How can the U.S. mitigate the opioid crisis?

By

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A Research Study
Presented to the
Faculty of the Department of Public Policy and Administration
School of Business and Public Administration

CALIFORNIA STATE UNIVERSITY, BAKERSFIELD

In Partial Fulfillment of the
Requirements for the Degree of

MASTER OF SCIENCE IN HEALTH CARE ADMINISTRATION

Fall 2022
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By

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2022
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This thesis has been accepted on behalf of the Department of Public Policy and Administration by their supervisory committee:

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Acknowledgments

First, I would like to thank my parents, who believed in me before and more than everyone else, including myself. Going through this program and my whole life abroad would not be possible without their constant sacrifices.

The competition of this study could not happen without the expertise, and continuous helps of Dr. Pallitto, our beloved program, director, and my thesis chair committee. I would also like to thank Dr. Commuri, our department chair, for taking the time to read my thesis and for his valuable comments.
Abstract

Dopamine is a hormone in our body that is responsible for pleasure and joy. Our brain can release dopamine with activities like working out or eating sugar. However, some structures outside the body can stimulate the brain to release dopamine, including opioids. Opioids were structured to combat massive pain for us, including decreasing pain after medical surgery. Later on, when people learned the effect of it on the body and experienced joy from it, they started abusing opioids. The history of opioid crisis in the United States started in 1999 when people started abusing prescribed opioids. With controlling over-prescription, people started using a cheaper and more potent substitution: Heroin. Heroin was the cause of the second wave of the opioid crisis in 2010. The third wave of the opioid crisis started due to synthetic opioids in 2013. there have been different programs and policies to control the opioid crisis and efforts to decrease the number of opioid overdoses. However, the data indicates that opioid-involved deaths have constantly been increasing (CDC, 2020). This case study tries to find relationships between the three phases of opioids in the U.S. and evaluate different policies to combat the opioid crisis.
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Chapter 1: Introduction

In 1990, opioid addiction became a problem in the United States (Centers for Disease Control and Prevention, 2020). However, after more than 30 years the opioid crisis continues in the U.S. According to the Centers for Disease Control and Prevention (CDC), the opioid crisis in the U.S. has three distinct phases (2021). The first wave started in the 1990s with the over-prescribing of opioid-based pain medication. Physicians prescribing opioids for pain management is a standard of care in medicine. According to CDC, the first wave of misusing opioid prescriptions started in the 1990s. The CDC defines opioid misuse or Opioid Use Disorder (OUD) as a problematic pattern of opioid use that causes significant impairment or distress. Part of the first opioid crisis wave in the 90s may be due to the recession. Many reasons make an individual misuse an opioid. However, the most important reason may be due to the rewarding system that opioids activate in our brain, which boosts the feeling of pleasure, robust and for a short time. The reward system in our brain works in a way that the result of a transaction is a substance that motivates the transaction to happen again. The brain's ventral tegmental area releases dopamine whenever we experience something pleasant. Through the mesolimbic pathway, dopamine will be transferred to the nucleus accumbens, an area in the ventral striatum affiliated with motivation and a reward system.

As the significant pipeline of opioid overdose deaths in the 1990s was due to prescription, nowadays, physicians avoid prescribing opioids as much as possible. As CDC claims, the second wave of opioid use in 2010 was no longer due to prescriptions but heroin abuse. As the access to legal opioids decreased due to fewer opioid prescriptions, the demand for cheap, widely available, and illegal options, which is heroin, increased. Heroin overdose was not specified by sex, age, or socioeconomic status. One of the main factors that makes heroin more
dangerous than other prescribed opioids is its use. Heroin is mainly used by injection, which puts
the users in danger of numerous infectious diseases. The third wave of opioids that started in
2013 and is still going on is due to synthetic opioids like fentanyl or tramadol. This wave is
significantly more potent than the previous two; CDC claims that every day 136 people die due
to opioid overdose.

Fentanyl is a powerful opioid synthesized in labs, which is similar to morphine but is 50
– 100 times stronger than morphine (NIDA, 2021). According to the U.S. Drug Enforcement
Administration, Fentanyl can be injected, snorted/sniffed, smoked, taken orally by pill or tablet,
and spiked onto blotter paper (2020). Although this third wave started in 2013, it is getting worse
in the U.S. yearly.

There are different physiological, psychological, social, and economic factors in the
opioid crisis (Webster, 2017). 60% of the propensity to become drug dependent and 54% of the
capacity to stop are determined by genes (Price, 2008). Individuals who struggle with mental
issues are more at risk of opioid misuse. A recent study indicated that Responders with
depression were three times more at risk of abusing opioids (NCBI, 2020). Hanon (2017)
claimed that unemployed individuals were at higher risk of opioid overdose. Statista reported
that 53.2% of females are unemployed (2021). Women are generally more unemployed than
men, so they are at higher risk of opioid overdose. As people living in lower-income
communities are more exposed to alcohol and substance, lower-income people are more at risk
of opioid misuse. Political science also effects the opioid crisis in the U.S.

One of the biggest businesses in the world, including the U.S., is the drug business. As
there is a substantial financial profit in it, different organizations want it to be continued. On the
other hand, governing people that care less about issues is more manageable. When people are
high on drugs, they care less about economics, inflammations, social justice, and inequities. There are significant gateways in the opioid crisis, including but not limited to marijuana (Harrel, 2009). Although, based on federal law, marijuana is in Schedule I drugs, politicians have been trying to decriminalize it in states (DEA, 2020). Different factors have kept the opioid crisis going in the U.S. for more than 30 years. This study explores the relationships between factors in the three phases of the opioid crisis to suggest how the U.S. can mitigate the opioid crisis. This study explores the relationships between factors in the three phases of the opioid crisis to suggest how the U.S. can mitigate the opioid crisis.

**Problem Statement**

Although CDC claims the rate of drug overdoses is higher in urban parts of the U.S., in some states, including California, the rates are higher in rural areas. The overdose rates in Kern County in 2019 were: 117 opioid overdose deaths, 54 Fentanyl overdose deaths (an increase of 93% from 2017), and 36 Heroin overdose deaths (an increase of 80% from 2017). According to CDC, most drug users are youths aged 21- to 25-year-old. According to Florence's article, most opioid overdose deaths are among users in the 25- to 34-year age group (2020). This consecutive number of ages indicates that the deaths due to overdosing on drugs are not an overnight process, which is good because it means this process had years to be stopped. Florence also claims a 38% increase in overdose deaths in the group aged 25- to 34- from 2019 to 2020 and a 1,312% increase since 1999 (2020).

The most vulnerable group in case of deaths by opioid overdose is among non-Hispanic white people without a college degree (Case 2017). The other finding may support this claim that the two races that contribute to the majority of society with mental health are two races of American Indian/Alaska Natives (22.7%), followed by white (19%) (American Psychiatric
No doubt, one of the foundation factors that lead to drug addiction can be mental issues. In another study, Jones claims that a substantial portion of dead people due to opioid overdose was white, male, middle-aged adults (2018).

**Purpose of the Study**

The purpose of this study is to explore the phases of the opioid crisis in the U.S. as well as explore possible solutions. This case study explores the U.S. opioid crisis from 1990 to 2022 from the healthcare industry, society, and political science. The proposition will be made by reviewing the literature, finding the root causes of this crisis, and the relationship between factors. Propositions can lead to a conceptual framework, which clarifies the myths and can be a solution to stop the opioid crisis in the U.S.

**Significance of the Study**

The opioid crisis has been ongoing in the U.S. since 1999. In 2020, 56,516 overdose deaths were reported, meaning more than 154 individuals die daily because of opioid overdose (CDC, 2020). The death of 154 individuals daily affects more than 300 family members' lives. The opioid crisis affects society in many ways. In addition to the problems of living with an opioid-dependent person, losing them as parents, spouses, or any other family member impacts our lives. Children of opioid-addicted people have to go through foster programs. With the increasing prevalence of the opioid crisis, there has been an 8% increase in foster kids since 2012 (U.S. Children's Bureau, 2021). Compared to the general population, foster children are likelier to have more teen pregnancies, marriages to partners who failed to provide emotional support, and social isolation (McDonald, 2009). On the other hand, more than two-thirds of the homeless population have drug abuse (American Addiction Centers, 2022). Nida (2022) claims that 85%
of the prison population has a current substance use issue or was imprisoned for a drug-related offense. Therefore, there should be more researches regarding how to control this crisis.

Based on results of the literature reviews, there is a gap among researches about three phases of the opioid crisis. This study is addressing this gap, as well as figuring out the factors that connect the gaps. This case study brings the opportunity to explore among researches and provide possible solutions for this crisis.

Methods

According to Creswell and Creswell (2018), research design indicates how the research question should be answered. He also claimed qualitative research method is the best when the researcher wants to explore a social or human problem. This study is a qualitative case study. While surveys and interviews can provide single-view data from an individual, case studies allow studying a single case from different perspectives. Yin believes a case study researcher should gather data from different sources, including but not limited to journals, news, and documented reports to increase the validity of the research. This research is based on Yin’s method. After reviewing the literatures and developing propositions from the evidence, I created the conceptual framework. Based on developed propositions, data from three opioid crisis phases will be analyzed and posted in chapter four.
Chapter 2: Literature Review

This chapter’s focus is a review of the literature on the opioid crisis. Among 50 chosen articles from various peer-reviewed journal article databases, including but not limited to ProQuest, Pub-Med, and grey literature from the CDC, the World Health Organization (WHO) and other government resources, I used 36 articles and reports due to their relevance to this study. The key search terms include: list them in italics. Additionally, this literature review provides a foundation for developing propositions used to develop a conceptual framework for this case study.

Opioids

In the nervous system of humans, specific receptors are implanted in the outer membrane of neurons (nerve cells) to relieve pain, reduce stress, and improve the body's general well-being (Gress, 2020). These receptors bind with a group of natural compounds made in our body called Endorphins. Endorphins are a group of hormones released by the brain and nervous system, more specifically the pituitary gland, naturally in response to stress, pain, and pleasant activities like eating and exercising (Kerrigan, 2020). These receptors also bind with other chemical compounds that have the same structure as endorphins and trigger the same chemical reactions as endorphins (Kaur, 2020). One of these external products is opioids. Opioids are a class of drugs that naturally exists in the opium poppy plant and may have various effects on the brain, including feeling relaxed and happy.

There are different terms constantly used in terms of consuming opioids. According to the National Institute of Drug Abuse (2020), misusing drugs, which usually refers to prescription drugs, means taking a medication in a manner or dose other than prescribed; taking someone else's prescription, even if for a legitimate medical complaint; or taking a medication to feel
euphoria. However, Opioid use disorder is defined as chronic use of opioids to the extent that it causes clinically significant distress or impairment (Dydyk et al., 2021).

As previously mentioned, Endogenous are the versions of opioids that our brain produces on its own. These chemicals bind to opioid receptors in our brains like opioid drugs. Our body uses endogenous opioids to manage pain. However, for different reasons, including but not limited to stress or surgery, our body may need more endorphins than our brain cells can create. Physicians prescribe opioids to reduce the pain our body is going through. This is the same for someone under mental pressure; they seek substances to help them relax. However, opioids can potentially cause high dependency, leading to drug misuse. The National Institute on Drug Abuse (2020) claims that taking a medication in a different way or at an extra dose than prescribed, taking a prescription from someone else, even if an individual has a valid medical complaint, or taking a drug to experience euphoria are all considered as drug misuse.

Opioid misusing has a long history in the U.S. Since the 1990s, the opioid class of drugs has seen a rapid increase in overuse, misuse, and overdose deaths referred to as the opioid epidemic or the opioid crisis (CDC, 2021). Although in 2020 and due to the COVID-19 pandemic, the U.S. had a drastic increase in opioid-related deaths. Since 1999, the number of overdoses has continuously increased (Figure 2). The CDC claims there have been three major waves of the opioid crisis in the U.S. (2021).
First Wave of the Opioid Crisis

The first wave of the opioid crisis in the U.S. was due to over prescriptions of opioids. Although pain control and comfort of patients must be the priority, there is evidence that most prescriptions are not helping and are being wasted. According to Hill (2017), 72% of the opioids prescribed for general surgery outpatient procedures are not used. Also, another research done by Bates (2010) indicated that 67% of urology prescriptions are also not being used. According to data, the number of opioid-related deaths in the U.S. has increased by 1700% over the past 30 years, while in Canada, there have been less than 10,000 opioid-related deaths since 2016 (Buchanich, 2016). There are data regarding over-prescribing in the U.S. that supports this evidence. In 13 states in the U.S., the number of opioid prescriptions is more than the number of people (Institute for Management Studies, 2016). However, in the same year, there were six
opioid prescriptions per 10 people in Canada. Different groups of people were affected by other waves of the opioid crisis. In the second and third waves, African Americans were more at risk than Whites. However, in the first wave of crisis, Whites were more significantly in danger (Figure 2).

**Figure 2**

*The Difference in Opioid Involved Overdose Deaths Rates From 1999-2020.*

![Opioid Involved Overdose Deaths Rates](https://www.cdc.gov/nchs/data/hestat/drug_poisoning_mortality/drug-poisoning-mortality.htm)


In the age group 15 - 65, the most affected by the first wave of the opioid crisis were White males between 35-45 years old (CDC, 2020). Figure 3 suggests that Public Health’s approach to overcoming the opioid crisis in society worked better for Whites. Although the opioid dependency is overall increasing, the rate of increase for Whites is slowest among other races and ethnicities.

When healthcare researchers pointed to the over prescription issue, physicians became more cautious with prescribing opioids. However, a considerable portion of society was aware of
opioids and their pain-relieving traits. Therefore, they started seeking a cheaper and easier substitution: Heroin (citation needed here). Heroin is an opioid drug made from morphine, a natural substance from the seed pod of opium poppy plants grown in Southeast and Southwest Asia, Mexico, and Colombia. According to National Drug Intelligence Center (NDIC), Heroin is a Schedule I substance under the Controlled Substances Act. Schedule I drugs have a high potential for abuse, and because they do not have a medical use in the U.S., they are illegal. Thus, the second wave of the opioid crisis happened in 2010 because of Heroin.

**Second Wave of the Opioid Crisis**

The evidence regarding deaths caused by opioids is staggering. Between 2002 and 2013, the number of heroin-related overdose deaths increased by 286%, and roughly 80% of heroin users admitted to misusing prescription opioids before using Heroin (Liu, 2016). Heroin can be used in different ways. Heroin can be injected, smoked, sniffed, or snorted. However, injection is the most popular way, which is another reason that makes Heroin more fatal. Probable injection-related diseases that can affect human bodies include, but are not limited to, hepatitis B and C, skin infections, HIV/AIDS, and bloodstream infections. Although Heroin is illegal, some states legalized it under specific conditions, such as limited personal use.

It is against the law in California to possess a controlled substance, such as prescription drugs obtained without a valid prescription, or illegal drugs like Heroin or cocaine; there are legal repercussions if someone gets caught with any usable amount. However, on February 25, 2021, the Washington State Supreme Court decided to outlaw possession of drugs such as cocaine, methamphetamine, and Heroin for personal use. As Radiol (2021) reported from one of the interviewees, business owners are worried about heroin users blocking their store entrance, sleeping in front of their store, or causing damage. The Washington State Department of Health
(2022) reported data that showed the number of opioid-related deaths was the highest between 2018-2022, suggesting that decriminalizing drugs leads to more drug-related deaths. However, there are treatments for Heroin addiction.

**Third Wave of the Opioid Crisis**

The third wave of the opioid crisis after over prescription (first wave) and Heroin (second wave) is related to faster overdoses, which brought out a need for a medication to reverse the effects of opioids. The third wave of opioids started in 2013 with a significant increase in the number of overdoses and death. The third wave was caused by synthetic opioids, particularly those involving illicitly manufactured fentanyl.

Fentanyl is a potent opioid made in laboratories with a similar structure to morphine but 50 to 100 times stronger than morphine (NIDA, 2021). Fentanyl can be used in various ways, including injection, smoking, sniffing, oral, or spiked onto blotter paper (DEA, 2020). According to the National Forensic Laboratory Information System, reports on fentanyl increased from 5,400 in 2014 to over 56,500 in 2017, as reported by federal, state, and local forensic laboratories in the U.S. (DEA, 2020). CDC claims that 82.3% of overdose deaths involved synthetic opioids (2020). Fentanyl became drug users’ best option due to low prices and its potency. Although fentanyl is used in the U.S. health care system to treat patients with severe chronic pain or severe pain following surgery, it is an illicit drug. Possessing fentanyl in California is illegal and is punishable under California Health and Safety Code 11350 (Wallin, 2022).

Although China has been a pioneer for pressing fentanyl into pills, powder, or mixed into other drugs at massive industrial-scale labs and sent to the U.S., Mexican cartels are increasingly manufacturing fentanyl to distribute and sell in U.S. (U.S. Department of Justice, 2022). Undoubtedly, states with a mutual board with Mexico are a better target market to sell drugs, but
the reach of the Mexican cartels extends inland; Kern County, in California is an example. From 2017-2019, there was a 93% increase in the rate of a fentanyl overdoses in Kern County, followed by 83% in Heroin overdose (Kernreturn, 2020). The Kern County Sheriff’s Office (2022) reported there had been 139 fentanyl overdose deaths in 2020, followed by 232 deaths in 2021; this is more than 40% increase.

**Medication-Assisted Treatment (MAT)**

Although the opioid crisis is not a new phenomenon, opioid overdoses are one of the leading causes for Emergency Department (ED) visits. The CDC (2016) claims that ED opioid overdose visits have increased by 27.7% between 2015 and 2016 across the country (2016). After stabilizing overdosed patients, the treatment for these patients includes outpatient (or in-patient) treatment, including the provision of information, which means ideally, the treatment for opioid use disorder will start immediately. However, these programs usually carry a significant wait list and are not available at the time of the patient's overdose. Even though medication for addiction treatment (MAT), including but not limited to methadone and buprenorphine, is prevalent and proved to be successful, having access to them is not equally accessible due to shortages of prescribers and treatment programs. D’Onofrio et al. (year) suggested that patients who received buprenorphine in their early overdose stages at the ED showed more engagement in office-based opioid addiction treatment. Thus, physicians need an alternative for MAT to get the best out of the post-stabilization stage of overdose. Also, not all patients suffer from OUD and drug dependency. Pharmaceutical scientists discovered a long-lasting opioid antagonist, which can be taken orally as another treatment plan; the antagonist for opioids is Naltrexone.

Methadone and Buprenorphine are two popular opioid agonists to treat opioid addiction. Methadone is a synthetic opioid agonist that works on opioid receptors in the brain, the same
receptors activated by heroin, morphine, and opioid pain medications. This helps to alleviate withdrawal symptoms and curb drug cravings. Methadone has been working for more than 40 years and must be dispensed through specialized opioid treatment programs. Methadone can be used daily and is available in liquid, powder, and diskettes forms. Buprenorphine is a partial opioid agonist. It means that although they bind to the same receptor, they activate the receptor less than a full agonist. However, in the case of withdrawing symptoms without euphoria and patients' tolerance, it is working as effectively as methadone. Therefore, Methadone and Buprenorphine both make the patient experience euphoria without using the actual opioid.

Vivitrol (the brand name for Naltrexone) and Narcan (the brand name for Naloxone) are both opioid antagonists (Healthline, 2021). There is a difference between an agonist and an antagonist (Table 1). Naltrexone is an opioid antagonist that blocks opioid receptors and prevents them from being activated. Unlike opioid agonists that decrease opioid cravings, Naltrexone prevents the opioid from creating rewarding experiences like euphoria. Barbara Jason, the director of the Pearson Center for Alcoholism and Addiction Research, claims that Naltrexone starts working within an hour after it is consumed orally (50 mg), and it will last between 24-36 hours after ingestion in the body. A higher dosage, like 100 mg, can stay in the body for up to 48 hours, and 150 mg can work until 72 hours. However, the optimal effect is within the first hour after consumption. The benefit of Naltrexone over the other MAT drugs (like Methadone, Suboxone, and Subutex) is that it is non-narcotic, non-addictive, and non-mood altering. However, Naltrexone were not a successful drug in MAT.
Table 1

*Agonist vs. Antagonist Physiologic Actions.*

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<th>Agonist</th>
<th>Antagonist</th>
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<td>Actions</td>
<td>Produces an action or response</td>
<td>Produces an opposite action or response</td>
</tr>
<tr>
<td></td>
<td>Initiates a physiological response when</td>
<td>Interferes with or inhibits the physiological action of</td>
</tr>
<tr>
<td></td>
<td>combined with a receptor</td>
<td>another</td>
</tr>
<tr>
<td></td>
<td>Is a drug that imitates the actions of</td>
<td>Is a drug that blocks neurotransmitters</td>
</tr>
<tr>
<td></td>
<td>neurotransmitters in the brain</td>
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Although Naltrexone seems to be the best plan, data indicates there is a 90% failure in naltrexone therapy. In 1984, oral naltrexone pills were approved by FDA for opioid overdose, and in 1993 for alcohol addiction. Oral naltrexone needs daily consumption, making it easy to be missed, which leads to relapsing. The monthly injection reduces the issues with daily pill taking. However, it can be excruciating with large needles and intra-muscular injections. All these reasons reduced the success rate of naltrexone to 10%. The other reason that made Naltrexone unsuccessful is its cost.

Murphy (2017) researched the cost-effectiveness of extended-release Naltrexone to prevent relapse among criminal justice-involved individuals with a history of opioid use disorder. Murphy estimated the incremental cost per quality-adjusted life-year (QALY), which was gained for XR-NTX versus treatment as usual (TAU), and the incremental cost of any additional year of using opioids. Although Naltrexone has a considerable effect on increasing QALY, the cost-effectiveness is highly dependent on the injection price. Murphy mentioned that the cost of extended-release Naltrexone is $1,309 per injection. Thus, the cost is another significant barrier to using Naltrexone.
With this vast number of overdoses on fentanyl, we need a potent antagonist that can reverse the overdose. Naloxone is a life-saving medication that can treat a narcotic overdose in an emergency. Naloxone is the generic name of Narcan. In 2015, the FDA approved the first naloxone nasal spray. In 2019, the first generic naloxone nasal spray was approved (FDA, 2019). In 2021, the FDA approved a higher dose of naloxone nasal spray—KLOXXADO® (FDA, 2021). However, Naloxone cannot be a 100% assurance for drug addicts to survive an overdose.

Although Naloxone is a life-saver medication in case of opioid overdose, it can save the life only under specific situations. In addition to common side effects of Naloxone, including but not limited to diarrhea, nausea or vomiting, stomach cramps, fast heartbeat, and increased blood pressure, what makes Naloxone not 100% effective is the short time, which it is effective in. Opioid overdose cuts of oxygen route to the brain; eventually, lack of oxygen will affect the cardiovascular system, and heart rate will slow down or even stop. The short time of 2 to 3 minutes for Narcan to work is before the cardiovascular system gets involved. As soon as the cardiovascular system is involved, Narcan cannot save the life anymore.

Researchers suggest physicians prescribe Naloxone along with any opioid that is being prescribed. Narcan can be used as an injection or nasal spray. The nasal spray form of Narcan is an over-the-counter purchase from a pharmacy. Some pharmacies like Walgreens, CVS, and RiteAid give out free Narcan (Aungst, 2022). Additionally, The California Department of Health Care Services (DHCS) provides free Naloxone to organizations to distribute under the Naloxone grant program (CDPH, 2022). Naloxone is a short-acting medication for emergency use, while Naltrexone is a long-acting prescription maintenance medication. Although Naltrexone is not the best option for a person going through an opioid overdose, patients prescribed Naltrexone showed more urine-negative results in a 6-month clinical trial (Lee, 2016).
Evidence shows that long-term abstinence is rarely achieved after detoxification of opioid overdose. Methadone can only be used in a licensed opioid treatment program, but naltrexone can also be used in outpatient programs. Although it has been proven that Methadone, buprenorphine-naloxone (BUP-NX), and naltrexone (XR-NTX) can reduce the relapse in opioid users, they are underutilized. Increasing medication used for treating opioid disorders is a priority over current prescription opioids in public health. There are some government programs for opioid misusing treatment. However, as Murphy (2017) said, the cost of treatments is one of the biggest barriers. There are different reasons for the high costs of drugs in the U.S.

Surprisingly federal government does not have the authority to control the price of drugs in the U.S. The cost of drugs is determined by companies that manufacture them; they set the price based on the formula, a multiplier of Average Wholesale Price (AWP) plus a dispensing fee. Based on Kesselheim’s (2016) findings, among 20 industrialized countries, U.S. citizens spend two times more than the other 19 countries per capita on the prescription ($858 compared with an average of $400 for 19 other industrialized nations). Almost 20% of the healthcare services costs are due to prescription costs. The most critical factor in high drug prices is that the FDA awards drug companies a monopoly right with their patents. The availability of generic drugs depends on the timeline of the original drug's patent, so that it may be delayed because of legal or business issues. The Drug Price Control Order Act (DPCO) was established in 1994 to reduce the price of drugs and ensure their quality.

Patent medicine is a nonprescription drug sold at drug stores and is usually protected by a specific trademark. The U.S. Patent and Trademark Office grants the patent, as the property right, anytime during the manufacturing and develop various claims. In a book called the Orange Book, the FDA has an official resource that serves as the gold standard reference for all generic
drugs, as well as their patents and any substitution. A generic drug is a medication created with the same purpose as an existing (branded) drug with the same ingredients. As generic drug creators do not develop or test drugs, the cost of generic drugs are 20-70% lower than the original branded drugs. The brand name (original) of Naltrexone is Vivitrol and Revia, a generic drug. While Revia is the oral version, only Vivitrol, the injectable, is approved by the FDA. Although the price of Naltrexone is high (as mentioned, more than $1,000 per shot), the cost of Vivitrol is almost $2,100 per shot. Therefore, we can see that the generic version costs almost half of the branded version (Yoon, 2019).

The best strategy for addressing the high prices of drugs requires a new approach from the FDA and the Federal government to give an exclusive right to pharmaceutical companies. A company that can manufacture a new formula may not be the only company in the states (or world) that can do it. Therefore, ensuring the timely availability of generic drugs, which will boost competition; granting government payers more opportunities for meaningful price negotiation; accumulating more evidence regarding the comparative cost-effectiveness of different treatment options; and educating patients, prescribers, payers, and policymakers about these options more effectively (Kesselheim, 2016).

Ethics of MAT

The court issued an Order to produce to direct the criminal justice to bring an already-incarcerated inmate before the court at a predetermined date and time. NIDA (2020) claims that 85% of the U.S. prison population has an active substance use disorder. Also, the Bureau of Prisons (2022) reported that 45.2% of incarcerations were due to drug offenses. Treating prisoners’ drug problems will reduce the possibility of them returning to jail for the same reason. NIDA (2021) claims, specifically opioid-dependent intimates are at higher risk of overdose after
release. Therefore, although a portion of society believes forcing treatment programs on the incarcerated is not ethical, the other portion believes treatment has to be forced on drug addicts because they cannot decide appropriately due to being on drugs. Due to uneven resources for different groups of people in society, disparities in sex, race, and socioeconomic status directly affect opioid dependency.

**Disparities in the Opioid Crisis: Treatment**

The court issues an order to produce to direct the jail to bring an already-incarcerated inmate before the court at a predetermined date and time. NIDA (2020) claims that 85% of the U.S. prison population has an active substance use disorder. Also, the Bureau of Prisons (2022) reported that 45.2% of incarcerations were due to drug offenses. Treating prisoners’ drug problems will reduce the possibility of them returning to jail for the same reason. NIDA (2021) claims, specifically opioid-dependent intimates are at higher risk of overdose after release. Therefore, although a portion of society believes forcing treatment programs on the incarcerated is not ethical, I believe it is the best plan for both prisoners and the rest of society. Due to uneven resources for different groups of people in society, disparities in sex, race, and socioeconomic status directly affect opioid dependency.

**Disparities in the Opioid Crisis: Racial-Ethnic**

Like any other health factor, misusing opioids has racial-ethnic disparities. Ford’s (2014) research determined the most vulnerable group and this can be beneficial for healthcare workers to be more conscious when prescribing opioids. Many researchers have suggested different risk factors for substance misuse among different races and ethnicities (Harrel, 2009). For instance, Harrel (2009) mentioned that Marijuana could be a risk factor (for later opioid use) in Whites, but a protective factor for Hispanics, and was unrelated to opioid misuse factor for Blacks.
Therefore, the assumption would be that race is an essential indicator of opioid misuse. However, Ford’s (2014) study reported opioid misuse prevalence among different racial groups: White 5.39 %, Hispanic 5.60 %, and Black 6.08 %, which suggests there is no significant difference in opioid misuse between different racial groups due to race.

Although the prevalence of opioid misuse was not significantly different among races, the risk factors for each group differed. The mutual risk factor for all three groups was age; the risk of misusing opioids increased with age in all three examined racial groups. Delinquency was another mutual factor in all three races; more delinquent adolescents were at higher risk. Place of residency was a risk factor only for Whites; the Whites living in non-urban areas were more at risk than Whites in urban areas. Religiosity was a significant factor only in Whites; non-religious respondents were at higher risk. Residential instability was a risk factor for Whites and Blacks; those who had to move many times were at higher risk than those with stable housing. Depression was a significant factor in Whites and Blacks; individuals who went through a depression period in their life were at higher risk than others. Risk bonds with family were a significant factor for Hispanics and Blacks, while a weak connection to school was a risk factor only for Hispanics. Peer’s effect was a significant factor for Whites, while personal attitude was a risk factor for Whites and Blacks (Ford, 2015). The same experiment by Wu in 2008 indicated different results.

Wu’s research (2008) indicated the following opioid misuse prevalence in different races: 7.8 % of Whites, 7.1 % of Hispanics, and 5.8 % of Blacks. This suggests that preventive actions were more beneficial for the White and Hispanic populations as the prevalence of misuse dropped among these two groups.
To address sexual disparities in opioid dependency, there should be an exact definition of each sexual orientation. Heterosexuals are individuals that are sexually attracted only to the opposite sex. Homosexuals are those who are sexually attracted to the same sex, and bisexuals are individuals that are attracted to both the opposite and same sex (CDC, 2022). Based on the CDC (2019), 91.2% of males and 77.6% of females in society are heterosexual; 13.9% of females and 3.4% of males are bisexual. CDC’s (2019) data also illustrated that 2.1% of males and 2.9% of females are homosexuals. Serdarevic’s research (2017) suggests that women are more at risk of opioid misuse than men. As minorities are usually vulnerable groups in society, they are the more sensitive group at risk of opioid misuse as well. Dustin (2019) added that bisexual women are most frequent in LGBTQs individuals for opioid misuse.

No doubt opioid misuse is not a genetic disease and cannot be sex-related naturally. What predisposes women are environmental and socioeconomic factors. Many types of research showed the relationship between poverty and opioid misuse. The U.S. Census Bureau (2019) reported that women continue to have higher poverty rates than men. The first factor of being in a group with less financial stability is unemployment. The U.S. Census Bureau (2019) data shows that 21.4 million of 38.1 million people in poverty were women. Figure 4 illustrates the racial and gender disparities in the poverty population of the U.S. Despite all progress in the labor market, women are paid less than men in the same position (Fransen, 2012), (Figure 3).
Figure 3

Poverty Rate Disparities by Gender and Race in U.S. 2019


Figure 4

Unemployment Rate in Men vs. Women 2022.

Gateways of Opioid Overdose

In most cases, overdosing on a drug does not happen over a night, which means most overdoses happen for people with a history of drug abuse. For decades, many researches have been done regarding legalizing Marijuana to help reduce opioid-related overdoses and deaths. However, a new study from Stanford University (2019) has found the complete opposite. Over a more extended period, states that allowed marijuana use for medical purposes had 23% more opioid overdose deaths (Stanford University, 2019). Therefore, blocking one of the pipelines that lead to opioid overdose may be banning Marijuana, because it is not helping to reduce the number of opioid deaths. The most important fact is that FDA has never approved Marijuana as a drug with beneficial effects. According to Statista (2020), Alaska and Massachusetts are the two top states allowing the most use of marijuana. Not surprisingly, the CDC (2020) claims the highest opioid-related deaths are in Alaska and Massachusetts.

Opioid Crisis during Covid-19 Pandemic

The federal Commission on Combating Synthetic Opioid Trafficking noted in a report that more than 100,000 people in the U.S. died from drug overdoses between June 2020 and May 2021, with synthetic opioids like fentanyl accounting for two-thirds of those deaths (NIDA, 2022). The COVID-19 pandemic's effects, like job loss, stress, and more depression and anxiety, have also led to more people using alcohol or drugs, like opioids. According to the report, At the height of the pandemic, more than one in ten Americans started or increased their drug use, resulting in even greater demand. Since many people harmed by fentanyl were unaware, they were consuming it, synthetic opioids present a new obstacle for prevention efforts. According to the report, "Educating the public that counterfeit pills can contain a fatal dose of fentanyl is an important potential goal because many people could be misled into using fentanyl disguised as
some other drug”. The commission stated that to reduce the number of overdose deaths, other harm-reduction services should be enhanced in addition to expanding access to naloxone. These services, such as naloxone distribution programs and syringe service programs (which provide access to and disposal of sterile syringes and injection equipment), frequently provide an opportunity to interact with people who use illegal drugs, provide them with information and lifesaving tools (such as take-home naloxone and fentanyl test strips used to determine if illegal drugs contain fentanyl), and possibly connect them with treatment and social services (Stephson, 2022).

**Political Science View of the Opioid Crisis**

After reviewing the opioid crisis from a public health perspective, reviewing from political science perspective would be eye-opening. As mentioned before, most opioids in the U.S. comes from other (primarily 3rd world) countries. Afghanistan is the biggest opium producer in the world (NPR, 2022). Afghan native sources claimed over 1Kg of opium is less than 50 USD. After transferring the morphine to the U.S. and making minor changes, U.S. drug sellers sell it for more than 20,000 USD (Drug Policy Facts, 2021). Therefore, there is an extraordinary profit happening in the drug business. These vast profits usually are the source for election campaigns and other political advertisements. Thus, some people are taking financial advantage of keeping the U.S. in the opioid crisis.

There are other political advantages to keeping the opioid crisis in society. In addition to activating the reward system in the brain, dopamine reduces sensitivity to the environment. Having people not care about economics, politics, social injustice, and other issues is a blessing for the government. There are three primary sources of making the brain release dopamine: sugar, sexual intercourse, and drugs. Obesity, STDs, and drug-related disease are the most
prevalent public health issues that the U.S. has been facing for decades. Therefore, there are many hidden hands in addition to public health in the U.S. opioid crisis.

**Conceptual Framework**

In place of theoretical framework, I developed conceptual model based on propositions. I followed Yin’s approach and constructed propositions from reviewing literatures. To create these propositions, I focused on research that offered solutions for the opioid crisis’s different phases. I constructed three propositions: the cost of MAT, gateways of opioid overdose, and the take-home naloxone program. The propositions are detailed in Chapter 3.

**Summary**

The opioid crisis in the U.S. started in the 1990s, with three critical points in 1999, 2013, and 2016. The first wave was due to over-prescription (1999), the second wave was due to Heroin abuse (2013), and the third wave, starting in 2016 was due to fentanyl. There were multiple strategies from the public health branch of the government to control these waves. However, the only strategy that worked was reducing opioid-prescription; all other practices to address heroin or fentanyl misuse were unsuccessful. I elected to use the word *unsuccessful* because society is still dealing with this issue after more than three decades. Neither categorizing heroin addicts into a "disabled" group, paying them, and providing heroin for them legally nor legalizing marijuana to reduce the use of fentanyl worked. As there are recognized medications for treating opioid dependency, better laws could address this issue. Also, there is a substantial financial profit from the drug business, which makes it tempting for those who need massive money in their business, for instance, election campaigns.
Chapter 3: Methods

In this chapter, the research design and method will be discussed. There are numerous ways of designing research, which makes any of them the most suitable based on the research question (Creswell & Creswell, 2018). Researchers use the quantitative method to test or confirm a theory. However, the qualitative approach is the most appropriate if the researcher wants to understand a phenomenon and construct a theory from the findings (Creswell & Creswell, 2018).

In this study, the phenomenon of the opioid crisis will be explored using an inductive approach. The inductive approach aims to develop a theory based on an analysis of data.

Research Design

The research question in this study is: How can the U.S. mitigate the opioid crisis? A qualitative study is the best method to explore this question. According to Creswell (1994), qualitative research is "a process of inquiry to comprehend a social or human problem based on developing a complex report on comprehensive opinions of informants, and undertaken in a natural context" (Creswell, 1994, pp. 1-2).

This study is based on the qualitative research method. A fundamental aspect of qualitative research methodology is the requirement for a deep understanding of the players' viewpoints, cultures, and world views to provide adequate explanations of social activities (Allan, 2020). Since surveys are the primary method of gathering quantitative data, these results inevitably reflect personal knowledge and consciousness. There have been many quantitate-based studies on the opioid crisis in past years. The literature review revealed a gap in research for explanations about the relationships and contributing factors during the three phases of the opioid crisis in the U.S. To answer the central research question of this study: How can the U.S.
mitigate the opioid crisis? a qualitative approach, precisely the case study method, is most appropriate.

In a case study qualitative research, extensive information is gathered about a single person, program, or event to understand more about an uncharted or poorly understood issue (Morse, 2014). Most researchers credit anthropological and social science studies from the early 20th century, when extensive, in-depth ethnographic studies of people and cultures were carried out utilizing this design (Stewart, 2014). A case study, therefore, is appropriate for examining a practice or process, the interactions that take place within those practices and processes, and the significance of those interactions (Crowe, 2011). According to Yin (2003), "the specific requirement for case studies emerges out of the desire to explain complex social phenomena" because the case study method enables researchers to preserve the comprehensive and significant aspects of actual events (2003).

According to Gustafsson (2017), a case study is an intensive, methodical investigation of a single individual, group, community, or other units in which the researcher examines in-depth data relating to several. Yin (2003) argues case study is empirical research that examines a current phenomenon in real-world events, mainly when the distinction between phenomenon and context is ambiguous. Yin (2003) also posits that a case study involves asking how or why questions about a current collection of circumstances over which the investigator has little to no influence. Additionally, case studies are favored for retrospection of a current event that cannot be further manipulated (Yin, 2018, p. 15).

Research Setting

There are different leaders in the case study with different epistemologies. The theory of knowledge at the core of epistemology focuses on how knowledge is acquired and validated.
Positivist, postpositivist, interpretive, constructivist, critical, and postmodern-poststructural are different epistemologies in case studies (Denzin, 2011). There are three leading case study researchers with different epistemologies. Robert E. Stake and Sharan Merriam suggest constructivism, which means the reality is constructed by the researcher (Yazan, 2015). Without asserting a postpositivist stance, Yin stated that the quality of case study research is supported by an emphasis on empirical inquiry from a realist perspective that upholds objectivity through a systematic approach (Harrison et al., 2017). Although Yin does not explicitly claim his epistemology in case studies, his general method of doing case studies or research points to a positivistic philosophical outlook.

Postpositivists contend that a researcher's beliefs, and personal identity, can affect what they see and, in turn, their conclusions. By making an effort to recognize and account for such biases in the ideas and knowledge that theorists produce, postpositivism seeks to arrive at objective answers. Postpositivist research methodologies support methodological diversity. It is predicated on the idea that the research topic being addressed should be considered when choosing the methodology used in a given study.

**Role of the Researcher and Reflexivity**

Reflexivity means acknowledging the researcher's role in the research. I come from a culture and background that any kind of smoking is a big taboo. I personally do not have experience of living with someone who smokes or has drug-dependency issues. Dealing with issues including homelessness, and different kinds of smoking was a new experience for me in the U.S. Finding Hallucinogens drugs prevalent in American society including LSD, mescaline, psilocybin, PCP, cannabis, ecstasy, ketamine, salvia and others was a big cultural shock for me. However, I did my best to not let any bias or personal opinion effect the data analysis.
As a qualitative researcher, I participated in the study process, and my existing knowledge, presumptions, and beliefs impacted me. Qualitative researchers are more self-conscious about their research (Creswell & Creswell, 2018). Reflexivity is the ability to be aware of one's prejudices, values, and experiences as they relate to a qualitative research study. According to Creswell and Creswell (2018), it is integrated into two pieces. The writer's personal experiences with the phenomenon are covered in the first section, and the researcher's analysis of the phenomenon is covered in the second section. As the qualitative researcher, I tried to minimize any previous biases that could affect my data analysis in this study.

Sample

This study is based on Yin's case study method. Yin (2003) suggests using a single-case study design when the case study is unique and critical. Single-case studies can be explanatory or exploratory. A common way of sampling in qualitative case study research is purposeful sampling (Yin, 2018). According to Creswell (2012), purposeful sampling is when a researcher chooses subjects and locations to learn about or comprehend the key phenomenon. Yin (2018) further defines purposeful sampling as the process of choosing study participants or data sources based on how rich and relevant their information is expected to be in connection to the study's research topics.

This study explores a unique phenomenon bounded in time by three phases, and according to the CDC, the phenomenon is now the leading cause of death in the U.S. for young adults. All data units for the sample were extracted from peer-reviewed literature, government reports, and documented news between 1990-2022, which was the time frame of the first and third opioid crisis in the U.S.


**Conceptual Model**

A proposition is a statement that makes an idea, suggestion, or plan known. A theory is a statement established as true using axioms and other theorems. However, a lesser-known theorem or one that is thought to be so simple or immediately apparent that it can be stated without justification is called a proposition. As Yin claimed, a theoretical proposition may play a critical role to increase the external validity of the research. For the theoretical framework of this study, I created propositions based on the literature review (Table 2). A conceptual model to guide the data analysis was developed using the study’s propositions as a priori categories (Figure 5).

**Table 2**

*Propositions.*

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**Data Collection**

A case study collects detailed descriptive data, in the textual form, about particular cases that are gathered, arranged, interpreted, and presented in a narrative format. For this study, I have examined different practices in addressing the opioid crisis in the U.S. I used a variety of resources that include scholarly journal articles, government reports, newspapers articles, interviews, and documentaries.

**Data Analysis**

Yin defines data analysis in a case study as “consists of examining, categorizing, tabulating, testing or otherwise recombining both quantitative and qualitative evidence to address the initial propositions of a study” (2002, p. 109). In case studies, data analysis frequently happens simultaneously with the data-gathering phase. The primary case study data analysis approach is referred to as OTTR, which stands for observe, think, test, and revise (Accountability Modules, n.d.). Observe: early observations are made, and unclear theories are made; Think: what further data are required to exclude alternative explanations or support the initial hypothesis is taken into account; Test: following observation or evaluation results in the gathering of further data; Revise: initial hypotheses are reexamined after study of subsequent observations and
evaluation (Accountability Modules, n.d.). The process of analysis must be progressive, allowing for reflecting on and shaping the following data collected from the original observations.

I followed four steps of my case study data analysis: establishing a database, creating initial codes, analyzing the coded data, and developing themes. A data repository is used to maintain a specific population of data in isolation to be mined for deeper understanding, business intelligence, or a particular reporting requirement. The coding process involves locating a segment in a text document or other piece of data, searching for and recognizing concepts, and discovering relationships between them. The case study data can be analyzed after completing data entry and coding. After analyzing the data and building relationships between the data, themes were identified.

**Methodological Rigor**

Explanatory research seeks to explain the causes and effects of a clearly defined problem, whereas exploratory research aims to examine the critical parts of an understudied problem (George, 2021). According to Yin (2014), case studies are preferred when addressing how, why, what, and who questions. There are several benefits of using a single case study, including that the conclusions are more practical than ideal. However, one limitation of a single-case study is the narrow focus on a phenomenon where findings may not be universal (Willis, 2014).

A case study's design is very crucial in terms of quality. Case study research uses four tests to assess the caliber of a case study design to ensure that the findings are accurate and consistent: conceptual validity, internal validity, external validity, and reliability are among the criteria (Yin, 2013). These tests ensure that a case study's claims are consistent, that the findings are reliable, and that the findings result from a computational process based on a recognized scientific approach.
Reliability aims to reduce bias and errors in a case study. The researcher must record the methods used in the case study so that another examiner can use them to assure dependability. Documentation is crucial because it demonstrates that an organized approach was taken when doing the case study, which increases the likelihood that the results would be the same if the case study were to be performed by another examiner following the same technique (Yin, 2013). In this thesis, I have documented data, legislation, and governmental actions from 1990 until 2022 in the U.S. regarding the opioid crisis. As different sources mentioned, there have been three primary phases of the opioid crisis in the U.S. In this study, I created a timeline for these three phases. By using Yin’s building explanation tactic, the dependency of the three waves on each other is shown in this study. Additionally, this study incorporated Yin’s (year) rival explanation approach to decrease the chance of bias and develop themes from the qualitative data.

I used a Microsoft Excel program to create the database and perform qualitative data coding. After literature reviews, I narrowed essential topics to the three opioid crisis waves, the cost of MAT, and gateway drugs for coding. Then, based on the prevalence of each code, I wrote the results section.

**Internal Validity**

Internal validity is also a challenge for qualitative studies. Internal validity tests whether the study’s planning, execution, and analysis provide unbiased answers to the research objectives. Qualitative research relies more on the researcher's personal abilities and is more vulnerable to the biases and quirks of the researcher.

Yin has four tactics to reduce the internal validity of a qualitative case study. The fundamental tactic in controlling internal validity is pattern matching. Matching patterns based
on real case study findings with anticipated patterns or hypotheses formulated prior to gathering information is known as pattern matching (Yin, 2013). Explanation building is the second tactic. The process of explanation building works in a way that the researcher creates an explanation for the case by creating a relationship between variables or conditions. The rival explanation is the third way to enhance the internal validity of qualitative research. Researchers should develop a rival explanation or proposition to confirm specific explanations for the evidence. The last tactic mentioned by Yin to improve internal validity is building a logic model, which can be achieved by simplifying patterns and creating a cause-effect relationship between evidence (Yin, 2013).

**External Validity**

Research based on the qualitative method has less external validity (Creswell & Creswell, 2018). Qualitative research is usually narrowed, especially single-case studies, which means the results cannot be generalized. Yin expounded that generalization is not produced from a single-case study (2018, pp. 20-21). Yin's (2003) approach for increasing external validity is an analytical generalization, which can be used to demonstrate that findings support observations. However, if the conclusions from the prior findings do not apply, it is essential to show that other plausible explanations exist in another (similar) case.

**Limitations**

In addition to Yin’s suggestions to address external and internal validity, he also has suggestions for other limitations of a qualitative case study, including conceptual validity and reliability. Yin (2003) claims there are three tactics to improve conceptual validity: using multiple resources to support evidence, establishing a series chain of evidence (which, in this study, the phenomenon has relationships in the timeline), and making sure vital informants
review the sources. This study does not include the corroboration of vital informants, which is a limitation for generalizing the findings.

**Institutional Review Board**

As the principal investigator of this study, I have earned the Collaborative Institutional Training Initiative (CITI) certification in human subject research (Appendix A). This research has gone through the Institutional Review Board process and has been determined to be non-human subject research.

**Ethical Considerations**

In order to maintain a balance between the potential risks of research and the expected benefits of the research, ethical problems must be taken into account at all stages of qualitative investigation. Ethical standards cover the need for honesty, informed consent, anonymizing and preserving participant data, the right to access participant data, and the obligation of confidentiality for all study participants.

Although this study did not have human participants, I have carefully considered all ethical considerations and given credit to all authors that have contributed data to this study. This thesis did not have a human subject, so all ethical considerations regarding participants are not applicable. Lastly, organization in this study are identified by their function, which provides anonymity.
Chapter 4: Results

The case study results are discussed in this chapter. Based on propositions derived from the literature, a conceptual framework was developed to determine the relationships between the three phases of the opioid crisis using three main factors: MAT cost, gateway drugs, and the Narcan program. I evaluate each of these factors and determined how each factor influenced each phase of the opioid crisis.

Data Collection

I started collecting relevant scholarly journals from databases that included: JURN, PubMed, WHO, PLOS, the U.S. National Library of Medicine, and the National Institutes of Health. I used search terms that included: opioid crisis, over prescription, Heroin, synthetic opioids, cost of medication, health insurance, Naloxone, Naltrexone, and Marijuana. I collected more than 50 articles and 36 of them are used for this study, as well as other documents including but not limited to reports. To answer the research question of how can the U.S. mitigate aid the opioid crisis? I developed certain categories based on case studies, which led to creating the propositions. The first category was the timeline of the opioid crisis in the U.S.; based on articles, there have been three main phases of the opioid crisis in the U.S. since 1999. The second category was regarding the government's plans to combat the crisis, in both cases of prevention and treatment. As the crisis continued after 30 years, there should have been barriers to the government's plans, so the third category in research was finding those barriers. As this study is exploratory research, there must have been meaningful data regarding possible disparities in the case of sex, race and ethnicity. Due to a significant increase in opioid overdoses in 2020, I made a specific domain for the Covid-19 pandemic's effect on the opioid crisis. The last category of case study research is regarding the political effect of the opioid crisis.
Yin claims that the qualitative researcher should allow the data collection to articles; interviews, documented reports, and newspapers can also be good data resources. Although some of the research areas could be covered just by reviewing the literature, some of them, including evaluating a program, depended on more evidence. Therefore, I used governmental websites to gather more data.

**Data Analysis**

*Cost of MAT*

The cost of healthcare expenditures in the U.S. has increased since 1995 (Figure 8). There are different reasons for high healthcare in the U.S., and the price of medical care is responsible for 90% of it (BCBS, 2022). The aging population, chronic disease prevalence, healthcare service costs, administrative costs, and rising drug prices are the five main reasons for the increasing cost of healthcare in the U.S. (Definitive Healthcare, 2022). As previously stated, most opioid-dependent individuals have mental health issues too. Therefore, it is possible that if mental health issuers were addressed, they would not have an opioid dependency. However, the costs are the most significant barrier to getting healthcare services for Americans.
Figure 6


All medication cost has increased since the first wave of the opioid crisis. The pattern of medication cost and opioid overdoses and (Figure 9). However, Medicare and Medicaid cover opioid treatment, and 8% of the U.S. population is uninsured (CDC, 2022). Naloxone is an emergency medication used to reverse the effects of narcotic overdose to save a patient’s life, while Naltrexone is a long-acting medication used to treat opioid dependency. Although there are programs to distribute naloxone at no costs, there are no free treatment programs for saving the overdose life. Naltrexone injections without insurance can cost $700 to $1200 per month.
In the United States, the opioid crisis started in the late 1990s, and since then, it has followed a geometric progression until today. In the timeline of the first phase of the opioid crisis in the 1990s, marijuana was illegal in most states. In 1990, only 5% of Americans used cannabis (NCBI, 2020). However, in the second critical point in the opioid crisis timeline, 2010, more than 7% of Americans were using marijuana. Marijuana was the most popular drug in 2010 (SAMHSA, 2020). In less than two years, another report in 2012 showed marijuana prevalence increased by almost 10% (Deborah, 2015). NIDA claims cannabis use from 2011-2020 increased by 12% (2022) (Figure 6). Opioid overdoses from 2011-2021 increased by more than 50% (NIDA, 2021).

The federal government classifies marijuana, heroin, and cocaine as a Schedule I drug with a high potential for abuse and little to no medical benefit (Barrot, nd). In 2013, under President Obama's administration, the Department of Justice (DOJ) announced it would not
interfere with marijuana regulations in states (Washington Post, 2013). However, in 2018, under
President Trump's administration, that policy was terminated, and the DOJ announced that
federal prosecutors might pursue criminal cases whenever there is a conflict between state and
federal marijuana laws (Garber, 2020). Based on a report by the Federal Bureau of Investigation,
more than a third of drug-related arrests in 2021 (170,800 of the roughly 490,000 drug
possession arrests) were due to marijuana possession (Barrot, nd). On October 2022, President
Biden made a speech regarding decriminalizing marijuana. He outlined that marijuana should
move to a lower category in the Controlled Substances Act because "Keeping marijuana on the
federal drug schedule will mean people will continue to face criminal marijuana charges" (White
House, 2022).

Despite federal prohibition, marijuana marketplaces in states where it is legal, make
billions of dollars annually. However, banks have traditionally been hesitant to collaborate with
businesses selling marijuana because they believe accepting deposits from these businesses could
violate federal anti-money laundering regulations. Even across states where the selling of
marijuana for medical purposes is permitted, federal law strongly forbids marijuana from
crossing state borders. Market imbalance is a result of federal restrictions on interstate
commerce. For instance, millions of pounds of marijuana perish yearly in Oregon due to farmers'
inability to export it across state boundaries, even to the nearby state of Nevada, where marijuana
is permitted for medical use but harder to grow (DEA, 2022).
**Figure 8**

*Percentage of the U.S. Population that Consumed Cannabis From 2002 to 2020.*

![Graph showing the percentage of the U.S. population that consumed cannabis from 2002 to 2020.](image)


**Take-home Naloxone Program**

Naloxone is a drug that can reverse an opioid overdose in seconds and can be used even by untrained individuals. Naloxone got approved by FDA in 1971 and became widely available over the counter in 2006 (Mass, 2021). The efficacy of Naloxone has been reported at 75–100% (NCBI, 2020). Naloxone can be used as an injections or spray. Nasal Naloxone became available in February 2016 (Adapt Pharma). According to McDonald’s study (2016), one death was reported among 123 cases of overdose victims who were administrated THN.

In addition to centers for distributing Naloxone to the community, since 2018, physicians have been required to prescribe Naloxone with any opioid for at-risk patients (Duan, 2022). As injectable Naloxone required training, it could not be available to all as take-home during the first phase of the opioid crisis in the 1990s. Nasal Naloxone, which individuals do not need the
training to use, became available in 2015 (BJA, nd). In 2010, 30 states in the U.S. had programs to train people for take-home naloxone (Davis, 2014). In less than two years after accessing nasal Naloxone in 2015, almost all states passed legislation tackling this issue in 2016, and it was reintroduced in 2017 (NCSL, 2018).

Naloxone distribution in communities may considerably lower the fatalities caused by opioid overdose. A study showed that the take-home naloxone program decreased overdose deaths to 65% less than expected (Keane, 2018). There is also another report from the CDC regarding how take-home naloxone reduced the number of opioid overdoses (Figure 7).

**Figure 9**

*The Number of Expected Overdoses Compared to Occurred Overdoses.*

*Note.* The number of survey respondents reporting beginning or continuing to provide naloxone kits to laypersons, by year — United States, 1996–2014 (https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm) In the public domain.
Results

The conceptual model of this study indicated three main concepts that could control the opioid crisis since 1999. Cost of medications, the Take-home Naloxone program, and gateway drugs were concepts that could control the opioid crisis in the U.S.; these concepts can be offered as solutions of the opioid crisis even in 2020.

Based on the results of the case study, legalizing cannabis had a significant influence on increasing opioid overdose rates, due to be a gateway drug. Data shows after the broad legalization of marijuana in 2018 by the majority of states, the number of overdoses increased more than twice. Based on the CDC, the number of overdoses in 2018 and 2021 were 46,802 and 107,622 respectively (2022). Regardless of this data, President Biden’s administration is trying to decriminalize marijuana on the Federal level as well. No doubt the result of this action will follow the previous pattern of increasing overdoses in the states. Therefore, an old mistake is repeated again.

The second concept in the conceptual model was focused on the take-home Naloxone program. Since 2015, when nasal naloxone became available for all, and take-home programs became more prevalent, the number of overdoses each year got less than expected. Therefore, although the number of overdoses due to other reasons had a positive slope in past years, the take-home naloxone program decreased the slope. By assigning more budget to increase the prevalence of naloxone in every town and city, the number of overdoses will decrease significantly. However, there should be treatment programs after relieving the patient from overdose with naloxone.

The cost of medication, the third key point in the conceptual model, has been consistently increasing in the U.S. Naltrexone is the most effective medication in the market for treating
opioid dependency, but the success rate of it is only 10%. One of the biggest barriers to Naltrexone efficiency is its cost. A patient needs to be under Naltrexone medication for three to six months (SAMHSA, 2022). Due to drug policies in the U.S., regulating a drug’s price is out of FDA’s control. However, there are ways to control the price of drugs, as well as keep the exclusive right of the manufacturing company.

**Theme 1: Naloxone vs. Naltrexone**

One of the most significant barriers to treating opioid-dependent individuals is the cost of medication-assisted treatments, including Naltrexone. On the other hand, the government has programs that offer free Naloxone to reverse the overdose. Although the free Naloxone program saved lives, as long as there is no treatment (using MAT, like Naltrexone), the opioid crisis will be an ongoing issue in the States. There needs to be parity in costs for Naloxone and Naltrexone because both are needed to rescue opioid-addicted individuals. If not, Naloxone itself would become a gateway drug for addiction recovery, because opioid-addicted individuals will continue doing drugs with the peace of mind that Naloxone will save their lives.

**Theme 2: Marijuana Needs to be Illegal.**

Although years ago, there were studies with the conclusion that marijuana would not affect the opioid crisis in society, recent studies proved there is a relationship between marijuana and opioid issues in society. Therefore, decriminalizing marijuana needs to be terminated in the States. the legislation of legalizing marijuana needs to be reversed to control one of gateways of opioid dependency.

**Theme 3: Bridge Between Phase 1 and Phase 2**

The first wave of the opioid crisis started in 1999, and it became a default in prescribing pain medication until now. In other words, none of the first, second, and third waves of the
opioid crisis terminated until today. Physicians need to find an alternative medication, including but not limited to anti-inflammatory medications, instead of opioids, to stop the loop of having patients devoted to opioids. Opioids are prescribed to combat the pain; nerves near the bone send the pain signal to the brain. Using anti-inflammatory medications physiologically will stop the process of sending pain signals by creating more space for the nerves next to the bone. This alternation can stop the bridge between phase 1 and phase 2, by terminating phase 1.

**Theme 4: Bridge Between Phase 3 and Phase 4**

Heroin became the biggest taboo among all drugs, mainly due to the way of using it. Heroin is mainly used via injection, which will be associated with being exposed to other diseases. However, fentanyl, due to being used orally or by sniff, seemed to be less dangerous to society. The primary connection between the second and third waves (Heroin and fentanyl) was the lack of information to the public.

**Limitations**

There are different limitations to case study research; they lack scientific rigor and offer less support for extrapolating findings to a larger population. Additionally, the case study may be influenced by the researchers' own feelings (researcher bias). Case study researches are usually difficult to replicate, which means they have low external validity.

**Summary**

The opioid crisis in the U.S. has depended on three main factors: medication cost, gateway drugs to opioids, and take-home naloxone. Given data supports a correlation between the number of opioid overdoses and all of these factors. Decriminalizing drugs like marijuana opened a gate for individuals to more potent opioids like heroin. Data indicated that the states that were pioneers in legalizing marijuana were the same states with the highest overdose rates.
The medication cost trend in the U.S. has been consistently increasing in the past 30 years. The high cost of medication limits healthcare access to society. Opioid medication is not an exception. Although the government waived the cost of naloxone by distributing free naloxone, the treatment in post-overdose time is not accessible for all. Various policies make healthcare, specifically medications, expensive in the U.S. The most critical factor in the high cost of medication is the lack of federal authority in establishing the cost of drugs. Focusing on these three factors can change the trends of the opioid crisis in the U.S.
Chapter 5: Summary and Recommendations

Based on this case study, various actions can be taken to mitigate the opioid crisis in the U.S. The most effective action is reducing the introduction of opioids to society by reducing opioid-prescribing; using alternative pain management medications that do not have an addictive side effect. Another efficient action is blocking one of the most significant pipelines to opioid addiction: marijuana. Lastly, although medication cost is the most significant barrier to its delivery in the U.S., the government followed different programs to provide Naloxone to the public to reduce the number of overdoses, which was significantly effective. As the medication for treating opioid dependency is discovered, opioid-dependent individuals can be treated by providing medications like Naltrexone to society at a reduced cost.

Recommendation 1: Opioid Alternatives

Over-prescribing has become a default in the U.S. healthcare system since the 1990s. The first wave of the opioid crisis did not stop until 2022. To break the cycle of patients becoming addicted to opioids, doctors must identify an alternative pain-relieving medication to opioids, like anti-inflammatory drugs. This transition will break the bridge between phase 1 and phase 2 by stopping phase 1.

Recommendation 2: Banning Gateway Drugs

As previously mentioned, gateway drugs had a significant role in the opioid crisis. States with the most cannabis use had the most significant number of opioid-related deaths. After the literature review and data analysis, I believe decriminalizing of marijuana use has to be stopped. There have been different drugs that were legal in the past, but are illegal now. The legal drugs in the 70s included but were not limited to LSD, GHB, and Magical Mushroom (NIDA, 2020).
Therefore, it is never too late for the prohibition of a drug. Although there will be people seeking marijuana even after illegalization, the average use in society will decrease.

**Recommendation 3: Free Naltrexone Program in addition to the Free Naloxone Program**

The cost of Naltrexone is one of the most significant barriers to its use. THN programs have been successful in society by reducing the number of opioid overdoses. However, mitigating the overdose and not treating the patient will not solve the issue. As both Naloxone and Naltrexone are required to save opioid-dependent people, hence there needs to be a parity in their costs. Therefore, *take-naltrexone* should be the next step for the *take-naloxone* program.

**Recommendation 4: More Research**

The offered recommendations have been made theoretically based on reviewing the literature. However, there needs to be more research regarding how implementing any of these recommendations will affect American society and how health policy will be initiated.
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Appendix A: Human Subjects Research Training

This is to certify that:

**Seyedehyasmin Moghaddamziabari**

Has completed the following CITI Program course:

*Students conducting no more than minimal risk research*

- **Human Subjects Protection Training - Students Conducting No More Than Minimal Risk Research**
  - **Course Learner Group**
  - **Stage**
  - **1 - Basic Course**

Under requirements set by:

**California State University, Bakersfield**

Verify at [www.citiprogram.org/verify?wc5f31b10-09c3-49c8-ba53-887774744b1d-52096763](http://www.citiprogram.org/verify?wc5f31b10-09c3-49c8-ba53-887774744b1d-52096763)
Appendix B: Case Study Protocol

<table>
<thead>
<tr>
<th>Stage</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background</td>
<td>The background of the opioid crisis starts with describing the structure of the opioid, its effect on the body, and biochemical interactions. It continues by describing the history of opioid use in the U.S. There have been three phases of the opioid crisis since 1990. This study also highlights racial disparities and the sex and age of opioid misusers. In the end, I will cover the role of government in the opioid crisis and governmental prevention and treatment in a different phase of different phases of the opioid crisis. Research Question 1: What is the relationship between the three phases of the opioid crisis? Research Question 2: What factors are considered to the opioid crisis movement through three phases?</td>
</tr>
<tr>
<td>Design</td>
<td>As this research is based on answering “what” questions, this study uses a qualitative method and single-case study approach with a focus on the three phases of the opioid crisis from 1990 to 2022.</td>
</tr>
<tr>
<td>Data Collection</td>
<td>Data collection is done by the principal investigator. Sources of data include scholarly journal articles, government websites and reports, and news media. Strings of textual data are entered into a Microsoft Excel spreadsheet where the conceptual model provides a priori categories.</td>
</tr>
<tr>
<td>Analysis</td>
<td>Data is analyzed in four steps: categorized, frequency distribution, pattern recognition, identify themes.</td>
</tr>
<tr>
<td>Plan Validity</td>
<td>Follow Yin’s approach to increasing internal validity by using explanation building and rival explanation; for increasing external validity, use analytical generalization for building the propositions.</td>
</tr>
<tr>
<td>Study Limitations</td>
<td>Like other case studies, the limitation of this study is the low capacity for generalization. One other mutual limitation of case studies is the possibility of being biased. Although case study leaders, including Yin, suggested ways to reduce these effects, they can be mentioned as limitations of case studies. One other limitation is time constraints.</td>
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</tbody>
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