration and additional police officers. This

figure is based on \$1.7 billion lost to sales tax revenue and \$10.1 billion to income tax, with a state median loss of \$147 million (Segel et al., 2019).

In the state of Maryland, medical treatment runs an average of \$13,700 for a patient that has overdosed, and the state cites that they spend an annual amount of approximately \$500,000 prosecuting drug cases (Lurie, 2017). Costs range per state, per capita from a median of \$1,672 to \$4,378 in the state of West Virginia, which experienced one of the highest death tolls from opioids in 2017 (Rembert, Betz, Feng, & Partridge, 2017). In Ohio, the cost to the state for opioid abuse is the equivalent of what the state spends on K-12 education (Segel et al., 2019). States have a limited financial pool from which to draw, and the more money that is spent on trying to control opioid abuse, coupled with the amount of money that states have lost in tax revenue, means that states have come up short when it comes to financially supporting treatment centers and other necessary resources to fight against opioid abuse.

One major issue surrounding treatment concerns the stigma attached to drug addiction. Saloner et al. (2018) cite that “stigma toward people who use opioids is correlated with low support for allocating substance use treatment resources and high preference for punitive policies;” furthermore, stigma can “impede help seeking by people with drug problems because they may fear negative social, legal, and employment repercussions if they disclose their drug use” (p. 29S). Removing stigmas from among the medical community, law enforcement, and policymakers should be a priority. Current estimates cite that only about one-fourth of those abusing opioids are getting the proper treatment that they need to recover (Saloner et al., 2018). A contributing factor to widespread drug use and abuse in the U.S. is the cross over from one opioid drug to another. Research out of the U.S. Surgeon General’s office cites that people who abuse opioid prescription medications are 40 times more likely to use heroin (Murthy, 2016). States have become much more conscious of the need for short- and long-term treatment options,

from first responders preventing overdose deaths to creating successful rehabilitation programs for opioid addicts.

### **Medication-Assisted Therapies**

One of the most critical components for the treatment of OUD are medication-assisted therapies (MAT). These are treatments that incorporate psychotherapy alongside treatment medications, as well as other supports (Volkow, Frieden, Hyde, & Cha, 2014). Research indicates that MATs are currently the most effective system for the treatment of opiate dependency and, ultimately, the best way to decrease unintentional overdose deaths (Connery, 2015). Physicians are now trained to view opioid addiction for what it is, a chronic disease, and develop long-term relationships built on trust is one way to ensure that the patient receives the help that they need to promote sustained abstinence (Volkow et al., 2014).

MAT has been shown to be a cost-effective approach to treating opioid addiction. It has been estimated that for every dollar spent on methadone and buprenorphine treatment, \$1.80 in social savings would be realized (Institute for Clinical and Economic Review, 2014). Most of these savings are achieved through reduced medical spending. Lynch et al. (2014) estimate that treating opioid dependent patients using buprenorphine and addiction counseling can reduce annual medical expenses for opioid dependent patients by \$20,000 per year. This is significant, since those with OUD were found to spend \$17,000 more per year in Medicare costs, \$15,500 in Medicaid costs, and \$13,700 in private insurance costs over patients without an OUD (Florence et al., 2016). As of 2016, the FDA reports that there are exclusively three drugs approved to treat opioid disorder: methadone, buprenorphine (Subutex<sup>®</sup> or Suboxone<sup>®</sup>), and naltrexone (Vivitrol<sup>®</sup>) (Wen, Borders, & Cummings, 2019).

Methadone is a full agonist and highly regulated treatment for opioid abuse that reduces opioid withdraws and cravings and can only be administered by certified treatment facilities.

Patients are required to visit these facilities every day to receive methadone medication.

Methadone was developed in Germany prior to WWII and used for the exclusive purpose of analgesia on soldiers (Barnett, 2009). In 1949, two researchers working at the U.S. Public Health Hospital in Lexington, KY, conducted experiments using methadone to treat heroin addicts and found great success (Joseph, Stancliff, & Langrod, 2000). They found that their patients responded best to slowly being tapered off of methadone for a total of 10-weeks although, once those patients left the hospital, 90% of them relapsed.

In 1964, The Rockefeller University, which is the oldest biomedical research institute in the U.S., received a grant through the Health Research Council (HRC) in New York City to treat returning WWII soldiers that were addicted to heroin (Barnett, 2009). The initial study consisted of six heroin addicts, all of whom had an eight-year average history of heroin abuse, who were administered 100 to 180 milligram doses of methadone every day until they exhibited consistent signs of recovery. Once the six volunteers no longer expressed a craving for narcotics, the researchers elected to keep them on a lower dose of methadone (80 milligrams per day). After some time, all six volunteers found jobs and did not relapse. Between 1964 and 2018, the number of patients taking methadone for the treatment of opioid abuse has grown to over 380,000 people through 1,611 methadone treatment centers across the U.S. (Vestal, 2018). The advantage to taking this drug over the others is that the patient may begin methadone treatment at the beginning stages of detox, while a disadvantage is that it takes time to achieve the consistent baseline dose needed for therapeutic effectiveness (Connery, 2015). During the initial time of fluctuation, the patient may choose to drop out of the treatment program, which would put them at a higher risk of unintentional overdose if they abuse opioids post-methadone.

Buprenorphine is a partial agonist, semisynthetic opiate, that was developed as an analgesic by Reckitt Benckiser Healthcare in the 1960s and was the first drug approved for the

treatment of opioid abuse by the FDA in 1970 (Saloner et al., 2018). It is 25 to 50 times stronger than morphine, and its use over the years has proven to be a success when a taper-off method is employed. As a result, researchers suggest that the drug be widely administered to hospital emergency departments and emergency clinics around the country, as well as in jails and prisons. There is a distinction between buprenorphine for pain relief and buprenorphine for treatment of an OUD. Physicians treating pain will prescribe Buprenex<sup>®</sup> to be administered via injection, while those treating opioid dependence will prescribe Subutex<sup>®</sup> or Suboxone<sup>®</sup> to be taken sublingual. Buprenorphine requires that the patient be in mild to moderate detox prior to administration so as to avoid severe withdraw (Connery, 2015). Withdraw reprieve typically occurs within one to three days, and the drug's ceiling effect protects against respiratory distress syndrome (RDS).

While it is common practice for medications to be administered off-use at the doctor's discretion once a drug label has been approved by the FDA, the agency has set strict standards against Buprenex<sup>®</sup> being used to treat an OUD because of how potent it is compared with Subutex<sup>®</sup> or Suboxone<sup>®</sup> (Wesson & Smith, 2010). While both are recognized as buprenorphine, Subutex<sup>®</sup> is a mono-product, which means that it is exclusively buprenorphine and Suboxone<sup>®</sup> is a 4:1 combination of buprenorphine and naloxone (Wesson et al., 2010). Researchers discovered that some OUD patients will routinely crush-and-sniff their medication, or they will dissolve the tablet and inject it; for this reason, Suboxone<sup>®</sup> is prescribed. If taken sublingually as directed, the buprenorphine will be absorbed by the back of the lips and the lining of the cheeks (buccal mucosa) and slowly dissociate from  $\mu$ -opioid receptors (Orman & Keating, 2009). However, if the pill is dissolved and injected, the naloxone will supplant the opioid agonist from the receptor.

As described in the Drug Abuse Treatment (DATA) of 2000, in order to be eligible to prescribe buprenorphine (schedule III substance) as a physician, opioid treatment training on-line

or in-person is required by SAMSHA, who will present the doctor with a waiver once that training has been completed (Thomas et al., 2017). In 2016, the Comprehensive Addiction and Recovery Act (CARA) was passed, which added that nurse practitioners and physician's assistants could also apply for the waiver after completing 24 hours of training. Once a doctor has obtained the waiver, they are then allowed to treat up to 275 patients at a time, depending on the specific designation. These waivers are tightly controlled by SAMSHA, and the maximum number of patients a doctor is allowed to treat depends on a number of predetermined factors such as the population size of the city in which a physician's home clinic resides (Rembert et al., 2017). Many physicians choose not to obtain waivers because they simply do not want the liability of treating OUD patients. As a result, there is a severe lack of treatment availability options for those that need it the most.

In Ohio, researchers indicate that the state had capability to treat only 40% of opioid abusers (Jones, Campopiano, Baldwin, & McCance-Katz, 2015). Out of 22,782 practicing physicians in the state in 2016, only 273 physicians (1.2%) obtained a waiver that allowed them to treat 30 patients at a time and 104 (0.6%) that were certified to treat 100 patients at a time (U.S. Department of Health and Human Services, 2016). This meant that approximately 18,000 of the 131,000 (14%) Ohioans recognized as having an OUD were able to be treated, assuming doctors across the state were operating at maximum patient capacity (Rembert et al., 2017). Unfortunately, a recent study was conducted which analyzed patient loads for physicians that possessed current DATA waivers. It was found that the majority of doctors were far below their patient limits and many had several months without having treated an OUD patient (Thomas et al., 2017). Some of the reasons for this included concerns over being reimbursed by Medicare and Medicaid, a lack of confidence on the part of physicians to be able to properly treat an OUD

patient, and poorly trained staff members. Many other states have encountered the same issue when it comes to treating opioid abuse.

Important to note is the disparity in the geographic availability of buprenorphine. Urban areas are currently the main locations of the drug's use, while rural locations are experiencing a dearth of available medical treatment, despite having just as big of an opioid abuse problem as heavily populated areas. As of 2011, there were only a total of 28 buprenorphine-providing opioid treatment programs in the nation's 1,231 rural counties (Stein et al., 2015). It should also be noted that according to the Office of the U.S. Surgeon General (2016), methadone and buprenorphine treatments cost approximately \$6,500 per year.

Naltrexone is a pure opiate antagonist that blocks the effects of opioid drugs and is also used to treat alcohol dependence; it was developed in 1965 and approved by the FDA in 1984 (Lee et al., 2016). Of the three drugs used to treat OUD, naltrexone is the most expensive at approximately \$14,000 per year and the least controlled by the FDA; any physician can prescribe the drug. Of the three drugs for treatment of OUD, naltrexone has the most complicated initiation profile since it requires the patient to completely detox from all opioids during a period of between one-to-two weeks before they start treatment (Connery, 2015). This is typically done by first administering methadone or buprenorphine. As a result, drug courts have become the most common use for naltrexone since this method of treatment often comes at the cost to the county or state (Rembert et al., 2017). Because of this, there is a greater risk that the patient will drop out of treatment. One great advantage with naltrexone is that this drug is ineffective for diversionary use due to its chemical design, meaning that the patient is unable to achieve euphoria with abuse via crush-and-sniff or dissolving and injecting (Connery, 2015).

Efforts are underway to grant access to MAT services through use of Medicaid coverage (Compton et al., 2015). In addition to these organizations, the American Society for Addiction

Medicine (ASAM) has been working with addiction specialist physicians to improve quality of care by publishing a set of standards to use in the field. As a result of these actions, research has found that methadone, buprenorphine, and naltrexone reduce dependency rates on opioids, as well as overdose deaths (Compton et al., 2015). Interestingly, these programs have also helped to reduce transmission of viral infections, and they have increased treatment program retention. Between the years 1995 and 2009, the city of Baltimore, Maryland experienced a decrease in fatal opioid overdoses by 50% as a result of the MAT program (Compton et al., 2015).

### **Treating Inmates**

Treating individuals with OUD in jails and prisons is another highly beneficial scheme for rehabilitation of incarcerated drug addicts; however, states and the federal government have been resistant to devoting tax money towards this population because they are convinced that recidivism rates will not change, and their constituents will turn on them during the next election. Historically, the U.S. corrections system favors retributivism or utilitarianism. The former believes that pain is necessary for rehabilitation, while the latter sees pain as unnecessary and instead seeks to utilize tools involved in deterrence and rehabilitation (Newman, 1983). Penological retributive theologies have had negative results in reducing crime and only ensure that those incarcerated will not get the drug treatments and counseling needed for actual rehabilitation (Greenwood, 1982).

A utilitarian approach is a far more pragmatic methodology in treating inmates to reduce recidivism, since the state is obligated by rehabilitation to care for an offender's welfare (Cullen & Gilbert, 2012, p. 32). Efforts to proactively seek out successful evidence-based drug rehabilitation programs would prove a means of increasing the humanity of the correction system (Cullen et al., 2012, p. 37). One major issue regarding drug rehabilitation programs in correctional institutions is whether or not they can be truly effective. Even if a prisoner is

rehabilitated inside the prison, the question of whether they will remain a law-abiding citizen is brought into question for various reasons. One of those reasons includes the fact that reentry is a very difficult process. There are reduced options for income above the poverty line, housing in a decent neighborhood, and the general stresses that accompany association with a previous criminal by everyone in that person's life (May & Wood, 2010).

Individual and group counseling have also had negative results on youth and adults, males and females; in fact, several reports show that counseling can cause an offender to be worse off by means of committing higher violations of parole than they would have been without counseling (Martinson, 1974). Various other alternative therapies, such as milieu therapy, has been explored in several different forms for numerous populations, but the results have been ambiguous at best (Martinson, 1974). One reason given for the high rates of recidivism concerns the fact that while incarcerated, inmates spend all of their time surrounded by other criminals, fostering an environment of experiential learning (May et al., 2010).

Ultimately, prisoners should continue treatment in their community after released via required social support networks set up in advance of release. Unfortunately, as of 2017, less than one-fifth of prisoners addicted to opioids while incarcerated obtained treatment for their abuse (The Sentencing Project, 2017). The Bureau of Prisons currently does not have a conventional addiction treatment program in any of its prisons, and most prisons and jails do not provide MATs to inmates (The Sentencing Project, 2017), though this appears to be slowly changing. During his speech at the annual conference of the National Commission on Correctional Health Care (NCCHC) in October 2018, the President of the American Association for the Treatment of Opioid Dependence (AATOD), Mark Parrino, noted that a new jail-based MAT guide was recently in distribution around the country with the hopes of implementing opioid rehabilitation for those incarcerated with an OUD (Klein et al., 2018).

NCCHC President James Pavletich states that he is highly in-favor of the MAT program based on years of positive recovery results at treatment centers outside of jails and prisons. While he encourages sheriff's offices and other jail-based cohorts to lead the way in this effort since the criminal justice system is the "largest source of organizational referrals to addiction treatment," he has been met with a lot of resistance surrounding the costs (Klein et al., 2018, p. 6). A representative from Advocates for Human Potential Inc., Dr. Andrew Klein PhD, who worked in large part to create the MAT guide, cited success from an opioid treatment program (OTP) in Rhode Island whose staff worked alongside corrections medical staff to administer methadone at all of RI's jails and prisons (Knopf, 2019b). Dr. Klein stated that drug and alcohol rehabilitation was paramount, indicating two-thirds of U.S. inmates struggle with some form of addiction. The impact of Klein's persistent petitioning, along with financial motives, might be the catalyst in institutional change. The nation's largest provider of medical insurance to correctional inmates, Corizon Correctional Healthcare, took notice of the two-thirds population and is working to create opportunities for rehabilitation that is physically beneficial to inmates and financially beneficial to Corizon shareholders (Knopf, 2019b).

Corizon is also motivated to rehabilitate based on a 2014 \$10 million lawsuit, where an inmate died in a Washington County, Oregon, facility because he was refused medical attention during his detox (Knopf, 2019b). Klein stated that the three most common causes of death to inmates that are going through detox in correctional institutions is dehydration (from diarrhea and vomiting), falling from a top bunk bed during a seizure, and suicide (Knopf, 2019b).

Currently, there is a shortage of speciality aftercare programs designed to reinforce sober living post-rehab, and a healthy support network could mean the difference between long-term sobriety and relapsing. Statistically, only 50% at best remain abstinent during the first year of their sobriety (Friedmann, Saitz, & Samet, 1998). Rehabilitation facilities are often overrun with

addicts needing treatment, and hospitals are not equipped to help with long-term addiction recovery. While most hospital patients are overprescribed opioids during almost all post-operative care among all surgical specialities (Chen, Marcantonio, & Tornetta, 2018), emergency room patients known as “frequent flyers” are also overprescribed for a number of reasons (Silversides, 2009).

Researchers indicate that emergency rooms (ERs) are not equipped to deal with the number of acute or chronic pain patients that they see daily (Chen et al., 2018). In part, this is due to the fact that doctors and nurses only have limited access to a patient’s medical history, especially those that are indigent and without insurance. Also, OUD patients will hospital shop and look for opportunities to complain of fictitious pain scenarios, or worse, physically harm themselves in order to obtain opioids (Silversides, 2009). Doctors knowingly prescribe opioids to patients with symptoms of OUD because they know that if they do not, and the patient submits a complaint against them, it will damage their career (Lembke, 2012).

ER medical staff is also very concerned about the repercussions of malpractice lawsuits brought by OUD patients. Some ERs have taken steps such as to deny treatment to OUD patients, or they will place a sign on the door of the ER, stating that they will not prescribe opioids; however, this is clearly the wrong approach since there is a need for analgesics in ERs (Silversides, 2009). It seems that the greatest concern in the medical community is the lack of knowledge surrounding these drugs (Lembke, 2012). Doctors, in-hospital pharmacists, and other medical staff are not properly trained on how opioids function, nor are they well versed on what to do with “frequent flyers” and others that are suspected of OUD. Doctors in private practice experience much of the same issues. Primary physicians are trained to screen for and diagnose addiction, but many do not possess the skills or have the time to deal with issues surrounding recovery. Additionally, there are serious financial constraints that hinder medical organizations

from helping a wider population of addicts, so it often falls to the support network to do what is necessary in supporting recovery efforts.

### **Social Support**

Social support is recognized as a major contributor to a recovering addict successfully abstaining from relapse. In a clinical setting, social support is identified as resources that are provided by other people, whether structural or functional. Structural support is the number of people in a person's life providing support, while functional support is the availability of functions such as emotional expressions and other tangible services to benefit the addict. Research has shown that the opioid user will benefit from the most prominent support system they allow into their life, although it may not lead to sustainable recovery (Friedmann et al., 1998). There is often a cycle that forms around many types of addiction, which leads to a person going through recovery only to relapse a short time later. In some instances, a person may stay sober for months or even years before they are triggered by some life event that sends them back into their addiction.

The vast majority of reputable recovery programs preach the same support network sermon for addicts of many kinds because there has been much success with sobriety while adhering to a particular network methodology. The most prominent social support network ideology, which has also proven to be the most pragmatic, is to have a recovered user seriously reevaluate their sphere of social influence (Friedmann et al., 1998). Numerous studies have found that when one surrounds themselves with pro-abstinence family, friends, and coworkers, they will achieve greater success with sobriety (Beattie & Longabough, 1999). Making this social transition proves very difficult for addicts since it involves breaking habits and ties with others that are unhealthy. Research has shown that just as addiction is powerful, so are the social connections that promote that lifestyle (Wasserman, Stewart, & Delucchi, 2001). Some believe

that this is due to acceptance by other like-minded users, all of whom have been shunned by society for their poor life choices. To be accepted by and emotionally connected to a person or cohort group of addicts satisfies cognitive dissonance related to drug use.

Social workers, therapists, and psychologists do have the necessary tools, but often struggle with retention rates, as a number of patients will inevitably drop out of view. Reports show that success lies in established trust with the addict, and maintaining both a loose and guarded relationship. It is more common that family and friends already have some degree of trust established with the addict and can get thorough to them when no one else is able. Zywiak et al. (2009) conducted a longitudinal series of interviews with recovering addicts called the Important People Drug and Alcohol interview (IPDA). One hundred forty-one participants who were dependent on cocaine were initially identified and interviewed before their rehabilitation began, using this as a baseline. Researchers then interviewed them at three and then six months and found that those that had maintained abstinence did so largely due to their large support network.

It is just as important for the support network to be educated on how to best help someone in recovery. Family, friends, and coworkers that wish to help should do so while regularly attending support groups such as NarcAnon, Alateen, and/or AlAnon (Wen et al., 2019). These meetings are designed to give the support system a blueprint for promoting healthy and positive support during recovery and beyond. This includes eliminating current and preventing future enabling interactions, which can easily derail the recovery process. This is especially true if there is a member of the support network that is currently or has struggled with substance abuse. This is just one example of numerous other complicated scenarios that can be worked out through support service agencies.

When a history of sobriety can be established, a former addict can prove tremendously valuable to the functionality of social support. This is a person that intimately knows the perils of use disorder and is able to sense deception and manipulation faster than others without such knowledge. It is common practice for a connection to be made with such an individual while in rehab. These individuals are known as peer supporters or peer coaches, and they are masters at realistically assessing how recovery is progressing. They have tactics proven to be successful, and they understand better than most the cost of rehabilitation.

In August 2019, a number of health and criminal justice professionals gathered at a townhall meeting in Columbus, Ohio, to discuss the current OUD status of the state, as well as offer suggestions on what Ohioans could do to participate in the reduction of unintentional overdose deaths from opioids. Amongst the panelists were an emergency room physician from The Ohio State University Wexner Medical Center, a lieutenant with the Westerville police department, a forty-year veteran paramedic that had worked in both large and small cities around the U.S., a recovering opioid addict (sober for two years) named Daryl, and a social worker that was currently employed with a methadone clinic in Columbus. The agenda was first a discussion on the current state of the opioid crisis in Ohio, then some treatment facts, and then detailed instructions on how to use the two doses of naloxone (Narcan<sup>®</sup>) that would be prescribed to each attendee at the end of the night.

Daryl, the former addict (or OUD victim as he labeled himself), stated that as he was one of the majority of addicts to fluctuate between sobriety and relapse, the single most important factor in his success was due to his specific support network. Daryl said that these people were ones that he could trust to not necessarily be on his side, but to be on the side of his sobriety. He said that there was a distinction that he had to learn through years of navigating the figurative landmine fields of opioid use. As a peer supporter, Daryl works with several current and former

addicts, training them on how to get and stay sober through building a strong social network. Additionally, he stated that one of the most common setbacks to engage people with OUD into treatment was that many of them did not have government issued identification (e.g., driver's license, birth certificate, social security card). This sentiment resonates on a national level.

In 2004, researchers in New York City who examined the barriers of enrollment to drug abuse treatment centers found that almost half of the participants in their study cited the hassle of applying to Medicaid as a reason for not applying for drug treatment (Appel, Ellison, Jansky, & Oldak, 2004). They added that applying for and obtaining new government identification, which is mandatory for enrollment into the Medicaid program, was cumbersome and time consuming. For instance, participants complained that in order to obtain another copy of their birth certificate, they would need to spend the entire day waiting in line at the Bureau of Vital Statistics, on top of having to pay the \$15 fee for each copy (Appel et al., 2004).

Some reported that they had attempted to obtain a driver's license, but due to the strict standard of the Department of Motor Vehicles, they were unable to show the five necessary documents that were required by the state to process their application. Additionally, there was a \$55 fee that many could not afford. Those that did have supporting documentation reported extremely long lines, and some reported that they were forced to return on a separate day for additional processing and wait in line again. This research is proof that eliminating bureaucratic red tape could provide the necessary documents that these individuals need in order to live productive and healthy lives.

### **Sober Living Houses**

Sober living houses (SLHs) are facilities in residential neighborhoods that provide supportive and safe housing for people that have recently completed drug and/or alcohol rehabilitation programs. The people that reside in a SLH are those that are attempting to maintain

abstinence through a community-supported, sober lifestyle (Polcin, Korcha, Bond, & Galloway, 2010). Voluminous research has shown that recovering addicts have much higher outcomes of sustained abstinence if they complete a rehabilitation program and fully utilize the tactics taught to them in SLH (Polcin & Henderson, 2008). Two of the most difficult obstacles for recovering opioid abusers are developing an abstinence-based support network and to maintain long-term and stable housing; SLH provides for both of these needs (Polcin et al., 2008). They are not held to the same state governmental abuse treatment standards, which allows for a greater amount of flexibility in the organization's structure.

While SLHs are not considered to be formal treatment programs, they do maintain a necessary amount of structure. The fundamental characteristics that define a typical SLH consist of the following: (a) residents are responsible for paying rent and maintenance costs associated with the facility; (b) residents must attend an approved 12-step program such as Alcoholics Anonymous; (c) residents are required to completely abstain from alcohol and drugs, with the exception given to those in need of mental and/or physical health medication(s); (d) residents are required to comply with all rules and regulations set forth by the SLH council, which includes paying rent and certain designated chores; and finally, (e) residents are welcome to remain in the house for as long as they wish, so long as they are in compliance with the previous four mandates (Polcin et al., 2008).

SLHs are similar to half-way houses in a number of ways; however, they also share certain distinctive differences. While half-way houses are funded by governmental entities, SLHs are self-sustained financial operations that obtain their funding from the fees paid by residents of the houses. Residents are able to pay these fees by jobs that they get through connections of the SLH and its residents, they can pay their fees through working at and on the house, or they can pay by means of social security or other such government assistance (Polcin et al., 2010).

Another difference is the length of time in which a resident may stay at a SLH. Half-way home programs all have a designated maximum length of stay, and once the resident reaches that point, they must move out of the house. SLH residents are able to stay in the house as long as they desire, as long as they continually obey the house rules and pay rent/fees. Finally, while half-way houses require their residents to be involved in a treatment facility for rehabilitation, SLH only mandates that their residents participate in a 12-step program (Polcin et al., 2010).

The dynamic of the SLH authority structure is also quite different from half-way homes and other sober living facilities such as the well-known Oxford-House Model, which was developed as part of the Federal Anti-Drug Abuse Act of 1988 (P.L. 100-690); (Polcin et al., 2008). SLHs typically either have one house manager (i.e., house owner) to develop and enforce the rules, while others take on a more social approach. In the latter structure, a council is developed and operated on a rotational system so that all residents can participate. Research into both authority structures has not shown one to be more indicative of success over the other (Polcin et al., 2008). SLHs have a high rate of success throughout the U.S., and research has noted that after a 180-day period of residency at an SLH, 61% of the participants studied remained sober and had a job (Polcin et al., 2010). Researchers confirmed abstinence using breathalyzers and urinalysis for drug screening.

According to the Medicaid.gov website, Medicaid is administered at the state level while governed at the federal level (Medicaid.gov, 2019). It is designed to serve an indigent population and provide health care coverage to all Americans that need it but cannot afford it. As of July 2019, over 72 million individuals were enrolled in Medicaid across all 50 states, with the federal government paying more than 60% of costs associated with the program (Medicaid.gov, 2019). Though the system is intended to provide treatment for people with OUD, many states have simply not been able to financially cover the dramatic rise in costs associated with the current

opioid epidemic. As discussed earlier, the majority of those with OUD fall below the federal poverty line (FPL) and therefore, cannot afford treatment, including long-term rehabilitation and sober living facilities. As part of Obamacare, states were allowed to expand Medicaid coverage to adults and children when their income(s) was at or below 138% of the FPL (\$21,000 for a family of three and under); (Medicaid.gov, 2019). As of October 2019, 34 states have elected to expand Medicaid, which has allowed for the expansion of treatment for those with OUD.

Post expansion, the uninsured rate fell from 32.4% to 12.8% (Scott, 2018). Prior to the Affordable Care Act, one in three people who were at or close to the FPL were uninsured. That ratio dropped to one in eight after states voted in Medicaid expansions. In 2017, researchers looked at a number of pre and post Medicaid expansion states to determine if those states were ordering and administering any more buprenorphine, which is the most popular drug used to treat OUD; they found a 70% increase in buprenorphine prescriptions in states that chose to expand Medicaid (Wen, Hockenberry, Borders, & Druss, 2017). They also found that the number of doctors with DATA waivers increased dramatically in expansion states. Thanks to expansions, states are able to allocate funds towards much needed opioid treatment centers, as well as opening new centers. Eighty-four percent of newly enrolled Medicaid recipients stated that having the healthcare coverage made it easier for them to work (Scott, 2018). Additionally, those on Medicaid were far less likely to have medical debt when compared with the uninsured population.

### **Opioid Interventions**

Interventions over the opioid epidemic are occurring on many fronts involving various groups through a uniquely complex set of schemes with the hope of achieving timely success over the growing rates of deaths. The following interventions are representative of how organizations are tackling intervention in practical ways.

Primary prevention is a series of educational initiatives that are targeted for schools and other community settings, and their goal is to disseminate knowledge and dispel misconceptions surrounding opioid use and abuse (Compton, Boyle, & Wargo, 2015). Two examples exist in Iowa state programs titled the Iowa Strengthening Families Program (ISFP) and Strengthening Families Program for Parents and Youth 10–14 (SFP 10–14). Randomized controlled studies showed that these programs were successful in delivering sessions surrounding the prevention of drug abuse as well as improving family skill-building (Spoth et al., 2013). Utah developed a statewide campaign using various media sources to remind people to use prescription medication only as directed by their doctor, and in other ads, they warn of the dangers surrounding opioid misuse and abuse (Compton et al., 2015). Through their efforts, the state saw a decrease in death due to opioids, although the state admits that there were contributing factors to the decline.

Another intervention concerns prescriber education through what is known as continuing medical education (CME) courses, which involve educational programs that focus on prevention, identification, and abuse treatments, as well as safe methods for prescribing (Compton et al., 2015). The National Institute of Health (NIH) created 12 Centers of Excellence in Pain Education and targeted training for physicians (Compton et al., 2015). There was also a series of online courses that spoke to improving prescribing practices that complimented the training. Researchers point out that although education does increase knowledge, it is unsure how effective these programs have been in producing positive results.

Prescription drug monitoring programs (PDMP) are databases used by states to assess information about prescribing practices. This information is accessible to pharmacists, clinicians, and law enforcement (in certain states) in order to identify overprescribing as well as doctor shopping by patients (Compton et al., 2015). Although almost every state has a form of PDMP, there is currently no standardized system in place, and the federal government does not require

its use. Research has shown that PDMPs lower rates of doctor shopping, prescribing, and events of opioid poisoning. In 2014, the CDC reported that PDMPs led to a 27% drop in death related to opioids in Florida and the state of Washington (Compton et al., 2015).

Another intervention involves initiatives by law enforcement, such as Good Samaritan laws that maintain anonymity for individuals who report overdoses so that they will not be arrested for drug charges. In 2010, there were only four states that subscribed to the Good Samaritan program; however, by 2014, that number increased to 24 states (Compton et al., 2015). There have also been a number of closures to clinics identified as pill mills by officers. From 2008 to 2015, the DEA partnered with local and state police agencies to expand the amount of Tactical Diversion Squads, which were developed specifically to target opioids. Additionally, the DEA increased their number of Diversion Investigators to conduct surveillance of registrants with the agency. These efforts contributed to Florida's 27% decline in opioid deaths as identified above (Compton et al., 2015).

One other intervention concerning law enforcement involves the distribution of Narcan<sup>®</sup> to local, county, and state police officers. Naloxone works as an opioid antagonist to counteract the effects of the drug, thus preventing overdose. Researchers found that when naloxone was provided to non-paramedic first responders (i.e., police and firefighters) in the state of Massachusetts, it reduced the number of overdose deaths (Davis, Ruiz, Glynn, Picariello, & Walley, 2014). Additionally, the criminal justice system "can play an important role in bringing people with substance use disorders into treatment and supporting continuity of care across community and correctional settings" (Compton et al., 2015, p. 6).

Opioid overdose prevention programs (OOPPs) exist to train bystanders in recognizing the signs of someone who is overdosing and then administer naloxone (Compton et al., 2015). Between 1996 and 2010, the Harm Reduction Coalition conducted a survey of local community-

based OOPPs. They reported that the organization saved 10,171 individuals from opioid overdoses by training bystanders and equipping them with naloxone (Compton et al., 2015).

A final example of an intervention currently being used to control opioids in the U.S. concerns the expansion of access to a program called supervised consumption services (SCS) or supervised injection services (SIS). These are legally sanctioned facilities that will allow people to consume the drugs that they have previously obtained either illicitly or legally (Drug Policy Alliance, 2019). There are a number of trained medical and non-medical staff members on hand to assist in preventing an overdose if needed. A larger part of staff duties includes discussing alternatives to drug use, providing access to drug rehabilitation and other medical services, providing clean needles to prevent the spread of diseases such as HIV and hepatitis, commonly associated with needle injections in the drug use community. It should also be noted that as of 2018, there has not been a single overdose death reported at any SCS or SIS anywhere around the world (Nursing@USC Staff, 2019).

As of 2019, there were more than 120 government sanctioned SIS sites around the world, including those the following countries: Switzerland, Australia, the Netherlands, and Canada. Berne, Switzerland was the first legalized SIS in the world, which opened in 1986; they see approximately 200 injections every day at their facility (Nursing@USC Staff, 2019). Sydney, Australia, had their first site open in 2001, and they see approximately 180 injections every day. Of the 15,400 clients that have come through that injection site, 12,000 have accepted referrals for other forms of care with help recovering from drug addiction (Nursing@USC Staff, 2019). The first legal SIS site in Vancouver, Canada, opened in 2003, and they see one of the largest populations of illicit drug injections at their site, covering approximately 415 per day and a total of 3.6 million people who have injected since they opened. They report that on average, there are six overdose interventions every day, and in 2017 alone, 3,708 individuals accepted primary care

interventions from a physician for various medical issues (Nursing@USC Staff, 2019). Finally, the Oslo, Norway, injection site which opened in 2005, has approximately 90 injections per day and in 2016 had a total of 295 overdose interventions.

Though each site is managed differently according to the rules and regulations set by each country's government, all sites generally share the same basic standard operating procedure. Drug users (referred to as "clients" by staff) who wish to utilize the SIS must first sign in at the front desk. They need not provide a government issued identification, but for the purposes of maintaining statistics, each person is required to use the same identifier each time they come in. Clients then wait in a waiting room to be called back into a secure area by site staff. One staff member at the Vancouver site mentioned that although they have a lot of supervised injections, the wait is not very long (Nursing@USC Staff, 2019). Once the client's name is called, they are led through a locked door, back into a larger room where the individual injection booths are located. The clients can choose to have their drugs tested before they inject, as well as obtain clean needles which are available at each station. The client then injects their drug under the supervision of trained staff who are prepared to administer Naloxone and/or CPR if necessary; many sites also have licensed nurses on staff to assist with other medical issues. After the clients have injected, they are led to another room where they are able to rest, if necessary, before leaving the facility.

Proponents of SIS cite numerous benefits including entry into OUD treatment centers, an increase in the number of medical services to those who might otherwise not obtain such services, a reduction in the transmission of HIV and hepatitis, an increase to public safety and a reduction of public disorder from drug users, and a reduction in costs associated with decreased arrest/incarceration rates and emergency medical services (Drug Policy Alliance, 2019). Site staff are there only to oversee injections and do not participate in the injections of the drugs, nor

do they handle any of the drugs that are brought into the site unless asked by the client to test the drugs. Those who oppose injection sites claim that they cause great harm to the community in terms of crime and drug increases; however, to date, there is no empirical evidence that supports these claims. In fact, evidence-based research from numerous SIS sites around the world indicate that safe injection sites, drug testing facilities, and needle exchange programs actually reduce crime and overall drug use (Kuo et al., 2019; Potier, Lapr evote, Dubois-Arber, Cottencin, & Rolland, 2014; Watson et al., 2018; Notley, Holland, Maskrey, Nagar, & Kouimtsidis, 2014).

In 2010, the Canadian federal government attempted to shut down all provincial SIS sites, citing that it would no longer approve the necessary federal drug law exemption that was needed for the site to operate legally. Vancouver immediately filed suit against the government, which eventually reached Canada's supreme court in 2011. The high court ruled that the health benefits exhibited by SIS sites were very convincing and even suggested that they open additional facilities when the need arose (Bayoumi & Strike, 2016). Injection sites in the U.S. do not currently exist, though there have been a number of states such as Colorado, Nevada, New York, Massachusetts, Pennsylvania, and others that have shown interest. The federal government has made it clear that they will not allow such facilities to operate, and if they find that one is planning on opening, U.S. Deputy Attorney General Rod Rosenstein said that he would incite swift and aggressive action to close such a facility (CBS, 2018). Additionally, Rosenstein said that he would criminally prosecute all involved, with the intention of seeking a lengthy prison sentence, as well as administering large fines and seizing all property.

San Francisco's mayor, London Breed, who has been personally affected by the opioid crisis with the unintentional death of her younger sister to a fentanyl overdose, has said that she is ready to fight the DOJ on this issue (CBS, 2018). In 2018, San Francisco passed Assemble Bill 186, which provided funding for the opening of a SIS facility. California Governor Edmund G.

Brown, Jr. vetoed the bill later that same year. Regarding the concepts behind SIS facilities, Brown stated that “enabling illegal and destructive drug use will never work” (California Legislative Information, 2018, p. 1). Less than a year later on October 2, 2019, U.S. District Judge Gerald A. McHugh ruled that SIS facilities that were designed to curb the death toll from this opioid epidemic could not be considered a crack house as described by the Controlled Substances Act, since there were medical staff on hand to supervise the injections, and the purpose of those staff members was to save lives (Rendell, Benitez, & Goldfein, 2019). This opinion will serve to support the creation of SIS sites in the U.S., such as Safehouse, which is slated to open two safe injection facilities in the city of Philadelphia by the end of 2019.

Ed Rendell (former Governor of Pennsylvania), Jose Benitez (Executive Director of Prevention Point, a nonprofit in Philadelphia), and Ronda Goldfein (Executive Director of the AIDS Law Project of Pennsylvania) have teamed up to create and manage Safehouse. They plan to have the operation of their SIS facility mirror Vancouver’s facility, with the added condition that before the client is checked into the site, they would first need to speak with medical personnel about enrolling in an OUD treatment plan, as well as other appropriate medical programs (Rendell et al., 2019). Safehouse creators state that they now need to raise \$1 million to cover the costs associated with running the facility since they will not petition the government for financial assistance. Rendell, Benitez, and Goldfein have all been personally affected by the opioid crisis and have vowed to do all that is within their means to combat this epidemic on the ground level.

## Chapter 5: Conclusion and Discussion

During the period from 1999 to 2017, the number of Americans that have died as a result of overdosing from prescription opioids has more than quadrupled (Scholl et al., 2019). However, this epidemic has a different appearance from the heroin epidemic of the 1980s and 1990s; 78% of the 47,600 people that died from opioids in 2017 were White (Scholl et al., 2019). Researchers agree that this current epidemic of opioid abuse is the largest of any drug epidemic in this nation's recorded history, and there must be corrective action taken to stop the number of people dying every day as a result (James et al., 2018). While millions of Americans became addicted to prescription opioids during the early 2000s, illicit forms of those medications (e.g., heroin) were drastically increasing in potency, and the costs to those buying on the street were steadily declining. One reason for declining costs was due to how these drugs were entering the U.S. Since the major source of import shifted from South America to Mexico (over 90%), the U.S. experienced a massive flow of both legal and illegal fentanyl, an opioid which was much more severe and potent than heroin ("Opioid Abuse and Sources of Supply," 2018). Dealers mixed fentanyl into heroin and cocaine to increase the strength of their product in order to beat out competition and attract new clientele.

While politicians and law enforcement agencies on state and federal levels have traditionally leaned heavily on a punitive solution, history has shown their efforts to be highly unsuccessful. Jails and prison are overcrowded, yet the drugs are still pouring in. The number of dealers is increasing day by day, and the product has become more potent than ever. Policymakers have begun to understand this and have changed outdated laws, replacing them with alternative measures that have helped to loosen the grip on this population of sellers and users.

Mass introduction of prescription opioids in the U.S. first originated by way of Purdue Pharma and the Sackler family as a means to aggressively market their newly FDA approved super-analgesic, OxyContin<sup>®</sup>. During the middle part of the 20<sup>th</sup> century, drug manufacturers and distributors depended on word of mouth to promote their drugs and were not engaged in direct marketing of their products to doctors or the public at large (MAHF, 2019). Three psychiatrist brothers named Sackler, working together to redevelop aggressive marketing strategies for their company Purdue Pharma, developed a predatory direct-to-doctor strategy. The Sacklers quickly observed the important role these selling techniques would play in an industry that had weak competition at best. Through manipulation of print and other media sources, as well as through connections at the FDA and other governmental agencies, they successfully launched the largest pain medication campaign in U.S. history (Keefe, 2019); however, they could have accomplished this feat without crucial help from leaders in a number of medical agencies.

Purdue Pharma owes much of their success in distribution to Dr. James N. Campbell, MD, President of the APS, for waging a medical war on pain with his campaign of pain as the fifth vital sign (P5VS); (Campbell, 1996). Campbell was able to convince two of the largest medical oversight organizations in the country, the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) and the Veterans Health Administration, to adopt P5VS, making OxyContin<sup>®</sup> a standard of analgesic care (Morone & Weiner, 2013). The equivalent of street hustlers, the Sackler family exploited all possible avenues to get their superdrug into the hands of every licensed physician and pharmacist, vehemently claiming that their drug was not addictive and if their patients exhibited addictive behavior, it was merely pseudoaddiction from too low a dose of OxyContin<sup>®</sup>, and doctors were pressured to double and triple the doses (Commonwealth of Massachusetts, 2018).

Lawmakers and other criminal justice professionals have developed a new approach to fighting the war on opioids. Instead of targeting their efforts on addicts and dealers as was done in the 1980s and 1990s, they are focused on white-collar entities. Civil and criminal lawsuits have been filed against numerous drug companies, hospitals, distributors, pharmacies, and medical staff as a means of combating this epidemic at the true source of the problem. The federal government is working to hold those accountable that have profited as much or more than illegal drug dealers (Gluck et al., 2018). There are currently 700 cases before one U.S. federal judge that has assured that justice in this matter will not be delayed. He has committed to ruling on all 700 cases within one year. As a result of this wave of opioid litigation, Big Pharma has been forced to pay out billions in settlements to states and local counties that have been harshly affected by their predatory practices. Additionally, The Joint Commission on Pain Management Standards has revised its pain guidelines in an effort to reduce the number of people being prescribed opioids, thus reducing the number of people who would become addicted to the drug (Gluck et al., 2018), and Purdue Pharma has canceled all direct promotion of OxyContin® to prescribers and medical staff (Gluck et al., 2018).

There has been a surge of coalitions and federal organizations taking a different approach, one that involves treatment and rehabilitation in a myriad of innovative ways. These involve education in schools and communities, especially targeting those areas that are hot spots for drug abuse (Compton et al., 2015). There is also a push for greater education for medical staff, law enforcement, and first-responders. This involves the reduction of prescribing pain medications in hospitals and training and equipping law enforcement on a life-saving, fast-acting drug named Naloxone, which, when administered to a person who has overdosed, has a highly successful rate of reversing the effects of an overdose and preventing death (Compton et al., 2015). Surveillance programs such as PDMPs that monitor prescriptions have been shown to

have a high success rate of reducing doctor shopping and regulating pill mills, while also tracking problem areas for state and federal law enforcement. The greatest downfalls with PDMPs are the lack of standardization for data tracking and the fact that not all medical agencies have participated. As more local, state, and federal treatment programs emerge in both urban and rural locations, and the rates at which addicts have access to treatment drugs such as buprenorphine increase, the expectation is that opioid addiction will begin to decrease (Johnson et al., 2018).

Research indicates that MATs are currently the most effective system for the treatment of opiate dependency and ultimately the best way to decrease unintentional overdose deaths (Connery, 2015). MATs incorporate psychotherapy together with treatment medications (Volkow et al., 2014), and physicians are now being trained to view opioid addiction for what it is, a chronic disease. MATs have been shown to be a cost-effective approach to treating opioid addiction, and it is estimated that for every dollar spent on methadone and buprenorphine treatment, \$1.80 in social savings would be realized (Institute for Clinical and Economic Review, 2014). This is significant since those with an OUD spend \$17,000 more per year in Medicare costs, \$15,500 in Medicaid costs, and \$13,700 in private insurance costs over patients without an OUD (Florence et al., 2016). There are currently three drugs approved by the FDA to treat opioid disorder: methadone, buprenorphine (Subutex<sup>®</sup> or Suboxone<sup>®</sup>), and naltrexone (Vivitrol<sup>®</sup>); (Wen, Borders, & Cummings, 2019). Efforts are underway to grant access to MAT services through use of Medicaid coverage (Compton et al., 2015).

Just as important as MATs to recovery is a strong support network. There is a shortage of these speciality aftercare programs, which are designed to reinforce sober living post-rehab. Obtaining a healthy support network could mean the difference between long-term sobriety and relapsing. Research has shown that the opioid users greatly benefit from a healthy and

abstinence-based support system (Beattie et al., 1999). The process of social reevaluation is one of the most critical steps in the process, as it includes cutting off unhealthy habits and relationships. Social workers, therapists, and psychologists are also great tools to take advantage of during and after recovery; however, research shows that a number of patients will inevitably abandon these treatment options and relapse. Those in the treatment industry report that success lies in establishing trust and maintaining a loose and guarded relationship (Zywiak et al., 2009).

Just as there were numerous circumstances that contributed to the development of this opioid epidemic, there will need to be numerous solutions to fight this battle. U.S. policymakers have been slow to address this issue for a number of reasons, and without their support financially and within the criminal justice system, the country will only sink deeper into the opioid abyss. Correcting this epidemic is not out of our capabilities, but it will certainly take decades to accomplish and will only be effective if government and non-government entities work together to hold Big Pharma accountable and build a strong bridge of recovery through treatment to all of those that have been affected.

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