A Public Health Ethics Approach to Substance Use Disorder

Adele Flaherty

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A PUBLIC HEALTH ETHICS APPROACH TO SUBSTANCE USE DISORDER

A Dissertation
Submitted to the McAnulty College and Graduate School of Liberal Arts

Duquesne University

In partial fulfillment of the requirements for
the degree of Doctor of Philosophy

By
Adele Flaherty

December 2021
A PUBLIC HEALTH ETHICS APPROACH TO SUBSTANCE USE DISORDER

By

Adele Flaherty

Approved September 23, 2021

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ABSTRACT

A PUBLIC HEALTH ETHICS APPROACH TO SUBSTANCE USE DISORDER

By

Adele Flaherty

December 2021

Dissertation supervised by Dr. Gerard Magill

The goal of the dissertation is to undertake an analysis of substance use disorders that focuses on a public health ethics perspective. The ethical argument focuses upon justifying the use of harm reduction and is primarily concerned with the current opioid crisis. While substance abuse/misuse over the course of history has been identified as a public health concern, this dissertation presents substance use disorders over the course of the lifespan, examining various contexts in which it can affect daily living and health outcomes. It achieves this by analyzing substance use disorders through the lens of the socioecological model of public health. This premise frames the foundation for this dissertation's central argument; namely, that governmental and healthcare organizations have an ethical imperative to provide equitable care to individuals with substance use disorders. Only after having established this normative foundation does this dissertation address obstacles to improving health outcomes of individuals with substance use
disorders and offer suggestions for how to overcome deficits in various aspects of society for such individuals.

This dissertation explores the ethical justification for developing a centralized strategy for addressing substance use disorder as a public health concern and not a criminal justice issue. The analysis provides an historical and contemporary view of substance use in the United States and globally to illustrate the need for change at various levels of society regarding how we perceive and respond to substance use disorders. The discussion of the public health ethical approach to substance use disorder informs the stance that governmental and healthcare organizations are uniquely situated to intervene to reduce stigma, increase access to diagnosis and treatment in various forms and reduce the incidence of substance use disorders such as opioid use disorder.

This approach emphasizes the impact various social interactions at the individual, interpersonal, organizational, community, and public policy levels have on the creation and perpetuation of stigma associated with substance use disorders; recognizing that because social norms and biases are slow to change without authoritarian influence and changes in the legal system, reform efforts need to focus on policy change to improve health outcomes for individuals with substance use disorders. This provides a normative framework to hold governmental, healthcare and community organizations accountable for ineffective and/or outdated policies and procedures that have a negative effect on individuals with substance use disorders. Together, these concepts provide an ethical framework to advocate for system-wide changes in the ways that public and private sectors of society approach and interact with health-related concerns pertaining to individuals with substance use disorders.
DEDICATION

To all of the individuals affected by substance use disorders, and those on their recovery journey.
ACKNOWLEDGEMENT

This work would not have been possible without the mentorship and support of Dr. Gerard Magill. Your wisdom and insight have been invaluable throughout this process and throughout my educational experiences at Duquesne. I am grateful to each of the members of my committee, Dr. Joris Gielen and Dr. Osuji for their guidance and feedback not only in the classroom but also outside of it.

Nothing has been more important, however, than the unwavering support and encouragement from my family, related and chosen. My husband Sean and my children Liam and Lenore, with their patience, understanding, and sacrifice, have made this experience possible. My mother-in-law Donna and her husband Phil have also been supportive as well, providing an extra hand when I (or we) needed it. The many friends that I have made along the way are also invaluable, providing feedback, insight, support, and joy that I sometimes had difficulty finding along the way. One special friend, my cat Chamberlain, was lost during this time, and he is dearly missed.

I love you all.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACA</td>
<td>Affordable Care Act</td>
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<tr>
<td>ACP</td>
<td>American College of Physicians</td>
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<td>AD</td>
<td>Advance Directive</td>
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<td>ADA</td>
<td>Americans with Disabilities Act</td>
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<td>AMA</td>
<td>American Medical Association</td>
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<tr>
<td>AMD</td>
<td>Age-related Macular Degeneration</td>
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<td>AUD</td>
<td>Alcohol Use Disorder</td>
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<tr>
<td>CALD</td>
<td>Culturally and Linguistically Diverse</td>
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<tr>
<td>CAPC</td>
<td>Center to Advance Palliative Care</td>
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<tr>
<td>CARE</td>
<td>Comprehensive Addiction Resources Emergency Act</td>
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<tr>
<td>CBT</td>
<td>Cognitive Behavioral Therapy</td>
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<td>CCCH</td>
<td>Center for Cross-Cultural Health</td>
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<td>CDC</td>
<td>Centers for Disease Control</td>
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<td>CLIA</td>
<td>Clinical Laboratory Improvement Amendments</td>
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<td>CMS</td>
<td>Centers for Medicare and Medicaid Services</td>
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<td>CP</td>
<td>Chronic Pain</td>
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<td>CPS</td>
<td>Child Protective Services</td>
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<td>CQI</td>
<td>Continuous Quality Improvement</td>
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<td>EBP</td>
<td>Evidence Based Practice</td>
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<td>EEOC</td>
<td>Equal Employment Opportunity Commission</td>
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<td>EOL</td>
<td>End of Life</td>
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<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>FDA</td>
<td>Federal Drug Administration</td>
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<td>GCDP</td>
<td>Global Commission on Drug Policy</td>
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<td>GINA</td>
<td>Genetic Information Nondiscrimination Act</td>
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<td>GWAS</td>
<td>Genome Wide Association Studies</td>
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<td>HCP</td>
<td>Healthcare Professionals</td>
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<td>HBV</td>
<td>Hepatitis B Virus</td>
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<td>HCV</td>
<td>Hepatitis C Virus</td>
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<td>HGP</td>
<td>Human Genome Project</td>
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<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>HOPE</td>
<td>Heroin Outreach and Prevention Education</td>
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<tr>
<td>HRP</td>
<td>Harm Reduction Principles</td>
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<tr>
<td>HSDF</td>
<td>Health Stigma and Discrimination Framework</td>
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<td>IASP</td>
<td>International Association for the Study of Pain</td>
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<td>IDU</td>
<td>Intravenous Drug Use(r)</td>
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<tr>
<td>IPV</td>
<td>Intimate Partner Violence</td>
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<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
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<tr>
<td>IWSUD</td>
<td>Individual with a Substance Use Disorder</td>
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<tr>
<td>IWOU D</td>
<td>Individual with an Opioid Use Disorder</td>
</tr>
<tr>
<td>JCHAO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations</td>
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<tr>
<td>LBP</td>
<td>Lower Back Pain</td>
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<tr>
<td>LCME</td>
<td>Liaison Committee on Medical Education</td>
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<tr>
<td>LEP</td>
<td>Limited English Proficiency</td>
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<td>Abbreviation</td>
<td>FULL FORM</td>
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<tr>
<td>LMIC</td>
<td>Low to Middle Income Countries</td>
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<tr>
<td>MAT</td>
<td>Medication Assisted Therapy</td>
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<tr>
<td>MHPA</td>
<td>Mental Health Parity Act</td>
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<tr>
<td>MHPAEA</td>
<td>Mental Health Parity and Addiction Equity Act</td>
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<tr>
<td>MUD</td>
<td>Marijuana Use Disorder</td>
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<tr>
<td>NAM</td>
<td>National Academy of Medicine</td>
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<td>NAS</td>
<td>Neonatal Abstinence Syndrome</td>
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<tr>
<td>NIDA</td>
<td>National Institute of Drug Abuse</td>
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<td>NIH</td>
<td>National Institute of Health</td>
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<tr>
<td>NPCRC</td>
<td>National Palliative Care Research Center</td>
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<tr>
<td>NQF</td>
<td>National Quality Forum</td>
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<tr>
<td>NSDUH</td>
<td>National Survey on Drug Use and Health</td>
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<tr>
<td>OMH</td>
<td>Office of Minority Health</td>
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<tr>
<td>ONDCP</td>
<td>Office of National Drug Control Policy</td>
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<tr>
<td>OUD</td>
<td>Opioid Use Disorder(s)</td>
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<tr>
<td>PC</td>
<td>Palliative Care</td>
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<tr>
<td>PCM</td>
<td>Patient Centered Model</td>
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<tr>
<td>PDMP</td>
<td>Prescription Drug Monitoring Program</td>
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<tr>
<td>PPOUD</td>
<td>Pregnant Persons with an Opioid Use Disorder</td>
</tr>
<tr>
<td>PQC</td>
<td>Perinatal Quality Collaboratives</td>
</tr>
<tr>
<td>PPSUD</td>
<td>Pregnant Persons with a Substance Use Disorder</td>
</tr>
<tr>
<td>PWID</td>
<td>People Who Inject Drugs</td>
</tr>
<tr>
<td>QI</td>
<td>Quality Improvement</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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</tr>
<tr>
<td>RTC</td>
<td>Residential Treatment Center</td>
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<tr>
<td>SEM</td>
<td>Socio Ecological Model</td>
</tr>
<tr>
<td>SEP</td>
<td>Syringe Exchange Program</td>
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<tr>
<td>SES</td>
<td>Socioeconomic Status</td>
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<tr>
<td>SLH</td>
<td>Sober Living Home</td>
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<tr>
<td>SUD</td>
<td>Substance Use Disorder</td>
</tr>
<tr>
<td>TC</td>
<td>Therapeutic Community</td>
</tr>
<tr>
<td>TIPS</td>
<td>Treatment Improvement Protocols</td>
</tr>
<tr>
<td>UDBHR</td>
<td>Universal Declaration on Bioethics and Human Rights</td>
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<tr>
<td>UNESCO</td>
<td>United Nations Educational, Scientific and Cultural Organization</td>
</tr>
<tr>
<td>UNODC</td>
<td>United Nations Office on Drug Control</td>
</tr>
<tr>
<td>VHA</td>
<td>Veterans’ Health Administration</td>
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<td>WHO</td>
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Chapter 1: Introduction

While the topic of opioid use disorder is on the forefront of academic debate in many disciplines, newer literature appears to focus on specific, life-altering situations. Although valuable, it is also necessary to acknowledge that individuals with a substance use disorder (IWSUD) are impacted by their status in other seemingly innocuous ways. As our understanding of substance use disorders continues to evolve, our current policies and practices surrounding individuals with SUDs necessarily needs to morph into something less discriminating and punitive and more inclusive and rehabilitative. Globalization has not only changed the capacity for acquiring substances of use, but it has also affected the rates of misuse and the ability for treatment. It also creates a challenge to traditionally Western ways of addressing ethical issues related to substance use. For example, evidence-based treatments for opioid use disorder (OUD) such as Medication Assisted Therapy (MAT) are promising, yet many individuals with an OUD do not have access due to outdated abstinence only policies either in certain healthcare programs or the court system. Contemporary policies such as those that fall under the umbrella of harm reduction; legal measures by states towards decriminalization of substances such as marijuana, and destigmatization efforts in healthcare practice are just some examples of practices and policies public health care ethics can inform.

In order to examine the impact of living with a substance use disorder it is important to acknowledge that general ethical approaches cannot be expected to provide policy makers, those involved with implementation of such policies, and other health care providers and personnel with sufficient practical ethical guidance. This is because...
approaches or recommendations – although useful – cannot consider and anticipate the peculiarities and nuance of substance use disorder, mental health and other public health related interventions and the complexity of the contexts in which they are created and implemented. This dissertation illustrates the need to develop more targeted ethical approach that considers the impact of interaction amongst a range of factors and at multiple levels on health outcomes. Consideration of these elements as discrete, yet interactive and intertwined forces can be useful in developing interventions to promote ethical practices with individuals with substance use disorders, their families and provide guidance for policymakers. For example: an analysis of the experiences of individuals with a SUD who interact with the health care system - or any other situation in which their status as an individual with an SUD is considered and may have any bearing on their experience - allows for an examination of the impact of their status at multiple levels. These may then be used in the development of interventions, policies and practices that benefit not only those individuals, but others with similarly stigmatized conditions and those with the power to exact positive change.

The aggregate of literature dealing with substance use disorders focuses primarily on issues surrounding consent and treatment, while few discuss other minutia related to living with a substance use disorder and/or how research on substance use disorders can benefit or burden these individuals. This dissertation acknowledges the origins and evolution of ethical debates surrounding substance use disorders as well as the role of current theories of global, organizational, and clinical ethics. It also examines the impact on healthcare organizations and providers that rely on such theories to navigate the developing landscape of addiction. However, its aim is to present examples of ways in
which these theories and policies can be enhanced or replaced with those that are more mutable and that consider the tenuous nature of human collaboration; the implications of which can be seen at all levels of society. The use of a socio-ecological approach also acknowledges the importance of analyzing public health issues from multiple levels. This necessarily shifts the point of focus from the micro (individual) to the meso (community) as well as macro (society, global) levels of interaction and impacts the practicality of traditional applications of ethical theory.

Harm reduction approaches and decriminalization of illicit substances are emerging as alternative options for communities who continue to deal with drug related mortality and premature morbidity from what are considered preventable causes – particularly those related to the current opioid crisis. The literature surrounding harm reduction ethics focuses on the multifaceted aspects of autonomy in substance use disorder, as well as justice, community, the common good, acceptable norms of research, multi-cultural values, and professional roles. Such an approach is useful not only in the treatment and prevention of SUDs, but it also empowers these individuals to contribute more fully to society by enabling them to participate more (for instance, in research studies). Decriminalization also comes up as a solution to the ethical discord that exists for individuals with a SUD, but like the concept of harm reduction with regards to substance use often challenges what is traditionally considered “morally acceptable.”

Exploration of the progression of distinct human experiences and accomplishments is necessary to provide a foundation upon which these new ethical approaches can be based. For instance, understanding how we have come to change our perception of substance use and/or death allows us to consider the factors that affect
human interaction on major (public) or minor (intrapersonal/interpersonal) scale. This can inform the ways in which contemporary ethical approaches, practices, or policies are updated or created. This dissertation argues that a more interdisciplinary approach, with an infusion of traditional and contemporary ethical theories as well as an incorporation of those related to behavioral sciences, is necessary to achieve a more holistic view of substance use disorder and its impact on daily living, while also providing examples of ways in which public health ethics as a distinct discipline can have a substantial impact on the healthcare outcomes of those individuals with a substance use disorder.

This work provides a longitudinal examination of life with substance use disorder(s). The analysis provides examples of how various levels of human interaction can affect the health outcomes of individuals living with a substance use disorder and in some capacities their families as well. After assessing scenarios in which an individual’s status as person with a substance use disorder may affect their access, experiences and outcome to health interventions or opportunities, it defends the use of a public health ethics approach to clarify, prioritize and justify possible courses of action based on evolving policy and practices, with a consideration of traditional and contemporary ethical theories that consider the values and beliefs of the stakeholders, as well as scientific and policy-related information. In light of this justification, the remaining sections explore the adaptability of the argument’s implications at the micro and macro levels of policy for healthcare and clinical research, justify incorporating an ethics of care and organizational approach for dealing with these implications, and finally formulate strategies for coping with the adaptably of the argument’s implications.
Public attention continues to be paid to the use and abuse of substances and their impact on public health. Recent prominent health crises relate to the impact of high prices of addictive substances such as oxycodone and the proliferation of lethal (and affordable) formulations of illicit heroin. These crises impact the way in which society views opioid and other substance use disorders (SUD) from blemishes of character to misfortunes of biology. As now manifest in the United States, this perspective challenges current approaches towards substance misuse. The thesis of this dissertation presents a public health ethics approach to substance abuse disorder. To address the ethical concerns associated with individuals with a substance use disorder (IWSUD) a public health ethics approach is presented to engage situations over the lifespan of an individual. The goal is to seek solutions to the inequities and unethical behaviors encountered in such instances. Hence, the analysis discusses the issues from historical, legal and ethical perspectives, engaging foundational and contemporary theories, practices or policies. Chapter one provides a general introduction. Chapter two presents substance use disorder as a public health issue and defends a public health ethics approach to these issues. Chapter three considers pivotal issues across the life cycle of patients, such as pregnancy and end of life, to argue that penalizing an individual with a SUD is unethical and counterintuitive to promoting overall health of individuals and the public. Chapter four then examines issues related to SUDs on a global level, particularly those related to chronic pain, the global SUD treatment industry, and human subjects research.

2. Public Health Ethics as a Context for Substance Use Disorder

Public health ethics itself is an emerging field in bioethical study. As health is not only a personal concern, but also a social one, it has the potential to not only examine and
explain certain health issues, but also to inform clinicians, educators, social workers, advocates, and policy makers on how to address certain health concerns. With the current health crises stemming from the introduction of highly addictive painkillers into the pharmacopeia, public health ethics has the power to make an important contribution by examining historical aspects of public health, drug policy and introducing potential solutions while making sure to consider the ethical implications of creating new policies to address these issues.

2a. The Opioid Epidemic as a Public Health Crisis

In October of 2017, President Donald Trump declared a Public Health Emergency in response to the opioid crisis emerging across the United States.1 This crisis affects public health in multiple ways. Its impact on hospitals and local municipalities treating overdoses cannot be overstated, but other health concerns have emerged that confound the problem. These include increases in the incidence of disease related to intravenous drug use such as HIV and Hepatitis C (HCV).2 The incidence of overdoses related to heroin, non-methadone synthetic opioids and cocaine has also increased exponentially since 2011.3 This is a result of stricter prescribing practices and rising pharmaceutical costs, which cause individuals to seek cheaper alternatives. The concomitant rise in injectable/intravenous drug use (IDU) and HIV/HCV lead governments where this trend was especially detrimental to implement community programs aimed at diminishing the number of new users while combating the rise in overdose and overdose-related deaths.4

As the spread of this syndemic continues across all corners of the United States, local and state governments began to concede that harm reduction measures may be the best solution to this problem.5 One example of initiatives that are being implemented is
the use of the opioid inhibiter known as Narcan by emergency responders and law enforcement – although some states are now adopting “standing order” laws that allow pharmacists to distribute the drug to anyone who wants to have it on them in case of an overdose. Syringe exchange programs are also gaining traction in communities ravaged by IDU, a move that is showing promise not only in the reduction of the spread of HIV and HCV, but also a reduction in health care costs.

Safe injection sites which - as of this writing – are still illegal in the United States, are also starting to garner consideration. By providing a place with medical personnel on site, cities such as Vancouver, B.C. provide users with a safe space to inject – reducing the number of used syringes, increasing the likelihood of entering treatment and reducing the number of new cases of HIV and HCV. Public awareness campaigns are another way in which communities are addressing this health crisis. Initiatives at all levels of government in the United States seek to highlight the risks and consequences of opioid use and abuse. Many of these initiatives include ad campaigns, family education and training for individuals who want to carry Narcan in the chance that an overdose occurs.

2ai. Public Health and the War on Drugs

The number of prescriptions for highly addictive painkillers such as Oxycontin have more than quadrupled over the course of 20 years, leading to an estimated 560,000 deaths (and counting) related to drug overdose, two-thirds of which were attributed to the use of opiates. The timeline of opiate abuse from as early as the 19th Century to now, shows the role of the pharmaceutical industry and ill-informed medical professionals in the emergence of this epidemic. Aggressive marketing, a renewed vigor for pain treatment and obfuscation of the effects of the potential for abuse of opioid based drugs
like Vicodin and Oxycontin are the culprits behind this trend in use and abuse of such drugs. Another side effect of this trend is the abuse of heroin, which has also grown exponentially over the course of the early 21st century. This is because heroin is cheaper, and in certain instances, easier to obtain than prescription opioids. In turn, heroin related overdoses have increased five-fold.

Another “hidden” side effect of the increase in opioid and heroin addiction is the increase in newly diagnosed HIV positive patients. After a 25-year decline in new cases attributed to IDU, a spike in the number of cases began to emerge. Statistical analysis also showed an increase in the number of individuals with HCV. Both of these trends can be attributed to several things: both are transmitted through the use of infected items such as injecting with needles previously used by those infected with either virus, as well as the use of items tainted with blood of individuals infected. Illicit substance use is also positively associated with other types of risky behavior such as unprotected sex - another way in which HIV is spread.

Much of the reason why efforts to decrease morbidity and mortality related to illicit drug use have failed is the criminalization of substance use and substance use disorders. The ongoing stigma regarding use and addiction impedes progress. Many across the United States and Europe have called for an alternative approach, from that of a criminal perspective to a public health one. Some states in the U.S. have taken measures to decriminalize the use of drugs such as marijuana, while some European countries (and in November of 2020, the state of Oregon in the United States) are taking or have taken measures to decriminalize all drug use. As a result, many nations adopting this approach have seen a decrease in new users, as well as crime and deaths related to overdose.
2aii. Ethical Considerations Around Clinical and Community Interventions

At the clinical level, ethicists and healthcare workers must consider the impact of micro-level interactions such as the patient-doctor relationship. Much of the opioid crisis occurred because of misinformation regarding the potential of addiction with the prescription of opioid based painkillers. Clinicians must show fidelity to their patients by staying informed on treatment methods. It is also unethical punish patients for their pain by limiting treatment – be it with opioid based medications or alternative therapies. A careful consideration of the patient’s pain levels, and treatment needs should be considered, all while observing laws currently in place to avoid improper distribution of prescription painkillers. By doing so they will adhere to the tenets of Beauchamp and Childress’ principlism.

At the macro level, the rise in morbidity and mortality related to opioid use affects society at many levels, and there are ethical concerns that those who treat individuals with SUDs, as well as those who write policy that influence access and affordability of treatment and prevention need to consider. For instance, the opioid crisis has created several burdens on society that need to be address. Loss of productivity, a rise in health care costs and increased costs related to the criminal justice system are but a few. Lack of access to proven, evidence-based forms of treatment only exacerbates these issues, and propagates the issues associated with opioid use. Policies such as those proposed by the current administration’s Commission on Combating Drug Addiction and the Opioid Crisis (The Commission) may provide solutions. The Commission recommends dozens
of measures related to treatment and prevention of opioid use disorders, including educational, policy and procedural measures.\textsuperscript{21}

\textbf{2b. Consent in the Public Health Context of Substance Use Disorder}

Individuals with substance use disorders in general have unique concerns with regards to consent both in the course of the disease and recovery. This is especially true for individuals with an OUD who may find themselves in situations whereby consent may be compromised due to use or as a result of long-term use. Individuals with an OUD are also susceptible to overdose. These and other disease-specific circumstances are importance to consider when honoring autonomous decision-making for all patients and research subjects.

\textbf{2bi. The Relationship Between Autonomy and Consent}

According to Beauchamp and Childress, certain conditions need to be met to achieve autonomous action: liberty and agency. These are achieved by decision-making that is free from coercion (liberty), as well as the capacity to act intentionally (agency).\textsuperscript{22} Informed consent is viewed as the corner stone of respecting the principle of respect for autonomy. This involves properly informing the patient of the potential risks and benefits of treatment, creating a plan of action, and assurances regarding the maintenance of privacy. Multiple theories examine autonomous action: spilt level and the three-condition theory. The former maintains that autonomous action is achieved by aligning basic, first order actions with higher-level second order desires. Three condition theory involves the navigation of intentional action, liberty and understanding. Deficiencies in any of these three conditions signifies a lack of true autonomous decision-making.\textsuperscript{23}
Competency is another vital component of autonomy and decision-making to consider. This is especially relevant to the current issue of SUDs, because oftentimes, when a medical intervention occurs, there may be a question about the individual’s ability to meet the necessary conditions for autonomous consent. Consent is either explicit or implied. This can be achieved either through action or inaction in either scenario. There are differing approaches in the discussion of what the components of informed consent are, although much of the literature cite competence, disclosure, understanding, voluntariness, and consent.24

In one sense, informed consent is achieved when a patient or subject has “substantial understanding” of their treatment or research options, where no coercion occurs and intentional authorization of action (or inaction) occurs.25 Otherwise, informed consent has evolved into an institutional and legal course of action in the course of medical treatment. In this application, minimal standards are set by entities that may not have the best interest of patients in mind. Rather, they may be more concerned with meeting standards set by the government without regard to the patient’s role in their own healthcare. This is especially important with regards to treatment of substance use disorders, where a “one size fits all” approach to treatment has proven to neglect the specific needs of certain populations of individuals within the substance abuse treatment system.

2bii. Determining Who Can and Who Cannot Give Consent

Another condition of autonomy is competency, which requires an individual to possess the ability to perform a task. This ability fluctuates over time and can be influenced by incidence of illness or morbidity related to the aging process.26 In
addressing the issue of opioid crisis, competency may also be influenced by the use of drugs – prescription or illicit. Ultimately it is the clinician interacting with a patient that decides if an individual is competent enough to decide about their health. While there are no universal methods by which to assess competency, there are testing instruments available which aide a clinician in deciding on competency.27 These are, by nature, subjective. Such decisions affect the rights of an individual and bioethicists should further contemplate the moral status of an individual or being. Several theories exist to address this concept. These theories exist to aid in the process of decision – either by effectively supporting first-person consent or eliminating it, thus creating the need for surrogacy.28

Those deemed incompetent and thusly, unable to provide consent, often designate or are appointed a surrogate to assist in treatment-related decision-making. This is typically done using an advanced directive (AD) or via court appointed guardian.29 Institutional ethics committees may also be brought on board to aide in decision-making. Guidelines such as the “best interest” or “substituted judgement” standard are also provided for surrogates to aid in such decision-making.

2c. Culturally Competent Care in Substance Use Disorder Treatment

It is also important to consider the ongoing inequities in treatment based on racial, ethnic, or sexual minority status. Currently, one third of the United States is comprised of racial, ethnic, and sexual minorities. That number is expected to increase to over fifty percent by 2050.30 It is vital, in the course of treatment of SUDs, that ethicists and medical professionals consider the impact this statistic has not only in the course of
general treatment of health issues, but also the specific treatment of diseases such as SUDs.  

2ci. Disparities in Substance Abuse and Treatment

The National Survey on Drug Use and Health (NSDUH) provides state and federal data on the incidence of substance use and abuse, as well as data on mental health. This information is provided to inform healthcare professionals and others interested in SUDs, as well as mental health issues, in order to inform future policy and treatment protocols. Data from 2015 – the first year the NSDUH considered analyzing data from sexual minorities – further illustrate the need to consider the unique experiences of those with SUDs that have minority status. While the data on sexual minorities is limited, what is currently available shows a higher use and higher likelihood of not only one, but multiple SUDs in that population.

It is also important to consider the different types of treatment that are currently available to individuals with a SUD. Treatment is provided depending on the type of SUD or SUDs (as many individuals have co-occurring disorders such as mental illness and SUD). Most treatment providers are considered either inpatient or outpatient and can last anywhere from 28 days to 12 months, depending on several factors such as availability and affordability. There is also another form of treatment available to some individuals with SUDs that are incarcerated. This is known as the prison Therapeutic Community (TC) model. This is similar to residential inpatient treatment and allows those wishing for sobriety prior to their release.

2cii. Ethical Considerations Surrounding Interventions for Minorities
Research shows that disparities in treatment engagement between racial/ethnic and sexual minorities and their counterparts also exists. A health service disparity is defined by the Institute of Medicine (IOM) as “difference in treatment or access not justified by the differences in health status or preferences of the groups.”

Evidence exists that shows racial, ethnic, and sexual minorities are less likely to engage in healthcare systems, receive lower quality treatment and have poorer health outcomes. Minorities tend to experience stigma at a higher rate than others with a SUD, both in their personal lives and at an institutional level, which likely deters engagement. At the institutional level, healthcare professionals can also deter engagement. Negative perceptions by those treating the individual can damage the relationship between the patient and those serving them. Education on SUDs is necessary to prevent this from occurring. Financial barriers also exist that hinder engagement. Accessibility to treatment is another barrier that needs to be considered.

Disparities also exist regarding treatment outcomes. Retention and successful completion - defined as “any planned discharge from treatment, including transfers to other facilities to continue further treatment” – are predictors of successful outcomes for those with SUDs. Minorities tend to have lower rates of retention and successful completion, often due to lack of satisfaction with the treatment process and the source of referral – meaning those coerced into treatment are less likely to have successful outcomes. Negative employment outcomes also affect treatment outcomes, while underrepresentation of minorities in supplemental services such as employment or legal counseling only serves to perpetuate such outcome disparities.
Ways in which to address these disparities are slowly being integrated into current models of health. Bioethical models of care such as the “patient centered” model (PCM), which challenges the practitioner to “see the world from the eyes of the patient” by considering the importance of open and honest communication and focusing on the delivery of care. Culturally competent care takes the PCM a bit further and specifically considers the need for promotion of cross-cultural and cross-linguistic interaction. It considers the organizational, structural, and clinical barriers that currently exists, and seeks to navigate around them. By incorporating these bioethical models of care into treatment, evidence shows that overall quality of life may be improved, as well as engagement, retention, and outcomes. The importance of public and private sector initiatives (such as policies issued by governmental entities addressing issues of disparities, or research and implementation of PCM of chronic care management by medical organizations) cannot be overlooked, as many such entities can influence the way in which SUDs are perceived and treated.

3. Ethics of Substance Use Disorder in the Life Cycle of Patients and Subjects

Public health issues affect individuals at every stage of life. In the case of substance use disorders and opioid use disorders, this is no exception. A person may be born to a mother who is in the throes of a substance use disorder and as a neonate, suffer some of the same symptoms she does as they are weaned off whatever substance they were born addicted to. Teenagers and/or adults may find themselves as individuals with a SUD, curious about what types of treatment may be available; they may wonder if they are more susceptible to certain substances than others. People who live with a SUD in adulthood may later find themselves in need of care at the end of their lives, all while in
active addiction or recovery from a substance related disease. Ethical considerations regarding substance use disorder have no boundaries within the life cycle. This section considers several issues that an individual with a SUD may face over the course of the life cycle.

3a. Beginning of Life: Substance Use Disorder and Maternal Health

The rise in OUDs in the general population also suggests that many women who are entering substance use disorder treatment may be pregnant. In the United States alone, reported rates of Neonatal Abstinence Syndrome (NAS) only serves to confirm this assumption. Over the course of roughly a decade (2000 to 2013) the rates of NAS increased five-fold from 1.5 per 1,000 births to 6.5 per 1,000 births.\(^4\)\(^6\) Despite the rise in the prevalence of NAS births in the United States, and the known higher risks of parental/maternal and neonatal morbidity and mortality in pregnant persons who use substances such as opioid during pregnancy, the population remains underserved. Barriers at all levels of society delay or inhibit engagement of pregnant persons with a substance disorder (PPSUD) with proper treatment.

3ai. Unique Characteristics of Substance Use Disorders and Women

It is important to understand that when discussing the impact of substance use disorders on individuals, biology and physiology have a significant influence on the ways in which different substances affect the mind and body. Women in particular have unique susceptibilities that aren’t found in men. The ability for childbearing also adds another caveat to the already complex dimensions of substance use disorders. It is important to not only explore the rates at which women currently suffer from SUDs, but to explore the specific ways in which women are uniquely and adversely affected that are of particular
interest to those who wish to address the gaps in care that women and PPSUD continue to face.

What data on women (non-pregnant and pregnant) does not show is that substance use affects women in different ways than men. A recent increase in the amount of research on women and substance use shows that, while men tend to show higher rates of substance use, emergency room visits related to substance use, overdose deaths and similar rates of substance use disorders (SUD), women tend to be more susceptible to the consequences of using addictive substances than men at the physical, psychiatric, and social levels. These differences are based both on sex and gender. Research has shown that differences such as those found in the way substances are used by women and how women respond to substance use create unique differences from men that affect how women engage with substance use, live with SUDs, and treat SUDs.47

In the case of opioids, not only do women tend to experience chronic pain at higher rates and require strong pain medications that contain highly addictive opioids. There is also a propensity for women to use these meds for off label use such as stress and anxiety.48 Other social factors make it difficult to obtain prescription opioids, which may lead to the introduction of heroin. Instances of use and misuse such as these this increases the likelihood of overdose. Although men still engage with emergency services related to overdose and die at higher rates, the past few years have seen an increase in the number of women who do the same.49

Another important difference to consider is the biological differences between women and men when it comes to reproduction. Although some substance use can affect the fertility of men and women, many women who have a substance use disorder do get
pregnant. Before exploring ways in which healthcare can improve the care in which pregnant persons with an OUD (PPOUD) a discussion about the biological, ethical, social, and legal implications that these women face is necessary.
3aii. Opioid Use in Pregnancy and Ethics of Care

Coinciding with the rise in the number of women using illicit drugs in recent years is the increase in the number of persons who are pregnant also engaging in their use. This increase in the number of women of childbearing age receiving opioid prescriptions has also led to an increase in the number of pregnant people taking opioids during pregnancy and those who go on to develop an OUD. The implications for both parental and fetal health are considerable, and the attention of many in public health, ethics and policy is now focused not only on the cause of such an increase, but also how to address this issue now properly and successfully and in the future.

When a fetus is exposed to opioids during its development, it can experience a series of adverse effects. Although the effects of opioids on the fetus aren’t directly known, risks associated with opioid use during pregnancy include: stunted growth, which leads to a low birth weight; preterm delivery; congenital heart defects; neural tube defects – defects of the brain, spine and spinal cord; gastroschisis; loss of the baby due to miscarriage or still birth and/or neonatal abstinence syndrome (NAS) which manifests as withdrawal symptoms (irritability, seizures, vomiting, diarrhea, fever, and poor feeding) in newborns. 1

Opioid use disorders are often addressed in PPOUD by incorporating MAT because the risk of harm to the fetus from withdrawal is too great. Despite evidence of treatment success in PPOUD who do receive treatment and policy initiative aimed at improving accessibility and affordability of treatment, barriers still exist that prevent them from receiving the treatment they need. 2 Availability and accessibility of treatment programs designed for women has also not coincided with the growing number
of women affected by substance use and misuse. There is also a lack of collaboration or coordinated care between providers including OB/GYNs, treatment facilities/programs, child welfare programs and other social programs geared towards advancing health and well-being.

The criminal justice system also has a strong influence on the decision of whether or not PPOUD seek treatment. Women who do enter the criminal justice can also expect huge gaps in the availability of evidence-based treatment and standard prenatal care. The U.S Healthcare system itself impedes the treatment process by placing limits on what drugs it will cover and how much.

To improve prenatal and perinatal care in PPOUD, there needs to be a shift in both the current models of substance use disorder treatment and institutionalized birth. One way to address this is to consider the influence of these policies on overall care.

An ethics of care also offers a different way to approach ethics and clinical decision-making. Compared to more traditional approaches to ethical decision making such as ethics of justice, whose focus is on universal moral laws that can be applied across situations, an ethics of care is more concerned with responding to the needs of others in complex, real-life situations. Proponents of ethics of care suggest that there is a pre-existing moral relationship between people; therefore, the question any provider needs to ask themselves when engaging with a patient is: “How can I meet my caring responsibility?”

The incorporation of an ethic of care approach into substance use disorder treatment facilities and pregnancy care models as an adjunct to the current bioethics of principiplism can provide a modified approach wherein the recognition of the needs of
others becomes a priority over adherence to institutional policy. An ethic of care approach in the context of the substance use disorder counselor and/or whomever is assisting with the birthing process provides an opportunity to equalize the relationship between the provider and the woman, provides the space for relationship building and allows them to meet the expectations of the interchange. Care ethics can also be influential in the mitigation of stigma.\textsuperscript{58}

3b. Life Cycle: Genetic Diagnosis, Prevention, and Treatment of Substance Disorders.

Technological advances in other aspects of medicine also impact IWSUD. Recent progress in genetic research includes human genome sequencing, as well as the development of myriad genetic tests for various diseases and disorders. Those involved in treatment of substance use disorders are particularly interested in the power of genetic testing to diagnose, treat, and ultimately prevent these disorders – especially with the increase in the amount of individuals’ diagnoses with OUDs. It is important as bioethicists the potential ethical, social and policy-related concerns that arise as a result of such advancements. An analysis of the history of genetic mapping, the potential use of genetic tests and an analysis of such concerns is necessary to lay the foundation for the future of genetics, genetic testing, and SUDs.

3bi. The Capabilities of Genomic Science

Data gleaned from the success of the Human Genome Project (HGP) allows scientists to conduct genome wide association studies (GWAS) to help identify genetic loci for diseases such as age-related macular degeneration (AMD). These discoveries opened the door for the creation of many genetic tests, such as those used to identify BRCA\textsubscript{1} and BRCA\textsubscript{2}, which are genetic markers related to breast cancer.\textsuperscript{59} Diagnostic,
predictive, carrier, prenatal, preimplantation, and more advanced newborn tests continue to be developed as a result of these advances. Genetic testing pertaining to SUDs specifically are also a result of the HGP and GWAS. Although in the early stages, many tests are already being used by clinicians to assist in the diagnosis, treatment, and prevention of SUDs – although their reliability at this time is in question.  

Despite the progress being made in genetic testing, bioethicists must also consider other factors that influence the expression of certain diseases and disorders. Epidemiological studies conducted on certain cohorts show that environmental factors such as hunger and smoke inhalation are shown to have an effect on the expression of certain gene traits, such as those linked to the suppression of certain growth factors and an increase into the potential for certain cancers. The study of such change in DNA that do not involve a change in DNA sequences is known as epigenetics, a relatively new area of research emerging out of the growing field of genetics. Such breakthroughs created interest in the ability of epigenetics to aid in the treatment and prevention of SUDs.  

Another emerging field in genetics is pharmacogenetics. Pharmacogenetics is the study of the influence genetic variation has on the body’s response to certain drugs – pharmaceutical and illicit. Certain genotypes cause variations in individuals that can affect the way drugs are metabolized and eliminated – affecting their benefit and potentially causing the individual more harm than good. Pharmacogenomics is the application of such knowledge to the development of drugs and drug therapies for various diseases and disorders. This can be used to streamline treatment and reduce the cost of care. The potential for use in the prevention and treatment of SUDs cannot be ignored.
3bii. Principlism and Policy Concerns

The advancement of fields such as genetic testing, epigenetics and pharmacogenetics is not without potential for ethical, social, and legal repercussions. Principlism is a practical method for ethical decision making in these areas. In terms of healthcare, informed consent is considered the primary manifestation of respect for autonomy. In terms of genetic testing, it is important to consider possible consequences of a diagnosis of a SUD or the potential for an individual to develop one. The information gained from testing may not only affect the individual going through the test, but family members as well.\(^{68}\) It is vital that those getting tested understand the benefits and risks of such an undertaking, as it has been shown to psychological harm. Psychosocial effects such as anxiety, increased stress levels and depression may occur during and after the testing process. These may also occur during genetic research as well. This speaks to the principle of nonmaleficence, which requires the minimization or elimination of harm.\(^{69}\)

Beneficence requires healthcare providers to do all they can to benefit the patient at all times. The potential for harm genetic testing and research may do must be considered before engaging in such endeavors. The potential for harm is a contemporary concern in all fields of genetics, especially because of the infancy of genetic testing, epigenetics, and pharmacogenetics. The information gleamed from such fields of study has the potential for misinterpretation and obfuscation of findings, not only for individuals being tested but those administering the tests who may not have the proper training.\(^{70}\)

Justice not only applies to equitable access to genetic, epigenetic, and pharmacogenetics research and its benefits, but a consideration of the impact of
environmental factors on individuals at a genetic level is also something bioethicists need to consider. While an examination of inequities in access to healthcare and testing is necessary, inequities in access to healthy living is also important to consider. This speaks to environmental justice, and those living in unhealthy environments also deserve to have their concerns considered.71

There are multiple ways in which bioethicists can address these concerns. One is an examination of the impact of such tests on social and legal policy. From such an examination, subjects, patients, and the public can have a clearer understand of their impact on public health. Discussion of issues such as discrimination, privacy, regulation and standardization of testing and research is vital to map out future action to ensure ethical treatment based on genetic information.72 Ultimately, legislation passed to suppress such unethical practices based on genetic information, but the pace of current genetic technologies makes it difficult for legislation to keep up. This is especially true in the fields of epigenetic and pharmacogenetic medicine, which currently have little to no protection under current laws such as the Americans with Disabilities Act (ADA) and the newer Genetic Information Non-discrimination Act of 2008 (GINA).73

It is also important to consider on a more specific level the impact of such loose protections on individuals with SUDs. Not only are there social implications surrounding the stigma of SUDs, but legal ramifications as well. Exposure of genetic information related to substance use can have an impact on individuals with an SUD, not only with regards to healthcare acquisition and retention, but employment as well.74 The potential use of such information in the hiring process may limit an individual’s ability to obtain and maintain employment. Currently, the laws regarding use of genetic data are limited
by the lack of knowledge regarding the potential for epigenetics and pharmacogenetics in the diagnosis, treatment and prevention of diseases and disorders – including SUDs.\textsuperscript{75}

Standardization and regulation of testing and research is also necessary. Governmental entities such as Centers for Medicare and Medicaid Services (CMS) and the Federal Drug Administration (FDA) are poised to improve and strengthen such standards, as well as formulate and regulate the use of all forms of genetic testing.\textsuperscript{76} The increase in direct-to-consumer testing only exacerbates this concern. Improved quality assurance only serves to address the potential for harm that can occur from misuse and misunderstanding of testing and research results.\textsuperscript{77}

3c. Substance Use Disorders and Care at the End of Life

The need for specialized care when debilitatugly ill or dying can arise at any point in one’s life. Palliative medicine has the ability to enhance quality of life for people who are diagnosed with a life-limiting serious illness. However, there are populations whose experience of palliative care may not measure up to the standard of care that most palliative patients receive. Individuals with substance use disorders (IWSUD) often encounter barriers to optimal care. Many palliative care programs do not know how to properly care for these individuals and their unique concerns. This section explores how our attitudes towards death have changed over time, which lead to the introduction of palliative and hospice care as distinct specialties. It examines common barriers to palliative care and the incidence of SUD in the palliative care population – with a particular focus on the oft overlooked older generations. Barriers particular to individuals with a SUD, followed by ethical considerations and possible resolution to these issues are also examined.
3ci. Death, Dying and Palliative Care

Addressing the issue of death, dying, and providing optimal palliative care for all patients – including those with SUDs – requires an examination of the evolving attitudes and behavior regarding death and dying. Technological innovations over the past few centuries have influenced the ways in which people in general have approached these issues, staving off the inevitability of death through the use of medicine and other modern treatment. While death is an incontrovertible biological and natural fact of life, as a social construct it is continuously changing. Such changes in how we comprehend death and our attitudes toward it coincide with the evolution of our life conditions in areas such as historical, social, economic, religious, political, and technological development. 78

French historian Philippe Ariès identified four periods of development post-Antiquity concerning the evolution of the understanding of death in common era Western Culture. Each of these periods influenced the way in which people discussed death, as well as how they handled it when it occurred. This varied from fully embracing death and a denial and fear of death. A period of time that death was not discussed and often hidden from sight the “forbidden death” period of time during the 19th and 20th centuries. 79 Others have expanded on his work to bring the analysis into the turn of the 21st century to present the “Spectacular death” time period, a period in which death, dying and mourning have increasingly become spectacles. 80 Clearly the way in which our society has changed over the course of time – increased medical knowledge, religious influx, changes in the family unit, the impact of pandemic disease, war and technological innovations – all have an influence on how we as a society understand and cope with death. With that, palliative care, hospice care and patient’s rights have become a compelling contemporary issue.
Caring for the dying has been part of a doctor's role for centuries. However, palliative and hospice care as we know it now is still relatively new and trying to define itself. Modern medicine introduced us to innovation in technology and treatment, which in turn gave us benefits such as a prolonged life span, but also gave us modern problems such as an increased likelihood for chronic and illnesses. As a result, over time emerged a movement towards the provision of medical services to address the consequences of living longer. The number of people suffering from chronic life altering and/or terminal illnesses looked to medicine to help them cope with the living and the dying aspects of their diseases.

The principles of palliative care include: a comprehensive and active approach to end-of-life care; the patient and family as the unit of care; improvement of quality of life and the promotion of dignity and effective and efficient care while responding to patients’ and families’ needs. Palliative care is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life. Palliative care services can be administered in a variety of settings, including the home, hospital beds, specialized units, outpatient clinics, (adult) day care centers, or bereavement services.

Despite the growing number of options related to palliative care both in the United States and globally, there are still gaps both in the amount of people who are and are not eligible palliative care, as well between those who can and are accessing and using it. One of the primary reasons for this is the variability in access due to geographic and other setting-related characteristics. Another barrier to access is the lack of adequate medical and nursing workforce with training and expertise in palliative care. There is also a lack of public awareness of what palliative care is and what services they provide.
Palliative care, hospice and its barriers do not end with these issues. There are particular populations of individuals that experience issues related to access based on certain health-related statuses that they live with currently or have lived with in the past, such as those with a substance used disorder. Their unique concerns require attention, so that they can be properly addressed. Individuals living with a SUD have their own obstacles to overcome related to utilizing palliative care services. Once providers understand and acknowledge that individuals with a SUD will patronize their services, they can then work to alleviate incongruencies of care. Lack of understanding of such issues can compromise palliative or hospice care for an individual with a SUD who is often under more scrutiny than other patients.

3cii. Enhancing Palliative Care for Individuals with a Substance Use Disorder

While the literature on ethical palliative care for individuals with a substance use disorder is scarce, there is a real need to address these concerns. However, in order to enhance palliative care for these individuals, the problem has to be addressed at multiple levels. Change at a societal level on the matter of death is necessary to assuage such fears and as Jacobsen asserts, is an emergent phenomenon. Studies on barriers to adequate end of life care not only highlight patient discomfort with having such conversations, but lack of understanding about what palliative care is, what the options are, access to such care as well as the lack of time afforded to clinicians to even attempt them. These concerns speak to other structural level issues that need to be addressed on this aspect of end-of-life care. Proper education of personnel on palliative care will prepare practitioners and other healthcare professionals to have conversations such as these with patients and their families. Such education should also include clinical ethicists, who may
be requested in assisting family members’ decision-making on palliative and hospice care.

Presenting with a substance use disorder makes any health-related decision more complex. Planning for palliative care as an IWSUD or as a family member of said individual is no exception. The barriers to ethical palliative care for this population not only include those previously discussed but are unique to individuals and populations affected by substance use disorders. This includes stigmatization and prejudice based on a highly stereotyped disease state. This often manifests in how such individuals are treated both in the health care system in general, but in palliative care as well. The barriers to ethical palliative care for individuals affected by substance use disorders are unique to this population. This includes stigmatization and prejudice based on a highly stereotyped disease state. This often manifests in how such individuals are treated both in the health care system in general, but in palliative care as well. This is especially true in marginalized populations such as the homeless, veterans, the LGBTQIA+ community and people of color.

There are also inadequate policies in pain management itself, let alone pain management in palliative and hospice care, to address the issue of how to safely treat chronic pain in individuals with an OUD. Methods such as pain management contracts which are punitive and discriminatory in nature, attempt to limit individuals access to highly addictive pain medications while creating an inherent lack of trust between the physician and patient while increasing the risk of misuse. Mitigation of this complex issue will require solutions at the structural and individual level. Addressing the stigmas related to SUDs will require an effort at a macro, educational and policy level. Updating healthcare curriculum to include more material related to SUDs as a disease, as well as their prevention, diagnosis and treatment will help create a stronger understanding of SUDs, and healthier perception of individuals who have them and/or are more susceptible to them.
As far as patient education regarding palliative care, stereotypes, and substance use disorder, one study suggested that having conversations with a “lay health advisor” or even just a neutral third party would assist families and individuals who have to decide regarding palliative care do so in a way that satisfies their desire to understand all of the options available to them. This introduced the possibility of bringing in “end of life doulas” who would not only be someone who can provide comfort for individuals who are dying and their families, but also be an advocate for patients with a SUD who may have unique needs and help relieve some of the moral distress that practitioners and families may be feeling. Small steps at the macro level such as these can be a catalyst for larger systemic change.

4. Global Ethical Issues of Substance Use Disorders

The introduction of new, stronger pain relievers such as Oxycontin and MS Contin in the 1990s helped ignite and fuel the ongoing opioid crisis affecting society on multiple levels. This – along with the push for pain as a fifth vital sign – helped usher in an epidemic that has led to a rising death rate and other co-morbidities related to misuse, abuse and addiction to prescription and non-prescription opioids. These problems, however, are not isolated to the United States - they have become a global phenomenon. Chronic pain has emerged as a global health issue and global bioethical problem.

4a. Chronic Pain and Substance Use Disorders

It is estimated that 20% of adults suffer from CP across the globe, with another estimated 10% newly diagnosed each year. The high prevalence of global chronic pain suggests that this is an issue that needs to be addressed – especially in light of the comorbidities that often accompany chronic pain, including (but not limited to) diabetes,
arthritis, depression, and asthma. It is important also to consider the impact of chronic pain on society, not only its impact on health systems, but economic systems as well. Here the dissertation will argue that pain needs to be considered a global public health priority.

4ai. Chronic Pain and OUD as Global Bioethical Problems

The WHO defines health as “A state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.” This includes freedom from pain. The International Association for the Study of Pain defines chronic pain (CP) as “any pain that persists or recurs for more than 3 months.” The WHO identifies chronic pain as one of the most significant causes of disability worldwide. Chronic pain impacts physiological, psychological, social and economic aspects of living. Physiological consequences include poor sleep function, cardiovascular diseases, sexual function, and neurological impairment. Psychologically, CP can lead to anxiety and depression. Social isolation and familial discord may also occur. Economic instability due to absenteeism and presenteeism related to CP is another consequence of the condition. The increase in prevalence of chronic pain and its undertreatment over the past several decades lead global health organizations such as the WHO and national health organization such as the American Pain Society to shift their views on pain management.

In 1986, Dr. Russell Portnoy and his mentor Kathy Foley published a paper suggesting that opiates were not inherently addictive; rather, their level of addictiveness depended on the individual to whom they were prescribed. This eventually led to the idea that opiates could be prescribed for non-cancer related pain - specifically chronic pain. A
campaign lead by the American Pain Society led to the Joint Commission on Accreditation of Healthcare Organizations (JCHAO) and the Veterans Health Administration (VHA) to adopt pain as the fifth vital sign and a measure upon which hospitals would be assessed. This led to a dramatic rise in the number of prescriptions for the potent opiate OxyContin worldwide. This increase coincides with an exponential rise in opioid related overdoses and deaths, as well as comorbidities related to injectable drug use such as HIV, HBV, and HCV.

An examination of chronic pain and the opioid epidemic as global biological problems requires an understanding of what a global problem is and what a bioethical problem is. It is also necessary to analyze specific qualities of what makes an issue a problem. According to ten Have referring to something as “global” requires us to acknowledge that boundaries are no longer clear. Global problems, however, have distinct features. They happen on a worldwide scale. They are not isolated to one region, and the effects are felt on a larger scale. They are interconnected in that one global issue is often associated with other(s), and it is difficult to try to alleviate one without addressing the other(s).

Global problems persist and require a long-term, sustained cooperation to create global solutions. They require a general scope that does not isolate the problem to certain people. When a problem is global, there is a need for global action – it cannot be solved by one organization or state. This requires collaboration, mutual respect, and a set of shared values. What makes a problem bioethical is if it has specific relevance and poses a normative challenge. That is, they have been recognized as having moral turpitude and create a desire for corrective action.
While it is important to discuss what makes problems global or bioethical, it is also necessary to analyze what makes a problem a problem in the first place. Three characteristics of problems are ambiguity, situation, and horizon. An issue is ambiguous when it lacks consensus. This results from a difference in context or situation. Bioethical problems require normative action on what should happen. However, this requires not only a consideration of the future, but reflections on the past. Problems are not only connected to future outcomes; they are based on actions from the past. By invoking this precedent-based approach for reflection, a horizon from which to conceive of issues as problematic is created.

4a1i. Global Bioethics: Theory, Practice and Solutions

According to the International Association for the Study of Pain (IASP), chronic pain is considered one of the most significant causes of disability worldwide. Its relationship to the opioid epidemic has been established; however, the opioid epidemic began as an American problem. Over the course of time since opioids became more readily available, countries like Canada, the UK, Spain parts of Africa and the Middle East have all seen a surge in opioid prescriptions, addictions and accidental deaths related to opioid use. Therefore, it is no longer an isolated problem. It has now taken on a worldwide scale.

Chronic pain is not an isolated issue. There are other problems that occur along with it that, without addressing, will only exacerbate the problem. By attempting to place a band aid on one problem (the pain) others cropped up (addiction, overdose related deaths, and increase in HIV and HCV/HBV). In this way both chronic pain and the result of its mismanagement (the opioid epidemic) are interconnected with other issues. While
Chronic pain may not be a new phenomenon, it has evolve(d) over time. Poverty and industrialization certainly contribute(d) to its occurrence, as do age and disease. Similarly, management of pain evolved over time from a very chary use of opiates for pain to a time where pain assessment became part of the way in which clinicians and hospitals were reimbursed. This led to a practice of catering to the patient with regards to chronic pain and pain management in many cases— the repercussions of which persist.

Chronic pain affects the population at various levels – from the individual suffering from it, their family friends and even coworkers. At a macro level it affects health care and economic systems on a community, state, and national scale. It is not isolated to a specific niche of people and has a general scope. This is also true of the opioid epidemic. It has moved beyond the individual with an OUD. It involves family, friends, coworkers, healthcare workers, law enforcement, the public and policy makers – not only in the United States, but abroad as well. It is not confined to a group or population of people.

The need for action is apparent with chronic pain and its unintended consequences. There is no one government or organization that can address either of these issues. Similarly, the opioid epidemic is multifaceted and requires collaboration between local, national, and international organizations. Governments alone cannot address this issue – it requires cooperation and consensus at all levels. Both chronic pain and the opioid epidemic also have specific relevance. These issues also pose a normative challenge.

Establishing these issues as a problem in and of themselves requires that they meet the requirements of ambiguity, situation, and horizon. In the case of the opioid
epidemic, there is no consensus on how to address the issue, and national and international policy regarding treatment and prevention is limited. Some nations adhere to a legal approach to addiction while others are taking to decriminalization and harm reduction measures. These criteria speak to the ambiguous nature of these problems. In bioethics, problems arise contextually. This is how a certain situation arises. Culturally based expectations and acceptance of pain as a normal part of living then determines whether that pain is considered a clinical issue that requires a clinical solution. There is no global consensus on how to address these issues, or that they are issues at all.

American Philosopher John Dewey considers problems forward-looking. However, it is also necessary to look backward in order to move forward. Antecedents – also known as precedents - need to be considered. These are events that provide the horizon by which we measure issues as problems. It is important to consider what preceded the rise in both chronic pain and the opioid epidemic to inform solutions and recognize future problems. Once chronic pain and the opioid epidemic are identified as global bioethical problems, the question of how to address the on a global scale remains. The United Nations Educational, Scientific and Cultural Organization (UNESCO) has been instrumental in creating a major development in global bioethics. A discussion of some of its principals in relation to chronic pain and the opioid epidemic, as well as an examination of the role of governance in their application is therefore necessary to considering how global bioethics can – in theory and in practice – help address these problems.

Of course, development of principles such as those in UNESCO’s Universal Declaration on Bioethics and Human Rights (UDBHR) is one thing, but their application
and enforcement is another. Without world government or political authority, it is difficult to envision how the ethical principles outlined in the UDBHR can be made meaningful. Global governance is defined as the “collective efforts of state and non-state actors to manage global problems.” Unlike ‘government’ – which applies to power, and authority given to states – ‘governance’ refers to these concepts at a global level. There is no director of these endeavors, which can complicate the execution of global action in a coordinated matter. In terms of CP, a lack of consensus on it as a disease - let alone a public health issue – creates a knowledge gap, which in turn creates a lack of agreement on how to handle it. As for the opioid crisis, some are hesitant to blame opioid use and misuse for the rise in opioid overdose deaths for fear of demonizing the positive aspects of their use. Doctors have also been sharply critical of the CDCs new guidelines regarding opioid prescribing, which they contend limit their ability to treat patients. According to The Commission on Global Governance of Health, global bioethics can play a vital role in developing new systems of global governance.

4b. Ethical Considerations in the Substance Use Disorder Treatment Industry

For as long as healthcare has been a commodity, those who saw an opportunity to make money off it have found ways to do so. From patent medicine to home health care scams, the propensity for people to benefit off the fears of others is nothing new. While the FDA and even the Department of Justice have stepped in at times to help quash such fraud, technological advancements, and the ingenuity of those running such programs has made them more difficult to detect and eradicate. The purpose of this section is to explore how the concepts of addiction, treatment and recovery have evolved over time, analyze what the current rates of SUDs are, what the current issues regarding fraud in the SUD
treatment industry are, ethical issues related to them, and how policy and organizational practices such as implementation science and quality improvement can act in accordance with organizational ethics and health policy to eliminate and deter such issues.

4bi. The Treatment and Recovery Industry: Historical and Contemporary Aspects

Drug use and addiction date back to ancient times. Archeological records show the presence of psychotropic plants and drug use in ancient civilizations as far back as early hominid species about 200 million years ago.\textsuperscript{113} However, the modern emergence of addiction medicine is often attributed to Calvinist theologians, who offered explanations for behaviors such as compulsive drinking. In the United States, Dr. Benjamin Rush is accredited with the development of the modern conception of alcohol addiction.\textsuperscript{114} He was the first physician to advocate for complete abstinence from any form of alcohol. He proposed a “multiple pathway” model for treatment that is not unlike modern models of treatment for substance use disorders, although some of his remedies would be considered highly unethical in today’s terms.\textsuperscript{115}

Other treatment methods emerged during this time. Abstinence only approaches such as that of temperance movement began to emerge in the 19\textsuperscript{th} century as well. Other methods were introduced into society to “cure” alcoholism around this time as well. These included reform clubs, inebriate asylums, sanitarias and cure centers that relied on proprietary home cures for relief. The lack of cohesion in methods led to the establishment the first professional organization for addiction treatment.

Focus on curing addiction then moved its gaze towards a growing problem: opiate addiction. Laudanum emerged as a popular cure all and the discovery of morphine made it a popular – albeit highly addictive – pain killer. Use of these drugs was open and
acceptable for the most part. However, cultural changes such as the influx of Chinese immigrants led to stigmatization and eventually criminalization of their use. Those suffering from opioid use disorder had some treatment available. However, these treatments were only administered in private practice, which alienated a large population of individuals with opiate addiction who could not afford them. Exclusivity in treatment was also prevalent for alcoholics. This phenomenon was only exacerbated by events in the 20th century such as the Harrison Tax Act, which helped change the landscape of addiction and addiction treatment.\textsuperscript{116}

Despite this, there were many types of treatments introduced in the early part of the 20th century, many of which were in response to ongoing and emerging addictions. At the turn of the century there was an attempt to create a vaccine for alcoholism. Treatment centers that used medicinal and behavior modifying treatment regimens for opioid and other addictions. Sterilization was also allowed by some states to curb alcoholism and other diseases. Morphine maintenance clinics briefly thrived in communities in response to the Harrison Act to treat morphine addiction. The Federal Government also became involved in addiction. The founding of Alcoholics Anonymous by Dr. Robert Smith and Bill Wilson in 1935, mutual support groups found themselves at the right place and time to grow exponentially and thrive.\textsuperscript{117}

During the latter part of the 20th century, policies such as were introduced that would go on to shape the future of diagnosis and treatment of addiction. In 1970, Comprehensive Drug Abuse Prevention and Control Act was signed into legislation relegating certain substances to schedules, classified by the potential for abuse and creating a new system for classifying and stigmatizing drug use. In 1987, the American
Medical Association passed legislation identifying alcoholism as a “complex disease that merited the serious concern of all members of the health profession.” The beginning of the 21st century is bringing changing attitudes towards certain types of drug use. The “War on Drugs” and “Just Say No” campaigns of the 1970s and 1980s are considered failures, and even politicians admitted illicit drug use at some point in their lives.

As society and technology progresses, science and clinicians are beginning to recognize both the ubiquitous and unique nature of addiction and are creating new theories and treatment models for addiction. Newer fields of study such as pharmacogenetics and pharmacogenomics may allow doctors to predict and more precisely prevent and treat such addictions. Such advancements cannot, however, prevent those who might benefit from heightened awareness of addictions from doing so. Promises. The scope of this is not limited to those who would sell counterfeit or tainted drugs – it has expanded to those promising addicted individuals and their families false hopes of recovery. According to recent data from National Institute on Drug Abuse, the drug and alcohol rehabilitation industry is a rapidly growing industry worth over 35 billion dollars a year in the United States. The industry currently lacks federal, state, and municipal oversight and regulation and therefore creates an environment where vulnerable people and families can be taken advantage of – much like the “snake oil” salesmen found throughout history. The current penal system is also not equipped to deal with opioid use disorders in a manner other than a criminal one – which not only exacerbates the courts but also perpetuates the cycle of use, overdose, and death.
An examination of ethical issues present in the treatment industry shows the unique issue present in these settings for IWSUD. If a patient is going into a treatment without a full understanding of the benefits of said treatment, it is not considered informed consent by Beauchamp and Childress’ definition and therefore respect for autonomy is not in adherence. With regards to beneficence in these cases, the treatment given in a treatment facility of sober living home should be beneficial to the patient; otherwise, it is unethical. Nonmaleficence requires that providers “do no harm” or inflict the least amount of harm possible to their patients. This is incompatible with a system that knowingly takes advantage of individuals who are suffering from a SUD who likely do not understand how to navigate the system and who may be unfamiliar with the benefits of evidence-based practices versus other types of treatment. Justice requires equitable access to treatment, as well as equitable forms of treatment. Although the Mental Health Parity and Addiction Equity Act, paired with the Affordable Care Act (ACA) made it easier for people with insurance to get treatment for mental health and substance use disorders, it leaves part of the population without insurance to go without (often costly) treatments.

These concerns also apply to those going through the U.S criminal justice system. Many rights of prisoners are stripped upon entrance into the penal system – the greatest of which is autonomy. There are often limited options for proper detox or MAT, and treatment choices “offered” to inmates is limited. What is offered is often mandated and limited to what the county or state offers. This begs an analysis of ethical versus unethical
treatment of prisoners in jails, prison, and drug court situations. There has to be a standard of care for everyone in the justice system – which is currently lacking.\textsuperscript{124}

The lack of oversight in sober living homes, treatment centers and drug courts, as well as the lack of consistent access to evidence-based treatment in the U.S. criminal justice system lends itself to the need for laws and regulations to be implemented to address these inconsistencies. There are some practical ways in which these issues can be addressed. These include policy changes – both at the federal and states level – as well as the use of methods for improvement within treatment centers that already exist. Implementation science, quality improvement and regulation are but a minor but necessary step towards improving the lives of people seeking recovery.

In 2017, the President's Commission on Combatting Drug Addiction and the Opioid Crisis published a report with 56 recommendations on how to address the current public health issue surrounding opioid use and misuse.\textsuperscript{125} This included policy recommendations that addressed concerns about regulation and reimbursement of evidence-based programs for SUD treatment, as well as the need to address personal and societal biases towards individuals with a SUD. It also addressed the need for MAT in the criminal justice system – in drug courts, pre-trial, during incarceration and afterwards.\textsuperscript{126} Some states are getting ahead of federal legislation and doing this on their own, while others are addressing legislation related to sober living homes, which were left out of the report.\textsuperscript{127}

Other micro level practices can have an impact on the experiences and outcomes of patients seeking SUD treatment. Research has shown that evidence-based approaches to substance use disorder treatment such as pharmacological therapies (such as MAT)
psychosocial therapies (such as cognitive behavioral therapy or CBT) and/or integrated therapies for people with co-occurring disorders have positive effects on substance use disorder and problems associated with it.\textsuperscript{128} Despite the evidence to support their use, integration of such therapies into community settings lags behind the science. Implementation science uses a variety of conceptual approaches and scientific data to not only implement certain treatment settings and evaluate their effectiveness, but to also examine the providers, organizations and systems within which a recipient receives treatment to see what areas may require improvement.\textsuperscript{129} Progress in this area will allow implementation researchers to address some of the ethical issues that have emerged at all levels, and possibly prevent them from ever occurring in the first place. Application of this and other continuous quality improvement methods to places integrating evidence-based practices into their treatment centers, drug court practices and correctional facilities may benefit from doing so and see better overall outcomes for individuals with a SUD.

4c. Ethical Concerns in Research on Subject with a Substance Use Disorder

Clinical trials are also an essential element of the healthcare process. Knowledge gained from clinical research allows researchers to not only develop screening and diagnosing tools, interventions for the treatment and prevention of disease it also generates understanding and appreciation of the unique experiences of subjects. One of the biggest obstacles to clinical trials is getting people to participate. In many clinical trials, incentives are offered to induce participation. There is an ongoing debate as to the ethical nature of offering incentives in exchange for participation in clinical research. However, with the rise in OUD over the past decade, there is a heightened sense of urgency in research on interventions for those with an OUD. These and other related
studies necessitate individuals with an OUD and/or another substance use disorder. This development has elicited ethical concerns about research on this population. The analysis examines an ethical approach specific to human subjects research and ethical concerns surrounding the use of incentives, with particular attention paid to vulnerable populations such as those with a SUD. Potential solutions to concerns surrounding the inclusion of individuals with a SUD and suggestions for future research will also be explored and discussed.

4ci. Ethical Considerations in Human Subject Research

Research whose aim is gain knowledge for the purpose of improving health and the individual and structural level needs to consider the ethical challenges inherent with doing so on other human beings. The primary concern of contemporary researchers and ethicists is that such research is done in such a way as to avoid exploitation and minimize risks. Traditional Western bioethics often measures ethical standards using the four-principal approach popularized by the work of Beauchamp and Childress. Ezekiel Emanuel et al introduced a more comprehensive approach for use in assessing the ethical nature of clinical research. This approach is helpful when discussing elements of research that are considered controversial yet often necessary, such as the use of incentives.

Autonomy/respect for persons, beneficence/nonmaleficence and the principle of justice are the pillars of (western) bioethical thought. However, as Emanuel et al. point out, existing guidelines are flawed. They are often reactionary in nature, with a focus on recent transgressions then an exhaustive examination of potential ethical problems. They are also myopic and reductive in nature, often deferring to other broader guidelines for direction. Emanuel at al. also argue such guidelines suppress the contributions of
large portions of the population such as pediatric patients. In order to address these deficiencies, Emanuel presents a more comprehensive approach to guide the ethical conduct of clinical research. Following these eight principles helps minimize the possibility of exploitation, simplifies identification and assessment of problems, and may assist in the creation of possible solutions. Each principle has benchmarks that elucidate each principle, along with practical considerations. These principles include the requirement for a collaborative partnership; social value derived from clinical research; scientific validity in data provided; Fair participant selection to minimize exploitation; a favorable risk-benefit ratio to participants and partners; independent review of the research; a rigorous informed consent process and respect for persons throughout.

Clinical research relies on the voluntariness of human subjects to participate, as well as a respect for and adherence to all principles of research ethics throughout the process. Once the Institutional Review Board (IRB) or other appropriate governing body has properly approved the research protocol and design, the practical aspects of research must begin - starting with the recruitment process. Successful recruitment of participants is one of the singular most daunting parts of clinical research. Many studies do not meet their recruitment goals, for many reasons. Incentives are often used to entice people to participate, and research supports their effectiveness. Although incentives come in many forms, analyses show that money is more effective than non-monetary incentives as an inducement to participate. This finding is also true in clinical research settings. Although this is practice is ubiquitous throughout clinical research, the ethicality of it remains a topic of controversy.
Proponents of providing financial incentives for individuals taking part in clinical research cite the need to boost the number of individuals who participate in trials as one reason. Payments are also seen as a way to provide a fair share to the benefits for the risk of sharing personal health data for which they are being paid. Some proponents also see financial payments as one form of appreciation given to participants for their involvement in the research. Another thing to consider is that for some populations, the provision of no incentives or non-monetary incentives further stigmatizes and reinforces economic disadvantages, which violates the principle of respect for persons.

Opponents of offering payment to individuals in exchange for their participation in research trials contend that it has the potential to be coercive and/or cause undue inducement to participate. Most agree that offering payment for research is not coercive, because no one is threatening individuals with harm by offering them financial incentives. There are concerns about the threshold for what constitutes inducements as undue – and as of now there is no consensus. Generally speaking, for an inducement be considered “undue,” and therefore ethically problematic, payment must be large enough to induce a person to take risks they would not accept with a smaller payment. Opponents of financial incentives also highlight the possibility of exploitation and biased enrollment.

These considerations are especially important when considering research on vulnerable populations. Vulnerable is forthwith defined as membership in a population that is susceptible to receiving injuries; open to attack or damage; and/or capable of being physically or emotionally wounded. Vulnerability applies not only to individuals, but to groups, communities, and countries. Such populations were at the forefront in the
creation of major ethical guidelines such as the Nuremberg Codes, the Belmont Report, and the Declaration of Helsinki. Therefore, special care must be taken with regards to research conducted on those who fall into this category. One group in particular raises concerns about research participation on account of their vulnerability: individuals with SUD(s). Not only is there controversy surrounding their inclusion in clinical studies, but ethical considerations about the impact of the use of incentives in this population is of particular interest to ethicists and researchers because of the unique impact it can have on the individual and overall research outcomes.

One of the foremost are the ethical issues in obtaining informed consent. Some insist that individuals with a SUD are incapable of making free and autonomous choices about participation in research studies. Others suggest that only those who have entered or intend to enter treatment have the capacity to freely consent to participate. That viewpoint assumes abstinence is the only competent choice and that treatment is voluntary. Other ethical considerations regarding capacity in individuals with SUDs focus on two issues: concerns surround the effects of intoxication on consent and that consequences of long-term drug use on cognitive skills may limit understanding necessary for proper informed consent.

Individuals with and SUD may engage in illegal activities during the course of studies, which leads to concern about privacy and confidentiality. Some study participants may face criminal charges if research data was linked to individuals by law enforcement. The principle of respect for participants requires that confidentiality procedures be put in place to protect privacy. Other privacy concerns include the use of geospatial mapping in data collection about “hot spots” for illicit drug use, which may
not only risk confidentiality concerns, but expose researchers and participant to undue harm. Concerns also exist about the effect of interview or survey research on vulnerable populations like those with a SUD, who may have lived experiences marked by violence and abuse. The assumption is that by investigating the personal histories of those with a SUD, researchers are “re-traumatizing” or “re-victimizing” them, therefore inflicting undue harm and violating the favorable risk-benefit ratio principle. This assumption is persistent, despite research that suggests that those who have experienced past trauma(s) may find talking through such experiences as beneficial and cathartic.

One of the most pervasive concerns with having individuals with a SUD in clinical research is the ethicality of providing financial incentives for their participation. The success of monetary incentives is established, and the concern about the influence of undue inducement on informed consent well-documented. However, there is a stronger reluctance to use them in this particular population because of the belief that financial incentives will be used to purchase drugs, alcohol or other illicit items which may put the subject at further risk of harm. While some studies suggest there is a relationship between financial payments and drug use, the only controlled study on the matter found that neither the means of payment nor the amount had any significant effect on drug use. Despite the existence of research that refutes held beliefs about capacity, informed consent, participation-induced re-traumatization and the influence of financial incentives, apprehension and uncertainty still exists with regards to this particular population.

4cii. Solutions and Suggestions for Future Research

Growing evidence shows that subjects with a SUD not only engage in research for reasons similar to the general population, they also generally use monetary and other
incentives in a responsible manner. Despite this knowledge, controversy surrounding the practice of providing them with monetary incentives still exists.\textsuperscript{150} Stigmas attached to SUDs have historically impeded engagement with healthcare providers, including those conducting clinical research.\textsuperscript{151} Therefore, it is necessary to educate and train providers to reduce stigma at the individual and structural level.

Stangl et. al have developed what is known as the \textit{Health Stigma and Discrimination Framework}, which is intended to be a “broad, orienting” approach to enable interdisciplinary researcher to standardize measures of stigma, compare outcomes and create more effective interventions for multiple health issues.\textsuperscript{152} Unlike other interventions, its focus is on the stigmatization process as it occurs across the socio-ecological spectrum, which varies across economic contexts – meaning it’s applicable to low, middle and high income countries.\textsuperscript{153} This differs from other interventions which have often been used in primarily high-income countries.\textsuperscript{154} The goal of this approach is for practical application to address not only historically stigmatized conditions such as SUDs, but the intersectionality of certain diseases and other statuses that conflate a number of health-related issues, including those found in designing and conducting clinical research.\textsuperscript{155} However, stigma reducing interventions are not the only way in which clinical research can promote the inclusion of individuals with a SUD and alleviate health-related stigma present in the designing and implementation process.

Harm reduction refers to interventions that are aimed at reducing problematic health-related behaviors. The harm reduction model is not exclusive to substance use disorders, even though its roots in the United States extend as far back as the 1900s when narcotics maintenance clinics were available.\textsuperscript{156} It is also the goal of those in harm
reduction that such principles become incorporated into standard practice of all healthcare providers – not just those who engage with populations that with to improve the health outcomes of their patients.157 Hawk et. al conducted research using mixed methods on an HIV clinic providing harm reduction-informed services.158 Interview with patients and staff yielded qualitative data which was then used to refine harm reduction concepts and develop harm reduction principles that can be generalized to other healthcare settings. These principles include humanism, pragmatism, individualism, autonomy, incrementalism, and accountability without termination.159

On its surface it may not seem like harm reduction principles (HRP) are applicable to clinical research, but a consideration of some of the barriers to participation and retention clarify the potential for their adaptation and incorporation into research design and practice. Actions such as properly tailoring the informed consent and withdrawal process to the needs of the individual; being pragmatic about consumption of substances; withholding judgement and punishment; understanding the nature of substance use and the benefits of participation regardless of the status of the research subject are all ways in which harm reduction principles can be used to create an equal research environment and potentially elicit unique results about the interactions and reactions lost in studies that disqualify substance users.

There is a paucity of qualitative data on stakeholder perceptions regarding the inclusion of individuals with substance use disorder in clinical research, aside from those that focus on providers and stigma.160 There is an equally limited amount of research available regarding the perceptions of research designers and other persons of power in clinical research on the inclusion of financial incentives. Qualitative research offers
insight into human thoughts, feelings and behavior that are lost in survey research methods.\textsuperscript{161} If we want to learn more about why individuals in positions of power in clinical research are apprehensive about providing financial incentives to individuals with a SUD and how their attitudes might be changed on the matter, it is important to conduct in-depth research that qualitative methods afford.

Such research can also contribute to the further development of the \textit{Health Stigma and Discrimination Framework} developed by Stangl and her colleagues by not only exploring where these attitudes stem from in these particular settings and in these particular individuals, but by also allowing for an assessment of various stigma reduction interventions in various professional environments. This data can then be used to help intervention designers assess, create, and improve upon available stigma interventions and inform proponents of the Health Stigma and Discrimination framework in development of practical ways to intervene and reduce or eliminate such stigma before it starts. An even bigger benefit is that this research can inform interventions for other highly stigmatized populations as well.\textsuperscript{162}

5. Conclusion

The purpose of this dissertation is to examine issues individuals with substance use disorders may encounter across their lifetime. This is done from the perspective of public health ethics. The current opioid crisis is introduced in detail, along with a discussion of drug use and drug policies in the United States, which is examined from an historical and public health perspective. Legal regulation of drug use has, through the course of history, created and perpetuated stigma against individuals who engage in it. In the past, legislation helped criminalize the use of substances which for some were
intended for symptomatic relief. Those who developed a substance use disorder, such as an opioid use disorder, were then left to relieve their pain and other symptoms by illegal means. This is where public health ethics can be used as a means to address the issue properly, on a larger, macro scale as opposed to the more traditional micro lens that other fields of ethics tend to use as a focal point.

Ethical concerns related to consent and cultural competency in the context of public health are also explored. This expands to include issues specific to different parts of the lifespan of an individual with a substance use disorder (SUD). The health of pregnant individuals with a SUD (specifically OUD) and ethical concerns related to perinatal health and the health of their infants are also explored. The unique issues related to being pregnant and having an opioid use disorder necessarily dictate the type of care one will seek out and receive. The lack of resources available to address these unique and complex needs will of course influence parental and fetal outcomes.

The power and influence of genetics on individuals with a SUD and their families is also discussed. Having access to our genetic makeup is both intriguing and intimidating. Much of what this type of information can do for individuals and families is unknown. For individuals with a stigmatized disorder such as a SUD, discovery of our human blueprint may have consequences that have not been considered before. It will be important moving forward to consider not only the ethical concerns related to gene therapy and SUDs, but legal and social ramifications of genetic exploration as well.

Inequities in end-of-life care for these individuals also sheds light on some of the areas where ethics can assist healthcare practitioners in the creation of a “better” or “good” death for all, regardless of disease state. Again, stigmas related to substance use
disorder create barriers in treatment and care in palliative care and hospice settings. These concerns aren’t limited to the United States, however. These are often addressed on a global scale to explore how other municipalities, countries, global and non-governmental organizations are tackling the issue of substance use disorders on a broad scale. This includes the aforementioned issues related to genetics, maternal health, end of life care, legal ramifications of substance use, as well as the use of individuals with a SUD in human subjects research. The concern related to human subjects research is primarily focused on the issues of consent, vulnerability, and the use of incentives.

Possible solutions to these issues all involve change from macro and micro levels. Changes in local and state policies (including those hospitals, local health systems, municipalities, institutional review boards and other organizations that interact with or affect the population of individuals with substance use disorders) may, as we have seen in the past, open doors, and minds for policies at the federal level that can impact the outcomes of individuals with a SUD. On a global scale, countries are changing their mind about the criminalization of substance use. Organizations such as Amnesty International are trying to influence policy makers to rewrite the penal code on substance use during pregnancy, for instance, allowing for pregnant persons with an SUD to get help through medical channels instead of criminal ones. Larger initiatives like these will necessarily influence the way in which healthcare workers practice with their patients and in turn can also influence public perceptions and reduce stigma.

Looking at the experiences of individuals with substance use disorders via these vignettes over the lifespan allows a broad look at the ways in which public health ethics can have an impact on the way societies approach stigmatized health conditions. If public
health ethics can have an influence on how individuals with substance use disorders are treated in healthcare and beyond, surely its potential is only limited to whatever marginalized population it has not considered.

4 Golding, Nicholas "The Needle and the Damage Done," 174-219
16 Global Commission on Drug Policy. "War on Drugs", 1-20
22 Beauchamp and Childress, Principles of Biomedical Ethics, 121-123.
23 Beauchamp and Childress, Principles of Biomedical Ethics, 121-2;131.
24 Beauchamp and Childress, Principles of Biomedical Ethics, 121-123;130-131.
25 Beauchamp and Childress, Principles of Biomedical Ethics, 122-23

Beauchamp and Childress, *Principles of Biomedical Ethics,* 117-119.

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Chapter 2: Public Health Ethics as the Context for Substance Use Disorder

Currently, the United States is experiencing what has been termed the “Opioid Crisis.” This is the result of years of misinformation and mishandling of strong pharmaceutical painkillers. To address this issue from a public health standpoint, it is essential to not only understand the history and effects of this crisis, but to also understand how the United States and other countries view drug use and abuse, the ethical considerations surrounding it and future implication this crisis may have on those suffering from opioid use disorder and society as a whole. This chapter will explore the evolution of this crisis and its repercussions, as well as the progression of drug regulation in the United States. It will also look at current drug policies in the United States and examine what other countries are doing to address similar substance use disorder issues. Ethical considerations and future implications will also be examined and analyzed.

2a. The Opioid Epidemic as a Public Health Crisis

On October 26th of 2017, President Donald Trump called for Secretary of the Department of Health and Human Services (HHS) to call for a Public Health Emergency – referencing the growing amount of people across the United States who were affected by the use of opioid painkillers.\(^1\) From 1990 to 2010, the amount of highly addictive painkillers such as OxyContin sent to hospitals, clinics and pharmacies quadrupled.\(^2\) Currently, according to the CDC, an estimated 142 people in the United States die each day from a drug-related overdose.\(^3\) Over the course of 16 years, an estimated 560,000 deaths attribute to drug overdose. That is quadruple the amount since 1999. Roughly two-thirds of these deaths can be linked to the use of opiates like Oxycontin, Percodan, heroin, and fentanyl.\(^4\)
Opioid abuse is not new in American history. In the latter half of the 19th century, an epidemic like the one currently sweeping across the United States took hold. Over the course of 50 years (1840s to the 1890s) opioid consumption skyrocketed 538%. This was a result of a lack of resources for symptomatic treatment for ailments such as diarrhea, hangovers, work injuries or chronic pain. Patent medicines containing opium and morphine were marketed to treat these and other common ailments, and sales were poorly regulated. The introduction of injectable morphine only exacerbated the problem. However, advances in bacteriology and public health helped reduce diseases associated with opium use. The combination of new analgesics, stricter laws on prescribing and literature admonishing the use of morphine by physicians curtailed this epidemic. The use of opioids in pain management slowly became taboo – especially after the Harrison Tax Act of 1914 criminalized the prescription of opiates to addicts.

Fast forward to 1952, where brothers Arthur, Mortimer and Raymond Sackler purchase a small patent-medicine company known then as Purdue Frederick. By the late 1950s – after several years of profiting off the sale of drugs with questionable efficacy and dangerous side effects – pharmaceutical companies such as theirs came under scrutiny for their unscrupulous acts. In 1962, the Kefauver-Harris Act was signed into law, curbing these practices, and requiring clinical trials, patents and proof of safety and efficacy of any pharmaceutical released on the market. After then, and until 1984, Purdue Frederick was more well-known for over-the-counter medications such as laxatives and antiseptics. Up until that time, Arthur Sackler was using his marketing skills to sell drugs such as Valium and Librium. In fact, his skills helped make Valium the first 100-million-dollar drug. By the 1980s, the attitude towards the use of opioids for pain management
was changing in favor of their use – largely because of a paper published in 1986 which suggested addiction was dependent on the individual, not the drug. Therefore, opiates could be safely prescribed on a long-term basis – if there is no history of a substance use disorder.\textsuperscript{11} As a result, companies like Purdue sought to patent and market drugs for such use. In 1984, they released the drug MS Contin for use in cancer patients. Later, as its patent came close to expiring, Purdue developed OxyContin, a time released version of the drug oxycodone for use in moderate to severe pain, which was released in 1996.\textsuperscript{12}

Like the unscrupulous methods Arthur Sackler used in the 1950s and 1960s with other medications, marketing for OxyContin was no different. The sales campaign by Purdue broke records – in sales, bonus amounts, and the amount of people employed as pharmaceutical representatives. In 1995 there were a recorded 35,000 Americans employed as pharmaceutical reps. By 2005 the number nearly tripled to 110,000.\textsuperscript{13} They infiltrated not only physicians’ offices, but also nursing homes, hospitals, and pharmacies – touting its benefits for pain management, as well as the low incidence of addiction (a “mere” 1%). Purdue Pharma also sponsored over 20,000 continuing education seminars promoting the use of opioids for pain management, again claiming a low incidence of addiction.\textsuperscript{14} Also around the time OxyContin was released, a movement towards treating pain as another vital sign had already begun to emerge, and by 1998, agencies such as the VHA and the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) designated pain as the “fifth vital sign.”\textsuperscript{15} Fueled by data from reports that assured medical practitioners that addiction from the use of opioids was negligible, the prescription of opioids grew exponentially. In fact, the number of opioid prescriptions written for patients with chronic pain rose from 670,000 in 1997 to over 2 million 5 years
later and quadrupled for patients using it for cancer pain (250,000 to 1 million over 5 years). Some of this was due, in part, to the introduction of prescription writing schemes known as “pill mills.”

Roughly the same year that Purdue began marketing OxyContin, what are known as “pill mills” began to show up communities like South Shore, Kentucky. Doctors like David Procter (an early proponent of opioid use for pain management) saw an opportunity to profit off prescribing opiates such as Vicodin, Lortab and - upon its release into the market, OxyContin - to patients who may not have actually needed such strong pain medications. Once the patients became addicted, these clinics would then sell prescriptions for cash. When patients could no longer afford their medications, or they were unable to obtain the drug, they began to search for cheaper alternatives, such as heroin – which is strikingly similar to OxyContin in chemical structure.

This pattern of drug seeking behavior directly led to the gradual and continuing rise in heroin use. Unlike the previous heroin epidemic that emerged in the 1960s, where a majority (80%) cite heroin as their initial opioid of choice, 75% of those currently entering treatment state that they started out on prescription painkillers before moving on to heroin, saying it was cheaper and easier to obtain. The introduction of black tar heroin into mid-size cities by cells of dealers from a small town in Mexico fueled the rise in heroin users and heroin overdose deaths. Dealers from Xalisco, a town in the state of Nayarit, Mexico sought to expand their market from the San Fernando Valley part of Los Angeles to towns further east. This expansion coincided with the rise in opioid addiction. The black tar heroin the Xalisco dealers brought in was cheap, and more
potent. Their method of delivery (likened to a “pizza delivery” type operation) made it easier obtain and harder to get caught.21

Because of these operations, the number of heroin users began to grow exponentially. From 2002 to 2016, the number of users jumped 135% - from 404,000 to 938,000. Heroin overdoses and overdose deaths are also on the rise. In fact, over the course of 6 years (2010-2016) the CDC reported a five-fold increase in heroin-related deaths.22 Unfamiliarity with the effects of illicit substances such as heroin often results in overdoses, but a growing number of cases of heroin overdoses and overdose deaths involve the introduction of other harmful substances without knowledge of the user. Synthetic forms of fentanyl – another prescription pain killer typically used for cancer-related pain – are now found in up to 50% of overdose deaths. The trajectory or deaths related to prescription fentanyl began to rise sharply in 2013, however, the most commonly found fentanyl “analogs” such as carfentanil, furanylfentanyl, and acetylfentanyl are illicitly made and more potent than prescription fentanyl.23 This has the potential to have a significant impact on the number of overdoses and overdose related deaths.

Another pattern began to emerge because of this increase in opioid use. The number of newly diagnosed HIV positive patients began to rise. After 25 years of decline in new cases of HIV attributed to injectable drug use (IDU) – from an estimated 40% in 1990 to 6% in 2015 – a spike in the number of cases emerged. This change was largely associated with the increase in cases found in Scott County, Indiana. In previous years, the county averaged 5 new infections per year. In 2015, 181 residents were newly diagnosed, 80 percent of which were from the town of Austin, Indiana.24 Although the
overall change in new cases was only 243 over the course of one year, the fact that there was an increase after decades of decline is concerning to those in the field of HIV/AIDS prevention and treatment, as the trend is starting to show up in other areas as well. For instance, in 2017 the Northern Kentucky Health department reported 18 new cases of HIV where IDU was indicated as a risk factor. That is at a minimum 3 times the average number of cases reported from 2009 to 2016 (0 to 5 per year). Cincinnati, Ohio reported a 40% higher rate of HIV positive individuals from 2016 to 2017, with a 250% rise in cases associated with IDUs.25

Health officials correlate these recent outbreaks with the current opioid epidemic.26 Individuals with an opioid use disorder often grind up the pills to be used for injection, as this method of use introduces the blood directly into the bloodstream – causing a quicker and stronger high. The same is true for the black tar and powdered heroin that so many with OUDs now use. Because possession of syringes without a prescription (either for a legal injectable drug or for the needles themselves) illegal drug users often share needles. This increases to risk of HIV. In fact, those who inject illicit substances are 28 times more at risk for HIV because of the practice of sharing needles.27 A recent study of cities where the rate of HIV was high showed that 40% reported sharing needles. However, there are other factors that put IDUs at risk for an HIV diagnosis. Research also shows a positive relationship between substance use and risky behavior such as unprotected sex. This intersection between sexuality and IDU is important to consider with regards to HIV rates, as gay and bisexual male IDUs are disproportionately affected by HIV/AIDS.28
The outbreak in Scott County, Indiana also showed another alarming trend: the rise of hepatitis C infections. Like HIV, the hepatitis C virus (HCV) is spread through the use of infected items such as needles used to inject drugs and less commonly through the use of personal items of those infected (i.e., toothbrushes). HCV causes damage to the liver, including cirrhosis and in some cases liver cancer. Prior to the recent surge in cases, baby boomers – those born between 1945-1965 were considered the most susceptible population, because, according to the CDC, many of them may have contracted it during the 70s and 80s, when standards for infection control were not what we have today. Plus, Hepatitis C was not discovered until 1989, and screening for it did not begin until the early 90s. In recent years, however, the face of those contracting HCV has changed.

In the case of Scott County, Indiana, the outbreak of HIV turned into one of co-morbidity, as 92% of those who had tested positive for HIV also tested positive for HCV. Nationwide, over the course of 10 years (2004 to 2014) the CDC also noticed a rise in cases of HCV. Among 18–29-year-olds, a 400% rise in diagnosed cases. In fact, diagnosis for those under the age of 30 accounted for 45% of new cases of HCV from 2006 to 2012. Among the 30- to 39-year-olds diagnosed, a 325% rise in cases was found. These both occurred concomitantly with a rise in opioid injections: 625% and 83% respectively. The HCV outbreak has also affected two other groups disproportionately: women and white Americans. From 2004 to 2014, HCV diagnoses increased 250%, while the rate of opioid injection rose 99%. In the same time period, HCV diagnosis in white Americans increased 300% with a 134% rise in opioid injection.
The data on HIV and HCV infection rates suggests that the rise in new cases of each can be associated with the national opioid epidemic. Increases in the number of IDUs injecting heroin and POAs is undermining efforts to minimize the morbidity and mortality associated with each disease. To address this issue, it is therefore necessary to understand what social and legal policies are in place that thwart these efforts. Criminalization of drug use is often cited as a catalyst for risky illicit drug use. Laws enacted over the course of centuries serve not only to demonize drug users, but as the statistics on HIV and HCV show, also proliferate unforeseen consequences.

2ai. Public Health and the War on Drugs

There is an ongoing stigma surrounding the use and abuse of illegal and certain legal types of medications in the United States – especially those with the potential for abuse. It is thought by many that if the United States and other countries can change the way in which drug use and abuse is viewed – not only by the public, but from a policy perspective as well – substance use disorders will be easier to treat and eradicate. An examination of the history of federal drug regulation (especially those Acts pertinent to this dissertation), an analysis some of the effects of these laws, and a discussion of current international practices helps to illustrate the possibility of changing how society views substance use and substance use disorders.

Prior to 1820, there was lack in standardization of medical practices – especially surrounding pharmaceuticals. Use of patent medicine was especially popular during this time. These medicines were touted as panaceas, but evidence of their efficacy did not exist (nor was it legally required). The American Medical Association (AMA) did not exist to help regulate the development of medicine. To create uniformity of medical
standards, the United States Pharmacopeia (USP) was established.\textsuperscript{41} Eleven doctors came together at a conference to establish standards for preparing and dispensing medications, including what medications should be used for, as well as dosing schedules and other pertinent information.\textsuperscript{42} A couple of decades later, in 1847, the AMA was established to aid in the protection of patients from the “quack” medicine of patent drugs, and better educational standards for and stricter licensing of physicians nationally.\textsuperscript{43} The establishment of the AMA allowed physicians to draw a consensus on what “real” medicine was, as opposed to some of the pseudoscience that proliferated society at the time. The influence of physicians who were part of the AMA (specifically those in New York, which was the port of entry for most medicines at the time) led to the lobbying for and passage of one of the first prominent pieces of legislation regulating pharmaceutical – the Drug Importation Act of 1848. This bill requires U.S. customs to inspect drugs imported from other countries to stop low quality drugs from coming into the U.S.\textsuperscript{44}

Perhaps one of the most important pieces of legislation – the 1906 Food and Drug Act or Wiley Act – was passed just a year later. Spurned by the contributions of the chief chemist at the Bureau of Chemistry’s adulteration studies Harvey Wiley, its main purpose was to ban international and interstate trafficking of adulterated and mislabeled food, drinks, and drugs. It also established an administration to oversee its enforcement – the Food, Drug, and Insecticide Administration (now known as the FDA).\textsuperscript{45} It was updated in 1938, following the deaths of 107 people (many of them children) after ingestion of a drug known as Elixir Sulfanilamide. This incident emphasized the need to address drug safety prior to hitting the market.\textsuperscript{46} It changed how drugs were regulated from then on, requiring proof of safety before selling, and began the requirement for prescriptions for
certain non-narcotic medications. The Durham-Humphrey Amendment (1951) further defined what drugs required medical supervision to be dispensed.\textsuperscript{47}

Over the course of the next 20 years, a rise in the abuse of marijuana, barbiturates and amphetamines caused more regulatory concern by the FDA. The Smoking Opium Exclusion Act of 1909 banned the possession, importation and use of opium for recreational use, although it could still be prescribed by a physician.\textsuperscript{48} Shortly thereafter, the Harrison Tax Act of 1914 was passed. This legislation gave the federal government the power to regulate the prescription of narcotics (cocaine and opiates) “in the course of their professional practice.”\textsuperscript{49} However, it only moved the demand for such drugs out of the doctor’s office and into the black market. Later, in the 1920s, Prohibition enforcement became tied to narcotics enforcement, and the Federal Bureau of Narcotics (FBN) was created to centralize narcotics enforcement. The passage of the Marihuana Tax Act of 1937 further criminalized recreational drug use. Until that point, marijuana was legal to grow and use.\textsuperscript{50}

Towards the Mid-20\textsuperscript{th} century, Congress passed more laws further criminalized drug use. The Boggs Act of 1951 later established mandatory sentences for certain drug offenses, and the 1956 Narcotic Control Act increased penalties related to their use, including the use of the death penalty in certain instances.\textsuperscript{51} Shifts in the attitudes from punishment for substance use began to emerge around this time. Enforcement of laws continued but support for severe punishment began to wane in the early 1960s. The medical approach to treatment of substance use disorders increased in popularity, as organizations such as the American Bar Association called for federal support of such an approach.\textsuperscript{52} The 1963 Presidential Commission wrote a report recommending relaxed
punishment for drug offenses, increased funding for narcotic research, as well as the
dismantling of the FBN. As a result, the Bureau of Drug Abuse Control was created, and
in 1968 merged with and eliminated the FBN.\textsuperscript{53} The end of the 1960s saw a rise in
substance abuse, particularly with heroin. As a result, President Richard Nixon made it a
point to focus much of his presidency reducing the incidence of drug use. As a result, he
heavily supported the passage of comprehensive drug laws.\textsuperscript{54}

In 1970, Congress passed a more comprehensive law known as the Controlled
Substances Act (CSA).\textsuperscript{55} This law replaced all previous laws on substance use and
categorized drugs into “schedules” – which place drugs into certain categories or
schedules of drugs depending on the establishment of therapeutic value, and potential for
abuse and addiction. Schedule 1 drugs are considered illegal (i.e., heroin, LSD) while
schedule 5 drugs are controlled substances with the least potential for abuse (i.e., Lyrica,
Lomotil). If no potential for abuse exists, drugs are considered “legend” drugs.\textsuperscript{56} This law
also led President Nixon to later establish the DEA in 1973, which established a more
centralized organization whose main purpose is to enforce the CSA at the federal level.

The regulation of drug over the 1990s and early 2000s focused more on concern
over synthetic drugs. Synthetic drugs are chemically produced in a laboratory, and when
produced clandestinely, do not typically have a legitimate, medical use.\textsuperscript{57} The fall in use
of cocaine and the increasing popularity of synthetic drugs such as methamphetamines
and MDMA (ecstasy) ushered in laws regulating manufacturing and use. The
Comprehensive Methamphetamine Control Act of 1996 (MCA) and The Illicit Drug
Anti-Proliferation Act of 2003 were passed to address the rise more specifically in their
use and established stronger civil penalties for establishing places where drug use occurs
(such as “raves”) and maintenance of such places. The MCA made it more difficult for manufacturers to obtain substances which were used in the manufacturing of methamphetamines, such as pseudoephedrine.58

This continued crackdown by law enforcement has led some to highlight the relationship between increased punitive measures and the rise in heroin abuse and related deaths. While patients can treat pain legally through their doctors, those with SUDs tend to obtain them through illegal channels.59 As the opioid crisis continues to unfold, governments at the federal and state levels have begun to establish policies and organizations to address this issue. Some of these are based on models other countries have started to adopt in response to similar issues with opioid and heroin abuse.60

In 2011, The Global Commission on Drug Policy (GCDP) published a report in response to the War on Drugs This report declared the war a failure, citing that money spent criminalizing producers, sellers and users of illegal drugs “failed to effectively curtail supply or consumption.”61 They assert that implementation of drug policies as a result of the declaration of war on drugs has created an host of unintended consequences including the growth of a vast global black market for illegal drugs; policy displacement due to scare resources used to fund law enforcement efforts; nomadic drug production in order to avoid arrest and incarceration; creation of newer, more dangerous substances, and the marginalization, stigmatization and exclusion of those who use and are treated for drug addiction.62 The GCDP also cite the increasing rate of those infected with HIV in nations where criminalization is the priority, as well as the rise in deaths related to illicit drug use.63
Nations who have implemented new drug policies that emphasize harm reduction and public health approach to substance use have shown an improvement with regards to the number of deaths related to heroin use, as well as HIV/AIDS. In particular, Switzerland responded to its growing heroin problem by addressing it as a public health issue, rather than a criminal one. Implementation of harm reduction policies such as needle exchange programs, safe injection sites, substance analysis, easier access to opiate replacement therapy and prevention programs has reduced the amount of opioid related deaths by 50 percent. These new policies and procedures have also reduced the amount of heavy consumption and new users, as well as the rate of drug-related crime.

Other European nations such as the United Kingdom, the Netherlands and Portugal have also implemented laws with a similar, public health focus. Research in the United Kingdom shows diversion to treatment in lieu of criminal prosecution shows a reduction in recidivism after treatment. The Netherlands has also implemented harm reduction strategies such as access to clean needles, larger scale treatment options, opiate replacement therapy and legalization of prescriptions for heroin in very specific circumstances. Like Switzerland, these policies have led to a reduction in crime and the number of new users. In 2001, Portugal became the first European nation to legalize all illicit drugs. A study several years later showed that not only did this have a positive effect on the effects of illicit drug use (a reduction in users and morbidity and mortality related to SUDs), but it also reduced the burden on police enforcement of drug related crime and the overall criminal justice system.
Having considered the history and current policies regarding substance use and substance use disorders, it is also imperative that ethical implications of the current crisis are also considered – at the micro level and at the macro level. If the United States is going to affect change on health crises such as the ongoing and evolving crisis surrounding opioid abuse, it is essential to discuss current ethical issues at the clinical level and at the level of public policy. With these considerations, it will be possible to formulate policies and procedures at both a clinical and societal level that may assist in the reduction of the morbidity and mortality of OUDs, HIV and HCV.

The unique aspect of this opioid epidemic is that it can be directly traced to the overprescribing of legal painkillers such as OxyContin. In fact, one study showed that 80 percent of heroin users began with prescription opioids. Understanding the role of physicians in contributing to opioid use disorder helps establish their ethical responsibility towards curbing this crisis. In order to understand current ethical concerns at a clinical level, this section of the dissertation will use the bioethical framework known as principlism.

Principlism is a framework for guiding decision-making based on four main principles: respect for autonomy, nonmaleficence, beneficence and justice. In Western medicine, the principle of respect for autonomy has emerged as the most regarded of the principles and is expressed most prominently through the process of informed consent. In the context of the patient-physician relationship, informed consent promotes autonomy by providing the patient with an adequate amount of information to decide about his or her treatment options. As discussed, due to the lack of knowledge about the capacity for
addiction to opioids, many physicians did not adequately inform their patients about the potential for abuse, thus igniting a chain of events that led us to the public health crisis we have now. Many did so because they lacked knowledge about medication and pain management, others (such as those running pill mills out of their clinics) were aware of the addictive nature of the drugs, but prescribed them anyway (again, without getting true informed consent).\textsuperscript{70}

Another dilemma to consider is how some physicians have reacted to the rise in opioid use disorders. In an attempt to reduce the number of opioids being prescribed (and to identify doctors that may be involved in the pill mill business) many states have adopted what is known as prescription drug monitoring programs (PDMP). These programs track what prescriptions a patient is receiving and allow prescribers and licensing boards to monitor for drug abuse, diversion, and doctor shopping.\textsuperscript{71} However, some physicians, wary of possible punitive measures due to what may be seen by certain entities (such as law enforcement or state medical boards) as “improper” prescribing practices, have begun to step back the use of opioids in treatment of chronic pain, limiting their use to post-operative or cancer patients.\textsuperscript{72}

This creates a new problem: under treatment of pain, which violates all four ethical principles.\textsuperscript{73} A patient’s autonomy is compromised when not given the option to choose among treatments available. Limiting treatment options such as the use of opioids also violates nonmaleficence and beneficence. True beneficence cannot be practiced in a situation such as this, where autonomy does not exist. That is, they are not adequately informed and therefore any decision they make may not be done with their best interests in mind. Inadequate treatment of pain is linked with comorbidities such as depression and
anxiety, and thus by revoking treatment with opioids or not using them in instances where they may be best suited for the patient violates principle of nonmaleficence.\textsuperscript{74} Lack of equal access to pain medications because of a physician’s reservation bout prescribing to “stay under the radar” of PDMPs also violates the principle of justice. Insurance companies also impugn doctor’s abilities to properly treat pain. Many insurance companies have, in the vein of trying to curb opioid morbidity and mortality and cut healthcare costs, have imposed their own limits on the number of opioids they will cover.\textsuperscript{75} The potential for harm here cannot be lost, as limited access to prescription opioids is a direct cause of the rise in heroin use.

Another increasingly common practice in pain management is the “opioid contract.” As concerns about iatrogenic addiction, drug seeking and diversion of opioids grew in response to rising prescription opiate abuse, some physicians began incorporating opioid contracts into the informed consent process. These contracts are written agreements between physicians and patients that outline key aspects of opioid therapy, including its risks, benefits, and goals of treatment.\textsuperscript{76} They are not legally binding; however, many states are beginning to mandate their use. They were originally intended as a tool to educate patients, but as the opioid crisis grows, they have become more punitive in tone. In some cases, patients are punished for non-compliance.\textsuperscript{77} This also furthers the perception of a paternalistic relationship between physician and patient, while diminishing the patient-centered relationship of mutual decision-making that many models of care are adopting.

Such provisions not only violate the principle of autonomy by diminishing the capacity to decide about one’s health, but they also have the potential to be harmful and
ultimately unbefitful for the patient. In many of these contracts, non-compliance means exit from the practice. This may lead the patient to engage in harmful activities such as use of illegal drugs, and sudden withdrawal is detrimental to physical health.\textsuperscript{78} Also, some of these contracts have provisions about quantity per prescription and require a patient to wait until a certain amount of time before they can receive another prescription. If a patient’s perceived pain level fluctuates, this could mean rationing of pills, withdrawal because of lack of adequate supply or drug seeking behavior through doctor shopping or initiation of illegal drug use.\textsuperscript{79} This potential for harm goes against the principle of nonmaleficence. Incidentally, little evidence has been found to show that these contracts are significantly effective in the reduction of opioid misuse.\textsuperscript{80} The possibility of further harm through stigmatization of the individual – not only in society, but by insurance companies – also questions the benefits of their use (which is counter to the ethical principles of beneficence and nonmaleficence).\textsuperscript{81}

Ethical concerns are not limited to the clinical level of the physician-patient relationship. The rise in opioid use disorders and the morbidity and mortality associated with them affect all levels of society. The opioid crisis has put an economic burden on the U.S., with an estimated annual cost of over 55 billion dollars.\textsuperscript{82} Much of this can be attributed to an increase in healthcare costs, but other costs such as the cost of lost productivity in the workplace and the increasing costs in the criminal justice system create new ethical dilemmas that must be considered. For instance, issues related to access to treatment in a rising number of individuals with OUDs, ethical issues related to addiction and employment, and ethical concerns of those entering the justice system who are currently grappling with addiction.
Consider the issue of current treatment options available to individuals with OUDs. While healthcare costs comprise roughly 45% of the societal costs of opioid misuse, only about 5% of that cost is used for substance use prevention and treatment. This is likely attributable to lack of access to and availability of proven treatment models. The most effective form of treatment for OUDs are Medication-Assisted Therapies (MAT). MATs are evidence-based treatment options that combine the use of prescription medications, counseling, and behavioral therapy to create a holistic approach to treating substance use disorders. In particular, OUDs can be treated using three different medications: methadone, buprenorphine, and naltrexone. These medications are taken on a daily basis, or in the case of Vivitrol (a newer, long-acting form of naltrexone) injected to reduce cravings and withdrawal symptoms.

Despite their proven effectiveness, these medications are underutilized. According to the 2014 National Survey on Drug Use and Health (NSDUH), of the 2.7 million Americans aged 12 or older who had an opioid use disorder, less than a million received MATs. The reasons for this disparity are varied, but the primary reason is lack of availability of these programs. As of 2017 roughly a quarter of public treatment programs and less than half of private treatment centers utilize MATs. Even in facilities that do have MAT, roughly a third of patients receive them. A number of barriers exist that contribute to limited access to MATs, one of which is the ongoing misconception by healthcare workers and the public in general that replacement therapy such as this merely moves the addiction from one drug to another. Many treatment facilities, sober living houses and agencies within the criminal justice system maintain a strict abstinence model, which contributes to low adoption of the MAT model.
Policy and regulatory barriers also exist. Coverage by public and private insurers is often limited and some may impose coverage limits, including quantity over the lifetime, prior authorization requirements and “fail first” criteria that require that an individual fails other treatment prior to the use of MATs.\textsuperscript{88} Even then, not all state Medicaid plans cover all 3 drugs that are available (only 28 currently do). This lack of equal access to resources such as MAT treatment or drugs used in MATs is in sharp contrast to the principle of justice. It could also be argued that beneficence and nonmaleficence are also in violation by those who do not offer patients MATs based on personal prejudices against the practice.

The opioid crisis also affects the workplace. In 2009, lost workplace productivity was one of the leading financial implications of the crisis, accounting for nearly 46% of total societal costs.\textsuperscript{89} Much of this was due to premature death (43.8% of costs), loss of wages/productivity (31%) presenteeism (8%), excess absenteeism due to medical concerns (7.1%) and incarceration (6.9%). Only 3.2% of these costs were related to excess disability. Also of note is the fact that employees with opioid abuse accounted for 64.5% and 90.1% of the cost of excess medically related absenteeism and disability.\textsuperscript{90} With the increasing number of American workers with an opioid use disorder, it is important to consider the ethical implications of addiction on the job.

While many employers provide Employee Assistant Programs (EAP) to refer employees to treatment, it is not required.\textsuperscript{91} Employers are also covered by the ADA and may require drug testing as a contingency for employment. Active illicit drug users are not protected under the ADA and may be barred from employment or fired for using. Some link the rise in opioid use as the reason there is a drop in participation in the labor
force to an all-time low of 62.4% in September of 2015. As of 2016, statistics showed
20% decline in men and 25% decline in women in the workforce.\textsuperscript{92} Workers either drop
out voluntarily because they cannot break the cycle of addiction, have no access to
treatment (either due to financial or locational burdens) or get fired due to use on the job
or active use outside of employment. This not only puts an economic burden at a societal
level (due to the need for financial assistance) but it puts an economic and emotional
burden on the individual with the SUD and their families.\textsuperscript{93} Looking at the situation from
an ethical standpoint, termination of employment due to active use may do more harm for
an individual with an SUD than good. An employer who does not allow for an alternative
to termination does not have the employees best interest, and this may be fueled by the
stigma of addiction as a moral failing and not a medical issue. These actions violate the
principles of beneficence and nonmaleficence. Inadequate knowledge and access to
treatment also violate the principles of autonomy and justice. An individual with an SUD
should be equipped with the tools to decide about their own course of treatment and do so
without fear of retribution from an employer.

Another cause for concern is the effects that policies put into place during the
Nixon and Reagan era have put the criminal justice system. As of 2015, the criminal
justice system in the United States spent roughly 8 billion dollars on crimes related to the
selling and consumption of opioids. This is of course related to the criminalization of
such activities, which has led to a significant increase in individuals arrested and
incarcerated for drug related crimes. In 2016 alone 1.57 million individuals were arrested
for drug violations - an increase of 5.63% from the previous year. Eighty-one percent of
these arrests were for possession.\textsuperscript{94} A substantial change in the amount of people
incarcerated for drug related offenses also occurred. From 1980 to 2014, state and federal prisons saw an increase of over 1,000 percent (roughly 41,000 to 488,400 drug offenders).95

This dramatic influx of prisoners not only puts a burden on families and the community (emotionally and financially), but it is detrimental to the lives of those incarcerated, as they are even less likely to receive treatment such as MATs than those who are not in the criminal justice system.96 In fact, there are currently roughly 2.4 million people in the United States are incarcerated. Of those 2.4 million, 65% are clinically addicted to illicit substances - including opioids - and only 11% receive some form of treatment for their addiction.97 This lack of treatment only exacerbates the problems associated with opioid epidemic, such as an increase in HIV/AIDS and HCV due to use of shared needles amongst prisoners.98 Again, this inequality in access to treatment is the antithesis of the principle of justice. However, armed with this knowledge, bioethicists can help influence the development of policies that not only address workplace issues, but treatment, prevention and punitive concerns related to substance use.

As the United States recognizes the impact that deceitful practices by pharmaceutical companies and improperly informed pain management practices by physicians has had on society, it is important to discuss possible future outcomes. With an understanding of the different issues that arise in the wake of its progress, it is necessary to examine how treatment and prevention can and need to change to accommodate all who are affected. Also, it is imperative that current policies adapt as a
growing percentage of the population require some form of assistance either with pain
management or substance use disorders.

Ultimately, the goal of addressing the opioid epidemic as a public health issue is
to eliminate the morbidity and mortality associated with opioid use disorder. To do so,
the gaps in treatment and prevention need to be filled. As previously mentioned, evidence
shows that the MAT model has proven to be more effective than traditional, abstinence-
based programs. The problem with lack of access in this case not only lies in the fact
that 85% of all counties across the U.S. do not have opioid therapy programs (OTP) but
38% of all counties have no treatment facility for SUDs. The problem gets worse as the
population density diminishes. Looking at metropolitan areas, only 10% of counties had
no SUD treatment facility (65 to 75% have no OTP facility), whereas 55% of rural
counties lacked any SUD treatment facilities, with 91 to 99% having no facility for
OTPs. Rural counties are also less likely to have facilities that take Medicaid, which is
an issue and a barrier to access to treatment in less populated, poorer areas.

To quell the tide of opioid overdoses and fatalities, treatment and treatment
facilities must be easier to access than is currently possible. One way in which this is
possible is to allow physicians to easily dispense buprenorphine, which currently requires
a waiver from the DEA as well as training on its use. Currently, 45% of counties lack a
doctor with a waiver to dispense this MAT drug. And unfortunately, even those with a
doctor with a waiver are challenged, because there is a cap on the number of patients they
can serve. Either easier access to waivers should be considered, or the requirement for
a waiver should be reconsidered. This will allow the use of evidence-based practices such
as MAT to be more readily available to people who may have limitations on the availability of treatment in their area.

Access to life saving drugs is not limited to treatment of the OUD, however. There is currently a movement across the country to make the anti-overdose naloxone (Narcan) easier to obtain and use. Available in injectable and nasal forms, when administered upon the initial signs of an opioid overdose, naloxone proves to be highly effective. While the WHO supports the distribution of naloxone beyond medical responders, states across the U.S. are not unified in this line of thinking. However, many states are now providing standing orders for naloxone, making it possible to dispense naloxone without a prescription. The difficulty also lies in the fact that not all emergency personnel or law enforcement who may be first responders to a possible overdose can administer to drug. Also, not all states with standing orders have a Good Samaritan 911 law in place to protect those reporting an overdose from any form of prosecution. A model of care needs to be developed to address these barriers, and procedures need to be in place to guide overdose victims to treatment. Education on its usage for those living with and those treating individuals with an OUD is also essential.

As far as prevention is concerned, strategies such as the one Kolodny et. al suggests address the issue with a three-tiered approach. Primary prevention addresses the core of the issue: overprescribing of opiates by ill-informed physicians. By requiring physicians to be educated about the risks associated with opioid use, the frequency with which these drugs are prescribed may diminish. However, not all states require such education, and the manufacturers who are now required by the FDA to provide educational programs to prescribers do not always provide accurate information on the
safety and efficacy of opioid pain relievers. Adoption of regulations requiring this education by all states may be a step in the right direction towards lowering the rate of prescribing, as one study out of New Mexico shows. Public education is also a vital tool for prevention, and national media campaigns, like the one used when HIV/AIDS broke out, have proven to be beneficial not only in reducing stigma, but risky behavior that may lead to disease.

Secondary prevention strategies involve screening for a health condition after its onset. The earlier an individual with an OUD is identified, the more likely it is to reduce morbidity and mortality related to the disorder. Although difficult to diagnose through self-reporting tools such as screening or urine testing (which only detects presence of a drug, not misuse), one way in which to detect an OUD is by monitoring the prescription of opioids. This is done using PDMPs, which can show if a patient is using multiple doctors and multiple pharmacies to get opioids – often a sign of an OUD. Evidence shows that their use is linked to declines in opioid prescribing and drops in visits to multiple providers. However, only a few states mandate their use, and therefore there is no uniformity to their method or the practice. If more – if not all – states require this, it could serve to address the issues of “doctor shopping” and pill mills and make interstate communication a reality.

Lastly, tertiary prevention strategies address the need for access and availability of treatment to prevent overdose deaths, medical complications, and psychosocial deterioration. Multiple strategies – including pharmacotherapies, psychosocial approaches, and harm reduction strategies – are recommended. These strategies have proven difficult to develop, implement and assess. However, it may be possible to
provide universal methods of treatment and prevention if policies are put into place at state and governmental level. After President Trump issued a Public Health Emergency regarding the Opioid Crisis, the President’s Commission on Combating Drug Addiction, and the Opioid Crisis (The Commission) issued a report commission with 53 recommendations on how the federal government could address the current opioid crisis.\textsuperscript{117} Although not law, these recommendations can serve as a guide to policymakers when developing legislation. The summary of these recommendations included 4 distinct categories: federal funding and programs, which would mandate funding for opiate and substance use related activities; opioid addiction prevention, with initiatives toward early screening in adolescents for prevention and nationwide prevention campaigns, as well as development of standardized prescribing practices for opiates, mandated prescriber education, PDMP enhancements and supply reduction strategies.\textsuperscript{118} The category of opioid addiction treatment, overdose reversal and recovery addresses barriers to access such as reimbursement, policy, availability of providers and current punitive measures for drug possession. Under research and development, recommendations related to research for the development of new, non-addictive pain relievers, treatment, and prevention strategies, as well as the desire to require post-market surveillance of any new controlled substance to monitor for the potential adverse effects.\textsuperscript{119}

Legislation that addresses the issues relevant to the prevention and treatment of OUDs has the power not only to assist individuals with an OUD or SUD, but also to guide the way in which SUDs are viewed by the public and handled in the healthcare and criminal justice system. Until the Mental Health Parity Act of 1996 (MHPA) and the subsequent update known as the Mental Health Parity and Addiction Equity Act of 2008
(MHPAEA), it was possible for health insurers to impose annual or lifetime dollar limits on mental health benefits that are less favorable than any such limits imposed on medical benefits. The Affordable Care Act (ACA) expanded the services covered by MHPAEA by making mental health SUDs part of the “Essential Health Benefit;” applying federal parity protections to mental health and substance SUD benefits into the individual and small group markets; and providing greater access to quality health care that includes coverage for mental health and substance use disorder services.

In the wake of the emerging opioid crisis, the United States House and Senate recognize the magnitude of the issue and are beginning to introduce legislation to directly address this issue. On July 22nd, 2016, President Barack Obama signed the Comprehensive Addiction and Recovery Act into law. The aim of this act is to address some of the disparities in treatment and recovery such as access to buprenorphine and Narcan. It also aimed to increase awareness, renew funding to PDMPs, formation of a task force for SUDs and address prescribing guidelines. On April 16, 2018, a bill known as the Opioid Crisis Response Act of 2018 was introduced. It contains language that would renew funding promised by the 21 Century Cures Act (which set to streamline the drug and device approval process) and restructure grants to states hit the hardest to boost access to treatment. Other provisions of the bill address the issue of prevention, citing ongoing concerns such as prescribing limits, data collection for monitoring purposes and another emerging issue: prenatal and postnatal health of babies born to addicted mothers. If passed, research and innovation in the field of SUDs would be bolstered, and funds would be allocated to address some of the unethical practices going on in treatment facilities and sober houses across the country.
Senator Elizabeth Warren and the late Rep. Elijah E. Cummings introduced a bill known as the Comprehensive Addiction Resources Emergency Act (CARE) in May of 2019. The bill is explicitly modeled after the Ryan White Act, which was introduced into law in the early 1990s as a means to address those communities hit hardest HIV/AIDS epidemic of the 1980s. If passed, it would provide support for federal research and prevention programs, as well as fund evidence-based treatment at a cost of 100 billion dollars over 10 years.\textsuperscript{125} Although the impact of this and other laws that are relatively new or are just being formulated, the impact of past policies such as the Ryan White Act cannot be overlooked, because up until the recent epidemic, the CDC saw a steady decline in the amount of new cases, as well as a prolonged life expectancy of those infected with HIV.\textsuperscript{126}

An analysis of the progression of the current opioid crisis and history of drug regulation in the United States, as well as discourse on our current drug policy compared to international approaches is vital to understanding how this public health crises evolved. Examination of ethical issues both at the clinical and community level and possible solutions are also necessary for stakeholders at all levels who can have an impact on related outcomes. As a result, a deeper understanding of the origins of the opioid problem reveal its effect on public health. It is with this and the information regarding treatment, prevention, and the influence of policy on public perception and health outcomes that bioethicists – specifically those whose primary focus is public health – can exact influence on policies that will help shape the future of healthcare in the United States – specifically in the realm of substance use disorders. Armed with this knowledge, policies and procedures can be implemented from the intrapersonal level to the larger,
structural level that impact not only the way in which individuals with SUDs are treated medically, but also how they are treated socially.

2b. Consent in the Public Health Context of Substance Use Disorder

The unprecedented rise in deaths related to opioid use has caused concern not only within the medical community, but communities across the United States. Concurrently, health officials have seen a rise in the rates of diseases associated with illicit drug use, resulting in a public health emergency. The issue of opioid use and misuse creates ethical dilemmas not only for healthcare providers, but the public in general. This section begins as an examination of some of the bioethical concepts related to healthcare such as autonomy, consent, competence, and surrogacy. Then it will describe and discuss the opioid crisis and some of the ethical issues that individuals and communities affected by it experience.

Western medicine views autonomy as the foremost concern in the medical decision-making process. Indeed, in bioethics, the principle of autonomy evolved into the prominent principle upon which many ethical debates are based. It is important not only to define what autonomy means, but also to examine it in the context of the normative ethical discussion as well as its place in the decision-making processes in clinical and research-based settings to understand and appreciate the value of this principle in the evolution of healthcare ethics.

To act autonomously is to engage in self-governance. Two basic conditions that are agreed upon to be essential to achieving autonomy are liberty and agency. Liberty refers to the individual’s ability to make decisions free from coercion, while agency refers to the individual’s capacity to act intentionally. An act is intentional if planned and
presented to an individual and executed according to that plan. Coercion, either real or perceived, can influence a patient's decision-making process. For instance, if a physician tells a patient in a hospital what goals need to meet before their release, it may affect the course of action that patient might take towards that goal, possibly hastening recovery at the expense of their long-term health outcomes. Agency can be diminished by illness (either mental or physical) such as a manic episode or dementia and can also affect the intentionality of action. If either of these conditions is compromised, an individual cannot be considered autonomous.

2bi. The Relationship Between Autonomy and Consent

The principle of autonomy is a normative principle derived from common moral experience and requires respect for a rational, autonomous individual's right to make decisions about their healthcare interventions. It is a protection against coercion and deception, concepts which are rooted in the conditions required for autonomous action. Respecting the principle of autonomy requires that a physician or researcher not only allow a patient or subject to make their own decisions but that they create an environment wherein the patient feels comfortable doing so. This includes a proper dissemination of information to the patient or subject on topics such as their medical condition, potential risks and benefits of treatments or procedures, as well as maintenance of privacy, confidentiality and obtaining consent for treatment or research. These considerations apply regardless of the patient’s ultimate choice. That is, although the patient may not choose what a physician or researcher sees as a “proper” course of treatment, the physician or researcher must respect that choice. Beauchamp and Childress maintain that,
in addition to the conditions of liberty and agency, the principle of autonomy is also vital to the development of theories of autonomy.\textsuperscript{132}

In *Principles of Biomedical Ethics*, Beauchamp and Childress examine two accounts of autonomous action: split level theories and three-condition theory.\textsuperscript{133} Split-level theories maintain that autonomy relies on the individual’s capacity for reflexivity in the decision-making process. In other words, a person is autonomous if they can align their basic (first order) desires with their higher level (second order) desires. The autonomous person in this theory is one who can reflect upon their first-order desires, subsequently, accepts or rejects them "in light of higher-order preferences and values."\textsuperscript{134} An example is a gambler with a (basic, animalistic) first-order desire to gamble but a higher (second order) desire to stop gambling. Giving in to the basic desire to gamble is, in this instance, considered non-autonomous behavior.

Beauchamp and Childress’ three-condition theory contends that a patient or subject is autonomous when they can decide, have sufficient information to make the decision and do so voluntarily.\textsuperscript{135} This theory not only acknowledges that the conditions of intentional action (agency or intentionality) and liberty (non-control) are required for autonomous action but also add that the condition of understanding is necessary. This means that a patient must understand an action for it to be considered autonomous. Deficiencies in understanding - be it due to illness, immaturity, or irrationality - can hinder understanding. A breakdown in communication can also limit a patient or subject’s comprehension.\textsuperscript{136} For example: if a research subject only has a cursory knowledge about potential outcomes of participation in a study, the condition of understanding is not met, and their decision is not considered fully autonomous (e.g., the
Tuskegee Syphilis Experiment). However, it is unreasonable to expect a patient or subject to have comprehensive knowledge of the pertinent subject matter, due to the depth of information necessary for full understanding. But, so long as there is a “substantial degree of understanding,” then Beauchamp and Childress contend that the condition is reasonably met. What constitutes “substantial understanding” may seem ambiguous, but there are standards that courts in the United States rely on to address this that will be discussed later within the context of informed consent.

Consent is permitting another individual to do something. Medically speaking, consent refers to a process (known as informed consent) that must be adhered to by health professionals, regardless of the context. A competent patient or research subject must give consent before any treatment, procedure, or research trial. However, there are situations in which consent in the context with which much of us are familiar (informed consent) is not plausible. Informed consent (or refusal) is considered an express or explicit form of consent. It may also be general or specific. For instance, if a research subject allows the storage of their DNA samples for future research, they may never know what research may be done on those samples or by whom. This is general consent. In specific consent, an individual would be giving consent only to have their DNA used for research on a specific disease or for a specific research project. Consent may also be implied, tacit or presumed. Implied consent is consent inferred from action. When a patient rolls up their sleeve for a blood draw or blood pressure measurement, the action implies consent. Similarly, tacit consent is given through non-action. When a patient goes in for surgery, they consent to whatever procedures are necessary to complete the surgery (they cannot give consent to new procedures when they are under anesthesia!). In
some countries, organ donation requires action to opt out, otherwise consent to donate is presumed. To understand the importance of autonomy in this process, concepts intrinsic to informed consent are discussed.

One way of understanding informed consent is to analyze it regarding its basic elements, in particular, the information and consent components. There are five components of informed consent upon which much of the literature agrees (competence, disclosure, understanding, voluntariness, and consent). Beauchamp and Childress break it down further into seven elements. They group competence and voluntariness together as “preconditions” to informed consent, add recommendation of a plan as an information element (along with disclosure and understanding) and break down consent into elements that include decision-making and authorization of a plan of action (or inaction).\textsuperscript{140}

Disclosure, although not entirely necessary for consent to be given (for instance, if a patient is a physician, they may already understand the procedure or treatment and therefore would not necessarily need or benefit from disclosure), is essential for those who would otherwise lack the adequate knowledge needed for decision-making. Standards of disclosure are dictated by the court system and primarily fall under the professional practice standard (which relies on customary practices as a measure) or reasonable person standard (which measures significance by relying on a hypothetical "reasonable person"). A third standard, the "subjective standard" has emerged as another way to gauge the adequacy of information. It does so by taking individual concerns and circumstances into consideration.\textsuperscript{141} As with the requirements proposed by Beauchamp and Childress in their three-condition theory of autonomy, understanding in this context is necessary for a patient to move on the last elements of informed consent: the decision
on a plan and the authorization of said plan.\textsuperscript{142} Put together, however, these elements do not represent what informed consent means. They serve to merely analyze the process.

Perhaps the most prominent example of respect for autonomy is informed consent. The concept of “informed consent” is the cornerstone of Western medical ethics. Informed consent affords the patient or subject autonomous choice by giving them the information needed to understand the risks and benefits of treatment, as well as the reasonable alternatives (including no treatment) so that they may make an independent decision.\textsuperscript{143} There is no singular definition of informed consent, so it is necessary to consider different ways in which informed consent is conceptualized.

Two meanings of informed consent have become entrenched in modern medical practice. In one sense, informed consent is the autonomous authorization of an individual to be treated or to participate in medical research. This only occurs when a patient or subject has "substantial understanding," is not coerced and intentionally authorizes a course of action (or non-action).\textsuperscript{144} It must be an informed and voluntary decision. These requirements overlap with the requirements found in Beauchamp and Childress' three-condition theory and emphasize the importance of autonomy in the process of informed consent.

In another sense, informed consent refers to its institutional and legal application. Authorization of action or non-action by a professional is determined in this case by social rules of consent that require certain obligations (such as obtaining a consent form) are met before proceeding with medical treatment or research.\textsuperscript{145} Minimal adherence to these policies may leave room for a gap in the informative intent of informed consent and therefore inhibit understanding by the patient. This can lead to poor decision-making on
the part of the patient or subject and in turn, the physician or researcher. Although these policies and procedures are likely to be informed by the standard of autonomous authorization, they are by no means bound to it or by it. Without the rigorous standards autonomous action requires, the patient may not know enough about the procedure to formulate relevant questions, and in turn the doctor may not get all the relevant information needed for the patient to decide. This calls into question the autonomous nature of this exchange.

2bii. Determining Who Can and Cannot Give Consent

In order to respect an individual’s autonomous choice, it must be determined if that individual is competent to make that choice. Patient participation in medical decision-making is one of the most important qualities of modern models of health care. Competency serves as a way of distinguishing which individuals do and which individuals do not qualify to participate in this decision-making process. This may seem counter to the principle of autonomy, however, competence is an essential component of informed consent.146

It is generally agreed that competency requires that an individual possess “the ability to perform a task”, but it is also important to understand that competency is relative, and context must be considered.147 An individual may be competent in the realm of education but incompetent in real estate. The ability to make competent decisions also fluctuates over time, sometimes because of age or illness.148 Therefore, an individual may be deemed competent in one situation and incompetent in another – even if they are making the same type of decision each time.149
There are many standards by which incompetence is determined. These are by no means exhaustive, and ultimately the physician measuring incompetence may decide what criteria the patient meets to be considered incompetent. The patient must be capable to make and communicate a choice. They must be able to understand diagnosis, prognosis, and information relevant to their treatment. Patients should also be able to reason to make their decision and rationalize why they made the decision. These decisions should not be made under duress or through coercion.

Although there is no universal standard to assess competency, there are strategies used to aid in clinical judgements. Testing instruments may be used, but many exist, and no instrument is generally reliable in assessing competency. A “sliding scale” strategy is a customary practice wherein the more a physician sees the decision as beneficial to the patient, the lower the threshold to prove competency. The lower the risk of harm to the patient, the lower the standard of competence and vice versa. Those who do not meet the criteria are considered incompetent, and as such, unable to make any medical decision independently. This decision subsequently affects the rights of the individual, and a consideration of how it affects an individual’s moral status is thus warranted.

Moral status tells us what entities should be protected by moral norms (i.e., what we treat as human versus what we treat as less than or non-human). There are disagreements about who should be given moral status, such as those with cognitive disabilities, animals, or human embryos. Five prominent theories emerged to address these issues: human properties, cognitive properties, moral agency, sentience, and relationship theory.
The human properties theory confers moral status to any entity that has human properties or characteristics - those born of human parents or containing human genetic code. This ascribes moral status to all human beings, including those whose status might traditionally be diminished such as infants, or those in persistent vegetative states. Using human properties as criteria for moral status neglects the possibility of engaging with a non-human being that shares similar capacities for moral relationships as humans. It also creates confusion about that status of animals that contain human cells and DNA, such as chimera or transgenic animals.

The next theory uses a specific set of cognitive properties to confer moral status on an entity. Cognition is understood as “processes of awareness such as perception, memory, understanding and thinking.” Properties of this theory include self-consciousness, freedom and capacity for action, ability to reason and understand action, capacity for beliefs, desires and thought, ability to use language for communication and rationality. Non-human species are not entirely ruled out. This theory is problematic in that it leaves those who are more vulnerable (such as infants and mentally disabled) with less moral protection.

The ability of an individual to be a moral agent is the central tenet of theories based on moral agency. Individuals are generally considered moral agents if they can make moral judgments about actions and their motives can be judged morally. The capacity to choose either moral or immoral action is what gives an individual moral status. This isolates the vulnerable in society, who are unable to make such choices for themselves.
The fourth theory is based on sentience, or the capacity to feel pain and suffer. All entities that are sentient and capable of feeling emotions (such as pain and pleasure) have moral status. Pain is morally significant in that it is to be avoided. Intentionally inflicting pain on someone or something (without moral justification) is considered wrong. Cognition is not required to confer moral status, as it is not required to feel pain or suffering. This theory, however, does not grant moral status for non-sentient humans or animals, such as embryos or invertebrates.

The final theory focuses on relationships. The existence of a relationship, either between humans or humans and animals, and the duties inherent with that relationship, confer moral status. For instance, the establishment of a doctor-patient relationship or the relationship between a researcher and an animal subject grants certain rights that do not exist outside of said relationships. This creates a hierarchy of those worth moral status, and necessarily excludes entities that are (subjectively) not deemed worthy in certain places or contexts.

While none of these theories provides a definitive standard for moral status, it is important to consider the relationship between competency and moral status with regards to decision-making. The act of declaring an individual incompetent certainly changes the moral status of an individual and takes away their right to “first-person” consent. In these instances, a surrogate decision-maker is appointed.

In 1990 Congress passed the Patient Self Determination Act, which mandates that all Medicare-certified institutions provide written information regarding patients’ right to formulate advanced directives (AD). This allows a patient to retain some autonomy, even when they lack the capacity to make an informed decision. In the absence of such
documentation, surrogate decision makers are appointed to make health care decisions for the patient.\textsuperscript{176}

For individuals without the capacity for judgement, a substitute decision-maker is brought in to make decisions on their behalf. In some instances, this is done because of an advanced directive. In the absence of an AD, surrogates are appointed through the court system or by default (i.e., next of kin).\textsuperscript{177} This paves a pathway for physicians to choose treatment that more closely aligns with the wishes of the patient. To properly make decisions for an incompetent person, the surrogate must be considered competent.\textsuperscript{178} They must try to get pertinent information regarding diagnosis, prognosis, and all forms of available treatment. This must be done with the patient’s interests in mind and in an emotionally sound, neutral way.\textsuperscript{179}

The family of the incompetent individual are often the first choice to become surrogates, although it is plausible that conflicts of interest within the family may occur. Defining what constitutes family may also complicate the situation.\textsuperscript{180} It is also important to understand surrogates are guides in the process, and by no means are their decisions final, especially if they conflict with what is in the interest of the patient. Health care professionals also have a role. Not only can they safeguard the patient from malicious intentions, but they serve to enhance the surrogate’s understanding of the medical issue(s).\textsuperscript{181}

An institutional ethical committee can also be brought in to assist with complex decisions if necessary and may be used to help educate the parties involved about their options.\textsuperscript{182} These committees often have policies in place regarding certain procedures such as withholding or withdrawing treatment. While they do not ultimately decide the
course of action, they help guide the process. Beyond these options lies the courts, who may intervene as a last resort or because a patient does not have representation.\textsuperscript{183}

When making medical decisions, a surrogate must follow certain guidelines or standards. The standard of substituted judgement requires the surrogate make decisions based on previously expressed wishes. It infers what the patient would choose in the circumstance at hand. This can be in the form of written or verbal directives such as an advanced directive or opinions expressed formally or informally in conversation.\textsuperscript{184} The use of substituted judgement standards serves to maintain (albeit weakly) the formerly competent individual’s right to autonomous choice by considering their desires when they were previously capable of such a choice.\textsuperscript{185} It assists in the interpretation of ADs by providing a means to analyze the thought processes a formerly competent patient might use to rationalize their current situation and decide.\textsuperscript{186}

The subjective nature of this process is evident. A surrogate can only infer what the patient might want in any situation from previous conversations or written ADs. This leaves room for errors in interpretation. The information provided may have changed over time or the course of an illness.\textsuperscript{187} Even with a legal document such as an AD or living will, the wishes of the patient may not be entirely obvious, and therefore in need of further examination. For instance, a patient may not have anticipated their illness, nor considered all options for treatment. A clarification of what measures deemed acceptable (i.e., what types of resuscitation are undesirable) may be needed.\textsuperscript{188} The more information we have, however, the better, as it helps physicians consider patient’s wishes, and decide in a way they feel confident is close to what the patient wants. This is not always an option. There are some individuals (such as children or the mentally disabled) who have
never been competent and not capable of such decisions. Others simply have not expressed any form of AD. This is where the other preferred standard, the “best interest” standard, plays a role.

When evidence does not exist about a patient’s treatment wishes, the best interest standard is used - although there are times when an AD exists and is overridden using this standard. A surrogate must balance the cost, benefits, and risk of any treatment-related decision, in congruence with socially accepted outcomes for treatment. In other words - what would most reasonable people choose? An assessment of the potential impact of treatment on life expectancy is necessary. The potential risks and benefits associated from providing or withholding treatment also require consideration. The cost of treatment is not merely financial; therefore, the emotional and physical burden of treatment also needs reflection. The affect treatment may have on a patient’s dignity is also a valid concern. Any doctrine that may inform the patient’s decision-making process (such as their religion) should also be considered.

The best interest standard is problematic in a few ways. Unlike substitute judgement, which is somewhat subjective, but has more “convincing” evidence, best interest standards leave more ambiguity. Also, what is considered best for the patient is up for debate from different people who may have different interests. This creates the potential for conflict, and the need to involve ethics committees and the court system. Best interest decisions related to treatment for children also marginalize them in the process. The capacity of decision-making in adolescents and younger children is limited by state laws. This leaves the decision-making to adults who may not (or may not be allowed to) take the child’s preferences into consideration. Some states, however, are
beginning to challenge previously held beliefs about age restrictions, thus creating room for consideration of capable adolescents (and possibly children) and to allow them to have a voice with regards to their treatment.  

Historically, addiction was viewed by society as a character issue or moral flaw. Science has since determined that addiction is a primarily biologically based phenomenon and is not a reflection of a person’s character or value to society. One of the prominent issues that is creating a public discourse about social responsibility regarding addiction is the emergence of the “opioid epidemic.” The impact of this health crisis resonates across the United States and includes consequences beyond the addiction element.

Over the course of 16 years (1999-2015), deaths in the United States resulting from drug overdose tripled. Between 1999 to 2009 the sale of opioids and deaths related to their misuse quadrupled, while utilization of substance abuse treatment increased sixfold. In 2015, the leading cause of accidental death in the United States (52,404 incidents) was due to drug overdose. Over 60 percent of these deaths involved misuse of prescription or illicit opioids. Heroin was the most common (12,989 deaths) followed by pharmaceutical opioid (12,727 deaths), non-methadone synthetic opioids (such as fentanyl) (9,580 deaths), methadone (3,301 deaths) and cocaine (6,784). Most of these deaths (over 80%) were ruled accidental.

By 2010, the increase in mortality rates related to opioid abuse leveled off, but the incidence of overdoses related to heroin, non-methadone synthetic opioids and cocaine all saw an increase between 2011 and 2015. This is a result of both increased restrictions on the prescribing of opioids and the rising costs of these drugs. An estimated 4 out of 5
new heroin users misused pharmaceutical opioids at some point and, when surveyed in 2014, 94% stated that they switched to heroin because it was a less expensive alternative. This compounds the problem, as patients who seek these drugs illicitly increase their risk of death, not only because of the potential for overdose because of lack of patient oversight by physicians, but also because outside established channels of drug distribution (doctor to pharmacy. The risk of unknowingly obtaining products that are laced with other hazardous ingredients (such as heroin laced with fentanyl) increases. What the patient may consider a “normal” safe dose may, in fact, be lethal.

The implications of this trend towards illicit drug use are not limited to the risk of tainted medications and overdose. Other insidious repercussions exist, specifically those related to the use of injectable drugs. In a recent study from the CDC, an increase in the amount of opioid abuse and treatment, as well as individuals who admit injecting illicit drugs correlates with a surge in the number of patients contracting the hepatitis C virus (HCV). HCV is transmitted through blood and bodily fluids of those infected, with injectable drug use (IDU) as the number one way in which it is contracted. The concomitant rise in IDU and HCV is a cause of concern, not only for mortality rates related to both, but for the potential of other diseases related to opioid abuse to increase. It would be difficult to prevent and decrease the incidence of infection and death related to these if other risks are not also considered. A syndemic such as the one we see with opioid abuse and HCV makes it difficult to properly address either disease. Syndemics consist of multiple health problems or epidemics. They are concurrent and synergistic, thus exacerbating the burden of disease in populations in which they are found. The
potential for another disease to become another part of this syndemic must not be ignored.

Mere statistical analyses of the opioid crisis only illustrate one aspect of the impact of opioid and heroin addiction. It is not limited to those suffering from the effects of addiction, but those close to them, local communities as well as nationally and globally. To appreciate the scope of the problem, bioethicists must consider its impact at each of these levels.

As previously established, the principal of autonomy is considered one of the cornerstones of western based medicine, regardless of how autonomy is defined by the patient – be it through individual choice or through the guidance of others. Informed consent is the practical application of this principal. Shared decision-making that respects the patient’s ability to make decisions based on personal values, beliefs, while considering risks and benefits of treatments serves as a foundation for an alliance between the patient and physician and can be beneficial for positive outcomes. However, obtaining informed consent necessary to establish and maintain such a relationship can be problematic for individuals suffering from addiction. The question that surfaces is the ability of addicts to make autonomous choices, especially with regards to treatment or research. Koopmans and Sremac maintain that there is no one correct answer to this question. What must be considered is the viewpoint of addiction as either a physiological disease, behavioral or moral issue. These explanatory models of addiction view autonomy differently. The disease state model suggests that compulsion to use inhibits autonomous choice, although proponents such as Neil Levy maintain that autonomy should be viewed on a continuum. That is, to say addicts are never autonomous
is akin to engaging in biological determinism and robs them of autonomy.\textsuperscript{213} The disorder of choice model concludes that addiction is not compulsory, and therefore addicts can make autonomous, volitional choices. The existential model of addiction posits that addiction is a moral, not medical condition. In this model autonomy is only considered within an existential framework.\textsuperscript{214}

Another ethical issue to consider is the possibility of coercion. Autonomous choice is contingent not only on the person’s ability to make a choice (agency), but also the nature of said choice. The concept of liberty in autonomous decision-making maintains that choices be made without coercion. The criminalization of certain forms of addictive behavior necessarily infringes on the ability of addicts to make uncoerced choices. Instead, treatment becomes part of the punishment process or to avoid criminal charges altogether. This temporary infringement on autonomy is considered a short-term sacrifice in the quest to restore long term autonomy.\textsuperscript{215} Clinical research trials may also promote coercion, especially when the research subjects belong to a vulnerable population and are given incentives such as vouchers or monetary compensation in exchange for their participation. Such methods may undermine the voluntariness of their decision to participate.\textsuperscript{216}

In the discussion of doctor-patient or investigator-subject relationships, competency is also a necessary consideration. It is up to the doctor (or investigator) to determine if a patient is competent to make choices about his or her own health. Without this determination, the patient’s right to informed consent is not entirely fulfilled. But like autonomy, competency is fluid. An individual may be competent in one moment, and in another instance (due to illness, age, or - in the case of addicts - the ingestion of drugs) be
deemed incompetent. In that case, the effects of addiction move beyond the doctor-patient relationship to that of family and friends who may be required to assist in the decision-making process.\textsuperscript{217}

When a patient is determined to be incompetent, family members often step in to make decisions for the family member.\textsuperscript{218} Families of addicted individuals carry a unique burden. In families without children, the spouse who is not addicted frequently acts as the head of household and surrogate decision-maker. Sometimes minor children must assume certain household responsibilities when an addicted parent (or parents) is (are) incapacitated. Typically, in cases where a child or adolescent needs treatment, parents act as surrogate decision-makers.\textsuperscript{219} This can be challenging in cases where the parent’s values and beliefs conflict with the affected child or adolescent. In these circumstances, it may be necessary to bring in a surrogate appointed by the legal system to consider the minor’s wishes. In any case, decisions beyond immediate medical treatment, such as the decision to commit an addicted family member to an inpatient program, although difficult, may need to be considered.\textsuperscript{220}

The consequences of substance abuse not only affect how family members engage with the healthcare system, but they can also be economic and psychological. Money spent on addiction can undermine a family financially and lead to criminality to maintain the habit. Partners or spouses of family members with addiction may experience emotional issues such as anxiety, anger, or denial of the problem. Physical symptoms such as poor health or chronic illness (i.e., high blood pressure) may also result.\textsuperscript{221} Children of addicts may also experience a lag in cognitive development, as well as behavioral or psychosocial issues.\textsuperscript{222} The current rise of opioid addiction and cases where
children are involved indicates that this crisis goes beyond just the user and may have lasting effects across generations. However, to properly understand and exact change on micro level relationships, an examination of the larger impact it has on society is necessary.223

Drug addiction is often cited as solely an individual or family problem – a character flaw. Social determinants of health, such as the location in which one is born, lives and work have an impact on the way in which not only an individual experiences disease, but how a community and society does as well.224 Socioeconomic status, education, and environmental factors such as access to health care or community support systems have a significant impact on health outcomes.225 Individual behavior is but one of many factors within a larger, structural framework that influences health outcomes. Other indicators such as home ownership, educational attainment, voter turnout and economic issues (such as unemployment or poverty) have also been identified as risk factors for substance abuse.226 Policies regarding resource allocation for substance abuse treatment and prevention are often developed without consideration of these risk factors. In the early 2000s, the Office of National Drug Control Policy (ONDCP) identified the need for a indicators or methods by which progress towards identifying “high-risk” communities in order to better allocate resources for drug abuse prevention and treatment. Gorman and Lebouvie concluded that more data driven assessments (such as the one they conducted) for policy development and evaluation regarding substance abuse prevention and treatment was necessary, although the risk factors they identified (using a social determinant of health approach) may not be universally applicable.227 And
despite the acknowledgement that health disparities exist because of these indicators, evidence shows that efforts to ameliorate them have thus far had minimal impact.\textsuperscript{228}

At the federal level, policies regarding drug use are prohibitive. That is, the use of certain substances is illegal, and therefore criminal. Since the War on Drugs began in 1971, the rate of incarcerations due to drug distribution and/or drug use grew from 110 per 100,000 individuals to 706 per 100,000 by 2012. From 1972 to 2000, there was a steady growth rate of 6 to 8 percent per year.\textsuperscript{229} One of the consequences of this is the rise of diseases related to injectable drug use among those who are incarcerated. Most recently, the rate of HCV amongst the prison population is also on the rise.\textsuperscript{230} As in the general population, this is fueled by lack of sterile equipment and resources for testing for HCV. United States drug policy, such as the “war on drugs” fuels stigma associated with drug use, which in turn prohibits the procurement of sterile needles and reduces the utilization of health care services associated with substance abuse.\textsuperscript{231}

Another potentially devastating impact of federal drug policy is the recent revision of guidelines by the CDC regarding the prescription of opioids.\textsuperscript{232} Individuals living with chronic pain are starting to see a reduction not only in the number of opioids prescribed per month, but also a reduction in the strength of these medications. This is not only a result of the adoption of these new guidelines by physicians, but health care organizations as well (primarily insurance providers).\textsuperscript{233} Insurance companies such as United Health Care or Cigna, have started monitoring patient’s opioid use more carefully, and have placed more restrictions on how much of the medications they cover each month. There is also evidence that some insurance companies also deny coverage of more expensive alternative for treatment of chronic pain.\textsuperscript{234} The consequences of these policies
are evident. Although the impact of these new guidelines is not immediately evident, restricting use and denying payment for non-addictive alternatives only serves to fuel the opioid crisis further. As previous studies show, many new illicit drug users cite access and price as reasons why they started in the first place.\textsuperscript{235}

This is not an isolated issue. Many communities across the United States are seeing a rise in the rates of injection drug use, HCV and HIV.\textsuperscript{236} Local and state governments now concede that harm reduction measures must be put into place not only to prevent the use of injectable drugs, but also to reduce the incidence of HCV and HIV in those who are current users.\textsuperscript{237} Some examples of these initiatives include syringe exchange programs, implementation of Narcan protocols in healthcare facilities and with first responders, safe injection sites, and public awareness campaigns.\textsuperscript{238}

Syringe exchange programs (SEPs) were first established in the United States in the 1980s in response to the HIV epidemic. Since then, the prevalence and incidence of HIV drastically reduced from that of the late 1970s and 1980s.\textsuperscript{239} The resurgence of HIV and HCV in communities affected by the opioid crisis caused many opponents of SEPs to reevaluate the need for these programs in their communities. Evidence shows that SEPs reduce HIV, HCV, hepatitis B, and the reuse or redistribution of contaminated syringes.\textsuperscript{240} They are also shown to be cost effective to taxpayers, as it is estimated that access to sterile syringes saves $3,000 to $50,000 per prevention of infection from HIV (which can cost anywhere from $385,000 to $618,000 to treat over a lifetime).\textsuperscript{241} Other goods and services such as educational materials, goods and services related to the prevention of sexually transmitted diseases, Narcan to prevent overdoses, as well as screening and referral services are provided as well.\textsuperscript{242} The offering of screening and
referral services is associated with an increased rate of entry into substance abuse
programs.\textsuperscript{243} As of 2013, only 204 of these programs existed in the United States.\textsuperscript{244}

Narcan (naloxone) is a pharmaceutical drug used to reverse the effects of an
opioid overdose completely or partially.\textsuperscript{245} It is typically used in hospital and emergency
services once symptoms of an overdose are suspected. However, in response to the rise in
deaths related to overdose, many states are working to make it more accessible to the
community. Currently all 50 states and the District of Columbia have passed some form
of legislation designed to improve access to naloxone.\textsuperscript{246} These laws provide easier
access to medical personnel who were previously not permitted to administer the
antidote, as well as individuals, healthcare personnel or organizations (such as non-
profits) who serve individuals suffering from opioid addiction. Forty states and the
District of Columbia have also passed laws to provide legal protections against arrest and
prosecution to individuals who report overdoses “in good faith.”\textsuperscript{247} Programs to educate
first responders and the public on the administration of naloxone are also being
implemented across the country. This training not only provides information on how to
recognize an overdose, but also instructions on how to administer it, and the tools to do
so – in the form of a naloxone take home kit. This is possible using a “standing order.” A
standing order is a physician’s order that, in this case, allows designated individuals to
distribute naloxone to whomever the physician includes in the order.\textsuperscript{248} In some cases,
this includes distribution to bystanders – those not directly affected but may intervene in
the case of an overdose. Half of the states in the U.S have some form of standing order
program, with 3 states currently implementing a statewide standing order, issued by the
top-ranking physician in each state.\textsuperscript{249} Although there are limited data about the
effectiveness of these programs, mathematical models predict that, at a minimum 1 life could be saved for every 164. Optimally 43,000 lives could be saved – roughly 1 for every 36 kits distributed. And because naloxone is relatively inexpensive, it is also considered an extremely cost-effective measure.\textsuperscript{250}

Safe injection sites are places where IDUs go to safely use drugs. Sterile equipment is provided to avoid contamination and the spread of diseases related to intravenous drug use. Health workers are on-hand to intervene in case of an overdose, provide basic health services, as well as treatment.\textsuperscript{251} There are currently around 100 safe injection sites operating in 66 cities – mostly in Europe.\textsuperscript{252} The only (legal) North American site is in Vancouver, B.C. Cities in the U.S such as Seattle and states like Pennsylvania and Oregon are now starting to recognize the need to provide a safe environment for users.\textsuperscript{253} These sites have shown to be effective in reducing the incidence of HIV, HCV and deaths related to overdose. They also reduce the number of discarded syringes, number of public injections and increases the amount of people entering substance abuse treatment.\textsuperscript{254}

The implementation of public awareness campaigns is just one other way communities are working to address the risks and consequences of opioid addiction. Currently there are initiatives at the local, state and federal level not only to reduce the number of opioids prescribed, but to reduce the risk of overdose, incidence of intravenous drug use and disease related to it, as well as educate those on how to prevent overdose related deaths through the administration of Narcan.\textsuperscript{255} Programs such as the Heroin Outreach Prevention and Education (HOPE) initiative provide educational tools in the form of online programs, as well as partnerships with other areas of the community to
provide toolkits to educate individuals (including physicians) on the dangers of opioid misuse and overprescribing, as well as assistance to those caught using. Instead of fearing incarceration, police departments such as the one in Nashville aid those suffering opioid addiction.256

Bioethics is poised to play a significant role in the treatment and prevention of drug abuse. Equal access to healthcare is one of the key aspects of the principal of justice. By examining the causes of the current opioid crisis, bio ethicists can assist in the development and evaluation of healthcare policies that can directly impact those who are affected – both individuals and communities. Current drug policies do not allow for equal access because they stigmatize individuals who use and are addicted to certain substances. Research into the strategies used to combat this crisis would only serve bioethics by examining the ethical nature of, and ethical issues related to these strategies to ensure justice for individuals who benefit from these programs. The relative newness of programs such as the HOPE initiative, the legality of Narcan use by healthcare professionals and lay persons and safe injection sites only provides new ground for bioethics to explore both philosophically and empirically. Findings from such studies could also be pivotal in the formulation of policies in guidelines in communities and at the governmental level, such as allocation of resources for prevention and treatment.

2c. Culturally Competent Care in Substance Use Disorder Treatment

Racial and ethnic minorities currently make up roughly a third of the population, with this number expected to increase to over fifty percent by 2050.257 This change in demographics is important to consider, not only in the context of social implications, but also the effect it will have on the health care system. Disparities in care among racial,
ethnic, and sexual minorities are well documented. However, it is important for bioethicists to explore the potential impact of this growth and find ways in which they can address the lack of equity in care minorities experience. This dissertation will identify the incidence of substance abuse among various racial, ethnic, and sexual minorities. Examples of the types of treatment available to individuals who are suffering from substance abuse will also be discussed, as well as the racial and ethnic disparities found in the various stages of treatment. It will also explore the bioethical models of care that are employed to eliminate inequities in the health care system and discuss their role, as well as the role public and private initiatives play in addressing the disparities in healthcare, particularly substance abuse treatment.

Research on racial, ethnic, and sexual minorities shows that there are different rates of drug use within and between each. That is, differences exist within African American/Black, Hispanic, Asian, Native American and LGBTQIA+ communities, sometimes as a result of location, education, employment status or gender.\textsuperscript{258} Outcomes of drug use also differ, with a disproportionate amount of racial/ethnic/sexual minorities experiencing major disease(s) related to drug use, such as HIV, HCV and cardiovascular disease compared to heterosexual Caucasians.\textsuperscript{259} Although a minority of individuals who engage in substance use go on to develop a SUD it is the most prevalent psychiatric disorder in the United States.\textsuperscript{260} An examination of the incidence of drug use is beneficial to understanding risk factors related to use, as well as disparities in outcomes as a result.

Every year, the NSDUH conducts a survey of interviews with a sample of 70,000 randomly selected individuals over the age of 12. The data collected provides state and federal level data on “the use of tobacco products, alcohol, illicit drugs (including non-
medical use of prescription drugs) and mental health in the United States.”

For the purpose of this dissertation, the data presented is limited to alcohol, marijuana, cocaine/crack, opioids, and heroin usage, as these are the most common drugs for which treatment is sought.

Marijuana use amongst those surveyed was around 42%, meaning almost half of people surveyed by NSDUH have, at some point in their lives, used marijuana in some form. Its use was highest for Biracial respondents at 52.4%, followed by Native Americans (50%) Caucasians (46.3%). Asians had the lowest rate of use at 18.6%. The survey also includes African Americans (40.4%), Hispanics (30.8%), and Native Hawaiians/Pacific Islanders (45.8%). For those who used marijuana in the past year (2016), 4.0 million met DSM-IV criteria for an SUD, which represents approximately 1.5% of the total population of the U.S.

The rate of alcohol use for Caucasians is also highest at 87%. Biracial respondents came in at 80%, with Native Americans at 76.4%, African Americans/Blacks at 75%, Native Hawaiian/Pacific Islanders at 74%, Hispanics at 71.9% and Asians at 66%. Overall, 81% stated they had used alcohol in their lifetime. NSDUH reports that among those who reported alcohol use in the past year, 15.1 million individuals aged 12 or older (5.6% of the total population) met DSM-IV criteria for a SUD. Hispanics were more likely than all the groups to binge drink, which is defined by NSDUH defines as “consuming 5 or more drinks on one occasion within the past 30 days.”

As far as cocaine use, Native Americans (21%) report using it at some point during their lifetime. Caucasians come in at the second highest with 17.1%. Biracial is next with 15.7%, followed by Hispanics (10.7%), African Americans (9.9%) Native
Hawaiians and Pacific Islanders (8.1%) and Asians with the lowest at 3.6%. Crack is considered separately, as it is a different formulation of the same drug. Cocaine is powder white crack cocaine comes in solid form. Cocaine and crack are also punished in differently, as a result of the 1986 Anti-Drug Abuse Act, which differentiated crack from other forms of cocaine, and made it use more punitive. Since then, disparities in sentencing cocaine from crack cocaine often favored powdered cocaine users, who tend to have higher socioeconomic status. As of 2015, 9.5% of crack users were Native American, 5% African American, 4.3% biracial, 3.5% Native Hawaiian/Pacific Islander, 3.4% Caucasian, 1.8% Hispanic and 1% Asian. Of those who used cocaine or crack in the past year (2016) 867,000 – 0.3% of the population – met the criteria for an SUD.

The incidence of painkiller and opioid abuse has seen a steady rise in the 21st century as a result of overprescribing by physicians, in many cases, to treat chronic pain. Among those surveyed, 15.2% of Caucasians and 15% of Biracial individuals admitted to using opioids and or prescription painkillers in a manner other than prescribed or without a prescription. Asians were least likely to report misuse (4.8%). Native Americans were next at 14.9%, followed by Native Hawaiian Pacific Islanders (11.2%). Hispanics (10.8%) and African Americans/Black at 10.6%. Overall 13.5% reported some use in their lifetime. Those with SUDs made up 0.7% of the population (for painkillers overall) and 0.6% of the population for opioids specifically.

Heroin use is also on the rise nationally. This too is related to overprescribing of opioids for pain because heroin is cheaper to obtain. In fact, deaths related to heroin overdose have risen over 500% in the past 15 years. This too is related to overprescribing of opioids for pain because heroin is cheaper to obtain. In fact, deaths
related to heroin overdose have risen over 500% in the past 15 years. Biracial individuals report the highest amount who have used heroin in their lifetime (52.4%) followed by Native Americans (50%), Caucasians (46.3), Native Hawaiians/Pacific Islanders (45.8), African Americans (40.4), Hispanics (30.8) and lastly Asians at 18.6%.  

As of 2016, roughly 626,000 – 0.2% of the population) people over the age of 12 had a SUD related to heroin use. While it may seem like a small percentage, it doubled from that of 2011 to 2015.

Only recently (2015) did NSDUH consider the importance of including sexual orientation on their survey, since recent studies show that sexual minorities are at greater risk for substance use and abuse than heterosexual counterparts. So while recent national data is limited, they found that sexual minorities were nearly twice as likely to have used marijuana (30.7%), 39.1 percent used illicit drugs (39.1%) and 1 in 10 (10.4%) misused prescription pain relievers in the past year. Sexual minority members were also more likely to be current cigarette smokers, as well as current alcohol drinkers (63.6%). Overall, 15.1% of the sexual minority population has a SUD (one or multiple) compared to 7.8% of the sexual majority population. The importance of collecting and analyzing such data cannot be overlooked. It can as impetus for further research into what factors create a difference in substance use and abuse. This knowledge can also be used to inform tailoring of SUD screening and treatment programs, potentially increasing their impact on racial, ethnic, and sexual minorities.

Prior to scientific study regarding addiction common misconceptions existed (and some persist) regarding the nature of addiction. Those struggling with substance abuse were thought to be morally flawed. It was believed to be a choice, and individuals who
abused substances merely lacked the will power to stop. The focus on morality and personality led society to see it as a punitive issue, and not a public health one. Instead of focusing on treatment and prevention, substance abusers were (and continue to be) punished for using. Because of scientific study, we now have a better understanding of the biological, environmental, and genetic facets of addiction. With these advances in scientific knowledge, health care is better equipped to develop treatment and prevention programs aimed at reducing the incidence of addiction.

Many types of treatment exist for individuals suffering from substance use disorders. These are typically catered to the unique needs of each individual. Some focus on the needs of those who are suffering from a singular disorder, while others are tailored to poly-substance abuse, or individuals living with comorbidities (multiple disease states, such as substance addiction and mental illness). The types of services offered are myriad and evolving, so they do not fit neatly into categories. However, those seeking treatment are typically entered into either inpatient treatment programs or outpatient treatment programs. These programs are designed to assist patients in behavioral changes by providing structure, various forms of therapy and in some cases, medication.

Inpatient or residential treatment requires an individual to stay at a specialized facility for substance abuse treatment. This can happen either at a specific unit in a hospital or a private facility whose focus is substance abuse treatment. The length of stay varies. Short term residential treatment may be 28, 30 or 90 days. The primary focus of this treatment is detoxification (also known as medically managed withdrawal). Evidence based methods of treatment such as individual or group counseling, as well as
art therapy and music therapy are also available to prepare the patient to return to their community and transition to outpatient therapy. And while short term rehabilitation programs are the most common, a doctor may determine that a patient requires longer, more intensive inpatient treatment. These types of programs can last anywhere from 6 months to a year but are relatively uncommon.287

There are alternatives to residential stays. Intensive outpatient programs are available and require the individual to attend therapy session multiple times every week for an initial period. Once a person completes the intensive portion of their treatment, they transition to outpatient programs, which meet less frequently. These programs allow for ongoing recovery. Individualized and group counseling sessions are part of this process as well. Other options include 12 step groups, such as Alcoholics Anonymous (AA), Narcotics Anonymous (NA) and Cocaine Anonymous (CA) or other non-profit self-help groups such as Life Ring Recovery or Women for Sobriety.288 Peer support is also available. Peer support is provided by an individual or individuals with common experiences to those they are serving (for instance, those who have recovered from substance abuse or PTSD). This is done one on one or in group settings.289 Outpatient treatment is the most commonly engaged forms of treatment due to the convenient nature of the model (it allows patients to be more engaged in the community) and its cost effectiveness.290

It is also important to consider another form of treatment known as the prison Therapeutic Community (TC) model.291 These programs, which are similar to residential treatment, provide an environment that promotes sobriety within and beyond the prison environment. They are often provided in specific wings of prisons where the inmates
pledge sobriety, separate housing or only during specific hours of the day. These programs are usually offered over a course of 6 to 12 months, and usually in the year or months before an inmates’ release. Although long term data is limited, recent studies show enrollment in these programs reduces the rate of recidivism and relapse, although some studies show the impact is greater when continuing therapy is mandated upon release.\textsuperscript{292}

While these options are available, equality in the engagement of substance abuse treatment is not. This not only affects patient outcomes, but it can also affect the rate at which individuals remain in programs, as well as their effectiveness. There are many reasons why access, retention and outcomes are different for an individual, but racial, ethnic, and sexual minorities tend to encounter more barriers, suffer poor retention, and experience negative outcomes at rates higher than other populations.\textsuperscript{293}

2ci. Disparities in Substance Abuse and Treatment

The NAM defines a health service disparity between population groups to be “the difference in treatment or access not justified by the differences in health status or preferences of the groups.”\textsuperscript{294} An abundance of evidence exists showing that racial and ethnic minorities are less likely to engage in healthcare systems, receive lower quality treatment and have poorer health outcomes.\textsuperscript{295} Research also suggests that these disparities also exist for sexual minorities as well.\textsuperscript{296} Although limited, research specifically related to substance abuse treatment for racial, ethnic and sexual minorities also suggests that disparities exist, specifically related to access, retention and outcomes of treatment.
A growing amount of literature on substance abuse treatment suggests that an association exists between treatment engagement and outcomes. Adults and adolescents report positive outcomes when engaged in substance abuse treatment. Adults show improvement in substance use, employment, and experience less engagement with the criminal justice system (including a reduction in recidivism). Adolescents are less likely to relapse. Despite this evidence, disparities in engagement with substance abuse among racial, ethnic, and sexual minorities exist. Previous studies indicate that African Americans and Hispanics report less access to mental health and substance abuse treatment services compared to non-Hispanic individuals. There are several barriers to access that can account for these disparities.

One major barrier to access is the stigma associated with substance abuse. Minorities tend to experience this type of stigma at a higher rate, both personally and institutionally. This is compounded in racial, ethnic in sexual minorities who may already experience stigma due to their race, ethnicity, sexuality (or a combination race/ethnicity and sexuality). This often deters people from seeking treatment. In African American communities, alcohol and drug use is often seen as a sign of weakness. Hispanics also tend to stigmatize drug and alcohol dependence at a rate higher than African Americans and whites. Asian American and Pacific Islanders may avoid treatment because revealing to their family or community that they have a substance use disorder may bring shame to them and their families. Religion and spirituality are also important to consider, as certain religions have negative attitudes towards addiction, and may influence an individual’s decision to seek treatment.
Healthcare professionals also tend to have a negative perception of individuals who suffer from substance use disorders. This is a result of lack of education on substance abuse and the benefits of treatment. This affects access in a couple of ways. First, if the person with an SUD perceives discrimination from healthcare professionals due to their SUD, they are less likely to maintain a relationship with that professional. In turn, they may not take the advice of that professional, and as a result seek treatment in the short term (such as through ER visits) or not at all. The lack of education on the practitioner’s part, as well as their perception of the addicts diminished will power and motivation may also influence whether (or what type of) treatment options are offered.

Another major barrier to access is financial. In the United States, racial and ethnic minorities have disproportionately low incomes as well as low rates of private health insurance. In fact, African Americans are twice as likely to be considered low or below poverty level income. Minorities also tend to be over-represented in the lower income category. Some 58% of minorities are considered low income (as of 2013) despite constituting less than half of the population. This translates into limited healthcare coverage. As of 2013, 38% of all low-income households had one parent without health insurance. In terms of race and ethnicity, 29% non-Hispanic whites had a parent without insurance coverage, 28% of African American households had one parent without coverage, 36% of Native American household, 35% of Asians, 36% of “Other” racial minorities and 56% of Hispanic households. The percentage of Hispanic households without coverage is likely due to unique challenges Hispanic immigrants face when trying to get coverage. Lack of documentation makes it difficult to get Medicaid coverage or other types of coverage benefitting low-income families. Sexual minorities also tend
to be disproportionately poor compared to their heterosexual counterparts, and only recent changes in healthcare policy (namely, the Affordable Care Act) have given LGBTQIA individuals healthcare options that were unavailable before (i.e., the ability to add same-sex partners onto their health plans). \(^3\)

This disparity is also present with regards to Medicaid, which is the largest provider of mental health and addiction services. As of 2014, 47.3% of Whites, 40% of African Americans, and 30% of Native Americans met new ACA eligibility criteria for Medicaid, compared with 81.1% of Asian Americans, 57% of Latinos, and 55.1% of multi-race individuals. \(^4\) Data on sexual minorities is limited, as only recently were individuals asked about sexual identity on federally sponsored surveys. Data on the health of sexual minorities has not been collected and reported until recently. \(^5\)

Having no insurance or being on Medicaid necessarily affects access to and utilization of substance abuse treatment services. While the ACA requires plans to cover addiction services, not all plans are governed by it. Even with coverage, patients may find it difficult to find treatment centers that accept their plan. Coverage also does not guarantee that the plan will cover the full extent of recommended treatment. For instance, the plan may only cover a limited amount of time or services. \(^6\) Recent (2014) studies show that African-Americans and Native Americans are still less likely to use substance abuse treatment services compared to whites and other minorities, even with Medicaid. \(^7\) This is attributed to living in states that declined the Medicaid expansion offered by the ACA. \(^8\) This uneven expansion of Medicaid, coupled with overrepresentation in low-income households, makes it difficult to seek treatment, especially if it requires time away from work. The choice between seeking treatment and earning a wage may be
difficult, and low-income jobs tend to offer less incentives to help workers seek the treatment they need.\textsuperscript{321}

Accessibility is also a barrier to treatment. Living far away from treatment centers, or not knowing where to go for treatment can impede on the ability of an individual to get treatment. Distance is especially a factor if the individual does not have their own means of transportation, or reliable forms of mass transit to and from the treatment center. Individuals who are wait-listed by facilities are also less likely to seek or continue treatment. These issues are prevalent in areas that have limited availability of mental health services, such as rural areas or areas with a substantial proportion of minorities.\textsuperscript{322} Lack of childcare is also an issue which can also impede entry into treatment programs.\textsuperscript{323} These barriers to access necessarily affect health outcomes of individuals with substance use disorders. Even when a patient gains access to treatment options, their experience within treatment can determine whether the individual continues with treatment or completes the treatment program.\textsuperscript{324}

Studies comparing treatment outcomes of racial and ethnic minorities consistently show that African Americans, Hispanics, and other minorities tend to experience less satisfaction with the treatment process and in turn, less successful outcomes. Retention rate and successful discharge rates are just some predictors of successful outcomes for those with substance use disorders. The availability of culturally competent care is also an indicator of success.\textsuperscript{325}

One of the major pathways to substance abuse treatment is through pressure by family, friends, employers, and legal authorities, with African Americans reporting higher incidence of pressure from family members than other minorities (and compared
Referral sources are strong indicators of successful completion of substance abuse treatment. Patients who are referred by employers or the criminal justice system tend to have higher retention rates and more successful outcomes than those with medical or family/self-referrals. Racial and ethnic minorities are more likely to have been referred to court mandated treatment because of the disproportionate number of racial-ethnic minorities who have interacted with the criminal justice system. The question of coercion then, becomes important to consider. Motivation is shown to predict both retention and engagement in community-based treatment for substance abuse, and studies also show its importance in successful post-incarceration treatment. Coercion into treatment of the justice system is, to some, detrimental to treatment. Some maintain that treatment can only be effective if the person is truly motivated to change; while others contend that outside coercion is necessary to ensure success. The literature on the effectiveness of coercion-based programs has mixed results but tend to show that when individuals are given more choices with regards to treatment, they have better outcomes. Recidivism rates tend to be higher in individuals who felt “oppressed” by treatment rules.

African Americans tend to have shorter retention than whites and are also less likely to complete a treatment program. Hispanics tend to have longer retention and completion rates than whites or African Americans. Native Americans tend to have lower retention rates and completion rates compared to all other minorities. Successful completion means “any planned discharge from treatment, including transfers to other facilities where the individual was expected to continue further treatment.” Incomplete treatment entails exit from a program due to non-compliance, death, incarceration or
against medical advice. African Americans are more likely than whites to quit or be expelled from treatment programs. Studies suggest that part of the disparities that exist here correlate to the race, ethnicity, drug of choice of the individual, as well as socioeconomic status. Asian Americans and whites more likely to complete treatment, regardless of drug. The disparity between African Americans and whites is most apparent for alcohol and methamphetamines, while the disparity is greatest between whites and Hispanics for heroin use. African Americans that used heroin, cocaine or marijuana were less likely to complete treatment compared to whites who abused alcohol. Hispanics using methamphetamines, cocaine or marijuana were also less likely to complete treatment than whites who abused alcohol. Hispanics and African Americans are also less likely than other groups to complete their treatment program upon the first visit. Native Americans also have poorer outcomes than all other minorities regardless of drug of choice. Part of this is related to the lack of services geared towards the needs of the Native American population. Again, data on the outcomes of sexual minorities is limited. However, recent studies show that the gender of sexual minorities is a strong indicator of outcomes, with sexual minority women more often reporting positive treatment outcomes.

Other disparities in outcomes exist. Negative employment outcomes post treatment is more often reported by African Americans and Hispanics than any other group surveyed. That is, either prior to treatment they were unemployed, and had difficulty finding employment during or after treatment, or they became unemployed during the duration of the treatment – which often affects compliance, retention, and completion rates. Underrepresentation of African Americans and Hispanics in
supplemental services such as employment or legal counseling also persists. Despite the
greater need among minorities for such services, they are not as readily available in
economically disadvantaged communities, where minorities are often overrepresented.\textsuperscript{342}
Communication is also a barrier to treatment. Immigrants – especially those who speak
Spanish, may not speak English, and therefore are unaware of resources available for
substance abuse treatment. A lack of staff available in some treatment facilities that speak
a second or third language such as Spanish is also a detriment to non-English speaking
minorities. Without proper communication, just as in other healthcare environments,
positive outcomes are difficult to come by.\textsuperscript{343}

While it is apparent from the data that a combination of individual, service and
system factors play a role in the outcomes for different racial, ethnic, and sexual
minorities, it is important to consider the evidence to develop substance abuse treatment
programs that tailor to the needs of each of these groups. The differences within and
between is important to consider when developing a successful treatment program.
Minorities, such as Native Americans, report general satisfaction with their treatment
program, but often cite lack of culturally aware programs.\textsuperscript{344} In fact, better outcomes and
higher patient satisfaction are often correlated with treatment programs attuned to cultural
competence and diversity.\textsuperscript{345} Governmental and healthcare-related institutions and
organizations are now making concerted efforts to incorporate what are known as patient-
centered care models and cultural competency components to their treatment models in
an effort to address this deficiency with hopes of improving patient outcomes.\textsuperscript{346}
In 2000, the Office of Minority Health (OMH) introduced Cultural and Linguistically Appropriate Services in Healthcare standards. The goal of these standards is to “improve health care quality and advance health equity by establishing a framework for organizations to serve the nation's increasingly diverse communities.” Patient-Centered and Cultural Competence Models are two prevailing approaches in healthcare systems aimed at addressing this issue.

The NAM defines patient-centered care as: “care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions.” By creating a framework that challenges practitioners to “see the world from the eyes of the patient,” patient-centered care provides an alternative to traditional, paternalistic medicine. Instead of denying patients the ability or means to make medical decisions, it acknowledges the uniqueness of the individual and gives them more power over their healthcare decisions.

Communication in patient-centered care is important because it ensures that a patient is making a fully informed decision based on their needs, wants and values. This is achieved through patient-focused interviews, which are less controlling and less aggressive and help ensure a comfortable, equal exchange between the practitioner and patient. Written correspondence, patient education materials, appropriate signage and electronic correspondence are also integral to a patient-centered approach to care. These provide alternative means of meeting the needs of the patient and promotes engagement in health-related decisions.
Patient-centered care also includes aspects of care related to access. This focus on delivery of care considers the fact that not every patient has equal time or resources to obtain health services. Extended office hours, same-day appointments and services that are convenient to patients are examples of some such services that are offered. Patient outcomes such as satisfaction, quality of life and functional status are also considered.\textsuperscript{353}

While the patient-centered approach aims to improve the individual quality of care, there are gaps in the approach. The lack of attention to the influence of sociocultural issues such as race, ethnicity and language on health-care interactions and decisions leaves the possibility for misunderstanding, improper care, and poor health outcomes. The model is admittedly “not directly responsive to racial and ethnic disparities in healthcare” but it is suggested that by fostering empathy, warmth and respect, disparities could \textit{theoretically} be reduced.\textsuperscript{354} Research that evaluates patient outcomes of intervention recipients is therefore necessary. Allocation of resources and policy formation are more likely when evidence-based models are used, not theoretical ones. Otherwise, implementation of this method may not only be ineffective for patients, but it has the potential to tax an already burgeoning healthcare system. Current research efforts in that area though, are lacking.\textsuperscript{355}

Cultural competency is a set of attitudes, practices and policies that promote effective cross-cultural and cross-linguistic interactions and communication.\textsuperscript{356} A culturally competent healthcare system understands and recognizes the importance of sociocultural factors on patients’ healthcare experiences and overall outcomes. incorporates an assessment of cross-cultural encounters, expands cultural knowledge, and adapts services to meet the unique needs of diverse populations.\textsuperscript{357} This dissertation
considers the model established by Betancourt et. al, which identifies three categories of healthcare where healthcare disparities occur and provides interventions for each. These barriers occur at the organizational, structural, and clinical levels of care.\textsuperscript{358}

Lack of diverse leadership in healthcare, as well as inadequate minority representation in the healthcare workforce constitute \textit{organizational} barriers. This affects quality of care, as considerations of minority patients are less likely to be implemented systematically. This negatively impacts minorities ease of access and overall satisfaction levels. One way to address this is to create initiatives for recruiting minorities in the healthcare field (although efforts thus far fall short).\textsuperscript{359}

\textit{Structural} barriers occur because of the complexity of health systems that do not meet the needs of a diverse population. The bureaucratic nature of engaging the health system and lack of interpreter services for non-English speaking patients exacerbates disparities.\textsuperscript{360} An emphasis on quality improvement (via patient satisfaction surveys) and data collection related to race, ethnicity and language preferences will assist health care systems in preparation for delivery of quality care. This data will help them develop policies and procedures that are more concordant with patient needs.\textsuperscript{361}

\textit{Clinical} barriers occur at the patient-provider level when differences related to values and beliefs about what health and illness are, or what is appropriate as far as disclosure or treatment exist. Misunderstandings affect patient satisfaction and ultimately, health outcomes. Proper cross-cultural education and training needs to be put in place for all levels of individuals who work in and around healthcare systems to eliminate these barriers.\textsuperscript{362}
Critics of this method highlight a few key areas where the method needs improvement. The lack of curricula to educate health providers remains an issue, and guidelines that are necessary to “train the trainer” are inconsistent and scarce. There is also no standard requirement nationally for medical providers to have such training. This model also needs evaluation to test its impact on health outcomes. Few organizational or policy level evaluations exist, and those that do tend to address service utilization, not patient outcomes. Others lacked external validity, generalizability, and efforts for replication. Despite the relatively recent incorporation of patient centered and culturally competent care into general treatment systems such as primary care physician’s offices and hospitals, the need for such care in specialty treatment programs such as substance abuse treatment centers has not gone unnoticed. Patients who feel as if their cultural needs are met report higher levels of satisfaction and tend to have more positive outcomes that those who do not.

Research has established that cultural and linguistically diverse populations (CALD) and sexual minorities have high rates of addictive disorders, yet lower rates of substance abuse treatment engagement, retention and completion compared to the majority population. There is also evidence that culture and context influence almost every aspect of the diagnostic and treatment process. This is also true at the intersection of race, ethnicity and sexuality. Patient-centered model and cultural competence model of healthcare delivery are poised to help address this specific issue.

Although the National Academy of Medicine (NAM) and other mental health researchers acknowledge the importance of incorporating a consumer perspective driven model of health care, and the need for patient centered care with regards to mental health,
relatively little research is available on the perceived benefit of the patient care model (PCM) in substance abuse treatment programs. Studies of mental health and substance abuse workers are more prolific, but necessarily neglect the patient’s subjective experience. As Betancourt et. al established, client perceptions of the relationship between client and therapist/specialist, as well as a consideration of the subjective perception of clients, are important, as they are key indicators of satisfaction and predictors of positive therapeutic outcomes. In a recent study by Meyer and Zane, clients from outpatient substance abuse treatment clinics were surveyed as to the importance of racial and ethnic elements of patient centered care. They found when differences in racial and ethnic experiences were not acknowledged and/or discussed by providers, satisfaction with treatment was markedly less. This perception was stronger with individuals who strongly identified with their race or ethnicity. Studies such as this can help healthcare providers address some of the gaps that presently exist in the PCM model – especially those related to racial and ethnic concerns. Considering communication is one of the key elements of the PCM, an open, honest dialogue about racial and ethnic concerns appears to be essential for some minorities in treatment.

In outpatient treatment programs in California, Latinx individuals often enter outpatient treatment with high risk factors such as homelessness and high frequency of drug use. These individuals were more likely to drop out of such programs. Introduction of the PCM – specifically those that provided linguistic services – showed a significant improvement in entry, retention, and completion of the program. Another study conducted by Schwartz et. al. incorporated the PCM into a methadone treatment program to measure its effectiveness on treatment outcomes. A control group of
individuals receiving methadone treatment with mandated counseling sessions was used. The other group was given the option for treatment. The program was also less strict on discharging patients for what is perceived as minor infractions (loitering, drug use during treatment). Although retention and reduction of drug use was not significantly different for the PCM program in this study, a potentially important initial find was that patients reported an improvement in perceived quality of life and reduced methadone doses.

Patient centered care in substance abuse treatment needs not only focus on retention and success via completion, but understand what outcomes are important to patients, and by doing so allow patients the opportunity not only to help shape treatment programs, but inform research on the effectiveness of PCMs in substance abuse treatment centers.

The cultural competence model of care is another bioethical model being incorporated into various levels of care. Recent studies show that culturally tailored treatment, such as those use by centers who practice cultural competence, is associated with more favorable outcomes for racial and ethnic minorities, compared to control groups. Studies suggest that culturally competent care can not only improve engagement on the individual level, but family level as well. Retention and engagement in CALD youth and their families improved in programs who integrated this model into their programs. These types of interventions appear to not only attract CALD populations to treatment but also improve the relationship between patient and client and reduce the treatment drop-out rates.

Recent studies that measure the integration of culturally competent care against control groups show some evidence that culturally sensitive methods such as matching clients with counselors based on race/ethnicity and language, congruence with regional
culture, belief systems and/or socioeconomic status is also associated with an increase in retention.\textsuperscript{382} This suggests that CALD clients are more likely to remain in treatment when treatment services are geared towards their needs.\textsuperscript{383} Outpatient treatment facility managers also report that knowledge of the CALD clientele in their service area was a better indicator of program success that then diversity of the treatment staff.\textsuperscript{384}

Although data on this subject is limited and underdeveloped, the need for such data is evident. These can be used by healthcare professionals, bioethicists, and policy makers as a conduit to studying the effectiveness of PCM and cultural competence in programs that treat minorities, as well as shape policies, procedures and legislation that can be adopted on a larger scale to address issues unique to racial, ethnic, and sexual minorities suffering from SUDs.\textsuperscript{385}

In 2000, the NAM released “Crossing the Chasm: A New Health System for the 21\textsuperscript{st} Century.” The goal of this report was to illustrate the disparities between ideal health care and actual healthcare people receive.\textsuperscript{386} In it, the NAM put forth a framework for quality assessment of healthcare known as the six “Aims for Improvement,” which included the call for patient-centered care. As a result, public sector (federal, state, and local governments) and private sector (health care institutions or professional organizations, foundations, academic institutions/policy research organizations) initiatives were established to close the gap in care. Their 2002 report “Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare” further examined the need for patient-centered and culturally competent care.\textsuperscript{387} Public and private sector institutions have not only worked to address these issues in the healthcare system as a
whole, but they also have, and continue to, attempt to address specific issues in health, such as mental health and substance abuse.

Many public-sector initiatives for patient centered and culturally competent care start at the federal level of government. In August of 2000, President George W. Bush issued an Executive order with the purpose of improving health care services in federally funded sites for people with limited English proficiency (LEP). As a result, the Office of Health and Human Services (HHS) Office for Civil Rights issued policy guidance (“Title VI Prohibition Against National Origin Discrimination As It Affects Persons with Limited English Proficiency”) discussion the enforcement of the Civil Rights Act of 1964 as it pertained to those who speak limited English.\textsuperscript{388} Subsequently, other federal agencies under HHS such as the CMS, the Health Resources and Services Organization (HRSA), the Office of Minority Health (OMH) and SAMHSA began initiatives to create training materials, fund and provide training, organize and deliver conferences as a means to establish culturally competent care in publicly (Medicare) and privately funded care systems.\textsuperscript{389} OMH specifically established 15 standards that serve as mandates, guidelines and recommendations for culturally and linguistically appropriate services (CLAS) in health care organizations, particularly those that are federally funded. SAMHSA specifically targeted cultural competence in mental health and substance abuse services.\textsuperscript{390} These efforts served to address the gaps racial and ethnic minorities experience in the healthcare system.

Governmental legislation has also been put forth since then the address disparities in care. The Affordable Care Act of 2010 not only expanded healthcare to individuals who typically did not have it (a large portion of which are racial, ethnic, and sexual
minorities) by providing incentives and requirements to bridge the divide. Its goal is to expand the number of health care settings closer to where people live and work, further diversifying the workforce and addressing cultural issues through clinical and community-based initiatives. It also requires those receiving funding for federal aid (Medicaid) to provide culturally competent services, and provisions are also in place to collect data on race, ethnicity, sex, and disability status to better understand and reduce disparities in health care.

Efforts were also made by private organizations such as the AMA, the American College of Physicians, (ACP), the Center for Cross Cultural Health (CCCH), National Center for Cultural Competence, Kaiser Permanente, and the Robert J. Woods Foundation. The focus of many of these organizations is on research and implementation of patient centered models and culturally competent care models into various healthcare settings. This includes hospitals, medical schools, and managed care organizations. The Association of American Medical Colleges and AMA established the Liaison Committee on Medical Education (LCME) accreditation standards in 2001 that require that faculty and students “have an understanding of diverse cultures and beliefs that can affect health as well as be aware of their own potential cultural biases” in order to get accreditation. The Joint Commission, which accredits 21,000 health care organizations and programs in the United States, initially implemented patient centered communication standards for hospitals in 2009, and further developed culturally competent care standards in 2012. As a result, hospitals and other health providers across the country have embraced the need for diversity, and cultural competence training is steadily becoming required of all employees, regardless of their roles in the system.
Patients in substance abuse treatment programs who receive patient centered and culturally competent care tend to have a higher level of satisfaction with their care. Outcomes also tend to be more favorable as well.\textsuperscript{397}

As has been the case in the past, legislation and other health initiatives can be useful for generating more equitable treatment in substance abuse treatment centers. For instance, SAMHSA continues to update Treatment Improvement Protocols (TIPS) which are “best practice” guidelines for treatment of substance abuse disorders, including guidelines for incorporating patient centered, and culturally competent models of care into the healthcare system and substance abuse treatment.\textsuperscript{398} They also supported the formation of the National Network to Eliminate Disparities, which also shares information, training to organizations and communities working to improve behavioral health for diverse populations.\textsuperscript{399} HHS continues to provide grants for research on racial and ethnic healthcare disparities and cultural competency (for instance the American Indian/Alaska Native health Equity Initiative).\textsuperscript{400} Findings from research such as this could be used to aid in the design and improvement of interventions to reduce disparities in substance abuse treatment.

Professional organizations like the American Society of Addiction Medicine also endorse the Patient Care Medical Home model in substance use disorder treatment, as it facilitates a partnership between the patient, physician/provider(s) and family, which has previously promoted positive rapport and favorable health outcomes, particularly for minorities.\textsuperscript{401} Requirements for data collection, such as those present in the ACA, will only serve to provide information for educators and researchers who wish to assess and improve culturally competent care. Efforts such as these can only aid in the improvement
of the quality of care received by everyone in the United States, regardless of race, ethnicity, or sexuality.

While not all racial, ethnic and/or sexual minorities experience high rates of substance abuse, significant disparities in engagement and outcomes in substance abuse treatment exist. Barriers to access such as health insurance, accessibility of programs and social stigma need consideration. Disparities in outcomes also exist. Recent bioethical models of care such as the PCM and cultural competence model have the potential to improve treatment through their incorporation into treatment protocols. The potential impact of public and private sector initiatives on equitable treatment for substance use disorders should not be ignored. An acknowledged lack of data on the effectiveness of cultural competency continues to exist, while continued efforts by healthcare providers, policy makers and academics (such as bioethicists) are needed to continue to improve cultural competence among health care professionals and organizations, which in turn would contribute to improving the quality of health care for minorities, and those in substance abuse treatment centers in particular.

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Chapter Three: Ethics of Substance Use Disorder in the Life Cycle of Patients and Subjects

This chapter provides a longitudinal examination of life with substance use disorder(s). The purpose of these analyses is to convey the impact of multi-level and multi-scenario interactions on health outcomes of individuals. This includes those living with a substance use disorder and in some instances their families as well. The way in which humans interact with their environment both on a biological and social level can affect their access to and experiences with health care. It can also affect humans in unseen ways. Being deprived of basic necessities such as food or being exposed to pathogens can affect humans on a genetic level and may manifest as disease in current and future generations. This chapter will examine OUDs and their effect on pregnant people and their children, explore how genetics factors into SUDs and how even at the end of life, having one may be detrimental to death.

3a. Beginning of Life: Substance Use Disorder and Maternal Health

The incidence of opioid use has steadily been on the rise since the early to mid-1990s. A change in the way medicine addressed pain management changed drastically after a push by the American Pain Society and organizations in other countries to re-classify pain as the “fifth vital sign.” This led to a surge in the number of opioid prescriptions being issued to patients and a rise in the incidence of opioid use disorders (OUD).¹ The rise in OUDs in the general population also suggests that many women who are entering substance use disorder treatment may be pregnant. In the United States alone, reported rates of Neonatal Abstinence Syndrome (NAS) only serves to confirm this assumption. Over the course of roughly a decade (2000 to 2013) the rates of NAS
increased five-fold from 1.5 per 1,000 births to 6.5 per 1,000 births.\textsuperscript{2} Despite the rise in the prevalence of NAS births in the United States, and the known higher risks of maternal and neonatal morbidity and mortality in pregnant women who use substances such as opioids during pregnancy, the population remains underserved. Barriers at all levels of society delay or inhibit engagement of pregnant people with a substance disorder (PPSUD) with proper treatment. The purpose of this paper is to explore the unique nature of substance use in women, discuss the various barriers to treatment, ethical implications, and strategies to not only get pregnant people with an OUD (PPOUD) to seek out care, but ways in which it can be administered that are geared specifically towards this population and its unique needs.

It is important to understand that when discussing the impact of substance use disorders on individuals, biology and physiology have a significant influence on the ways in which different substances affect the mind and body. While women are not the only individuals who can get pregnant (for instance, transgender men can also be gestational parents) this section of the dissertation pertains to the unique experience of gestational parents who were assigned as female at birth and identify as women. There is also a paucity of data on outcomes of pregnant persons who do not identify as women/female. Women in particular have unique susceptibilities that are not found in men. The ability for childbearing also adds another caveat to the already complex dimensions of substance use disorders. It is important to not only explore the rates at which women currently suffer from SUDs, but to explore the specific ways in which women are uniquely and adversely affected that are of particular interest to those who wish to address the gaps in care that women and PPSUD continue to face.
According to the NSDUH, an annual survey conducted by SAMHSA, an estimated 164.8 million people used some form of substance (tobacco, alcohol, or another illicit substance) in the past year (2018).³ Broken down by substance, the data show that overall, an estimated 47 million people in the United States aged 12 or older reported current (past month) tobacco use, with 27.3 million of those individuals reporting that they smoked a cigarette a day and 10.8 million of these individuals smoking over a pack a day. As large as these rates may seem, they are actually lower than previous years and have been steadily declining.⁴ In 2018, about 139.8 million Americans reported current alcohol use. Roughly 48% (67.1 million) of those reporting engaged in binge drinking (defined as 5 or more drinks in one sitting for men and 4 or more in one sitting for women) and 16.6 million were considered heavy drinkers (binge drinking on 5 or more occasion within the past 30 days).⁵

For the purposes of NSDUH, SAMHSA identifies illicit drug use by obtaining data related to the use of marijuana, cocaine (including crack), heroin, hallucinogens, inhalants, and methamphetamine, as well as for the misuse of prescription stimulants, the misuse of tranquilizers or sedatives, and the misuse of pain relievers.⁶ According to the NSDUH definition, use without a prescription or use at a higher dosage or using more often than prescribes qualify as misuse even if it was for the purpose of pain relief.⁷ In 2018, nearly 1 in 5 Americans (19.4%) reported illicit drug use within the past year, with marijuana use driving the increase over the previous 3 years (45.5 million users or 15.9 percent). This is likely due to changing laws related to marijuana use nationally (in the United States). Prescription pain relievers were the second most common form of illicit drug use at 3.6 percent or 9.9 million. However, the number of people misusing
prescription pain relievers largely decreased from previous years (2015 – 2017) except in adult over 26 (only in comparison to 2015-2016, not 2017).\textsuperscript{8} NSDUH defines prescription opioid misuse as heroin use or the misuse of prescription pain relievers. The survey estimates that in 2018, 10.3 million people aged 12 or older misused opioids in the past year, including the aforementioned 9.9 million prescription pain reliever misusers and 808,000 heroin users. In 2018, approximately 506,000 people misused prescription pain relievers and heroin concurrently.\textsuperscript{9} These numbers are also largely on the decline, but primarily due to a decrease in the use of prescription pain killers, not heroin.

While rates of SUD are typically higher in men than women, evidence suggests that this gap has narrowed over the course of the past 20 years.\textsuperscript{10} This is especially important when considering that research finds substance misuse to be most prevalent in women during their reproductive years. The World Health Organization Mental Health Survey notes that while there are significant differences across cultures, those where gender roles are less traditionally defined tend to have a smaller gap in the prevalence and incidence of SUDs between women and men.\textsuperscript{11} It must also be noted that in “traditional” cultures men have more access to often-misused substances. However, when controlling for access, the likelihood of substance use does not differ between men and women.\textsuperscript{12} For the purpose of this paper, the incidence and prevalence of substance use will be relegated to that in the United States, also using data culled from the NSDUH. According to the 2018 NSDUH, the rate of tobacco use amongst women remained steady, showing a slight decline between 2017 and 2018. While the decline is promising, women 12 or older still make up roughly 40% of all tobacco users in the United States. It is important to note that these rates do not include the rising trend of vaping (the use of
electronic cigarettes) as SAMHSA had yet to include this data in their annual survey as of 2018. Alcohol use in women aged 12 years and over hovered around fifty percent (50.9%) – roughly the same amount since 2015 with no significant changes. Among those women around half (55.5%) who were not pregnant reported alcohol use, with around 25% reporting heavy drinking and 5.5% reporting heavy drinking.\textsuperscript{13} Approximately 5.1% of women 12 and over reported having an alcohol use disorder during this time (3 out of 4 women who live with a SUD also report struggles with alcohol use). Illicit drug use by women (overall) showed a sharp rise since 2016, mostly in the category of marijuana use with a significant change from 12.5% to 13.8%.\textsuperscript{14} Approximately 15% of women engaged in illicit drug use in 2018. Over the course of one’s lifetime, around 43% of women will do so.\textsuperscript{15} Following the overall trend, prescription opioid misuse was the second highest form of illicit drug use. In 2018 4.9 million women (3.5% of the overall population) misused opioids. Of that, 4.8 million misused prescription pain killers (97.9% of opioid misusers), 292,000 were heroin users (6.0% of opioid misusers) and 187,000 engaged with both (3.6% of opioid misusers). Most (51.2%) of prescription drug misusers received them from a friend or got them from a prescription/stole them from a health provider (40.8%). The most misused prescription opioid was buprenorphine (29.4%) followed by methadone (19.4%) and oxycodone (10.5%). While there is little to no change in heroin use and heroin use disorder over the course of 2016-2018, there is a decline emerging in opioid misuse over that time period.\textsuperscript{16} Estimates of overall substance use among pregnant women suggest that the prevalence of use is less than that of non-pregnant women. The recent NSDUH substantiates such estimates. Overall substance use increased between 2015 and 2017, but from 2017 to
2018 the data shows a significant \( p < .05 \) decrease in illicit drug use (marijuana, opioid and cocaine) amongst pregnant women, with rates of current tobacco (11.6\%) and alcohol (9.9\%) use in pregnant women also shows a slight decrease from 2017 to 2018 as well.\(^{17}\)

What this data on women (non-pregnant and pregnant) do not show is that substance use affects women in different ways than men. It not only has social implications but biological ones as well. To understand the need for pre and postnatal care that caters to the unique needs of women, it is first important to have a basic understanding of the ways in which substance use itself affects women differently at a biological level.

3ai. Unique Characteristics of Substance Use Disorders and Women

A recent increase in research on women and substance use shows that while men tend to show higher rates of substance use, emergency room visits related to substance use, overdose deaths and similar rates of SUDs, women tend to be more susceptible to the consequences of using addictive substances than men – at the physical, psychiatric, and social levels. These differences are based both on sex and gender. Research has shown that differences such as those found in the way substances are used by women and how women respond to substance use create unique differences from men that affect how women engage with substance use, live with SUDs, and treat SUDs.

For instance: relative to men, women exhibit a shorter latency from the initiation of substance use to the onset and progression of SUDs. This is what is referred to as the “telescoping effect” wherein women begin using less amounts and/or less potent forms of a substance but rapidly evolve from use to dependence.\(^{18}\) Substance use disorders also appear to progress more rapidly in women than in men. Women may be more susceptible to the craving and relapse aspect of these disorders, making it more difficult to break the
cycle and achieve recovery. Another important distinction between men and women with regards to substance use are the reasons they engage in the first place. Women experience chronic pain at higher rates than men, which is often treated with prescription opioids, which are highly addictive. Women also suffer from mental illnesses such as depression, anxiety, and PTSD, and may turn to illicit substances as a means to cope. The same is true for women who have experienced trauma such as domestic abuse, sexual and physical assault.

It is clear that women tend to use tobacco less than men and prefer low nicotine cigarettes over other forms of tobacco for which people were surveyed. It is also known that women tend to smoke to regulate mood and stress. What is unknown at this time is if it because women are more sensitive to nicotine, like the sensation less than men or if there are other social factors at play. Women do, however, feel the effects of nicotine withdrawal more than men. As far as alcohol, men tend to use and misuse alcohol (binge or heavy drinking) at rates higher than women – although women and girls aged 12 to 20 have slightly higher rates of binge and heavy drinking than male contemporaries. Long term drinking in women is more detrimental to overall health than in men, with women suffering from an alcohol use disorder (AUD) dying from alcohol-related illnesses at 50 to 100 percent higher rates than men with an AUD. Problematic drinking also presents other health risks such as a higher risk for unplanned/unwanted pregnancy, sexually transmitted disease(s) from unprotected sex, violence and/or sexual assault and breast cancer – especially in families with genetic predisposition. Part of the reason alcohol affects women so differently is the fact that men and women metabolize alcohol differently, which is due to differences in gastric tissue activity. As a result, data has
shown that even when women and men of similar size drink a comparable amount of
alcohol, women tend to have higher levels of ethanol in their blood, and thus get
intoxicated more quickly.  

Marijuana use is also similar to other illicit substances in that men tend to use it at
higher rates than women (although this gap is also narrowing). Like other substances,
the effects of use in men and women differ. Research shows that it affects women’s
spatial memory more than men and men report marijuana-induced high more than
women. Marijuana use disorder (MUD) is an indication of at least one other mental
health disorder for both sexes, but men tend have higher rates of other SUDs and
antisocial behavior, while women with a MUD suffer more from anxiety and panic
disorders. The severity of MUD is higher for men as well, but women develop MUDs
more quickly than men. This may be related to sex hormones in women that affect the
sensitivity to the rewarding effects of THC. However recent research on rodents suggests
it may be related to differences in the functioning of the endocannabinoid system, the
system of brain signaling where THC and other cannabinoids exert their effects.  
Stimulants such as cocaine and methamphetamines also affect women differently, with
research that shows women to be more sensitive to their rewarding effects. The likely
culprit in this case is estrogen. Although women are quicker to take cocaine and use it in
higher amounts than men, there are little differences in learning, concentration, and
academic achievement related deficits. It is postulated that this is due to differences in
blood flow to frontal regions of the brain between male and female cocaine users. These
sex-related differences may actually provide protection for female cocaine users from
certain types of brain damage. Despite this “benefit” women are more susceptible to
cocaine’s effect on the heart and other blood vessels. Use of methamphetamine in women - which often starts earlier and lasts longer than in men - often co-occurs with depression at higher rates than men. Most women who start methamphetamine do so to sustain energy and lose weight.²⁸

Prescription opioids are of particular concern in women because women are more likely to experience pain as severe and are also more likely than men to develop chronic pain.²⁹ They are more likely than men to have an opioid use disorder (OUD) as well. Women also use opioids without a prescription at a higher rate in order to treat pain, and misuse prescription opioids to treat other conditions such as anxiety or stress. Instances of use and misuse such as these this increases the likelihood of overdose. Although men still engage with emergency services related to overdose and die at higher rates, the past few years have seen an increase in the number of women who do the same. Data shows that from 1999 to 2016, deaths from prescription opioid overdoses increased more rapidly for women (596 percent or sevenfold) than for men (312 percent or fourfold).³⁰ Rising costs of prescription opioids has led many to seek relief from illicit drugs such as heroin, and for women the pattern is similar. Women tend to use less amounts of heroin and inject less than men. However, women tend to die from overdose sooner. It is speculated that this may be due to outside pressure from drug-using partners. It may also be related to the fact that women tend to combine heroin and prescription opioid use at higher rates than men, which can have dangerous and deadly consequences.³¹

Another important difference to consider is the biological differences between women and men when it comes to reproduction. Although some substance use can affect the fertility of men and women, many women who have a substance use disorder do get
pregnant. This adds an additional layer of complexity to a disease that is already difficult for women to manage who are not pregnant. Before exploring ways in which healthcare can improve the care in which pregnant women with an OUD (PWOUD) a discussion about the biological, ethical, social, and legal implications that these women face is necessary.

Coinciding with the rise in the number of women using illicit drugs in recent years is the increase in the number of women who are pregnant also engaging in their use. The implications for both maternal and fetal health are considerable, and the attention of many in public health, ethics and policy is now focused not only on the cause of such an increase, but also how to address this issue properly and successfully now and in the future. This requires an understanding of how OUDs affect pregnant women and their families, as well as a consideration of how this pressing concern has affected the way in which public health and other institutions reacted (and continue to react) to this issue.

3aii. Opioid Use in Pregnancy and Ethics of Care

Opioid use disorders in women in the United States are not a new phenomenon. They can be traced to the 1870s, when morphine and heroin became available to treat pain. During this time, the majority of those with an OUD were women. Recent data from the NSDUH, shows a significant rise in the prevalence of opioid use in women of childbearing age in the United States over the past 20+ years. In fact, women make up 65 percent of total opioid prescriptions. Between 2008 and 2014, 39.4% of Medicaid insured women and 27.7% of privately insured women of reproductive age (15 to 44 years) received an outpatient prescription for opioids. This increase in the number of
women of childbearing age receiving opioid prescriptions has also led to an increase in the number of pregnant women taking opioids during pregnancy and those who go on to develop an OUD. Approximately 86% of pregnancies in individuals with a substance use disorder SUD are unintended, which leads to a plethora of uncertainty regarding the continuation of pregnancy, guilt surrounding termination of the pregnancy and/or continuation of the pregnancy even though termination is desired.\textsuperscript{35} This has also made a significant impact on the number of pregnant people seeking treatment.\textsuperscript{36}

Living with an OUD goes beyond the symptoms of dependence. Stimulation of the brain’s reward system is the primary reason people continue to use drugs. The compulsion to continue using opioids in this case leads to tolerance and for some dependence and addiction. However, prolonged opioid use affects the body beyond what it does in the brain.\textsuperscript{37} Those who live with an OUD often suffer from gastrointestinal issues related to opioid induced constipation, which over the long term may lead to an increased number of hospitalizations, psychological distress, and a higher risk of death. Respiratory system effects as a result of chronic opiate use also include sleep-disordered breathing, including central sleep apnea, ataxic breathing, hypoxemia, and carbon dioxide retention. Other respiratory-related side effects include respiratory depression, bradycardia, and hypotension – all of which are common in an overdose situation. Long-term opioid use is also associated with cardiovascular events (an increased risk for myocardial infarction or heart failure), central nervous system effects (hyperalgesia, opioid neurotoxicity), musculoskeletal effects (increased risk for fractures), endocrine system effects and immune system depression.\textsuperscript{38} Considering what we know about what
opioid use can do to a “normal” human body, the introduction of a pregnancy adds another layer to the complex nature of OUDs.

Opioid-related problems not only affect the woman and her unborn child/children during pregnancy. Issues related to opioid use, misuse and OUD can also affect other family members – including children the mother already has. Child or adolescent poisoning and overdose, impaired parenting, and attachment (greatly affected by misuse), material deprivation (especially with regards to finances that go towards paying for drug use and not towards children or prenatal care) and extended separation of children from their parents due to incarceration, psychiatric treatment, foster care or death are all pathways by which OUDs can affect the health and safety of children and other members of the family unit.  

Approximately 5.1% of pregnant women report opioid misuse, which is likely under representative of the actual number due to stigma and other social and legal factors related to opioid use and pregnancy. Pregnant women with opioid use disorder not only risk suffering the aforementioned effects of opioid use in the short and long term, but pregnancy further complicates OUD because of the potential effect(s) of opioid exposure on the fetus. While there is little known about fetal safety of opioids because clinical trials often exclude pregnant women for ethical reasons, and post market data is often limited. Most prescription opioids (excluding oxycodone) are therefore classified in the Food and Drug Administration’s (FDA) pregnancy category C, which indicates “evidence of potential harm to the fetus from animal studies and the absence of well-controlled human studies.” Oxycodone is classified as a category B drug, which indicates “no evidence of harm to the fetus from animal studies and the absence of well-controlled
Illicit substances such as heroin and adulterated forms of the drug fentanyl are also category C because of a lack of data regarding their use during pregnancy.

When a fetus is exposed to opioids during its development, it can experience a series of adverse effects. Although the effects of opioids on the fetus aren’t directly known, risks associated with opioid use during pregnancy include: stunted growth, which leads to a low birth weight; preterm delivery (birth before 37 weeks); congenital heart defects; neural tube defects – defects of the brain, spine and spinal cord; gastroschisis (a birth defect of the baby's abdomen, where the intestines stick outside of the body through a hole beside the belly button); loss of the baby due to miscarriage or still birth and/or neonatal abstinence syndrome (NAS) which manifests as withdrawal symptoms (irritability, seizures, vomiting, diarrhea, fever, and poor feeding) in newborns. If and how these effects manifest depend on several factors: the fetus’ stage of development; the strength and dose of the drug; the genetic make-up of the mother, which affects how much of the drug is active and available and other factors related to the mother. Male infants are also more likely to manifest symptoms of NAS, and receive more pharmacological interventions than female infants. While there is no current evidence that opioid exposure, in and of itself, results in developmental delay or any other lasting effects on the exposed child, the convergence of issues related to opioid use disorder can have long-lasting effects on development. In fact – alcohol exposure has been shown to have much more profound physical, developmental, and behavioral effects.
Research regarding risk factors in pregnancy shows that material hardships such as food insecurity and housing insecurity, combined with contextual psychosocial factors including maternal depression, intimate partner violence, history of post-traumatic stress disorder (PTSD) and learning disabilities may also affect maternal and fetal health outcomes in PWOUD.\textsuperscript{46} Food and housing insecurity in PWOUD are also associated with low birth weight and affect medical care continuity which can also produce poor health outcomes for mother and child, because the focus on meeting nutritional and housing needs often overshadows any medically-related needs – be it prenatal care or another confounding issue: treatment.

From 1992 to 2012 the percentage of pregnant women admitted to treatment facilities reporting a history of OUD increased from 2\% to 28\%.\textsuperscript{47} Opioid use disorders are often addressed in PWOUD by incorporating Medication Assisted Treatment (MAT) because the risk of harm to the fetus from withdrawal is too great. Maintenance through the use of opioid agonists such as methadone and buprenorphine is the standard of care and is shown to improve outcomes. Buprenorphine in particular has an easier taper, improved safety profile, and provides a shorter duration of NAS. However, methadone is preferred in women who may require higher stabilizing doses.\textsuperscript{48} It is also not recommended that women who have been on one medication or the other switch medication during pregnancy, for fear of withdrawal symptoms. There is also research being done into the use of naltrexone (an opiate antagonist used as emergency and/or maintenance therapy to block the effects of opiates) to treat PWOUD, especially those who were using it prior to pregnancy.\textsuperscript{49} However, current data show the risk of using it often outweighs the benefit. Use during pregnancy in women with OUD may precipitate
opioid withdrawal if the patient is currently opioid-agonist dependent. This can cause spontaneous abortion or premature labor; increase their vulnerability to relapse and increase the potential for opioid overdose due to reduced tolerance and increased receptor sensitivity.  

Another benefit of these medications is their minimal transference to breastmilk and ultimately the infant. Breastfeeding in infants with NAS, in particular, is shown to improve outcomes by shortening the duration of NAS symptoms and improving the bonding between mother and child. The goal of MAT therapy during pregnancy is to prevent withdrawal and minimize fetal exposure to illicit substances, thereby reducing the burden of OUD on pregnant women and infants. It also helps decrease risk-taking behavior thereby reducing the acquisition and transmission of diseases such as hepatitis C and/or HIV. This therapy, combined with other services such as social and psychological care, has been shown to be successful for women and their infants.

Despite evidence of treatment success in PWOUD who do receive treatment and policy initiative aimed at improving accessibility and affordability of treatment, barriers still exist that prevent them from receiving the treatment they need. These are found at the micro and macro levels of society.

At the micro level, one powerful barrier treatment is the stigma attached to illicit opioid use. Even in patients with a “legitimate” or non-stigmatized illness such as cancer, stigma about the use of opioids presents itself in interactions between family and friends, as well as health professionals such as physicians and/or pharmacists. In a study of 250 oncology patients, Kollas et. al found that over half (54%) experienced opioid stigma and 73% experienced difficulty filling opioid prescriptions. One-third
(34%) cited pharmacists as the source of said stigma and cancer survivors reported experiencing “significantly more” stigma from friends and family or from the staff at hospitals and emergency rooms than those with an active form of cancer.54

Pregnant women with an OUD not only suffer the stigma associated with illicit opioid use, but they are also subjected to the “double stigma” of doing so while pregnant. Pregnancy adds additional moral consideration because not only are the choices and actions the woman makes affecting her, but they also affect an unborn fetus whose health outcomes are now primarily dependent on her (genetic predispositions aside). Pregnant bodies are seen as potential sites of risk, which is located within the woman’s body and assumes that the woman has the ability and the responsibility to manage such risks during their pregnancy.55 Drug use is viewed as deviant, self-destructive behavior which is often laden with moral judgments associated with personal “choice.” Failure to conform to gendered norms of pregnancy and femininity can create stereotypes that are adopted both by the pregnant woman and society in general. This necessarily shifts the blame to the mother and ignores context or structural considerations.56

Women seeking treatment often cite social/personal stigma as one of the biggest barriers to engaging in effective treatment. Much of this stigma comes from providers who are not properly educated in substance use disorders and opioid use during pregnancy in particular. 57 This stigma manifests itself in prenatal treatment and postpartum care, particularly from NICU nurses who may find that the unique and time-consuming needs of NAS infants increases frustration and the tendency to use judgmental body language and speech towards mothers with an OUD.58 Pregnant women with an OUD in prenatal treatment also report similar behavior from providers. Such stigmatizing
behaviors often deter PWOUD from seeking or continuing treatment, sometimes leaving healthcare providers ill-prepared to provide proper post-partum care for mother and infant.\textsuperscript{59}

Structural level stigma is also a factor with regards to seeking out and engaging in treatment. Structural stigma is the “societal-level conditions, cultural norms, and institutional practices that constrain the opportunities, resources, and wellbeing for stigmatized populations.” \textsuperscript{60} For this particular population, such stigma is evident not only in the micro-level interactions that these women have with providers and other members of society, but also in the ways in which macro level institutions are embedded in society preclude women from getting proper treatment. One barrier, in particular, is the way in which the healthcare system itself stigmatizes women with an OUD – let alone those who are pregnant. Seeing as men are – and typically always have been – the majority of the population who live with a SUD, treatment facilities have primarily been designed with their needs in mind.\textsuperscript{61} For instance: many PWOUD have other children, but residential and outpatient treatment centers do not typically have childcare services. This in turn deters women who do not have access to it otherwise. Many women seeking treatment also have partners who may also use. Many traditional treatment facilities have strict rules pertaining to use by partners, which presents another barrier.\textsuperscript{62}

Availability and accessibility of treatment programs designed for women has also not coincided with the growing number of women affected by substance use and misuse. As of 2017, only 19 states have specific programs for women, with only 12 states giving priority access to pregnant women for state-supported programs.\textsuperscript{63} Some states only have one such facility, making it difficult if not impossible for women to benefit. One study on
noted that participants from their study site were 104 miles away from the closest treatment program for women that accepted pregnant women. Many of them cited transportation issues (not having a vehicle or having an unreliable vehicle) as one of the reasons they were unable to participate at that site.\textsuperscript{64}

There is also a lack of collaboration or coordinated care between providers including OB/GYNs, treatment facilities/programs, child welfare programs and other social programs geared towards advancing health and well-being. Even if there was, there exists knowledge and practice gaps in best practices before, during and after pregnancy.\textsuperscript{65} So, while some women may receive treatment, the lack of understanding about the most beneficial way to screen and care for PWOD may in fact lead to lack of engagement and retention, thereby causing further detriment to maternal and fetal health.

Housing insecurity also influences whether or not a PWOD seeks treatment. Inability to pay rent/mortgage, temporarily living with others due to financial hardship (perhaps from unemployment or underemployment) and outright homelessness affect the continuity in prenatal and postnatal treatment and may affect access to various forms of public assistance from which many PWOD and their families would benefit. This coupled with food insecurity detracts from focus on maternal and fetal health (especially in the form of accessing treatment) and affects health outcomes for both. Substance use and material hardships such as these are also significantly correlated with intimate partner violence (IPV), PTSD, learning disabilities and maternal depression – all of which deter treatment.\textsuperscript{66}

However powerful stigma is at the level of care, the criminal justice system also has a strong influence on the decision of whether or not PWOD seek treatment.
Prosecuting women for substance use during pregnancy is unique to the United States, and began here in the 1970s, with the first criminal charges brought against a woman for using drugs during pregnancy in 1977 against Margaret Reyes. Reyes was charged with two counts of felony child endangerment for her heroin use during pregnancy, but the charges were later dropped because the California Court of Appeals declared that the statute was never intended to extend to unborn children. Over the course of nearly 50 years (1973–2017) 45 states have sought some form of legal action against women for exposing their fetus(es) to drugs and/or alcohol. Thirty-six states recognize fetuses as potential crime victims. Twenty-three states also require providers to report suspected maternal drug use.

These states have been emboldened by legislation such as the Child Abuse Prevention and Treatment Act which mandates reporting to Child Protective Services (CPS) if an infant is identified as being exposed to illicit substances and/or alcohol in utero. Punitive policies such as these and those enacted by states that charge PWOUUD with crimes such as child abuse, child neglect, chemical endangerment of a child, homicide and assault necessarily deter PWOUUD and other substance use disorders from seeking treatment out of fear of being identified, prosecuted and/or losing custody of their children. They also turn providers into agents of the state, charged with enforcing legal mandates. These laws disproportionately affect minorities and women of lower socioeconomic status, who (because of bias and discrimination which are born out of stigma) are up to 10 times more likely to be identified/reported than white mothers - despite similar rates of drug use. Such laws also have not shown a significant impact on
drug use. Instead, evidence shows more of a negative impact on the number of women seeking and receiving treatment.\textsuperscript{72}

Even then, when PWOUD do enter the criminal justice system, there is also a decreased chance of receiving appropriate treatment. Research shows that the most predictive factor of whether or not a PWOUD receives the standard treatment is if they are referred by the criminal justice system. In fact, 90\% of states with prenatal child abuse laws do not include MAT in their treatment of incarcerated PWOUD, with 75\% of drug courts - which are designed to reduce drug-use relapse and criminal recidivism – do not permit women to use MAT.\textsuperscript{73}

Other, macro-level barriers to treatment include the U.S. healthcare system. Medicaid is the payer for approximately 50\% of total births in the United States and covers 80\% of NAS births.\textsuperscript{74} What makes this challenging is the fact that not all state Medicaid covers MAT. Medicaid does not cover methadone maintenance in most states with laws permitting litigation and/or criminal charges for illicit drug use in pregnancy.\textsuperscript{75} In fact, as of 2013 only 20 states included it on their preferred drug list, and 11 states currently (2017) have lifetime treatment limits. This means that once a certain amount of methadone use is reached, it is no longer covered, making it difficult for women with an OUD using the drug as part of ongoing MAT. Buprenorphine faces similar scrutiny by Medicaid and other insurance plans. However, there are added barriers to receiving buprenorphine. These include prescribing requirements which limit who can prescribe it and how many clients they can have on a yearly basis, and payment restrictions, which limit where certain insurance plans can be used – such as in physicians’ offices versus outpatient treatment facilities.\textsuperscript{76} Other considerations such as the quantity limits for
reimbursement and pre-requisites for step-therapy can also interrupt or deter treatment prior to, during and post pregnancy. Understanding that the first year postpartum is the most crucial for the mother - as it is the time period where relapse, overdose and death are most likely to occur - denial of MAT over the long term can, in fact, be a matter of life and death.\textsuperscript{77}

The ways in which the U.S. Healthcare system approaches substance use disorders, treatment for substance use disorders and the issue of substance use in pregnancy has created a wide range of barriers to proper care for mothers and their families. These barriers challenge ethical principles that guide the healthcare profession. Prior to an exploration of the ways in which care ethics can transform treatment for PWOUD as it currently exists, it is essential that these ethical dilemmas are addressed.

While professional codes of ethics exist throughout the healthcare system, they are merely grounded in ethical principles. However, these codes are insufficient by themselves to guide practice due to ethical dilemmas and concerns that emerge during the course of system engagement – be it through research, prevention or treatment related to disease. Issues related to treatment of PWOUD are complex, but it is important to consider how the current models of care are insufficient for upholding even the most basic of the principles upon which these codes are founded.

In the United States, medical providers are often guided by the principles of autonomy or respect for persons, beneficence, nonmaleficence and justice. Autonomy or respect for persons merely requires that the process of informed consent be carried out. This is especially of concern in PWOUD who are not only making decisions regarding their health, but the health of their unborn child and indirectly the health of their family.
unit (whatever that entails). This is also extremely important because of the criminality of substance use in some jurisdictions. Pregnant women with an OUD should be properly informed about the laws pertinent to their state regarding screening for and reporting of maternal substance use. This should not only occur during their prenatal visits but at the delivery as well. Any screening should not be conducted without properly informing the PWOUD of potential punitive consequences—this not only includes getting the local/state criminal justice system involved but child welfare services as well. While apprehension of these consequences is a deterrent to engaging with the healthcare system during pregnancy, improper disclosure is also in violation of the autonomy principle. This is also true with regards to research participation by PWOUD. Those who are approached—be it while incarcerated or through their treatment program—should be assured that their participation is autonomous, voluntary, and done without coercion. Oftentimes pregnant women (deemed “healthy” or otherwise) are excluded from research, which also denies them the autonomy to decide whether or not to participate.

There is also a movement in the field of midwifery to address what has been termed “rhetorical autonomy” in the birthing process. That is, when women adhere to medical advice and guidelines for care, it appears they have autonomy and self-determination over their bodies. However, when women decline recommended care, the respect for autonomy becomes a façade as providers of care challenge the woman’s ability to make decisions for themselves through the use of persuasion, coercion, threats and withdrawal of care. This especially rings true for PWOUD—especially those who are involved with the criminal justice system or child welfare services—who are often forced
into certain types of treatment and their improvement often measured by prescribed successes.  

Beneficence is the promotion of the wellbeing of others through actions that provide positive benefits and actions that prevent harm. It asks that providers assess whether or not the treatments or services provided are beneficial. Providers must ascertain the quality of such services as well and ensure that their benefit(s) outweigh any risks. Upholding the principle of beneficence also requires that providers adhere to minimum standards of practice, utilizing current research and best practices. With regards to treatment for PWOUD, it is established that current treatment services are not entirely adequate for care of women with substance use disorders, let alone pregnant women with SUD(s). Despite health-related policies such as those found in the Affordable Care Act (ACA) that are written to allow women to seek “essential health benefits” that includes treatment for SUD(s), what is currently available does not meet the needs of PWOUD and therefore is not beneficial. Research has also shown that the source of stigma and incongruent care for women with an OUD before, during and after pregnancy is inadequate education with regards to addiction and the influence of other structural stigmas that stem from dated and/or punitive policies. These policies necessarily prohibit treatment centers from providing the standard care that is designed for the benefit of PWOUD, thereby putting mothers and their infants at disproportionate risk. It is also important for providers to consider the risk/benefit ration of different types of screening protocols. Biologic screening tells providers that substance use is or is not present. However, it does not elicit its extent. That is, it is only a snapshot of what is occurring during pregnancy. Despite this, positive results on such screening may trigger
reporting to state authorities which may endanger the PWOUĐs outcomes. Routine use of such practices may also deter women from engaging with the healthcare system, increasing risk.\(^87\)

Nonmaleficence expands on the principle of beneficence with regards to avoiding harm.\(^88\) This principle requires that providers not encourage participation of subjects/patients in therapies or other interventions that could result in harm to the subject/patient. It also requires that harm does not come to them as a result one’s inaction. In the case of women with an OUD, the harm may come from engagement in a system that is not built to fully address their needs before, during and after pregnancy. It has to be considered that some women with an OUD do plan their pregnancies, considering the number of unplanned pregnancies reported by PWOUĐ is not 100 percent.\(^89\) If providers are not properly addressing the possibility that women planning pregnancies either naturally or through other means have an OUD, we may be putting them and their unborn child(ren) in harm’s way. If properly addressed of course, providers can work with these women to mitigate potential harm. If providers are not screening all pregnant women for substance use, there is also the risk that substance use during pregnancy goes unidentified and again, puts the woman and her child(ren) at risk.\(^90\) The lack of access for some to MAT or adequate MAT – be it because of involvement in the criminal justice system or because of laws in place that criminalize substance use during pregnancy, regardless of reason – also undoubtedly puts women and their child(ren) in harm’s way. Oftentimes incarcerated pregnant women are expected to withdrawal on their own because jails and prisons more often than not do not have MAT at the facility nor are they partnered with a third party to provide such treatment.\(^91\) If a
mother goes through withdrawal because she cannot access necessary MAT it could cost her her life and/or that of her fetus.  

Fidelity requires the building and maintenance of trust, as well as relationship building between patients/subjects and providers. It requires adherence to patient confidentiality while reinforcing the “informed” part of informed consent – that is, what is being told to them is truthful. Positive behavior change arises from trust that is often implicit in the provider – patient relationship. However, because of the nature of substance use in pregnancy, women with an OUD seeking prenatal treatment may lack trust because of reporting requirements. This makes building and maintaining such trust difficult for providers who are tasked by some states as “criminal enforcers.” Confidentiality is also compromised in these cases, which in turn erodes trust between the PWOUD and her providers.

The principle of justice is equated with fairness. In terms of health care this means fair/equal distribution of resources, equal access to care and equal rights to care. It also discourages discrimination in accordance with the fair opportunity rule. The fair opportunity rule states that no one should receive social benefits on the basis of undeserved advantageous properties. It also holds that no person should be denied social benefits on the basis of the undeserved disadvantageous property. Unfortunately, adequate treatment for PWOUD is often impeded because of lack of access, be it because there is not a facility available, lack of transportation to said facility, or lack of adequate resources such as public assistance to utilize treatment services. This disproportionately affects minorities and those with a lower SES. And although the ACA is written in such a way that it allows women to seek substance use treatment in a system aimed at the
overall health of mother an infant, standard models of care are not equally available to women across the United States. Stigma related to substance use also denies equal access to good maternity care. Women who have OUDs who become pregnant live in fear of the retributions related to being identified. This not only includes the consequences related to the criminality of substance use during pregnancy, but the social consequences as well – not only from families and the public in general, but from providers as well. These too deter women from seeking and maintaining treatment and are issues other populations of women do not necessarily encounter.

Understanding the ethical issues present in the current model of care for PWOD will guide policy makers, health care providers and those involved in the criminal justice system in the development of a model of care that upholds all of these principles and ensures better outcomes for mothers with a SUD and their families. The consideration of deficits in these areas informs the enhancement of current standards of practice and can highlight the need to make these services more ubiquitous. Bioethical theories, concepts, and practices such as those related to care ethics are but minor components in a larger system that is in need of adaptation to current needs not only for women but PWOD in particular.

In order to improve prenatal and perinatal care in PWOD, there needs to be a shift in both the current models of substance use disorder treatment and institutionalized birth. These systems as currently organized are inherently unethical. SUD treatment facilities are expected to adhere to legal and financial policies of the state and federal government while lacking the education, staff, and resources necessary to provide the standard care to women and/or pregnant women with an OUD. The case is the same for
those providing maternity care during this time. Doctors, nurses, and midwives are expected to place allegiance to hospital policy and local laws while failing to meet the unique needs for PWOUD, thus furthering the potential for harm to the mother, child and potentially her family.

One way to address this is to consider the influence of these policies on overall care. Structural stigma created by criminalization of substance use during pregnancy has created an entire system of substance use disorder treatment that discriminates against the most vulnerable of our population. Ideally, the solution to this would be to overturn laws such as those in Tennessee, South Carolina and Alabama which specifically target girls and women who use illicit substances during pregnancy. However, there appears to be a movement to further criminalize such actions than to reduce any penalties. This despite international criticism of such practices by the United Nations Special Rapporteur on the Right to Health – an independent human rights expert appointed by the UN Human Rights Council. The Special Rapporteur has specifically called for states to suspend the application of “existing criminal laws to various forms of conduct during pregnancy.” They also state that punitive laws such as those in the United States “violate the right to health when they discourage or prevent individuals from obtaining medical care and from freely making their own healthcare decisions.” The United Nations Educational, Scientific and Cultural Organization (UNESCO) Universal Declaration of Human Rights (UDHR) also explicitly states that:

“Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including… medical care and necessary social services… motherhood and childhood are entitled to special care and assistance.”
So, one way in which policy makers and other individuals of influence might address these policies at the federal and state level would be by taking a right-to-health-approach to states’ laws, policies and practices around pregnancy which could ensure that substance use and the need for drug treatment is not a reason for bringing women into criminal justice systems.  

Despite these obstacles, providers of substance use treatment and pre and perinatal care for PWOD can improve outcomes by addressing those apparent in their systems of care. The ACA attempted to address these inequities by including provisions related to “essential health benefits” such as substance use disorder treatment, while highlighting the needs of women. The Mental Health Parity Act also expanded access to such care. Recently SAMHSA (2018) also responded to growing disparities in the treatment of women with OUD with national guidelines specifically for pregnant and parenting women, highlighting the importance of a “women-centered” approach to treatment. Integration of an “ethics of care” into such models is one way to address the disparities that women in general experience - not only in navigating substance use disorder treatment, but in the birthing process as well.

An ethics of care offers a different way to approach ethics and decision-making. Compared to more traditional approaches to ethical decision making such as ethics of justice, whose focus is on universal moral laws that can be applied across situations, an ethics of care is more concerned with responding to the needs of others in complex, real-life situations. Instead of relying on abstract rules or principles, ethics of care solves ethical dilemmas by considering responsibility (to care), relationships and context. Proponents of ethics of care suggest that there is a pre-existing moral relationship
between people; therefore, the question any provider needs to ask themselves when engaging with a patient is: “How can I meet my caring responsibility?”

Political philosopher Joan Tronto proposes a model of care with four phases of caring and four elements of care. The phases do not necessarily occur in sequential order and at times they may overlap. These phases include caring about, taking care of, caregiving and care receiving. This means when a provider encounters a patient, they recognize their need for “X” in their initial assessment. In phase two (taking care of), the provider sees a responsibility to respond to the patient’s need. In phase three (caregiving), the provider takes action to address the issue. In phase four (care receiving), the provider assesses the success of the intervention with the patient (care - receiver). The relationship between patient and provider is a distinctive aspect of the ethics of care, and the last phase of this process helps maintain it.

The four elements or fundamentals necessary for effective caring include attentiveness or the ability of individuals to recognize the needs of others; responsibility; not in terms of obligations, but in terms of the responsibility to care for one another. The (third) element (competence) requires those providing care to do so adequately and competently, while the final element – responsiveness – relates to the experience of the person receiving care. Being a patient is to be vulnerable at some level because of the imbalance of power in the patient-provider relationship. It is therefore more important to understand the care receivers perception of care than the care givers, so no abuse of power occurs.

The incorporation of an ethic of care approach into substance use disorder treatment facilities and maternity care models as an adjunct to the current bioethical
framework of principlism can provide a modified framework wherein the recognition of the needs of others becomes a priority over adherence to institutional policy. An ethic of care approach in the context of the substance use disorder counselor and/or whomever is assisting with the birthing process provides an opportunity to equalize the relationship between the provider and the woman, provides the space for relationship building and allows them to meet the expectations of the interchange. 108 An ethic of care requires an emphasis on relationships, which is part of the rationale for supporting women-centered forms of care in SUD treatment programs and maternity care. 109 Such an approach includes an emphasis on building and sustaining healthy relationships with providers and counselors. These interactions can in turn help women who have likely experienced abuse, neglect or exploitation as children or adults build healthy relationships outside of the clinical environment. 110 Care ethics can also be influential in the mitigation of stigma. One study showed programs that focused on educating medical students about substance use problems by establishing working/training relationships with people with substance use disorders showed a decrease in their stigmatizing attitudes and increased comfort levels towards working with this population. 111

Multidisciplinary models of substance use disorder treatment for PWOD include prenatal care, opioid replacement therapy counseling, case management services, parenting classes, delivery-related services, management of NAS and primary care for the entire family. These programs incorporate harm reduction principles, which are inherently person-centered and contextual, and integrate families into the treatment process. 112 They also incorporate trauma-informed care into their programs, a component which is woefully lacking in traditional models of substance use disorder treatment and
maternity care. Trauma-informed care acknowledges the role of trauma and works with the patient to effectively navigate without causing further stress or re-traumatization. This requires the establishment of safe, trusting and empowering relationships between PWOU and their providers.\textsuperscript{113}

Perinatal quality collaboratives (PQCs) work to improve the quality of care for mothers and babies using proven quality improvement (QI) methods.\textsuperscript{114} These state or multi-state networks of teams have helped inform the creation of programs such as the Children and Recovering Mothers (CHARM) program in Vermont and the Pregnancy Recovery Center at Magee Hospital in Pittsburgh, PA – both of which have shown improved outcomes in the form of increased retention and completion of program, sustained recovery, greater likelihood of acquiring stable housing, improved birth weights and higher percentages of mothers retaining custody of their children.\textsuperscript{115}

Of course, these measures merely address the clinical aspects of maternity care and substance use disorder treatment in PWOU. The criminal justice system still has an integral role to play in whether or not pregnant women who use illicit substances during pregnancy seek any form of treatment or prenatal care. An emphasis on an ethics of care in such programs would allow providers to consider contextual issues related to punitive measures in their state or locality and adjust their protocols according (i.e., the types of screening they do). If and when a change in occurs in the way we handle women who use illicit substances during pregnancy, incorporating an ethic of care could transform what we recognize as care for PWOU.

It is apparent that the opioid crisis not only affects those who are living, but it also has the potential to affect those who are not yet born. Despite this, efforts to mitigate the
incidence of NAS are thwarted by laws that criminalize substance use during pregnancy. These laws, coupled with the effects of stigma, food and housing insecurity, intimate partner violence and other material hardships create barriers for women who might seek treatment for their OUD/SUD and perinatal care. Ideally a change in policy regarding substance use during pregnancy would help alleviate this issue, but states are currently moving towards more punitive measures, not less. Despite this, there are ways to address inequities in the systems of care and improve outcomes for mothers and their families. Integrating an ethics of care can help expose and address the unethical practices found in current modalities, including those influenced by stigma (structural and personal) and in doing so, assuring PWOD and their families that they receive optimal care.

3b. Life Cycle: Genetic Diagnosis, Prevention, and Treatment of Substance Use Disorders

In recent years, genetic research has expanded to include human genome sequencing, as well as advances in mapping genetic variations at the individual level. As a result, genetic testing has evolved to help identify, treat, and in some circumstances, prevent the onset of disease. With a growing concern related to addiction, more research is being done to isolate the genotypes that are more vulnerable to addiction, and therapies are in development to assist those more susceptible to substance use disorders. The introduction of genetic technology into the field of addiction necessitates an analysis of the potential ethical, social and policy issues related to research and treatment in this area. This essay will look at the history of genetic mapping, discuss genetic tests that are currently available and analyze how these tests are being used to diagnose, prevent, and treat substance use disorders. Discussion of ethical issues at the clinical and policy level will also be addressed.
3bi. The Capabilities of Genomic Science

To properly understand the ethical, social, and legal policy implications from the use of genomic research and genetic testing for diagnostic and treatment measures relevant to addiction, it is vital to follow the progression of gene mapping, as well as how diseases are identified at genomic levels. This section focuses on a few scientific discoveries that helped usher in the technology we use today, as well as some of the tests available for use in diagnosis, prevention, and treatment.

The history of the mapping the human genome can be traced back to the final year of the American Civil War. In 1865, Gregor Mendel – an Augustinian monk – presented work he had done crossing a variety of pea plants over the course of several years. His work showed how traits are passed down from parent to offspring, and thus established a foundation for genetic research. 116 Rosalind Franklin photographed the helical structure of DNA in 1952, and in 1953 James Watson and Francis Crick created a model showing the structure of DNA as a double helix, speculating that the nature of the structure suggested a “copying mechanism.” 117 These and subsequent scientific discoveries led to an interest in mapping the human genome. In 1984, the U.S Department of Energy (DOE) began discussing the possibility of such a project with the National Institute of Health (NIH) and other international groups. Several years later, the National Research Council recommended a project to do just that.

The Human Genome Project (HGP) began in 1990 as a collaboration of both the NIH and DOE as well as international scientists. The goals of this project included the provision of a "complete and accurate" sequence of the human genome, as well as the sequences of other organisms. The development of innovative technologies to obtain and
analyze the data was another goal. It was also determined that an examination of the social, ethical, and legal ramifications of such scientific advances was also necessary. The HGP was originally designed to be a 15-year project. The first eight years of the project were to be spent developing genetic maps and advancing technology necessary for sequencing DNA. The sequencing of genomes of other organisms such as bacteria, yeast, fruit flies, mice, and nematode occurred at this time as well. The latter half of the project focused on the development of a larger scale DNA sequencing operation. Implementation of larger scale "sequencing centers" across the globe allowed for higher output, as each center was assigned a specific portion of the genome. Although in an article written in 1998 about the progress indicated moderate gains, the project finished two years ahead of schedule in 2003.\textsuperscript{118}

In the years since its completion, there have been major advances in the field of genetics and subsequently, medicine. The development of a haplotype map (or “HapMap”) gave scientists more resources to help identify genetic variation in certain types of illnesses and allowed for a more thorough exploration of the environmental factors that attribute to variations in health. Data gleaned from the HGP has also allowed scientists to move beyond speculation about the genetic components of disease. Subsequent Genome-wide Association Studies (GWAS) shed new light in this area. For instance: before this study, the genetic loci for Age-related Macular Degeneration (AMD) had yet to be identified, although immunological factors had already been established. Due to the work of several concurrent GWAS post HGP, variation in the role of a certain chromosomal region confirmed a major genetic determinant of AMD existed.\textsuperscript{119} These
studies also confirmed the potential GAWS had for future research in the genetics of complex disease.

The HGP did not just unlock the human “instruction manual,” it also opened the door for the creation of myriad genetic tests. Currently there are over 2,000 genetic tests that test for a variety of disorders, such as the BRCA1 and BRCA2 genetic test, which tests for gene mutations related to breast cancer. Such tests allow individuals and their physicians to devise a treatment plan for the disease. They also have the potential to prevent certain conditions from occurring. To understand the emerging potential of these tests (especially in relation to substance abuse disorders), an exploration of the types of testing is necessary.

Genetic testing analyzes human DNA, RNA chromosomes or proteins that detect abnormalities that are linked to an inherited disease or disorder. These are often classified by their purpose. These include diagnostic testing, predictive (or presymptomatic) testing, carrier testing, prenatal testing, preimplantation testing, and newborn screening. These tests screen for several categories of genetic disorders. These include conditions with missing or extra chromosomes (aneuploidy) such as a trisomy (extra chromosome) or monosomy (missing chromosome). Inheritable diseases are caused by genetic mutations. A few examples of inheritable diseases detected by genetic testing include Tay-Sachs, cystic fibrosis, and haemochromatosis.

Although diagnosis of genetic disease is not limited to analyzing genomes. For instance, some conditions are diagnosed via physical examination, family history, routine hematology, pathology studies, and/or radiological examinations. Diagnostic genetic testing is often used to confirm a suspected diagnosis because of physical or
psychological symptoms that are manifest in the patient. One example of this type of
genetic test is testing for Fragile – X in a boy with mental retardation. Another would be Huntington’s disease. In the latter case, an individual might present symptoms of a movement disorder, and their physician would then administer a test to either confirm the diagnosis or rule it out.

Predictive or presymptomatic genetic testing is used in individuals who are asymptomatic but may have a predisposition for a disease – either because of the particular population to which they belong or due to family history. The previous example of Huntington’s disease falls into this category, as well as diseases such as Alzheimer’s and certain types of cancer. The results of predictive genetic testing are marred with uncertainty, as they are only indicators of the presence of certain genetic markers for disease. However, the goal of predictive genetic testing is to provide an individual – and oftentimes their family – with information that can be used to assess risk and plan for (potential) treatment options.

Prenatal testing allows parents-to-be to test their fetus(es) for potential genetic disorders. The two main types of prenatal genetic tests are screening tests and diagnostic tests. Screening tests are used to predict if the fetus has a chromosomal disorder such as Trisomy 18 or Trisomy 13. This is done by testing samples of maternal blood, which contain DNA from the placenta, in combination with ultrasound screening. Carrier screening tests are also available both prior to and during pregnancy. These allow parent(s)-to-be to ascertain if they are a carrier of certain types of gene mutations. Diagnostic prenatal tests are used by collecting fetal cell via procedures such as amniocentesis or chorionic villus sampling (CVS). These tests can test for potential
aneuploidy or specific chromosomal disorders as requested by the parent(s). Preimplantation testing is also available for those going through in vitro fertilization. This type of genetic test screens for potential genetic disorders in embryos before it is implanted in the uterus. This is often offered to those with higher potential for such disorders.\textsuperscript{129}

Newborn screening is not a new phenomenon, but the with the genetic data gleamed from the HGP, many more tests have been developed that can screen newborns for genetic disorders.\textsuperscript{130} These tests are typically done within 48 hours of birth and include screens for various disorders such as sickle cell disease, phenylketonuria (PKU) and maple syrup urine disorder. Each state in the United States has different requirements on which screenings are mandatory, but generally each state follows guidelines set up by the Recommended Uniform Screening Panel, which is comprised of roughly 34 “core” and 26 secondary conditions.\textsuperscript{131}

Genetic testing shows the potential for diagnosing disease. It also increases the potential for genetic information to be used in the prevention and treatment of certain diseases and disorders. This has specific implication on individuals who have or may have a proclivity towards substance abuse. With genetic information gleamed from the Human Genome Project it is possible to inform those who are interested in finding a more personalized approach to the diagnosis of substance abuse. These tests may also assist researchers in developing better methods for the prevention and treatment of individuals with substance use disorders (SUD).

The NIDA defines drug addiction as a “chronic, relapsing complex brain disease, characterized by compulsive drug seeking, craving, loss of self-control and impaired decision-making.”\textsuperscript{132} There is an overwhelming amount of evidence that suggests that there is an active genetic component to addiction. Prior to the completion of the HGP,
family, twin and adoption studies on alcohol dependence showed a high (40 to 60 percent) heritability of the disorder, whereas more recent studies on illicit drug use almost mirrored rates of alcohol dependence (although some showed a more extensive estimated range of heritability - 45 to 79 percent - depending on the drug). Once the data from projects such as the Human Genome Project, HapMap and GWAS started to become available for research, the genetic uncertainty of addiction became less opaque.

Genes alone do not account for the propensity towards addiction. Neurotransmitters such as dopamine, serotonin, opioid peptides, endocannabinoids, and glutamate also contribute to the manifestation of the disease. Environmental factors also contribute. These can include a problematic home life, poor performance at school, the economic status of one's community or ease of access to alcohol or illicit drugs. Other biological factors such as developmental stages also contribute – the younger an individual is when they experiment with alcohol or drugs, the more likely they are to develop an addiction. This may be a result of the alcohol or drugs changing parts of the brain, as it is still developing, even beyond the legal drinking age of 21. Even when considering this, scientists estimate that, in addition to environmental impact, genetic factors account for 40 to 60 percent of an individual’s vulnerability to addiction. This percentage is higher in individuals who suffer from mental health issues such as schizophrenia, depression, anxiety or ADHD, as it is speculated that addiction and certain psychiatric disorders may have common biological foundations.

Although the association between genes and addiction is not all that new, the data scientists can gather from genome-wide association studies have assisted scientists in creating genetic tests that can help doctors and patients in the diagnostic stage (such as
Alzheimer’s disease, food allergies or breast cancer). Laboratories are also creating tests that assist physicians with patients who may be predisposed to alcoholism or opioid addiction. Some market these products to consumers at home. In fact, before the FDA stepped in to regulate the direct-to-consumer home genetic testing industry, companies like 23andMe, GenovateDNA and deCODE marketed products over the internet that claimed to test for several addiction-related phenotypes, such as those associated with alcoholism, nicotine addiction and heroin. And although genomic medicine has come a long way, tests such as those for opioid addiction are marketed to physicians (especially in the wake of the current opioid crisis) despite the reliability of those tests coming into question. "They [the tests] may be getting ahead of the science." In other words, there is no data to show how well the tests that are currently available prove risk. Despite this assertion, many doctors are using these diagnostic tools as a means to assist them in patients who are either currently battling substance abuse disorder, or who may be concerned with their potential for abuse. These tests allow them to incorporate practices aimed at the prevention and treatment of their substance disorder.

Although genetic testing can provide an accurate blueprint of an individual’s genes, it is important to consider that there may be other factors that influence the expression of certain conditions and diseases. For instance, extensive epidemiologic studies have been conducted in individuals exposed to the Dutch famine in late 1944 to spring of 1945 (also known as the Dutch Hunger Winter) to show that environmental factors such as hunger can affect the expression of certain traits. These studies suggest that adult-onset disease risk is associated with adverse environmental conditions early in development. Epigenetics is the study of changes in gene expression that do not involve
a change in DNA sequences (those involved in coding DNA: Adenine, Cytosine, Guanine and Thymine). These changes may involve chemical alteration(s) to the DNA molecule itself, alterations to the proteins that bind with DNA to form chromosomes and RNA interference, which is involved in gene expression by binding with DNA at certain sites. These types of epigenetic changes are durable and are capable of spreading from generation to generation (as was found with the study of the Dutch famine). This is achieved either through mitosis (cell division) or meiosis (sexual reproduction).

Recent studies show that these changes occur in humans, as well as other animals and plants, and can be linked to exposure to factors such as nutritional deprivation, poor maternal care, or maternal stress. Timing is also an important factor with regard to epigenetic changes. The stage of development during the time of exposure to epigenetic-altering phenomenon – be it during gestation, as a newborn child, or even as an adult – can also affect the consequences of such exposure. For instance, in the study of the offspring of those who survived the Dutch famine, those conceived during the periconceptual period of pregnancy (the period before conception to early pregnancy) have less DNA methylation of an important growth factor known as insulin-growth factor II (IGF2). Those who were exposed later in gestation (for a minimum of 10 weeks and shortly before birth) did not have this epigenetic marker but did suffer from lower birthweight than those exposed during the periconceptual period.

This association between timing, exposure and how these factors affect gene expression is important to our understanding of how environmental factors affect growth, development, and our overall health. Somatic cells in the body are essentially the same genetic material. However, different cell types exist because of epigenetic mechanisms
that regulate the expression of genes in cell division. Epigenetic programming also controls what are known as “transposable” elements in the genomes. These “jumping genes” are DNA sequences that are highly mutable, highly repetitive and although they are capable of generating new genetic variation and flexibility, they are also capable of damaging other genes – which may result in mutations like those found in cancer. Imprinting is also an epigenetic function found in normal cells. Genomic imprinting influences what types of diseases or conditions are inherited. In this instance, it depends on the “parent-of-origin.” That is, imprinting selectively “turns off” a gene either from the mother or the father. The “parental conflict hypothesis” basically suggests that it matters from which parent you get a gene, and may explain why certain conditions only manifest themselves if you get them from your mother OR father (and not both).

Epigenetics in normal cell development also allows an organism to adapt to the environment in which it is developing, thereby altering its phenotype, adjusting for the anticipated environment, and increasing its fitness.

Normalcy aside, disruptions in these processes can have lasting and detrimental effects. Abnormal epigenetic effects are widely accepted as the cause of many cancers. Evidence also exists that shows that adult-onset disease may be encoded epigenetically at early stages of development (in utero and as a newborn). Maternal exposure to certain types of endocrine disruptors such as synthetic estrogens may interfere with reprogramming of the fetal germline, leaving behind epigenetic effects across generations. Low-dose radiation may also have an effect on epigenetic regulation, which may increase the potential for transgenerational carcinogenesis. Exposure to toxic contaminants in the air such as those from smoking tobacco or air pollution has been
shown to have a transgenerational effect. One such study showed paternal smoking to affect the weight of their sons (but not their daughters) by age nine. Those who smoked early in life tended to have heavier sons than those who smoked later or not at all. Another study showed the effects of smoking on grandchildren – highlighting the impact that it can have not only on the next generation, but their children as well. Grandmothers who smoked while pregnant increased the risk of having grandchildren who developed asthma by the age of five. Other factors such as dietary intake (both in utero and throughout the course of development), in-vitro fertilization (IVF) and maternal behavior are also examples of how our environment and personal decisions can exact epigenetic changes.

In terms of substance use disorders, it has been shown that introduction of drugs of abuse such as cocaine, opioids and alcohol can trigger epigenetic alterations that affect reward, psychomotor activity, drug craving and relapse. Vulnerability to addiction, response to drugs of abuse, as well as drugs used to aid in recovery may also be determined by epigenetic factors. It is also important to consider the impact of sociocultural factors on epigenetic change, especially with regards to substance use and abuse. Studies show that individuals who have suffered socioeconomic disadvantage, elevated levels of stress and/or physical abuse at an early age (infancy to preschool age) correlate with different methylation patterns, as well as differences in epigenetic profiles of genes related to mental health and drug addiction.

In light of these breakthroughs in epigenetic research, possibilities are beginning to emerge for the use of such knowledge in the prevention and treatment of SUDs. Research done on rats indicates that certain epigenetic markers can be altered by using
certain types of epigenetic drugs that inhibit DNA methylation and remove certain epigenetic marks from genes. Although the research in this area is limited, it shows the potential for the identification of DNA methylation differences associated with different substance abuse disorders, as well as the potential to use epigenetic medicine for the prevention of future SUDs.\textsuperscript{162} It may also be used in the treatment of individuals who are in recovery. At the environmental level, the information gleaned from the study of epigenetics can help develop an intervention which may serve to limit or reverse the effects of outside stressors, as some interventions (such as those related to stress or environmental enrichment) have shown to reverse addictive phenotypes.\textsuperscript{163} Although the field of epigenetics with regards to preventing and treating addiction is relatively new, it has been effective in shedding light on the confluence of molecular, biological and environmental factors in addiction. Breakthroughs in epigenetic medicine certainly help to inform the field of pharmacogenetics, which also uses genetic data to aid in the prevention and treatment of substance use disorders.\textsuperscript{164}

\textit{Pharmacogenetics} studies the influence of genetic variation on the response to drugs (pharmaceutical or illicit).\textsuperscript{165} Genetic variation can affect the way in which drugs affect an individual, not only therapeutically, but in terms of adverse or “side” effects. In other words, some individuals may have the genotype (genetic makeup) necessary to metabolize certain drugs. In individuals with a different genotype, the same drug may be toxic to their systems, or they may find little to no benefits from taking it.\textsuperscript{166} The lack or excess of genes, or certain genetic mutations can cause a change in the metabolic process, thus either inhibiting clearance of the drug from their system (which can lead to toxicity), or acceleration of elimination to the point that the drug is ineffective.\textsuperscript{167}
Pharmacogenomics is, broadly speaking, the application of pharmacogenetics to the development of drugs and drug therapy.\textsuperscript{168} This promises to make the research and development of drugs more efficient, and therefore more cost-effective. Pharmacogenomics can also play a role in increasing the effectiveness of pharmaceutical therapies while decreasing morbidity and mortality rates. In the long run, this is likely to reduce the cost of care not only on the clinical side but for pharmaceutical companies as well.\textsuperscript{169} Take for example the treatment of leukemia: when treating leukemia, a commonly used class of drugs known as thiopurines are used. However, there is a percentage of the Caucasian population (10\%) that have a genetic variation that reduces their ability to metabolize the drug.\textsuperscript{170} A genetic blood test allows clinicians to discover this and tailor their treatment to fit the needs of the individual. Otherwise, before requiring the tests, individuals who did not metabolize the drug well often had to limit their treatment because of adverse side effects, which would allow relapse of the cancer. Instead, hospitals like St. Jude now require the test before treatment. This not only makes the treatment more manageable (and tolerable for the patient) but may reduce the number of treatments needed – saving time and money\textsuperscript{171}.

Pharmacogenomics also show promise with regards to substance use disorders by providing those treating individuals with SUDs genetic information that may assist them in prevention and treatment.\textsuperscript{172} Genetic variation in dopamine receptors is positively associated with susceptibility towards addiction – even to the point where specific genes are associated with certain substances like nicotine, alcohol and cocaine.\textsuperscript{173} Given this knowledge, it may help identify what substances and individual are more susceptible to, and help doctors and patients make informed decisions about current and future health
outcomes. This also gives doctors (and in some cases, pharmacists) a look at the variation in genotypes that promote or inhibit the use of certain medications. In alcoholics, individuals with certain alleles (a variant form of a gene, usually as a result of mutation) responded better to treatment through the use of Naltrexone than others who did not have the same allele.\textsuperscript{174} In this instance, knowledge about the consequence of drinking while having this allele may be helpful for prevention (initially or in the prevention of a relapse), as the study also showed those with certain alleles were more susceptible to abuse or relapse. Although limited in quantity and scope, some studies that have been conducted on treatment for cocaine and heroin also show that certain genotypes respond better to treatments such as methadone (mostly in terms of adverse effects, not necessarily treatment outcomes).\textsuperscript{175} By providing a genetic map, pharmacogenetics can help inform clinicians about what avenues of care to take for the individual patient, not just patients in general. This is what is known as personalized medicine.\textsuperscript{176}

\textbf{3bii. Principlism and Policy Concerns}

The field of genetics and is rapidly advancing. Breakthroughs in genetic engineering and gene editing technology in plants and other organisms are set to revolutionize modern medicine. The ability to precisely change genetic material opens a new set of concerns – including how we use genetic testing to diagnose, prevent and treat illness, disease, or other disorders. With that in mind, ethicists, clinicians, policymakers, educators, and other healthcare professionals must consider the ethical, social, and legal implications of these emerging technologies.

Four commonly accepted principles in bioethics are the principle of autonomy, the principle of beneficence, the principle of nonmaleficence and the principle of
A consideration of each of these is vital to ensure ethically responsible care for any individual who is undergoing genetic testing or research involving the collection of genetic material for examination. Autonomy is considered one of the cornerstone principles of ethical care. Autonomous individuals are deemed to have the capacity to act with intention, free from coercion or manipulation of any kind. One of the manifestations of respect for authority in the realm of healthcare is the process of informed consent. Traditionally, informed consent involves working with an individual before any treatment or procedure to ensure they understand the nature of the procedure, as well as the risks, benefits, and limitations of the said procedure. What is unique to genetic testing (and especially genetic research) is the nature of the information being collected and the way in which it is used, shared, and stored.

Genetic data may not only affect the individual, but it can also have an effect on other family members. It is important to address these issues prior to collecting genetic data to ensure that the individual involved has a clear understanding of who has access to details of their genomes. Anxiety regarding the way in which genomic data is handled is cited as a reason many are reluctant to undergo genetic testing, for fear employers, insurers or law enforcement may use it as a form of genetic discrimination. Therefore, privacy concerns should be addressed in advance. Privacy falls under the realm of respect for autonomy, as it is “the right of the individual to control their own body, actions, and personal information.” Respecting privacy and maintaining confidentiality, in this case, means that the patient is assured that their genetic information will not be used or shared in a manner other than what is intended and the patient consents to.
Providing adequate amounts of information to the patient before testing or research and ensuring that information does not go to individuals or entities without the patient's consent also shows respect for the principle of nonmaleficence. Nonmaleficence either avoids or minimizes harm. Inadequate information about genetic testing or the scope of clinical research they may participate in can have detrimental effects on an individual and their family. If there isn't an understanding about the nature of testing for addiction for instance, an individual who shows susceptibility to drug or alcohol addiction may not understand that probability does not necessarily mean certainty. Disclosure of genetic information also has the potential for harm. Genetic discrimination is not a new phenomenon in the United States, and disclosure of genetic information to anyone other than those the patient or subject consented to increases the potential for this to occur. Drug abuse and addiction still carry a social stigma, and the possibility of others discovering this diagnosis without authorization has the potential to cause significant social and psychological harm.

This leads to another ethical consideration regarding genetic testing for diagnosis, particularly for substance abuse disorders. The principle of nonmaleficence calls for avoidance or minimization of harm. Yet, in a study on the effects of learning about genetic susceptibility to alcoholism, it was evident that those in the study who were led to believe they had the genetic marker(s) associated with alcoholism suffered psychological harm. Those who believed they did show a decrease in positive affect, increase in negative affect and significantly less perceived sense of self-control over their ability to quit drinking. Refraining from genetic testing when it is not necessary - especially with regards to disease such as addiction that is still highly stigmatized – should be
encouraged. At the very least a thorough discussion of the potential social and psychological effects should be part of the informed consent process, and counseling provided to minimize the impact.\textsuperscript{187}

Another element to consider is the impact that waiting for a test result may also have on an individual (and/or family). Psychosocial effects such as anxiety, increased stress levels and depression may occur during this time.\textsuperscript{188} Depending on the situation - especially with someone who may want to use the results as a starting point for recovery - time may be of the essence. Setting up a support system in the interim time between testing and results may be necessary. Genetic counseling and social supports may also be necessary upon diagnosis. \textsuperscript{189}

There are similar concerns in the field of pharmacogenetics and epigenetics. Participation in pharmacogenetic therapy and research will require genetic testing, and the implications of knowing one’s genetic makeup can be beneficial or detrimental – depending on the outcome and the perspective of the patient.\textsuperscript{190} This aspect again relates to the principle of non-maleficence. There is also a risk/benefit to consider when altering therapy based on trials which, by their nature, are largely scaled down compared to “traditional” methods. Epigenetics must also consider the impact of altering treatment and consider the potentially harmful effects on current and future generations at the epigenetic level.\textsuperscript{191} Epigenetic research must also consider the potential for harm during the research process. Studies on DNA methylation and the potential for alteration of methyl markers is currently conducted in animals by administering drugs of abuse and measuring methylation levels during use and withdrawal.\textsuperscript{192} Should these studies ever go to human trials, consideration of the use of such drugs of abuse may make it difficult to
further the research in this area due to the vulnerability of those who have (or may be vulnerable to) SUDs. Also, biological evidence of substance use may further stigmas used against those who still believe having a SUD is indicative of poor character and personal life choices. Again, assurance needs to be made so that the patient understands the nature of epigenetic testing and issues related to confidentiality of genetic information.193

Benficence is often cited as the reason why individuals should get genetic testing; the principle of beneficence requires healthcare practitioners to do all that they can to benefit the patient at all times. With regards to genetic testing, the line between doing good and enacting harm may seem a little blurry. The debate about testing for incurable diseases is an ongoing one, so considerations must be made about the benefits of testing for the individual. In genetic testing, it must also be assured that the benefits of screening indeed exist, that an association between the genetic makeup of an individual and disease exists. Sometimes the information about genetic tests is misleading and can obfuscate study findings. For instance, a test devised by Daniel Levey et. al isolated 11 genes and found that specific alleles more frequently occurred in people with alcoholism than without, and made the claim that based on their study, “it may be possible someday for young people to take a blood test and learn if they’re susceptible to alcoholism” despite the low predictive ability of their test (0.54).194 This type of enthusiasm about genetic testing can be dangerous and detrimental to individuals seeking answer about current or potential issues with regards to addiction. It may make an individual who receives a false "low risk" test engage in more careless behavior around addictive substances. It may also cause false "high risk" results that can impair a person's
psychological well-being. Care must be taken with regards to testing to ensure what is being done for the individual is, indeed, good.\textsuperscript{195}

Reduction or elimination of barriers to access, thus safeguarding fair access to resources for those who need them, supports the principle of justice.\textsuperscript{196} A key role for anyone in healthcare is to ensure that the needs patients or subjects are being met, including inequities in access to genomic technologies. This means equitable access to genetic, epigenetic and pharmacogenetic testing to all groups, regardless of socioeconomic status, race, ethnicity, sexuality, or geographic location. The cost of participating in pharmacogenetic clinical trials or subsequent drug therapy also needs consideration.\textsuperscript{197} What hinders this in the United States is lack of equitable access to healthcare, therefore limiting access to many who lack the financial resources to obtain such services. If the costs of pharmacogenetic testing are not covered by insurance companies, for instance, consumers must absorb the cost, which only furthers questions about equitable access.\textsuperscript{198} Equal access to employment and healthcare regardless of genetic information also upholds the principle of justice. Individuals who desire to get genetic or pharmacogenetic testing should not avoid it out of fear of discrimination from employers or healthcare providers based on genetic information. Assurances against this may aid in the decision-making process and promote further treatment should they need and or want to do so.\textsuperscript{199}

Another aspect of justice that needs to be examined is that of \textit{environmental} justice. The EPA defines environmental justice as “fair treatment and meaningful involvement of all people regardless of race, color, national origin or income with regards to the development, implementation and enforcement of environmental laws, regulations
and policies.” With regards to epigenetics. That is, those less fortunate should not be subject to environmental toxins that may produce epigenetic changes - which in turn can be catalysts for certain diseases - at higher rates than others. This can occur at a clinical or societal level if policies are not in place to prevent them.

It is also essential to discuss the implications of genetic, epigenetic and pharmacogenetic testing and research on social and legal policy to ensure that patients, subjects, and the public understand its impact. A discussion of risks and benefits are needed to ensure safe and appropriate use and to address any concerns about the data collected in the research and testing process. These concerns include those related to discrimination, privacy, regulation, and standardization of genetic tests, as well as implications of the use of epigenetics and pharmacogenetics may have on healthcare.

Concerns over the use of genetic information because of diagnostic testing manifested early in the development of genetic testing. As technology progresses, the possibility of its use for non-medical reasons increases. Subsequently, policies addressing the collection and usage of genetic information began to develop at the state level to curb discrimination based on an individual's genetic makeup. Policy makers were concerned with the potential for workplace, insurance and other forms of discrimination associated with diagnostic testing. African Americans in certain parts of the United States in the 1970s were subject to such discrimination, which is why genetic testing can and has led to discrimination in hiring practices, insurance obtainability, and school entry. In this instance, a law (National Sickle Cell Anemia Control Act of 1972) was enacted to ensure this would no longer occur. Many states began to adopt such laws, but they were inconsistent, indistinct, and difficult to enforce. This was partly because the technology...
of mapping the human genome and developing genetic testing rapidly outpaced the implementation of legal protections. The scope of what genetic testing could accomplish also hindered the ability of policymakers to anticipate what measures were needed to sufficiently protect the privacy and usage of genetic information. Federal laws such the Health Insurance Portability and Accountability Act (HIPAA) and the Americans with Disabilities Act (ADA) only minimally addressed issues related to the acquisition and sharing of genetic information. HIPPA prohibited limited health coverage or increased premiums because of data acquired through genetic tests. It did not, however, address employment issues.  

Without adequate legal protections, the process for the research and use of genetic information lacked consistent guidelines. Growing concerns surrounding these inconsistencies lead to the passage of the Genetic Information Nondiscrimination Act (GINA) of 2008, which was enacted as a federal law prohibiting genetic discrimination in certain instances and provided a minimum standard for states to follow for health insurance and employment. Despite this, GINA does not cover every aspect of health care. It does not apply to life insurance, disability insurance or long-term care. It also does not address lending, mortgage, or school-related issues. The provisions in the act also limit the scope of protections to asymptomatic individuals undergoing treatment as a result of diagnosis through genetic testing. Genetic information in this instance refers to “information about an individual’s genetic tests, the genetic tests of family members, and the manifestation of a disease or disorder in family members.” It does not, however, protect the usage, acquisition, or disclosure of medical information related to “a manifested disease, disorder, or pathological condition of an employee”, including those
that may have a genetic basis. It neglects to define “manifest disease” or “pathological disorder,” so ambiguity regarding what falls into either category still exists. It also fails to define what tests are considered genetic and therefore, protected under law. GINA also does not cover members or veterans of the United States Armed Forces – of which a significant percentage suffer from a substance abuse disorder. The challenge for epigenetic testing is that it is unclear if epigenetic tests are considered by GINA to be genetic. This means it may be possible to discriminate using epigenetic information in areas such as employment or obtainment of health care or long-term care.

The legal implications for individuals with addiction are apparent at multiple levels. Diagnosis of addiction via genetic testing may only show a proclivity for addiction. In terms of the ADA and GINA, the scope of protection varies depending on if an individual is asymptomatic or not. The ADA does not recognize the predisposition for disease as a disability, and although certain types of addiction are protected as disabilities under the Act, protection against genetic discrimination based on the acquisition of genetic information is not explicitly addressed. In fact, in 2008, the ADA outright rejected the assertion by Equal Employment Opportunity Commission (EEOC) that individuals who were discriminated against due to health information obtained by genetic testing as disabled individuals. Although not explicitly discussed, this omission likely applies to epigenetic testing as well. Epigenetic markers or predisposition to epigenetic change are unlikely to be considered a disability under the ADA as it currently is, considering the Supreme Court ruled that it was “not intended to cover individuals whose impairments may be mitigated through the use of eyeglasses and other corrective
measures.” By this reasoning, Individuals who are asymptomatic with epigenetic change would not likely be covered under any of the provisions of the ADA.\textsuperscript{215}

GINA, however, \textit{only} protects individuals who are asymptomatic, meaning GINA would not protect someone already in the throes of addiction (where the disease is manifest). This only serves to slow the progress of genetic and pharmacogenetic research (especially regarding the diagnosis of certain types of addiction), as the potential for workplace and healthcare-related discrimination may make individuals wary about engaging in research and testing.\textsuperscript{216} Some states recognize that gaps in protection exist and are beginning to take legal action to implement laws to ensure the privacy of genetic information and prevent genetic discrimination.\textsuperscript{217}

On the other hand, some at the national level seek to strip away some of the protections GINA and the ADA afford workers. As recently as March of 2017, legislators addressed the issue of disclosure of genetic information in workplace wellness programs. A new bill (the Preserving Employee Wellness Programs Act) introduced would exclude workplace wellness programs from limitations put forth by the ADA and GINA regarding medical examinations and collection and use of genetic testing for insuring employees and rewarding participants.\textsuperscript{218} The threat of an Obamacare repeal may also relegate genetic information to a preexisting condition status and exclude certain individuals from coverage. The ramifications on individuals who suffer or have a proclivity for addiction may be substantial, as alcohol and substance abuse was previously considered a pre-existing condition and used to deny health care coverage. In a time where addiction is still stigmatized, and many go without treatment; as a result, the lack of an ability to do for financial reasons may only serve to make the current problem worse.\textsuperscript{219}
Policies regarding the standardization and regulation of testing are spearheaded by two federal organizations: Centers for Medicare and Medicaid Services (CMS) through its Clinical Laboratory Improvement Amendments (CLIA) and the Federal Drug Administration (FDA). CLIA established criteria necessary for laboratories to conduct clinical testing, including standards related to the quality of testing taking place. Though the CLIA evaluates the analytical validity of such testing – that is, the constancy and accuracy of detecting the presence or absence of a genetic variant – concerns were raised about the lack of standards for evaluating clinical validity. This refers to the relationship between genetic variants and the presence, absence, or risk of having certain diseases or conditions. In other words, does the presence of a genetic variant undoubtedly show an increase in the incidence or risk of having or developing diseases?

The FDA has made little progress towards making evaluations of clinical validity a standard practice in the process of genetic testing. Currently, it uses what is known as “enforcement discretion” to assess tests, which means that while they have the authority to regulate tests, they choose not to. This is true of laboratory developed tests where one lab is used for certain types of genetic testing. Now, with the pervasiveness of direct-to-consumer testing (such as 23andMe) and rapid changes in testing technology, they are starting to develop guidelines for evaluating clinical validity of tests. However, as of January 2018, these guidelines are only in draft form and therefore are not legally binding.

An exploration of the current policies put forth by the government related to regulation and standardization of genetic testing shows the need for an update of current evaluation requirements. Federal agencies such as CMA and the FDA can only serve to
enhance the benefits and understand the risks by addressing this issue. Tests that promise to properly diagnose and possibly assist clinicians and physicians with prevention and treatment of certain conditions such as substance abuse disorders, admittedly are unable to prove clinical validity. Some merely show that genetic variants exist. This can lead to inaccurate results which undoubtedly affect how doctors and patients address health risks. This can be especially detrimental to an individual dealing with (or potentially dealing with) addiction.\textsuperscript{224}

An analysis of the various types of genetic testing shows that there is the potential for its use in all aspects of substance use disorders: diagnosis, prevention, and treatment. It is evident at this time that more research into the genetics behind addiction. That is, as of now, it is difficult to pinpoint at the genomic level (with strong certainty) what genotypes exist exclusively in individuals with a proclivity towards substance abuse. However, with the emergence of fields such as epigenetics, a better understanding of how the interaction between genes and the environment may affect the manifestation of diseases such as addiction may provide more cogent answers. Pharmacogenetics and pharmacogenomics are also poised to help identify specific genes that facilitate addiction, and tailor therapies to prevent and treat individuals debilitated by the disorder.

Ethical implications exist at a micro (clinical) and macro (social/legal policies) level. The principles of autonomy, beneficence, nonmaleficence and justice can be met at both levels. At the micro level, doctors and those interacting with patients should consider the unique implications of genetic testing and research – be it for diagnosis, treatment, or the development of pharmacogenomic drugs through clinical trials. It is essential that clinicians and researchers who are administering genetic tests be properly
educated on the tests, which may prove difficult as new tests and technologies continue to emerge at a rapid pace. It is also important to consider the repercussions of testing and research on the individual, families and potentially society as a whole. At the macro level, policy makers need to consider the implications these new technologies have on how genetic information may legally be used. Laws that pertain to the use of genetic discrimination lag behind the current technology. Genetic discrimination in the workplace and through certain types of insurance companies is a distinct reality, and laws should be re-examined to consider the way in which the use of genetic information is evolving. This will ensure that genetic information is handled properly, which in turn may promote participation in testing and research. This has the potential to not only improve the overall health of individuals, but society as a whole, especially at a time when opioid addiction is gripping the nation.

3c. Substance use Disorders and Care at the End of Life

Palliative medicine has the ability to enhance quality of life for people who are diagnosed with a life-limiting serious illness. However, there are populations whose experience of palliative care may not measure up to the standard of care that most palliative patients receive. Individuals with substance use disorders (SUD) often encounter barriers to optimal care. Many palliative care programs do not know how to properly care for these individuals and their unique concerns. This paper will explore how our attitudes towards death have changed over time, which lead to the introduction of palliative and hospice care as distinct specialties. It will also examine common barriers to palliative care, the incidence of SUD in the palliative care population – with a particular focus on the oft overlooked older generations. Barriers particular to individuals
with a SUD, followed by ethical considerations and possible resolution to these issues will also be examined.

3ci. Death, Dying and Palliative Care

Understanding the role of palliative and hospice care in the process of dying requires an examination of how our attitudes about mortality and death have evolved over time. The United States in particular, has not always held the same views about death and dying that we do today. Technological innovations over the past few centuries have influenced the ways in which people in general have approached these issues, staving off the inevitability of death through the use of medicine and other modern treatment. However, the contemporary views of death and dying can only be understood if the different attitudes towards it are reviewed.

Death itself may be universal, but just as every culture has found ways of living differently, they have also found different ways to deal with death, dying and the effect it has on those who are left behind. Although the problem of death has been and will likely remain an integral part of human existence, it is not in and of itself a static condition. While death is an incontrovertible biological and natural fact of life, as a social construct is it continuously changing. Such changes in how we comprehend death and our attitudes toward it coincide with the evolution of our life conditions in areas such as historical, social, economic, religious, political, and technological development.²²⁵

For instance, in early primitive societies rudimentary medical practices and inadequate defenses against predators caused death to be a familiar experience. They either feared death as an unknown, unnatural experience or revered it because of their perception that it was not an extinguishing of life; rather it was seen as a transition to a
different plane of existence. Those who feared death as an accidental occurrence did not prepare the living for such an experience, while those living during these times who perceived it as an other-worldly transition prepared the dying for this transition by various pre-death rituals and funeral practices.\textsuperscript{226} In preliterate societies, a belief that the dead somehow exerted influence over the living left some in the corporeal world living in fear, while others lived in reverence. Funeral rituals therefore were often designed to honor the dead or "to offset fears about the potential malevolence of the dead towards the living."\textsuperscript{227} Ancient Greeks believed that a person’s spirit continued live after death. It was during this time post-mortem that knowledge was attained. Burial rituals of the Greeks, Romans and Egyptians all reflect a belief in life after death, as archeological digs have unearthed the dead surrounded by artifacts that may have been used during their lifetimes but were also presented as if they were expected to be used in the afterlife and/or next life.\textsuperscript{228}

French historian Philippe Ariès identified four periods of development post Antiquity concerning the evolution of the understanding of death in common era Western Culture. The first period he called “tamed death.”\textsuperscript{229} This time period covered roughly a millennium – spanning to the 11\textsuperscript{th} Century. Ariès recognized four common characteristics of dying during this era. First: people who lived during this time period lived with a familiarity of death, an implied acceptance of their fate and the fate of humanity. A second characteristic was that the dying person was usually positioned for death: most prominently lying in bed, observing whatever prescribed religious ritual for moving on to the afterlife was appropriate. Thirdly, death was a ritual organized and presided over by the dying person. This ritual was carried out in a public, ceremonial
manner, lacking in theatrics and with no great show of emotion. Finally, it was customary
to have family members, neighbors and even children at the bedside as the individual
died. During this time people were not as concerned with what happened to their bodies
postmortem – although the preferred they not be buried in cities or near housing of the
living for superstitious reasons.

Around the 11th and 12th century these attitudes started to change. The time period
noted a change in the subject of death from the act itself to the individual who was dying.
This personification of death became the defining feature of a time period Ariès titled as
"One's Own Death." Attitudes towards death in these centuries reveal the importance
given to the self and to one’s own existence. Although the familiarity with death did not
change, the relationship an individual had to it did. This is related to a shift in how the
Last Judgement was viewed in Christianity. The idea that one’s good and bad deeds
would be weighed upon their death made it more personal. The moment of death became
more significant and more important for people to witness, as it became more about
witnessing the moment before judgment and not simply the moment before death. During
this time, doctors could assist with healing, but any attempt to prolong life was regarded
as blasphemous. Unlike in previous centuries, permanent burial became more
common. The dead were more likely to be buried in individual tombs, with personalized
inscriptions and decorative artwork. Such artwork was used to warn others against moral
corruption and/or as an expression of their love of life.

Although the shift in 11th century thinking was subtle and gradual, the 18th
century brought on an abrupt change in how western culture viewed death. Up until this
time period there had been a familiarity with death and the dead. The person dying was
the only one concerned with their death. Family members, friends and neighbors were merely invited as witness to it and in more contemporary terms witness to their final judgement before death. As Ariès notes, as the 18th century arrived there were dramatic changes in the attitudes towards death in what he named the “thy death” period, which was also known as the period of the “beautiful death.” Death was exalted, revered, feared, and worshipped. For a short time, the notion of death became eroticized in art and literature. Like the sexual act itself, death became more of an act that tears man from his daily life, forcing from him a sudden expression of emotion – a break from the banal. Whereas death had once been so familiar, it evolved into something that was now intolerable and full of emotion. Family, friends, and neighbors came to the bedside of the dying not to witness their death, but to mourn it. Ariès notes that this century was the century of mourning. People were more afraid of the deaths of others than their own. There emerged “cults of mourning” and “cults of memory” that were fueled by this fear. Tombs became symbols of the presence of loved ones after death, and families began to bury their own on their property. The Industrial Revolution began to create employment and wealth, and a class of individuals (bourgeoisie) with the means to attempt to prevent it. National health started to become relevant to economic matters, and the concept of a medical market to address such concerns emerged in the 18th century. This coupled with a change in the family roles regarding health to a remarkable change in responsibilities regarding death. Instead of the individual or Death signaling mortality, now it would become the doctor who signaled death.

By the late 19th century, however, it would become apparent how these and other social/economic changes impacted Western attitudes on death and dying. Although we
continued to hold on to our fear of death, innovations in medicine and technology allowed us to find ways to try and avoid it. Continuing on the work of Ariès and others it is evident that establishing palliative care and hospice care as distinct medical fields coincides with changes in 20th century attitudes about death. There is also a contemporary development, marking a significant change from mid-19th to mid to late 20th century thinking as well, beginning around the turn of the 21st century.

During the emergence of Ariès’ “forbidden death” era of the late 19th and early 20th century, he noticed that the attitudes associated with the “tamed death,” were rendered obsolete in less than half a century. Once omnipresent, the topic of death all but disappeared from the forefront of society. What was at one point shared and celebrated became forbidden and shameful. Instead of recognizing and preparing for death like those in the early millennia, the dying person was often purposefully deceived by those mourning a death that had not occurred yet. They omitted or outright lied about aspects of the dying person’s health. This was done to spare the dying any emotional turmoil.

Ariès attributes it to two major developments during this time. First was the emergence of the “medicalization of death.” Death became a technical cessation, determined by decisions made by one or more doctors. Families now no longer had the means at home to care for sick and dying family members. The hospital became not only a place for curative medicine, but a place to go to die because it was inconvenient to do so at home. More people died in the hospital than at home during this time (1930s-1950s). Arrangements historically made by the individual rested solely with the family now, who were tasked with become “masters of death.” It was part of their job to ensure
a “good death,” or at least one that caused the least embarrassment or provided the most grace and dignity for the patient and family.

The other development was what Ariès’ called the “privatization and banning of mourning.” This occurred as a result of the growing sentiment that life should, above all else, be happy. Death was now seen as an ugly thing and as such removed from prominence. Emotions associated with death were seen unfavorably. The origin of this sentiment are the remnants of the “beautiful death” era, infused with a new sentiment characteristic of modernity: one must avoid disturbances and the strong and unbearable emotion caused by dying and by the presence of death. This was not done just for the dying person’s benefit, but for the benefit of society and those close to the dying person. This is evident in postmortem practices as well. The practice of embalming the dead for purposes of viewing after death gained popularity in the 19th century – especially in the U.S. This is but another way of acknowledging death, but in a way that does not entirely accept or conceal it.

As the 20th century progressed however, what was once considered forbidden, hidden, invisible, denied and taboo in contemporary society has once again evolved into something unique to the time period. Death is no longer in the shadows. In fact – we are surrounded by it. Sociologist Michael Jacobsen calls this time period from the turn of the 21st century to present the “Spectacular death” time period, a period in which death, dying and mourning have increasingly become spectacles. It is a time in which society has developed and obsessive interest in appearances that simultaneously draws death near and keeps it at arm’s length. This allows us to witness it at a safe distance with equal parts fascination and abhorrence, while sparing ourselves the emotional labor. This “new
mediated/mediatized visibility of death” is one of the facets of the spectacular death that
distinguish this era from others. Pictures of death are often used to get impact, entertain,
and provoke attention, rather than invoke religious meaning or provide a meaningful
narrative.\textsuperscript{233} Fascination with celebrity deaths connotes an invasiveness and intrusiveness
now not only in their lives but their deaths as well. This cultural fascination found in the
media and in the “highbrow” arts as well as commercialized or mundane art forms is,
according to British sociologist Geoffrey Gorer a “sublimation of the modern repression
of death and as an outlet for such cultural fears and frustrations.”\textsuperscript{234}

A second dimension of this spectacle expands Ariès discussion about American
burial and mourning culture emerging in the “forbidden death” time period. This is seen
as an increasingly important factor in recent changes in Western death mentality at the
turn of the 20\textsuperscript{th} century. This uniquely American tendency associated with a new type of
euphoric consumerism challenges many of the traditions previously circumscribing death.
Because of the commercial nature of burial and burial services, death is now not only
turned into a spectacle through the media; it is also used as a means to increase sales and
the rapidly inflating costs of such services. Images of death are now used to sell products
and services.

A third dimension is what Jacobsen calls the “re-ritualization of death.” The
modern “forbidden” death relinquished the rituals – religious or otherwise - associated
with the human encounter with death. Counter to this is the gradual rise of new rituals
and the reappearance and reinvention of old ones. These include practices such as playing
popular music at the ceremony instead of solemn religious music, inventive ways of
transporting and photographing the dead, emphasis on creating living wills and innovate
ways of preserving the remains of the dead such as jewelry and other items made from cremated ashes. In the online age people are also creating “digital legacies” on sites like Find-A-Grave or on internet funeral parlor obituaries.

The final noteworthy distinction of the spectacular death age is the palliative care revolution. In the previous time period, where the medicalization of death and its accoutrements lied about death and dying. Medicalization has now conversely transformed into patient rights, creating and an awareness in the context that in the dying and their families and friends are kept informed and asked to make their own decisions. In the mid to late 20th century a movement known as the “death awareness movement,” or “death with dignity movement” began. The emergence of this movement is associated with the opening of the world’s first purpose-built hospice, St. Christopher’s, in London in 1967. The positive reception of Elisabeth Kübler-Ross’s book On Death and Dying in 1969 and subsequent establishment of hospices and palliative care units are also indicative of shift in death mentality. It was because of these changes in particular that palliative care developed as a distinct philosophy and specialization. It has become a topic of academic attention and specialization, including disciplines outside of medicine such as sociology and psychology. There is also an increasing desire to re-introduce the home as the place where people die instead of dying in aseptic and sanitized institutional settings such as the hospital or nursing home.

Clearly the way in which our society has changed over the course of time – increased medical knowledge, religious influx, changes in the family unit, the impact of pandemic disease, war, and technological innovations – all have an influence on how we as a society understand and cope with death. With that, palliative care, hospice, and
patient’s rights have become a compelling contemporary issue. An understanding of what modern palliative and hospice care is and what it looks like now, as well as a consideration of the barriers that still exist is also necessary for proper discussion of issues surrounding such care for individuals with substance use disorders.

Palliative care and hospice care themselves are not entirely new. Caring for the dying has been part of a doctor’s role for centuries. However, palliative and hospice care as we know it now is still relatively new and trying to define itself. Modern medicine introduced us to innovation in technology and treatment, which in turn gave us benefits such as a prolonged life span, but also gave us modern problems such as an increased likelihood for chronic and illnesses. As a result, over time emerged a movement towards the provision of medical services to address the consequences of living longer. The number of people suffering from chronic life altering and/or terminal illnesses looked to medicine to help them cope with the living and the dying aspects of their diseases.

Palliative care as we know it is much more complex than it was in its early stages throughout Europe and as it began to gain popularity in the United States in the 1960s and 1970s. This was in part due to the efforts of Dr. Cicely Saunders and her colleagues at St. Christopher’s Hospice in London – the first purpose-built hospice that opened in 1967. Her efforts coincided with the publication of *On Death and Dying* by Dr. Elisabeth Kübler-Ross in 1969. Early 20th century medicine made it possible for people to live longer, and people were not dying at the same rates or for the same reasons they had in previous centuries. Instead of dying from infectious diseases like pneumococcal pneumonia, people were more likely to die from atherosclerotic diseases (i.e., myocardial infarction, stroke, or congestive heart failure). Death did not occur as quickly as before
(hours or days). Instead, there was an increasing period of chronic illness and dying that occurred over much longer periods of time. This change in life expectancy and the experience of dying changes conversations people had about death and dying. According to Kübler-Ross, these were conversations those with terminal illness wanted to have. Dr. Saunders’ ideas about using the hospice as a place to teach and perform research moved from London to the United States soon after in 1974. In that same year Balfour Mount, a urologic surgeon, founded the world’s first hospital-based palliative care service, at the Royal Victoria Hospital of McGill University in Montreal, Canada.

Palliative medicine was first defined in the United Kingdom in 1988, when it was recognized as a medical specialty. To define palliative care the World Health Organization (WHO) offers the following definition:

“Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.”

Using this definition, the principles of palliative care include: a comprehensive and active approach to end-of-life care; the patient and family as the unit of care; improvement of quality of life and the promotion of dignity and effective and efficient care while responding to patients’ and families’ needs.

Palliative care is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy, radiation therapy or pain management. It also includes those investigations needed to better understand and manage clinical complications. Therapies geared towards improving or maintaining physical well-being also include those geared towards psychosocial and spiritual support.
These include patient-centered interventions such as dance therapy, music therapy (often used in both psychosocial and spiritual exercises), art therapy, dignity therapy, life review, meditation, meaning of life intervention and focused narrative interventions.

Palliative care services can be administered in a variety of settings, including the home, hospital beds, specialized units, outpatient clinics, (adult) day care centers, or bereavement services. These services are separated into two categories: basic palliative care and specialist palliative care. Basic palliative care includes actions that any health care service would take to improve the care of terminally ill patients and their families. Such care is not limited to cancer diagnoses. Individuals with congestive heart failure, kidney failure, chronic obstructive pulmonary disease, AIDS, Alzheimer’s and other terminal or life-limiting diseases may also require palliative services. In primary care services, basic palliative care should include regular home visits and telephone support. In nursing homes and similar service facilities, basic palliative skills including an understanding of symptom management guidelines and care pathways, and decision-making protocols for frequently encountered ethical dilemmas such as those related to nutrition and hydration.

Specialist palliative services are those specifically set up to offer professional care to patients and their families. These are offered at an independent location with specific managerial, training, and financial resources. Once basic services have been implemented, specialist services are called upon to address the needs of more complex patients with more complex interventions. These interventions are focused more on quality of life and the patient’s needs, rather than the prognosis itself. Services supplied in these settings may also include educating family members about the patient’s illness,
treatment, and medications, as well as respite care for caregivers. However distinct they may seem, basic and specialist services should be complimentary, synergistic, and cooperative.

There are not only different levels of palliative services, but there are also different types and locations where these services are administered. The most prominent one of these are hospices, where the modern approach to palliative care was established. To qualify for hospice services, patients must meet certain requirements. The patient's doctor, often in conjunction with a hospice doctor, must determine that the patient is terminally ill, with a life expectancy of six months or less. Conventional hospices are community-based organizations devoted to the care of patients and their families. Their model of care, multidisciplinary teams, high levels of satisfaction and strong community ties have been central to the establishment of palliative care in small communities around the world and have help the concepts and principles of palliative care spread to all levels of health care.

Support teams are available in various settings and act as a multidisciplinary team consultation service that operates without having assigned beds. These teams are usually made up of one or more doctors and nurses, and cooperate with other specialists such as social workers, chaplains, psychologists, physical therapists, and other professionals. They provide a level of intervention that coincides with the patient’s needs. This means they may only provide advice/counseling or are directly/completely involved with the patient’s care. Home care teams are typically comprised of one or more doctors and nurses, as well as other pertinent professionals. They operate out of the patient’s homes in
coordination with the primary care physician, local hospitals and other hospices when needed.

Palliative Medicine Units have beds devoted to palliative care. These are found throughout the healthcare system: from small independent hospitals to large hospital systems or cancer centers. Some of these beds are disease specific (cancer, AIDS) while others are mixed. Palliative care units can be for specific populations if necessary and offer a wider variety of interventions. Acute palliative care units are typically housed in cancer centers and hospitals and look after younger patients with more complex diagnoses. Those housed in health care centers and long-term care facilities cater predominately to older patients who often present with social problems and require longer stays. 242

Outpatient clinics provide accessible, flexible care, and can be run by home or hospital support teams or combined with an inpatient unit. The services offered by such teams ranges from counseling of other teams to direct and/or urgent care if necessary. Day care centers provide medical services in conjunction with other services such as occupational therapy, support groups, rehabilitation, or recreational therapy. They may also be available to provide more complex services such as those that require interdisciplinary interventions or procedures such a catheter replacement or intravenous care.

Ideally, these services would be available to patients in a comprehensive palliative care network or system. These would be imbedded in networks that work together to provide such services. Palliative care patients would have a case manager that would coordinate these services and help with issues related to finances and scheduling. This
would require collaboration and consensus by other area health resources as well as leadership, and participation of the health authority/network.\textsuperscript{243}

Despite the growing number of options related to palliative care both globally and in the United States, there are still gaps in the amount of people who are eligible for palliative that are actually accessing and using it. This is not isolated to the United States, it is occurring across the globe. Developing an understanding of barriers to accessing palliative care will allow the medical community and policy makers to create pathways for those who currently lack resources to get quality end of life care.

According to the World Health Organization (WHO), each year an estimated 40 million people worldwide need palliative care. Unfortunately, only about 14\% of people who need palliative care receive it.\textsuperscript{244} In the United States, it is estimated that about 6 million (approximately 1.8\% of the population) may benefit from palliative care services, yet less than 2 million (1.6-1.8) access these services each year.\textsuperscript{245} One of the primary reasons for this is the variability in access due to geographic and other setting-related characteristics. Until recently, palliative care services were only available to patients who were enrolled in hospice.\textsuperscript{246} However, the number of palliative care teams found in hospitals has grown exponentially. As of 2019, approximately 72\% of all hospitals with more than 50 to 299 beds have a palliative care team today, up from 65\% in 2015 and 7\% in 2001. Ninety-four percent of hospitals with 300 beds or more have a palliative care team. These hospitals currently serve 87\% of all hospitalized patients in the U.S. - an increase from 82\% in 2015.\textsuperscript{247}

Regardless of the fact that many more hospitals have palliative care teams in their facilities than ever before, geographic location and regional characteristics have an
influence on the availability of palliative care for patients. For instance, a 2019 study by the Center to Advance Palliative Care (CAPC) showed that 90% of hospitals with palliative care are located in urban areas, while only 17% of rural hospitals with 50 or more beds report palliative care programs. That means someone with a serious illness living in heavily urban areas – such as those found in the northeastern part of the United States - have access to significantly more hospital palliative care programs than those living in regions that are largely rural – such as the south central part of the country.

Other characteristics such as tax status (profit, non-profit), status as a freestanding children’s hospitals (largely urban), whether the hospital is designated as public or a sole community hospital (which are often the only option for people lacking health care or for those who are geographically isolated) or if a hospital has less than 50 beds also influence access to palliative care. For profit hospitals (35%), hospitals with fewer than 50 beds (36%), sole community hospitals (40%) and public hospitals (60%) were all less likely to have a palliative care team. So, despite growth in the amount of palliative care teams in American hospitals, access to palliative care depends on where you live and the type of hospital to which you are admitted.

Another barrier to access to palliative care is the lack of adequate medical and nursing workforce with training and expertise in palliative care. Currently, the United States has 7,600 physicians who are board certified in palliative care. Unfortunately, these numbers are dwindling. With the number of Medicare eligible individuals 65 and older increasing at a rate of 10,000 per day, the ratio of palliative care doctors to patients comes to roughly 1 for every 808 patients. Overall, this means that many providers who are working with patients who have a serious illness and referring to palliative care are
not adequately trained to handle end-of-life (EOL) care. This trend will continue as burnout among these specialized providers continues, and the number of incoming physicians remains stagnant. One workforce study commissioned by the America Academy of Hospice and Palliative Medicine in 2010 estimated (conservatively) that there would be a shortcoming of at least 2,787 full time physicians, which equates to roughly 6,000 palliative medicine physicians, given the frequency of part time participation in that field. This estimate did not, however, factor in the still unmet need for outpatient specialist-level palliative care, which is one of the greatest barriers to access for seriously ill patients who aren’t in the hospital yet do not meet the qualifications for hospice.\textsuperscript{251} There are also barriers within the medical field that keep residents from receiving specialty training. Primary funding for graduate medical education is Medicare, which caps the number of slots in teaching hospitals each year at 80,000 – a number that has not changed since 1997 despite changing demographics and the introduction of new specialties like palliative care.\textsuperscript{252}

In areas where palliative care specialists are not available, primary care physicians often fill in the gap. However, studies have found that certain types of providers are less likely to refer patients for palliative or hospice care. One study of 231 physicians in the United States revealed that cardiologists (40\% referral) pulmonologists and other subspecialty physicians (55\%) referred terminally ill patients to hospice care less than oncologists (68\%). Another study found that some nurses resisted hospice referrals when there was adequate treatment at home, while some of the nurses simply had limited knowledge of hospice referrals.\textsuperscript{253} Other studies show that some healthcare providers simply lack formal training in palliative and EOL care. There is also a culture in medicine
that states physicians and other health professionals are trained to prolong, so referrals to hospice care might seem like a medical failure or deprive patients of hope.\textsuperscript{254}

In a study on hospice and palliative care nurses perception on barriers in EOL care, communication was the number one issue they identified that needed improvement – both between healthcare teams and providers and providers, the patient, and their families.\textsuperscript{255} Healthcare providers often remark that they either “lack time” or are “reluctant” to have conversations about EOL care because patients aren’t “sick enough” yet. Physicians also cite that their patients are not always ready for or receptive to the conversation. Other providers are simply unaware of what options are available for seriously ill or dying patients.\textsuperscript{256}

There is also a lack of public awareness of what palliative care is and what services are available through it. This particular barrier to access is wrought fear surrounding conversations about the end of life, as well as misinformation about what palliative care and hospice requires from the patient, including the notion that they must forgo all treatment.\textsuperscript{257} Initiating these conversations is often the most difficult for patients who have not experienced a close family member’s or friend’s death. In one study regarding end-of-life communication barriers, it was found that 58\% of those interviewed did not want to engage in such conversations with their providers. They cited that they didn’t like to talk about issues related to death or did not want to discuss certain options like hospice care.\textsuperscript{258} Other patient-related barriers include lack of awareness of hospice as an option, preference of more aggressive therapies, conflict between spiritual beliefs and the goals of palliative and hospice care and an inherent mistrust of the medical system (which was largely found in African American and other minority communities).\textsuperscript{259} Many
of these perceptions also stem from a lack of knowledge or poor observations regarding what palliative and hospice care are. For instance, that hospice care “bumps people off” or is a sign of “giving up.” These individuals may also be unaware of the severity of their illness, which depends on how truthful the doctor and family have been about their prognosis. Patients and their families may also believe that acknowledging the severity of their illness may hasten the patient’s death. Lack of information and misinformation can indeed prohibit patients from gaining access to quality care at the end of their lives.\

Concerns related to cost and insurance coverage of palliative and hospice care by healthcare consumers, their families and even providers also create barriers to utilization of these services. What is beneficial to know is palliative care consultation is associated with reductions in hospital costs of more than $3,000 per admission, and for the sickest patients (with four or more diagnoses) these savings are closer to $4,800 per admission. Many families simply do not understand what is covered by their insurance companies cover with regards to palliative care and hospice. A study by the National Hospice Foundation shows that 90% of Americans do not realize that hospice care is fully covered through Medicare. In fact, Medicare, Medicaid, and most private health insurers provide a full array of palliative care services for patients who are hospitalized or in hospice care and their families. However, this is not the case for all people who may have debilitating illnesses that require care coordination, pain management, 24-hour assistance and/or social and spiritual support. The difference is that hospice care requires that the patient is terminal (life expectancy of six months or less) and under Medicaid rules they must be willing to forgo curative treatment. For those who do not fall under these categories, the options for palliative care are often more limited through public and
private plans – unless paying out of pocket. Misunderstanding of costs associated with palliative care and hospice and the lack of consensus amongst third party plans on what palliative care is and what services are covered is yet another major deterrent for patients and families who may benefit from its services.

Palliative care, hospice and its barriers do not end with these issues. There are particular populations of individuals that experience issues related to access based on certain health-related statuses that they live with currently or have lived with in the past, such as those with a substance use disorder. Their unique concerns require attention, so that they can be properly addressed.

3cii. Enhancing Palliative Care for Individuals with Substance Use Disorder

Individuals living with a SUD have their own obstacles to overcome related to utilizing palliative care services. Once providers understand and acknowledge that individuals with a SUD will patronize their services, they can then work to alleviate incongruencies of care. The actual number of individuals in palliative or hospice care with a substance use disorder is not entirely known, although some studies suggest that the numbers probably mimic that of the overall population. The 2018 NSDUH estimated that 19.7 million (6.0%) Americans aged 12 years or older had a SUD. Other studies estimate that up to 25% of palliative care and hospice care patients present to treatment with an active SUD or in recovery from one. While the exact number may not be currently known, it is important to consider the impact that the changing landscape of the overall population and incidence of substance use disorder may have on current and future understanding(s) of palliative care patients.
Consider that the U.S population of persons 65 and over is rising exponentially. It is projected to double from its 2002 population of 35 million to 70 million by 2050. According to the Global Burden of Disease Study, mental health, and SUD conditions account for 7.4% of the global disease burden worldwide, and this percentage is expected to increase. Neuropsychiatric disorders (including SUDs) are also expected to comprise 5 of the top 10 causes of disability worldwide. One model by Joseph Gfrorer predicted that the number of elders (65+) with an SUD would grow from 1.7 million (2016) to 4.4 million (2020). The U.S. Census Bureau estimates that by 2050 the U.S population of persons 65 and older will increase to 70 million, while worldwide assessments estimate that by 2047 the world’s population of individuals 65 and older will outnumber the number of children globally. Despite research that suggests that drug use diminishes as individuals age, the Baby Boomer generation continues to show a higher rate of drug abuse and misuse than previous generations. The potential for opioid abuse related to pain management has also increased with the introduction of highly addictive drugs such as Oxycontin and increasing costs associated with its production and distribution.

Other illnesses that can cause cognitive impairment and affect judgement such as Parkinson’s, Alzheimer’s and stroke are more also prevalent in individuals 65 and older. Diseases such as dementia that are associated with cognitive function deficits and judgment impairments other are also associated with an increased risk of SUDs. This development may affect the way in which older patients receive care – particularly at the end-of-life – especially considering there is little research available on the effects of SUD on an aging brain. With 94% of the palliative and hospice care patients entering care at
65 or older, certainly a consideration about the impact of SUDs, cognitive function and risks at the end-of-life is necessary if optimal care is to be provided.

The impact of an influx of older adults with comorbidities including SUDs on a palliative care model that is already ill equipped to handle palliative patients with an SUD cannot be understated. While the amount of empirical research on geriatric palliative care is scarce, there is evidence that the type of care older adults are receiving is already severely lacking compared to their younger counterparts. This means that the unique - and in some cases unknown or misunderstood - needs of older adults with SUDs often go unchecked or are misdiagnosed. Inconsistent screening protocols might cause providers to overlook the symptoms of SUDs or attribute them to the diseases or comorbidities associated with their enrollment in palliative care. Although the aforementioned effects of stigma on individuals with a SUD and the further detrimental effects of ageism may also influence if and how an SUD is treated in palliative care. Not only can unconscious or conscious stigma and/or bias related to substance use disorders impede the healthcare experience for this population, but the additional burden of ageism can also further inhibit seeking and obtaining care and have a negative impact on patient outcomes.

Another population of those with SUD that needs to be considered are those with a SUD who may be long time users that develop another debilitating or terminal illness that may warrant palliative or hospice care. Currently, the average age expectancy of individuals with SUDs that are the greatest burden on the United States hovers in the 50s. Despite the fact that many opioid overdose deaths occur in individuals in the 18 to 44-year age range, the average lifespan of an individual with an OUD is approximately 53 years – and that average is on the rise. However, those who engage in illicit opioid use
(people who inject drugs or PWID) are at risk of other infectious diseases such as HIV, Hepatitis C or an STI. Over time, damage to the liver and the immune system may make these individuals more susceptible to other disease, or cause irreparable liver damage, leading to death.

For individuals with an AUD the average life span is between 47 to 53 years for men and 50 to 58 years for women. Alcohol use is currently the 3rd leading preventable cause of death in the United States behind tobacco use (1st) and poor diet and physical inactivity (2nd). Long term alcohol use can cause problems such as alcoholic hepatitis, fibrosis and cirrhosis, heart disease, pancreatitis, or stomach cancer. Tobacco use disorder cuts at least 10 years off of the lifespan of smokers and is associated with a wide variety of co-morbid diseases associated with it, such as cardiovascular disease, COPD, lung cancer and coronary heart disease.

Many of those with OUD or AUD have co-occurring substance use disorders, which may exacerbate any one or a combination of issue. In fact, over 83% of those who reported having a SUD reported drinking alcohol in addition to other substance use. Individuals who reported opioid use were also more likely to have a cocaine use disorder and use of other hallucinogens such as MDAMD (ecstasy). The long-term effects of health as a result of cocaine use include malnourishment, increased risk of stroke, inflammation of the heart, seizures, Parkinson’s disease, and other impairments of cognition. Long-term use of ecstasy and other hallucinogens can cause cognitive disorders, mood disturbances, and increased risk of cerebrovascular accidents.

The health outcomes of individuals with SUDs can be impacted by the kind of care they receive to mitigate some of the effects of the drug in the long term. Those
individuals who quit smoking before the age of 40 regain about 90% of the years lost to smoking. In individuals who quit drinking, brain functions such as those related to dopamine and serotonin begin to normalize. However, this is the ideal. Recovery is a life-long process, and often takes more than one attempt before an individual can maintain abstinence from their substance of abuse. Efforts to incorporate harm reduction practices into local, state, and federal health care may also increase the likelihood that individuals with an SUD present for palliative care later in life with chronic conditions that may or may not be related to their substance use. Syringe exchanges, pre-exposure prophylaxis through drug therapies such as PrEP and recent introduction of safe injection sites in Pennsylvania are just some of the harm reduction methods that prevention deaths and stave off the spread of infectious diseases associated with substance use.

While palliative care and hospice care is “typically” associated with patients who are 65 and older, some may present as younger individuals with debilitating illness related to their long-term drug use. It also needs to be considered that younger palliative care patients may simply be those who present with both a SUD and a terminal illness unrelated to their substance use. Others may fit the typical patient mold (65+) but also have a SUD along with other cognitive and medical issues. Either way, the unique needs, challenges, and barriers that these individuals face also need to be considered when administering quality end-of-life care.

While individuals with a SUD face similar barriers to access as the rest of the population, there are barriers that are unique to this population. Perhaps the biggest barrier facing individuals with a SUD is the stigma associated with these disorders. In
fact, there exists such a gap between the number of individuals with SUD(s) and those who receive treatment that the NIDA identified understanding and decreasing the stigma of SUD as a major priority moving forward.\textsuperscript{279} Stigmas set an individual or group apart from “normal” society, thus inviting stereotyping, prejudice and negative actions and behaviors towards those who possess what sociologist Erving Goffman called the “mark of disgrace.”\textsuperscript{280} Substance use disorders are more highly stigmatized than any other health condition, therefore individuals living with them experience negative reactions at a higher rate.\textsuperscript{281} More often these individuals are perceived as dangerous or unpredictable, unable to make autonomous decisions about treatment or finances, perceived as blameworthy or responsible for the SUD, non-compliant or not receptive to treatment and/or moral failures.\textsuperscript{282} This perception not only comes from the public, it persists in the medical field, despite what science shows about the nature of addiction. It manifests in the form of lower quality care and hesitance or resistance to administering certain types of treatment. It can affect the individual with a SUD in the form of self-stigma: that is, awareness of public attitudes, beliefs, and behaviors towards someone with their illness can affect mental and physical health.\textsuperscript{283} This can lead to lower self-esteem, decreased self-efficacy, and feelings of uselessness. Structural stigma also occurs in the form of lower levels of funding for treatment, limited access to treatment modalities and other institutional policies that enhance stigma and further marginalize those with a SUD.\textsuperscript{284}

Increasing rates of opioid use disorders related to the rise in use of prescription opioids, heroin and synthetic opioids raises questions about the prevalence of SUDs – and specifically OUDs - in patient populations that may require palliative care. Ongoing prejudice and discrimination towards those with a SUD/OUD can create a barrier to
palliative care treatment. A recent (2016) study of physicians in various fields showed high levels of desire for social distance from people with an OUD: many were unwilling to have a person with prescription OUD marry into the family (79%) or to work closely with the respondent on the job (77%). More than half (66%) viewed people with prescription OUD as more dangerous than the general population.\textsuperscript{285} Palliative care providers in particular remain hesitant to provide care to a chronically ill person with any history of an OUD for a variety of reasons. One recurring theme is, as one palliative care nurse put it, “We are not trained in addictive medicine.”\textsuperscript{286} Others fall back on misconceptions and misrepresentations of OUDs fueled by structural and public stigma: “This is not a comfortable situation for a clinician to be in, where now I have to be a cop.”\textsuperscript{287} Another concern is the possible legal ramifications of exceeding prescribing limits, or the repercussions associated with unintentional consequences such as an overdose. These, in and of themselves, can attach stigma related to the prescriber’s intentions and actions.\textsuperscript{288} Ongoing stigma towards individuals with past or current histories of OUD in these instances only serves as yet another barrier towards palliative care.

For instance, individuals who have a debilitating or terminal illness like HIV, AIDS, Hepatitis C, or cancer may qualify for palliative or hospice care at some point over the course of their illness. During this time, they may also require pain management. Chronic pain management for those with a SUD is already of concern, especially considering it is known that individuals with active or history of substance abuse are known to be at high risk for undertreatment for pain.\textsuperscript{289} So while diversion or misuse of pain medications in palliative or hospice care time may be related to OUD, other factors
such as those related to maladaptive coping (chemical coping) or uncontrolled pain (pseudoaddiction) may also be a cause. Those with an active SUD are also at a disadvantage in places that cannot or will not accommodate current/ongoing drug or alcohol use. This may put an additional burden on their health if they are denied palliative care or are forced into withdrawal. Lack of understanding of these issues can compromise palliative or hospice care for an individual with a SUD who is often under more scrutiny than other “normal” patients. Currently there is a paucity of studies regarding hospice and palliative care medicine providers competence to diagnose SUD, but one study did show that less than half (48%) had a working knowledge of addiction and a majority (60%) had 4 hours or less training on opioid misuse.

One population of individuals in particular who live with a substance use disorder that face extreme difficulty in accessing palliative and hospice care are the homeless. A majority of homeless individuals have a history of illicit drug use. Forty to sixty percent of homeless individuals have used some type of illicit drug in their lifetime. Not only are there barriers to accessing end-of-life care such as lack of residence (available for home-based care), lack of identification, health insurance, transportation, and strong support system. Systematic barriers such as geographic location, lack of local palliative care services, lack of hospice beds available in system that can assist them and system requirements for a primary care physician to refer them for palliative care also prevent this population. Homeless individuals with a SUD often deprioritize their health because of the difficulty of day to day living and the influence/patterns of their substance use. Persistent stigmatization and discrimination, coupled with lack of knowledge related to
palliative care and negative past experiences in the health care system also deter homeless individuals from engaging with palliative care services.293

Acknowledging that there are gaps both in the administration of palliative care to individuals with SUDs and the amount of empirical research being done to analyze and address such gaps is vital to the process of improving and enhancing palliative care to this population. It is promising that there is growing academic interest in this issue, as the paucity of literature is in and of itself an ethical concern. No universal solution currently exists. However, there are multiple strategies that exist which may be useful in alleviating inequities that still exist in palliative care models across the globe. Although systematic research of palliative and hospice care for individuals with a SUD is scarce, what we can draw from what little research we do have on this particular population, as well as documented experiences of addicted and non-addicted individuals in palliative care to assist in the generation of recommendations for improving and enhancing current models of palliative care so that they meet needs that are unique to the population of individuals that are living - and dying - with an SUD.

The WHO describes palliative care (PC) as an essential component to overall health and well-being.294 As a practice, it is recognized as a human right by the UN Committee on Economic Social and Cultural Rights’ interpretation of the right to the highest standard of health (General Comment 14), which provides that states are obliged to respect the right to health by “refraining from denying, or limiting equal access for all persons to preventive, curative, and palliative health service.”295 Despite such assertions, barriers continue to exist for those who need palliative care services – especially in low to middle income countries (LMICs). To address the concerns unique to individuals with a
SUD who require palliative care, it is essential that the barriers and challenges that continue to plague the field of palliative care in general be addressed. Only then can necessary attention to matters specific to individuals with a SUD be given and solutions specific to the needs of this population can be suggested.

To achieve the necessary analysis, solutions should be considered at multiple levels. The socio-ecological model (SEM) allows for a consideration of multiple factors that determine access and use of palliative care services. This is true for adults and children with life-limiting or terminal illnesses. The SEM typically has four levels: personal/individual level; organizational level; health system level; and policy/payment level. An examination of suggestions at each level, both for PC in general and PC for individuals with a SUD will be included in this analysis.

In a 2020 review of challenges present in the provision of PC for cancer patients – particularly those living in LMICs, Abu-Odah, Molassiotis and Liu – noted that there were several policy and/or payment level challenges to implementing and maintaining adequate palliative care, including policy challenges (legislation, research and f); lack of funding; lack of a comprehensive national PC plan; inadequate or inappropriate legislation and policy; fragmented or weak health care system and lack of government support. On a global scale, the WHO identifies lack of integration of PC into national health policies and systems as a barrier to PC.

As for the United States, the National Academy of Medicine (formerly the IOM) recommends financial and policy reform by public and private insurance and healthcare delivery programs for patients with serious illnesses or in need of end-of-life care. They note that any financial incentives that currently exist are written into Medicare and
Medicaid reimbursement guidelines, often resulting in fragmented care, increasing the risks of unnecessary services which in and of itself constitutes Medicare fraud and/or abuse.299

Issues such as these at the policy and payment levels of care can be addressed by designing and implementing a national PC policy. This can be achieved through the involvement of stakeholders, budget support and negotiating for secure government or health insurance funding provisions. Enhancing and increasing research about PC were also identified as essential policy facilitators which help in identifying the needs of and gaps present in the delivery of PC. In 2014, the WHO held its first global resolution on palliative care, calling upon WHO and Member States to improve access to palliative care as a core component of health systems. In attempt to address gaps that persist in access and utilization of palliative services globally, they emphasized the need for state level policy enhancements which include: health system policies that integrate palliative care services into national health-care systems; policies that strengthen and expand human resources, including training of existing health professionals and inclusion of palliative care curricula into training programs for new health care professionals; educating volunteers and the public, and policies that ensure the availability of “essential medicines” for managing symptoms, particularly opioid analgesics.300

Recommendations from national (U.S) stakeholders such as the NAM, the CAPC and the National Palliative Care Research Center (NPCRC) are similar to those of the WHO. These organizations emphasize the need for policies that enhance clinician skills, workforce development, increased public awareness (especially at the state level), payment reform, enhanced quality and standards for palliative care services and
promotion of palliative care research. Since the recognition of palliative care as a distinct medical subspecialty in 2008, organizations such as the CAPC and NPCRC have offered guidance at the state and national level to address these concerns. Some states have passed laws that require continuing education in palliative care and closely-related topics such as pain management and safe opioid prescribing. Private health plans now recognize and require clinician training in basic palliative care components. There is now board certification for palliative care for physicians and palliative care certification for nurses as well. Changes in payment systems are also in progress. In particular, Medicare allows specific payment for advance care planning and complex chronic care management. This changed occurred alongside an effort by CMS’ Center for Medicare and Medicaid to test new access models that expand access to PC specialists. Several private insurance companies are also changing the way they address payment for palliative care at hospital and non-hospital levels. To address the issue of quality of palliative care the National Quality forum (NQF) established the Geriatrics and Palliative Care Standing Committee to review and enhance quality measures for older adults receiving PC services more rigorously. Research focused on palliative care has also received more attention and finding in recent years.

What some of these global and national level reports sometimes fail to consider or adequately address are the barriers to PC that exist within organizations, such as limited physical infrastructure (i.e., buildings, equipment and supplies, beds, chairs, etc.) and geographical considerations (i.e., people living in a rural or remote area) that could also hinder access. These could be addressed within policies created at the state, national
and global level—a specifically those related to funding, training and workforce. While gaps in these areas persist, progress in recent years is encouraging.

A micro level analysis of the barriers to palliative care show that individual and social level barriers largely focus on knowledge, attitudes, beliefs, skills, and the culture of families, healthcare practitioners and the general public. The greatest barrier in this regard is the deficit of knowledge surrounding what palliative care services entail and the use of opioid analgesics. These barriers could be addressed by providing continuous education for providers, as well as adequate education to patients, families, and the general public regarding PC services. This should also apply to the use of opioid analgesics. Confronting opiophobia at the provider and public levels is essential to improve attitudes towards their use and may serve as a means to mitigate stigma in this area as well. Provision of person-centered palliative care that includes cultural aspects of care and value a patient’s personal preferences and beliefs is another step towards enhancing access to and provision of these services.

The gaps that exist in palliative care services for individuals with a SUD (IWSUD) are not unlike those of the general public. These barriers also exist for this population at all levels. There is fear of stigma, lack of knowledge about how palliative care services can sufficiently and ethically support IWSUD by the public, patients, families, and providers. At the organizational and policy/payment level there is a lack of infrastructure that acknowledges and supports their unique need at the end of life. Research conducted with IWSUD receiving palliative care also highlight the disparities in treatment they receive.
Common themes throughout the narratives of this population include stigma prior to and after acceptance into palliative care. Feelings of isolation often affect their motivation to initiate PC and for many respondents persisted in treatment. This was more prevalent in individuals who presented with physical or mental comorbidities or “chaotic” life stories. This is particularly relevant for people with an OUD and those who drug of use is heroin because of the treatment regimen, which itself may cause further stigmatization from social and health care systems. Pain management is the pivotal concern in palliative care, and the use of opioid analgesics is common. This often creates concern on the part of the patient and/or the provider. However, there is a general consensus in terms of palliative care that it is not the condition of OUD in and of itself that is of concern. Rather, it is the potential for ongoing misuse of substances (opioids in particular) and lack of date on its impact on PC outcomes continues to persist. However, there are strategies that can be used to address these and other previously explored concerns at multiple levels of influence in palliative care.

Addressing issues specific to PC patients with a SUD requires more strategic interventions that focus on the distinct concerns of this population. At the policy level, dramatic measures are being taken with regard to prescribing practices related to pain management and treatment of OUD in response to recent surges in the amounts of overdoses and overdose-related deaths amidst the COVID-19 pandemic. The American Medical Association (AMA) is recommending many restrictions on prescribing be lifted or eased for the duration of the pandemic, including the removal of restrictions on Medicaid preferred drug lists to help avoid medication shortages, while also ensuring coverage for methadone for patients receiving care in an opioid treatment program;
waiving testing requirements and in-person counseling requirements for refills for patients with chronic pain and allow for telephonic counseling to fulfill state prescribing and treatment requirements and suggests the adoption of provisions that allow for continuity of service for syringe services programs and provision of personal protection equipment (PPE). The AMA is also encouraging the adoption of laws that allow Schedule II-V controlled substances to be dispensed for more than 30 days and removes existing refill limitations.\textsuperscript{310}

Although these policies are temporary in nature (for the time being), there is the potential for such policies to evolve into more permanent solutions to issues surrounding OUD in general. This may have a positive impact on IWSUD and IWOUD in palliative care. As the medical community and society in general recognize the need for pain management and management of SUDs to be more flexible, national, and state level policies may be changed that in turn will make PC with a SUD/OUD more equitable. However, as discussed, broad level governmental policies are not the only sources for concern in this area.

Recent research conducted by Ebenau, Dijkstra, Ter Huurne et. al (2020) with healthcare professionals (HCP), volunteers and “experts-by-experience” in the palliative care field, as well as patients of palliative care with a SUD further illustrates the incongruity of such care (real or perceived) by those closest to it.\textsuperscript{311} Lack of education, infrastructure, cooperation and continuity of care along with compartmentalization of healthcare services frequently cited by HCP as barriers to PC, while stigma and unfamiliarity with PC was oft cited by patients and their proxies challenges in all aspects of PC. Although these impediments affect outcomes for PC patients with SUD similarly,
there are proposed solutions specific to this population that are congruent with those for palliative care services in general.

As stigma continues to hinder efforts to provide equitable care for IWSUD in general aspects of healthcare, let alone for specialty services such as PC, the general consensus amongst providers and consumers of PC services is that there is a general lack of education both on PC and SUDs themselves. One way to address this is to provide health care providers with foundational understandings of stigma and how it manifests in healthcare. This would necessarily require updating current medical curricula to include training on this issue – not only as it applies to SUDs, but in general. The use of a theoretical framework such as Stangl, Earshaw, Logie et. al.’s Health Stigma and Discrimination Framework (HSDF) would be beneficial in this regard, as it updates previous frameworks that tend to focus on one condition in isolation, or generally only mental health conditions. The HSDF follows the process of stigmatization across the socio-ecological spectrum of health, which varies according to economic context. It also makes an important delineation from other frameworks, in that it does not distinguish the ‘stigmatized’ from the ‘stigmatizer’, thus eliminating the chance of developing an ‘us’ versus ‘them’ mentality that is inherent in the stigmatization process. This framework could not only be used in clinical training, but also as a guide for intervention development, measurement, research, and policy.

Another approach to mitigating stigma in the treatment of IWSUD is through the use of “dignity-enhancing care.” Initially developed by Chris Gastmans for nursing, dignity enhancing care privileges dignity while providing care. People with SUD/OUD are often not treated with dignity because of their health condition. Dignity-enhancing
care uses lived experience as a starting point to address this. It employs interpretative
dialogue as a normative standard to access the other’s lived experience. To respect a
person’s dignity, it is imperative to understand the ‘wholeness’ of the person, which is
achieved through effective, personal communication with the patient. The aim of the
communication is to understand the patient as a person, then, in response, design the care
plan. The purpose of this approach is to heal, not only to fix the wound. This is
particularly important in palliative care patients, who are striving to find ways to improve
their quality of life while living and dying with serious illness(es).

Provider education should also include a component that focuses on substance use
disorders, as they are not isolated to any aspect of health care. As reports have shown,
interest in and need for palliative care training for medical students and nurses is on the
rise. Despite this, there is a distinct lack of experience in palliative care staff with
IWSUD. IWSUD interact with the health care system for the same reasons any individual
without an SUD would, so it is vital that HCP have at least a basic understanding of the
pathology of SUDs and their effect on the physical, psychological, and social aspects of
health. Education of this type certainly complements and supports any education of
stigma and stigmatizing health conditions, as SUDs are increasingly one of the most
stigmatized health conditions.

Updates to curricula on PC and SUDs should also consider incorporating trauma-
informed care methods. Trauma-informed care emphasizes the need to recognize the
prevalence and pervasive impact of trauma on the lives of the people they serve and
develop trauma-sensitive or trauma-responsive services. PC providers who are educated
in these methods will also be well equipped to handle the unique needs of some IWSUD
who are more likely than other to have experienced some form of trauma. This can assist practitioners in the development of an appropriate treatment plan that considers such factors.

Provision of PC services must also adapt to provide equitable care for IWSUD. This will require organizational changes, as policies and procedures for caring for this population within the purview of PC are underdeveloped or non-existent. These may include: changing the way(s) in which PC patients are screened for drug use/misuse; creation of “contracts” for people with a known SUD/OUD when entering into PC (although the ethicality of such contracts is now a hot topic for debate); developing/expanding interdisciplinary relations with departments such as addiction therapy to provide additional, disease-specific supports; incorporating evidence-based treatments such as MAT into PC and collaborating with researchers to develop/improve protocols for IWSUD within the health system being served.

Public education on substance use disorders has changed dramatically over the course of the first part of the 21st century. In a sharp contrast to the punitive nature with which drug use and misuse was handled in the 20th century, the U.S federal government has gradually shifted its drug control approach to a policy focused on prevention, treatment, and rehabilitation. In 2018, the U.S Surgeon General released “Facing Addiction in America: The Surgeon General's Spotlight on Opioids”, which calls for a change in the way society addresses substance use disorders. It emphasizes the importance of focusing on prevention and treatment and considering the biological, psychological, and social factors that influence SUDs. This change in focus can facilitate more cogent understandings about SUDs and OUDs in particular and influence the way
in which people who have SUD/OUD engage with the healthcare system. However, media continue to control certain narrative about the opioid epidemic, which perpetuate negative stereotypes about substance use/misuse in general. Creation of public health educational campaigns such as “Life Unites Us” in Pennsylvania or “Stop the Stigma” – a national level effort - serve to inform the public about the realities of substance use disorders and may also help mitigate personal-level stigmas that often prevent people from seeking help for their SUD.

On the same level, public health campaigns for palliative care can also promote awareness and education surrounding palliative care services. In 2020, the All-Ireland Institute for Hospice and Palliative Care held its seventh annual Palliative Care week in hopes of raising awareness about the impact palliative care can have on all stakeholders in end-of life care: patients, providers, and families. In the United States, the America Hospital Association is attempting to improve patient and public education on palliative care by partnering with the Center to Advance Palliative Care (CAPC). By asking hospital and health system leaders to reexamine their approach to palliative care they hope to assist providers in identifying patients needing additional support and build holistic care plans. The hope is to make palliative care and discussions about end-of-life services more common and easier to access.

It is the hope that the convergence of all of these things with provide at the minimum adequate palliative care services throughout U. S and global health care systems. Global/national level policy changes, changes in organizational infrastructure, updated health provider curricula and training, and community/personal level interventions such as public health campaigns may all have a unique, positive effect on
IWSUD and people in general with regards to access to and experiences in palliative care. In the meantime, it is essential that all stakeholders in palliative care focus on issues at every level of care to ensure equitability for everyone who would benefit from its services – including those with a substance use disorder.

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Chapter Four: Global Ethical Issues of Substance Use Disorders

Although the recent opioid crisis began in the United States, its effect is not confined to our borders. The effects of changing policies and procedures surrounding how pain is diagnosed and treated here have rippled across the globe. This chapter examines the evolution of such phenomena in various contexts, including how global bioethical concerns emerged from a domestic medical issue, how this is being exploited in terms of its treatment as well as how clinical research can adapt to be more inclusive and address concerns of those with substance use disorders – especially those affected by opioid use disorder.

4a. Chronic Pain and Substance Use Disorders

The United States has been in the grips of an opioid crisis since the 1990s, coinciding with the introduction of new, stronger pain relievers such as Oxycontin and MS Contin. This—and other radical changes in the way in which medicine approaches the issue of chronic pain helped usher in an epidemic that leaves in its wake a rise in death rates associated with overdose and other co-morbidities related to misuse, abuse and addiction to prescription and non-prescription opioids. These problems, however, are not isolated to the United States - they have become a global phenomenon. The purpose of this paper is to address chronic pain as a global health issue and global bioethical problem. It will also focus on the unintended side-effects of treatment of chronic pain with opioids – specifically the opioid epidemic – as a global bioethical problem. It will analyze global bioethical framework and the role of globalization in global governance while considering their influence on these problems and offer ways in which global
bioethics can influence policy and practices related to proper pain treatment and management of the opioid crisis.

The WHO defines health as “a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.”

This includes freedom from pain. To understand how chronic pain became a global health issue as well as a global bioethical problem, it is important to understand what chronic pain is, the prevalence of it in developed and developing countries, as well as some of its repercussions. This will allow a better understanding of how the global pain crisis is related to the global opioid epidemic. According to the WHO, chronic pain is one of the most significant causes of disability worldwide. The International Association for the Study of Pain (IASP) defines chronic pain (CP) as any pain that persists or recurs for more than 3 months. There are myriad causes of CP – most commonly musculoskeletal conditions – which include (but are not limited to) osteo- and rheumatoid arthritis, fibromyalgia, and bone fractures. Other common causes of chronic pain include HIV/AIDS, migraines, neuropathy, neurological disorders, stroke, and cancer. Pain related to cancer, however, only accounts for 1 to 2 % of chronic pain worldwide. The most debilitating condition from which individuals suffer CP is lower back pain. The IASP estimates that roughly 21.5% of individuals worldwide suffer from CP, with 10% newly diagnosed each year. A comparison of developed vs. developing countries does show CP to be more prevalent in developing countries. A meta-analysis of literature on rates of chronic pain by Johnson et. al reported 33.9 % of those living in developing countries have CP versus 29.9 % in developed countries. They do believe the rate in developing countries could be higher due to underreporting.
Females and the elderly suffer from CP at a higher rate than men. This has to do with the fact that women tend to suffer from conditions such as abdominal pain and bone fractures (often due to bone loss) at a higher rate. The elderly also suffer degenerative diseases at a higher rate and are more susceptible to injuries that can cause pain. Aside from the pain experienced from the initial injury or disease state, patients suffering from chronic disease are at risk of developing further complications because of CP. These include further physical symptoms related to the progression of disease or changing pathophysiology of an injury, psychological issues, social impediments and economic barriers and burdens because of treatment.

Chronic pain impacts several physiological aspects of living. These may become more severe as the injury evolves or disease progresses. For instance - it is highly correlated with disturbed sleep. Roughly 50 to 89% of individuals suffering from CP report poor sleep function, the degree of which in some cases directly correlates with the severity of pain. Cardiovascular health is also greatly impacted, with chronic pain being a significant indicator of risk for developing hypertension. According to Fine, this occurs because of the way in which the body processes pain. He postulates that the mechanism by which the body maintains blood pressure at constant levels (baroreflex) is also involved in pain suppression. In those with decreased baroreflex sensitivity, the possibility for hypertension and cardiovascular morbidity increases – especially in those with previously poor cardiovascular health. Sexual function may also be impacted. Individuals with CP may have difficulty with arousal, self-consciousness about their condition or fear of more. There is also the potential for cognitive impairment, such as
memory loss or attention, as well as other neurological changes such as loss of neocortical gray matter or abnormal brain chemistry.13

Beyond the physiological consequences of CP lie the psychological, social, and economic impacts. Patients with CP are more likely to develop psychological orders such as anxiety or depressive disorder. They also experience suicidal ideation and attempt suicide at a higher rate than those without CP.14 One study conducted by Kinney et. al compared rates of major depression in individuals with lower back pain (LBP). Their results show that out of those surveyed who experienced acute LBP only 8 % reported major depression, while those with LBP for a duration longer than 6 months, the rate increased significantly to 46 percent.15

The social impact of chronic pain should also not be overlooked. Complications of CP – be it physical, psychological, or economic – often limit social contact. Studies have shown that roughly half of individuals surveyed who suffer from CP report that symptoms related to their condition kept them from social events with family and/or friends and had a detrimental impact on contact with family.16 Not only that, negative emotions related to guilt anger and irritability can also have a negative impact on interpersonal relationships and increase levels of stress amongst family and friends. This leads to another import consideration – the impact that CP can have on family. Similar feelings of guilt, anger, stress, and resentment can occur – especially when the individual with CP requires assisted care. They may become overburdened and/or burnt out. It may also affect their social and work life as well.17

Pain has a higher economic burden then most other health conditions. Absenteeism is associated with a high percentage of the cost of productivity in many
developed countries such as Sweden, Denmark, and the United Kingdom. Presenteeism was associated with higher economic loss related to loss of productivity due to poor work performance than absenteeism in a US study. It accounted for 71% or 61 billion dollars’ worth of economic loss. Individuals with CP are also at risk for either being forced out of their current position due to their inability to complete tasks. They are also at a higher risk for leaving the work force and entering long term disability. Complications from CP increase the odds of leaving the workforce at a rate seven times that of workers without chronic pain.  

As the evidence shows, CP can have a significant impact on the quality of life. A negative correlation between intensity of pain and quality of life exists. Therefore, it is suggested by many dealing with pain management that CP be addressed at its earliest stages to minimize its impact on the individual’s daily activities and overall satisfaction with life. However, this shift in thinking about pain has not been without consequence. Undertreatment of pain in the 20th century has brought about an epidemic which has expanded beyond our borders and across the globe.

4ai. Chronic Pain and OUD as Global Bioethical Problems

The shift in how modern medicine viewed pain and pain management began in the United States back around 1986. Russell Portnoy and his mentor Kathy Foley published a paper suggesting that opiates were not inherently addictive; rather, it depended on the individual to whom they were prescribed. This eventually led to the idea that opiates could be prescribed for non-cancer related pain - specifically chronic pain. Over the course of a decade the approach to prescribing opiates had gone from one of conservancy to aggressiveness. A campaign lead by the American Pain Society led to the
Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Veterans Health Administration (VHA) to adopt pain as the fifth vital sign and a measure upon which hospitals would be assessed. \(^{20}\)

Coinciding with this paradigm shift was the introduction of OxyContin (chemical name oxycodone) – a drug twice as strong as morphine – in 1995.\(^{21}\) Aggressive and deceitful marketing tactics by its manufacturer Purdue Pharmaceuticals lead to a dramatic rise in the number of prescriptions for OxyContin *worldwide*. From 1995 to 1996 the number of prescriptions (globally) increased by 8 million. Global sales for OxyContin rose from US$48 million to US$2.4 billion from 1996 to 2012.\(^{22}\) Between 1991 and 2009, the number of OxyContin prescriptions rose by 300%. In Canada, prescriptions for oxycodone rose 850% from 1991-2007.\(^{23}\) At the same time, a rise in morbidity and death related to the use of opioids emerged. In the US alone, the number of deaths related to accidental opioid overdose for those aged 25 to 64 exceeds that of motor vehicle crashes since 2008. In Canada, Europe and Australia similar phenomenon occurred.\(^{24}\) The increase in volume of prescriptions was largely driven by misinformation about the addictive nature of OxyContin, lack of awareness regarding proper dosing, patient demand, and cavalier prescribing practices.\(^{25}\)

Another emerging trend is the correlation between opioid availability and heroin use. In countries such as Estonia or Finland where heroin shortages lead to the introduction of other illicit opioids such as fentanyl and buprenorphine. Conversely, in the United States the rise in heroin can be attributed to stricter prescription policies and the increased cost of OxyContin itself.\(^{26}\) Around the time that OxyContin was introduced, drug traffickers in Mexico seized upon the opportunity to market a cheaper
alternative to it – thus creating a nationwide epidemic of heroin users that transcended socioeconomic status. This is not isolated to the United States. The United Nations Office on Drugs and Crime (UNODC) reports that much of the world's heroin is cultivated in the Middle East – some 430 to 450 tons per year – primarily in Afghanistan. The heroin trafficked along the northern and Balkan routes from Afghanistan and Myanmar largely provide heroin to Russian and Western European Markets. Similar trends exist with the introduction of illicit forms of fentanyl, which are also on the rise in recent years because of availability and cost or prescription opioids.

In addition to the increased morbidity and mortality related to the abuse of opioids themselves, the rate of other diseases related to IDU began to emerge as the rate of opioid use disorders began to rise. People who inject drugs (PWID) are at a higher risk for diseases such as HIV, HBV and/or HCV. Injection drug use is highly associated with new HIV infections, with rates as high as 80% of new cases in Europe and central Asia. As of 2017 an estimated 36.9 million people worldwide have HIV. The WHO estimates that of those with HIV an estimated 2-15% also have HCV (90% of which are PWID) and 5 to 20% have HBV. Practices such as sharing needles to inject opioids and engaging in risky behavior such as unprotected sex increases the risk of contracting HIV and therefore HCV and HBV. Individuals with HIV have an increased risk of developing chronic hepatitis, which can cause other maladies and ultimately death.

The emerging syndemic negatively impacts the ability to address diseases individually, exacerbating healthcare resources and depriving individuals of the human right to health. Examining the crisis from a global bioethical perspective allows us to see beyond the local issues and address them at a broader, more encompassing level. An
examination of what constitutes a global bioethical problem and some of the ways in which bioethicists seek to address them is therefore the next step towards examining the role global bioethics can play in this ongoing epidemic.

Global bioethics evolved from medical ethics and traditional Western bioethics that were popular in the latter part of the 20th century. This evolution – spurred by scientific and technological advances, as well as globalization – allows bioethicists to examine new and different problems related to this phenomenon. An examination of what constitutes global bioethical problems will allow an understanding of why chronic pain and the unintended consequence known as the opioid epidemic are problems worthy of global bioethical study.

An examination of chronic pain and the opioid epidemic as global biological problems requires an understanding of what a global problem is and what a bioethical problem is. It is also necessary to analyze specific qualities of what makes an issue a problem. According to ten Have referring to something as “global” requires us to acknowledge that boundaries are no longer clear. Global problems, however, have distinct features. They happen on a worldwide scale. They are not isolated to one region, and the effects are felt on a larger scale. They are interconnected in that one global issue is often associated with other(s), and it is difficult to try to alleviate one without addressing the other(s). Focusing on one will make it difficult to completely alleviate the issue entirely and will only exacerbate another. Trying to reduce malnutrition without acknowledging that other factors such as urban planning, food processing and food distribution proves difficult when one does not understand that they are intertwined. Global problems persist and require a long-term, sustained cooperation to create global
solutions. They require a general scope that does not isolate the problem to certain people. When a problem is global, there is a need for global action – it cannot be solved by one organization or state. This requires collaboration, mutual respect, and a set of shared values.33

What makes a problem bioethical is if it has specific relevance and poses a normative challenge. For a problem to have specific relevance requires that it negatively impacts health and human life. Addressing the problem requires a multidisciplinary approach, along with contributions from international organizations such as the WHO. Organ trafficking, for instance, is a widespread concern that negatively impacts the health of those whose organs are being harvested as well as those travelling abroad to receive transplants.34 The issues of organ trafficking, and transplant tourism illustrate normative challenges. That is, they have been recognized as having moral turpitude and create a desire for corrective action.35

While it is important to discuss what makes problems global or bioethical, it is also necessary to analyze what makes a problem a problem in the first place. Three characteristics of problems are ambiguity, situation, and horizon.36 An issue is ambiguous when it lacks consensus. There are differences in opinions, disagreements, or indifference to the issue. Problems also lack consensus. This results from a difference in context or situation. Some may view water pollution as a purely economic or policy issue, while others may see it as a bioethical problem. However, acknowledgement of the problem motivates action towards a resolution. Bioethical problems require normative action on what should happen. However, this requires not only a consideration of the future, but reflections on the past. Problems are not only connected to future outcomes, but they are
also based on actions from the past. By invoking this precedent-based framework for reflection, a *horizon* from which to conceive of issues as problematic is created.\(^{37}\) Although we have discussed what chronic pain and how and aggressive push to manage it in the mid-1990s led to the current opioid epidemic that is sweeping the globe, they have not been established as global bioethical problems as outlined by the criteria outlined by ten Have. Before moving on to how global bioethics can address these problems, they must be established as such.

Chronic pain has been a topic of ongoing debate– particularly the undertreatment of such pain.\(^{38}\) This is true in developed and developing nations. It is not an issue isolated to one country or a group of countries. According to the International Association for the Study of Pain (IASP), chronic pain is considered one of the most significant causes of disability *worldwide*.\(^{39}\) Its relationship to the opioid epidemic has been established; however, the opioid epidemic began as an American problem. Over the course of time since opioids became more readily available, countries like Canada, the UK, Spain parts of Africa and the Middle East have all seen a surge in opioid prescriptions, addictions and accidental deaths related to opioid use.\(^{40}\) Therefore, it is no longer an isolated problem. It has now taken on a *worldwide scale*.

Chronic pain is not an isolated issue. That is - there are other problems that occur along with it that, without addressing, will only exacerbate the problem. For instance, chronic pain disproportionately affects those with low socioeconomic status, females, the elderly, children, and those with physically demanding jobs.\(^{41}\) Providing treatment for chronic pain only alleviates symptoms of other larger problems related to economics and health care. As we have seen with the opioid epidemic, economic costs of medications as
well as unequal access to treatment for pain and addiction have exacerbated the problem
with pain – forcing some who can afford the basics of care such as a doctor’s visit or
medication to rely on pill mills and heroin or other illicit opioids. By attempting to place
a band aid on one problem (pain) others cropped up (addiction, overdose related deaths,
and increase in HIV and HCV/HBV). In this way both chronic pain and the result of its
mismanagement (the opioid epidemic) are interconnected with other issues.

While chronic pain may not be a new phenomenon, it has evolved over time. Poverty and industrialization certainly contribute(d) to its occurrence, as do age and
disease. Similarly, management of pain evolved over time from a very chary use of
opiates for pain to a time where pain assessment became part of the way in which
clinicians and hospitals were reimbursed. This led to a practice of catering to the patient
with regards to chronic pain and pain management in many cases– the repercussions of
which persist.43

Chronic pain affects the population at various levels – from the individual
suffering from it, their family friends and even coworkers. At a macro level it affects
health care and economic systems on a community, state, and national scale. It is not
isolated to a specific niche of people and has a general scope. This is also true of the
opioid epidemic. It’s moved beyond the individual with an opioid use disorder (OUD). It
involves family, friends, coworkers, healthcare workers, law enforcement, the public and
policy makers – not only in the United States, but abroad as well. It is not confined to a
group or population of people.

The need for action is apparent with chronic pain and its unintended
consequences. There is no one government or organization that can address either of
these issues. Social determinants of health such as socioeconomic status, stress (mental and physical) at work, rurality, occupational status, race, and education all correlate with levels of chronic pain.\textsuperscript{44} The health sector alone cannot address these issues – it requires collaboration with other sectors. Similarly, the opioid epidemic is multifaceted and requires collaboration between local, national, and international organizations. Governments alone cannot address this issue – it requires cooperation and consensus at all levels.

Chronic pain has not been regarded as a relevant bioethical issue until recently. It has often been treated as a symptom of other diseases as opposed to a disease in and of itself, relegated to the realm of medicine.\textsuperscript{45} The Global Burden of Disease Project began in 1990 as a means of integrating, analyzing, validating, and disseminating data on 291 diseases and injuries, 1,160 sequelae and 67 risk factors to be used to improve health systems and eliminate health disparities.\textsuperscript{46} Studies such as this one began to show the impact chronic pain has on life expectancy and disability. Over the course of 20 years, the incidence lower back and neck pain increase 57 percent, with lower back pain causing the most years lived with a disability than any of the 291 conditions studied.\textsuperscript{47} This makes chronic pain problematic for health and human life, seeing as it is prevalent and the consequences of such are not limited to the physiological. Having been deceived about the potential for addiction to OxyContin, the effects of treating pain with opioids didn’t immediately become apparent. However, once the rate of OUDs began to grow exponentially, the U.S. started to take measures by creating an abuse deterrent version of the medicine. This only exacerbated the issue as users found ways to use this version or resorted to using black tar heroin.\textsuperscript{48} The effects were also felt globally. Now, in other
countries such as Norway, Denmark, Greece, and Canada, up to 30% of deaths in individuals aged 20 to 29 are opioid related. Both chronic pain and the opioid epidemic have specific relevance. First and foremost, these issues are related to health and human life. They also require a multidisciplinary approach. Neither can be solved within one sector.

Both issues also pose a normative challenge. The WHO acknowledges that health is a human right, as is access to pain relief and recognizes any barriers to such as “failure to provide essential medicines and relieve suffering but also as human rights abuses.” Characterizing chronic pain as such a moral violation motivates action towards alleviating the problem. The daily death toll in the United States alone is around 45 individuals with OUDs or comorbidities of illicit opioid use, with the global average hovering around 323 daily. Despite this, only about 10% of those needing treatment received it. These circumstances are certainly unjust, unacceptable and demand action, thus also providing normative challenge for bioethicists, medical professionals, and policy makers.

Establishing these issues as a problem in and of themselves requires that they meet the requirements of ambiguity, situation, and horizon. Over the past 20 years, undertreatment of pain has been acknowledged as a public health issue. However, the focus by medical professionals is primarily on the treatment of cancer-related pain and palliative care. In chronic nonmalignant pain, confusion exists about treatment goals and doubts about the realities of nonmalignant pain cloud consensus on what constitutes chronic pain and how to properly treat it. In the case of the opioid epidemic, there is no consensus on how to address the issue, and national and international policy regarding
treatment and prevention is limited. Some nations adhere to a legal approach to addiction (like the United States for the most part) while others are taking to decriminalization and harm reduction measures.\textsuperscript{53} These criteria speak to the \textit{ambiguous} nature of these problems.

In bioethics, problems arise contextuality. That is, they depend on the point of view of those observing them. This is how a certain \textit{situation} arises. For instance, research shows that culture influences the way in which a person perceives, experiences, and communicates pain. Culturally based expectations and acceptance of pain as a normal part of living then determines whether that pain is considered a clinical issue that requires a clinical solution.\textsuperscript{54} Peacock and Patel illustrate this with examples such as Australian Aborigines, who have high rates of lower back pain, but do not consider it a health issue, and therefore only report symptoms when asked. Otherwise, they did not seek treatment. In the case of the opioid epidemic, in some countries such as the U.S, substance use disorders are often perceived as a legal problem rather than an ethical problem. In countries such as the Portugal have decriminalized illicit drugs and have therefore moved the focus from a legal issue to a public health issue. This difference in perception and action on such problems generates the uncertainty necessary to address them as problems and attempt to create solutions.

American Philosopher John Dewey considers problems forward-looking.\textsuperscript{55} However, it is also necessary to look backward in order to move forward. Antecedents – also known as precedents - need to be considered. These are events that provide the \textit{horizon} by which we measure issues as problems. In the case of chronic pain, it is important to consider some of the events that led to the prevalence of chronic pain
throughout the globe, such as industrialization or past surgical practices. As for the opioid epidemic, varying views on the treatment of nonmalignant pain combined with aggressive and deceitful marketing practices, as well as gross undereducation regarding pain treatment. Consideration of these antecedents helps bioethicists identify a problem and inform future problems as well.

After consideration of the elements of what makes an issue a global bioethical problem, it is evident that global chronic pain as well as the global opioid epidemic qualify as such. They both meet the criteria previously set forth for all three elements: they are global, bioethical, and indeed – problems. The issue now is how global bioethics addresses these problems.

4a ii. Global Bioethics: Theory, Practice and Solutions

The establishment of chronic pain and the opioid epidemic as global bioethical problems leads to the next question of how to address these issues. The United Nations Educational, Scientific and Cultural Organization (UNESCO) has been instrumental in creating a framework that is a major step in the development of a global bioethics. A discussion of some of its principals in relation to chronic pain and the opioid epidemic, as well as an examination of the role of governance in their application is therefore necessary to considering how global bioethics can – in theory and in practice – help address these problems.

In 2005, UNESCO adopted the Universal Declaration on Bioethics and Human Rights (UDBHR) to provide a framework of ethical principles to guide states when formulating bioethical legislation and policies, particularly those related to “medicine, life science and associated technologies” used on humans. The declaration is not a
legally binding document. Rather, it is “hortatory, aspirational and educational.” Within the Declaration are 15 bioethical principles that go beyond the traditionally Western tenets identified by Beauchamp and Childress. It is unique in that it integrates human rights discourse and bioethics, which allows for global outreach and a basis of interpretation of bioethical principles that is consistent not only within the context of newly developed principles, but international law as well. That is – one cannot restrict one principle unless it complies with others. Such laws bolster the normative power of bioethics by asserting such principles are universal and non-negotiable. Human rights discourse also asserts that the ends do not justify the means. Such discourse also allows for practical applications as it has been shown to be instrumental in developing policy. It has also inspired new forms of action on legislation and policy such as advocacy. In this way it is possible to go from intention to application.

There are several articles in the UDBHR that are particularly relevant to the issue of chronic pain and the opioid epidemic. Article 10 addresses three of the most important principles in bioethical discourse: equality, justice, and equity. It states that “the fundamental equality of all human beings in dignity and rights so that they are treated justly and equitably.” This article was included to address the ongoing inequalities, injustices and inequities that exist and persist because of globalization and advances in science and technology. This is especially relevant to both the global burden of chronic pain and the opioid epidemic in the context of health care. Soaring health care expenditures affect access to health care for chronic pain and the opioid epidemic (and its comorbidities), thus perpetuating both epidemics and the side effects thereof in individuals who can’t afford treatment.
Discrimination and stigmatization are addressed in Article 11. It states: “No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.” The article was written as a sanction against the two concepts and is related to ethical issues associated with “medicine, life sciences and associated technologies.” Stigmatization of patients suffering from chronic pain often relates to the fact that some chronic conditions such as fibromyalgia have no organic pathology to explain the persistent pain and disability. This in turn can lead to discrimination by physicians and others who cannot “see” the disease. Stigmatization towards those with SUDs is a significant barrier to treatment. The public and non-specialist physicians commonly stigmatize individuals with SUDs – largely because of ignorance about them. Problem drug use is seen as a moral failing and not a disease, which again often leads to discrimination in and outside of clinical settings.

Article 14 of the UDBHR addresses the issue of social responsibility and health, specifically that the promotion of each is “a central purpose of governments that all sectors of society share.” It posits that health at its highest attainable standard is one of the “fundamental rights” of human beings regardless of “race, religion, political belief, economic or social condition.” It also states that scientific and technological progress should advance access to health care, medicine (especially for women and children), and contends that health is “essential to life itself and must be considered to be a social and human good.” It also states that scientific and technological progress should advance access to health care, medicine (especially for women and children), and contends that health is “essential to life itself and must be a social and human good.” It discusses
nutrition, water, living conditions, elimination of poverty, literacy, and marginalization. For chronic pain and the opioid epidemic, the most relevant aspect of this article is not only the assertion that the highest attainable standard of health is fundamental, but also that access to quality healthcare and medicines is essential. Lack of health care (or low-quality healthcare) and lack of access to adequate medicines are barriers to diagnosis and treatment of chronic pain and the co-morbidities associated with the opioid epidemic.64

Although it may not be immediately apparent, Article 16 also applies to both problems. This article asks for the consideration of future generations: “The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.”65 As discussed, problems are forward-looking, so it was seemingly inevitable that a global bioethics framework would consider that impact on present technological advances on future generations. The introduction of fields such as pharmacogenomics and pharmacogenetics can influence what medications patients take for chronic pain, as well as what medications are best suited for individuals suffering from and OUD or HIV.66 However, the ethical implications are not only social in nature. Epigeneticists caution that manipulation of genes and introduction of certain medicines may have (currently unknown) deleterious effects for future generations.67

As ten Have notes, development of such principles is one thing, but their application is another. Such principles only become meaningful once they are put into practice. In this instance the dilemma is the execution. Without world government or political authority, it is difficult to envision how the ethical principles outlined in the UDBHR can be made meaningful.68 Global governance is defined as the “collective efforts of state and non-state actors to manage global problems.”69 Unlike ‘government’ –
which applies to power, and authority given to states – ‘governance’ refers to these concepts at a global level. This new term is a response to the increasing globalization that has diminished the power of nation states. It is multifaceted, focusing on global problems, the necessity of collective action, involving a variety of ‘actors’ – intergovernmental organizations (UNESCO, WHO), NGOs (i.e., Doctors Without Borders or Médecins Sans Frontières), media, social movements, philanthropic foundations (i.e., Bill and Melinda Gates Foundation), religious institutions, universities, media, professional organizations etc. – with various levels (regional, national, global) with distinct objectives such as equality, justice, human rights, peace etcetera.

Cooperation on the international level is not new, and in fact has been ongoing since the breakout of cholera in the last half of the 19th century. However, there is a renewed interest sparked by several developments: the introduction of new diseases, the development of the relationship between trade and disease, the impact of neoliberal policies on public health and the surge in global health partnerships in the 90s, which provides more resources for health assistance, despite the growing health expenditures. There is no director of these endeavors, which can complicate the execution of global action in a coordinated matter. For instance, the Ebola outbreak in 2013-2014 was handled poorly and is used as an example of failed global governance. While the WHO shouldered the blame for its delayed initiatives to stop the Ebola outbreak, it is not just one actor in this instance that was to blame. It is short sighted to put the blame on one entity when there are gaps at various levels of governance. These include knowledge, which can cause disagreement of the nature of the problem; lack of agreement on the best policies to address the problem due to divergent normative perspectives; inconsistent
policies because of these different normative frameworks; global institutions ill equipped for global governance due to insufficient resources and authority and weak/limited regulations regarding compliance.72

In terms of CP, a lack of consensus on it as a disease - let alone a public health issue – creates a knowledge gap, which in turn creates a lack of agreement on how to handle it. Pain is also not always considered a health concern at all (as is the case with the Aborigines). As for the opioid crisis, some are hesitant to blame opioid use and misuse for the rise in opioid overdose deaths for fear of demonizing the positive aspects of their use. Doctors have also been sharply critical of the CDCs new guidelines regarding opioid prescribing, which they contend limit their ability to treat patients.73 Again, inconsistencies in how the problems associated with opioid misuse are understood and viewed can inhibit progress towards global governance over the problem – especially when these inconsistencies still exist at local and national levels.

According to The Commission on Global Governance of Health, global bioethics can play a vital role in developing new systems of global governance.74 This will require a reevaluation and reimagining of globalization and governance. As ten Have notes, global health governance is dominated by a “globalization from above” perspective.75 Policies from this perspective are decidedly one-sided and rely on the power of the state to enforce laws. “Globalization from below” allows there to be a dialectic between the local and global in a manner that involves everyone – not just those who have interests not related to global health, such as purely economic concerns. Embracing this type of globalization will allow for a broader vision of governance and development of a framework that contains common values and objectives. This requires the involvement of
more actors and stakeholders such as NGOs and the scientific community, as well as practices born of diverse types of leadership. 76

Governance from above limits the input of local states to inform the global issue of chronic pain. If it allowed that larger, national, and international organizations such as the WHO or UNICEF alone dictate the course of action on problems such as chronic pain, it ignores the local complexities of such an issue. This is also true with the opioid epidemic. Localities (such as the U.S.) do not treat pain and opioid addiction the same way. Chronic pain continues to be undertreated – either because of a lack of consensus on what constitutes chronic pain, how to treat it or for fear of repercussions from agencies who now regulate pain management such as governmental organizations like Prescription Drug Monitoring Programs (PDMPs) 77. Many forms of addiction are still stigmatized. This has been shown to limit the influence of any type of governance – local or global – on outcomes. 78 Efforts are being made to address both chronic pain in the scope of mistreatment and the problems related to the opioid epidemic. While the efforts are not currently global in scope, there are ways in which global bioethics can influence policy related to mistreatment of chronic pain and the opioid epidemic.

A discussion about chronic pain and the opioid epidemic as global bioethical problems would be incomplete without a discussion of how global bioethical considerations might help address these issues. For this paper, the focus will be on how to treat chronic pain and opioid addiction without increasing the incidence of SUDs/OUDs as well as curbing illicit drug trafficking – an increase of which has also contributed to the opioid epidemic.
In accordance with the UDBHR, there is an imperative to reflect on “rapid developments in science and technology, which increasingly affect our understanding of life and life itself” which in turn demands a global response the ethical implications of such developments. The introduction of pain as a “fifth vital sign” was both a blessing and curse. It brought light – at the very least in developed countries such as the United States, Canada, and the UK – to the undertreatment of pain. However, in the context of the introduction of OxyContin and the pain scale, it complicated the problem. Pain is still undertreated in developing parts of the globe, while there is hesitation to treat CP with opioids in developed parts of the world because of the subsequent problems related to OUDs. This epidemic is handled differently depending on how drug use and abuse is viewed nationally. A discussion of how a global effort could help alleviate these problems is needed, seeing as neither of these issues is isolated.

According to the Human Rights Watch there are currently 3 major barriers to pain treatment across the globe: lack of health policies that favor palliative health development, lack of relevant training for health care workers and anti-drug legislation that blocks access to essential medication for those suffering from CP. Countries such as the Netherlands have launched national campaigns to both highlight the incidence of pain and the benefits of pain management. It is essential for countries across the globe to address pain in a similar manner – as a public health concern as opposed to focusing on pain as mere symptoms of other ailments – in order to stop the spread of opioid abuse and the consequences that come with it.

In 1971, President Richard Nixon declared that drug abuse was “public enemy number one” and initiated the United States’ own “War on Drugs.” Forty years later,
the Global Commission on Drug Policy (GCDP) declared this “war” to be a failure and proposed a global approach to solve the issue of drug abuse. This does not begin and end with supply of illicit drugs - of which the Commission notes that local efforts in the U.S have failed to curtail. Instead the commission suggests that a global effort to decriminalize the use of certain illicit drugs will help alleviate problems associated with drug abuse. They assert that implementation of drug policies as a result of the United States’ declaration of war on drugs has created a host of unintended consequences, including the growth of a vast global black market for illegal drugs; policy displacement due to scarce resources used to fund law enforcement efforts; nomadic drug production in order to avoid arrest and incarceration; creation of newer, more dangerous substances, and the marginalization, stigmatization and exclusion of those who use and are treated for drug addiction. The GCDP also cite the increasing rate of those infected with HIV and HCV in nations where criminalization is the priority, as well as the rise in deaths related to illicit drug use.

Instead, the GDCP Report cites that nations that have implemented new drug policies emphasizing harm reduction and a public health approach to substance abuse have shown an improvement with regards to the number of deaths related to heroin use, as well as HIV/AIDS and HCV. In particular, they cite nations such as Switzerland and how it responded to its growing opioid and heroin problem by focusing on it as a public health issue, not a criminal one. Implementation of harm reduction policies such as needle exchange programs, safe injection sites, substance analysis, easier access to opiate replacement therapy and opioid abuse prevention programs have reduced the amount of opioid related deaths by 50 percent. These new policies and procedures have also reduced
the amount of heavy consumption and new users, as well as the rate of drug-related crime.\textsuperscript{87}

Other nations such as the United Kingdom, the Netherlands and Portugal have also implemented laws with a similar focus on harm reduction.\textsuperscript{88} Research in the United Kingdom shows diversion to treatment in lieu of criminal prosecution results in a reduction in recidivism after treatment. The Netherlands also implemented harm reduction strategies such as access to clean needles, larger scale treatment options, opiate replacement therapy and legalization of prescriptions for heroin in very specific circumstances.\textsuperscript{89} Like Switzerland, these policies have led to a reduction in crime related to drug abuse and the number of new heroin users. In 2001, Portugal became the first European nation to legalize all illicit drugs. Subsequent studies show that not only did this have a positive effect on the effects of illicit drug use (including a reduction in morbidity and mortality related to illicit drug use), but it also reduced the burden on police enforcement of drug related crime as well as a reduction in the burden on their criminal justice system overall. \textsuperscript{90}

As ten Have et. al suggest, coverage of treatment for substance use disorders is one of the highest public health priorities currently. \textsuperscript{91} The principle of social responsibility and health requires that all have access to such treatment, regardless of economic situation, residence, or any other socioeconomic determinant of health. However, the need for treatment is not the only responsibility a globally based system of care has to curb both the mistreatment of pain and the illicit use of opioids. There is also a responsibility to regulate the production and distribution of all forms of opioids – legal and illicit.
As the GCDP Report suggests, decriminalization of certain drugs will not only curtail their use, but also decrease the number of drugs being trafficked into countries for illicit use.\textsuperscript{92} The problem, however, does not reside solely in the number of illegal drugs being produced and distributed across borders. OxyContin and other similar opioids are not entirely illegal. The FDA regulates all prescription and non-prescription (over the counter drugs), including pain medications such as OxyContin. Part of their oversight does include drug trafficking, which is a global (illicit) trade involving the cultivation, manufacture, distribution, and sale of substances which are subject to local drug prohibition laws.\textsuperscript{93} However, responsibility also lies with them regarding what drugs make it to market. After its approval by the FDA in 1996, OxyContin went on to become the most abused prescription drug within a decade of use.\textsuperscript{94} In an effort to curtail the misuse of OxyContin (via crushing and snorting or injecting the drug), in 2010 the FDA approved of an abuse-deterring form of OxyContin which rendered the drug “unusable” if broken. Not only did this not work (substance abusers found ways around it) it only exacerbated the problem by increasing the price of the medication, thus diverting the market to the cheaper, illicit forms such as heroin and other synthetic forms of opioids such as fentanyl.\textsuperscript{95} The increasing price of pain medications worldwide opened the market for increased illicit drug use, as was the case with black tar heroin from Mexico infiltrating U.S. markets and various forms of opioids imported from Afghanistan that feed Asian, Russian and European markets.

The GCDP suggests that a global effort is necessary to curb the illegal heroin market that exacerbates the global opioid epidemic.\textsuperscript{96} By focusing on it as a global health problem – not merely a criminal issue – the morbidities and mortality associated with
opioid misuse and abuse can be curtailed. Local efforts to diminish the use of heroin have been ineffective. In fact, opioid-related deaths are on the rise in the United States, fueled mainly by abuse of synthetically manufactured fentanyl – another type of opioid that has become popular on the black market because of its low cost. Prescription opioid related deaths increased 11% from 2015 to 2016 and heroin related deaths increased by nearly 20% over the same period of time.\(^\text{97}\)

Mitigating the production of prescription opioids has also not resolved the issue of opioid abuse. From the beginning of its distribution, doctors found a way to profit of OxyContin’s addictive nature.\(^\text{98}\) Some providers operated what are known as “pill mills,” which entails distributing pain medication (usually opioids) without a legitimate medical purpose. Patients also took part in profiting off of such medications through what is known as drug diversion, which is a medical and legal concept involving the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use.\(^\text{99}\) Since the problems related to the introduction of OxyContin and the fifth vital sign emerged in the late 1990s, there have been efforts by the FDA to curtail its distribution. Limits have been imposed on how much a doctor can prescribe by insurance companies as well as Centers for Medicaid and Medicare.\(^\text{100}\) These approaches appear to be counterproductive. A global approach both to the issue of pain treatment (finding a universal way in which we address pain) and the opioid epidemic (decriminalizing drug use and providing adequate forms of treatment while finding ways to regulate production and distribution of pain medications in a way that is ethically responsible) could – as the case of several European countries has shown
- decrease the rate of mistreatment of pain, opioid addiction and the comorbidities associated with it.

This section highlights the mistreatment of pain and its unintended consequences – primarily the opioid epidemic and morbidities and mortality associated with it. It also addressed these issues in the context of global bioethics – both the theoretical and practical application of global bioethical frameworks. It outlined chronic pain and the opioid epidemic as global bioethical problems that needed to be addressed on a larger scale – beyond the local. In order to uphold the human right to health, pain needs to be addressed on a global level, as local efforts – especially in nations where drug use and drug abuse is criminalized – are not adequately addressing the issue of pain or opioid abuse. In fact, the problem appears to be getting worse in these countries. A discussion of possible global solutions suggest that attention not only needs to be made to how we frame the concept of pain and substance abuse, but also to how pain medications are distributed. Limits on the amounts of certain pain meds that can be distributed and/or will be covered by insurance companies only opens the door for black market operations for illicit drugs. A concerted effort by international organizations such as the WHO is necessary to ensure that not only proper, medically sanctioned care for pain is encouraged, but also the monitoring of illicit drug use - which is necessary to better understand when opioid dependence and opioid overdose is occurring. Acknowledging that chronic pain and the opioid epidemic are not merely a local problem opens the door for global initiatives. Incorporation of a global bioethical framework – such as the UDBHR - in creating policy related to these issues will provide an avenue of support that
– as is evident in developed nations such as Portugal and the Netherlands - is equipped handle these issues.

4b. Ethical Considerations in the Substance Use Disorder Treatment Industry

For as long as healthcare has been a commodity, those who saw an opportunity to make money off it have found ways to do so. From patent medicine to home health care scams, the propensity for people to benefit off the fears of others is nothing new. While the Federal Drug Administration and even the Department of Justice have stepped in at times to help quash such fraud, technological advancements, and the ingenuity of those running such programs has made them more difficult to detect and eradicate. The purpose of this essay is to explore how the concepts of addiction, treatment and recovery have evolved over time, analyze what the current rates of SUDs are, what the current issues regarding fraud in the SUD treatment industry are, ethical issues related to them, and how policy and organizational practices such as implementation science and quality improvement can act in accordance with organizational ethics and health policy to eliminate and deter such issues.

4bi. The Treatment and Recovery Industry: Historical & Contemporary Aspects

To understand the current issues regarding the SUD treatment industry, it is important to understand how the industry came to be. This involves a look at the origins of drug use and addiction globally. It also requires an examination into how societies have viewed SUDs over time, as well as the evolution of treatment methods into the 21st century. According to evolutionary biologists, drug use and addiction date back to ancient times. Archeological records show the presence of psychotropic plants and drug use in ancient civilizations as far back as early hominid species about 200 million years ago.
At the dawn of European colonialism, and perhaps for 40,000 years before that, Australian aborigines used nicotine from two different indigenous sources, as did North and South Americans later. Cocaine was ingested by people of the western Andes almost 7,000 years ago. Alcohol dates to the Stone Age, while the medicinal and recreational use of cannabis dates to 6000 B.C in China. Ancient Sumerians had the first written records, which indicate that the use of opium was prominent in their culture.\textsuperscript{103}

Abnormal use of addictive substances such as these goes back to Alexander the Great in 323 B.C. where his death at 33 was preceded by years of heavy drinking. Philosophers such as Aristotle wrote of the effect of withdrawal on the body and Roman physician Celsus described dependence on drinking alcohol much the way modern physicians as well as the DSM-IV describe alcoholism: in terms of alcohol dependence as a disease.\textsuperscript{104} However, the modern emergence of addiction medicine is often attributed to Calvinist theologians, who offered explanations for behaviors such as compulsive drinking. Scholars such as Dutch physician Nicoleas Tulp went on to adopt such models to explain certain types of behavior once considered sinful.\textsuperscript{105} In the 17\textsuperscript{th} and much of the 18\textsuperscript{th} centuries there were mixed views of drunkenness; some saw it as troublesome, others did not. Many agreed it was problematic but very few saw it as a medical condition. It was not until the latter part of the 18\textsuperscript{th} century that a paradigm shift began to develop, and drunkenness began to be associated with words like “compulsion” and “addiction”- primarily by physicians.\textsuperscript{106}

In the United States, Dr. Benjamin Rush is accredited with the development of the modern conception of alcohol addiction.\textsuperscript{107} Temperance organizations were also established during this time. By the late 18\textsuperscript{th} and 19\textsuperscript{th} century, people began to associate
the habits ascribed to alcoholism with their own and sought treatment. As was common for the medicine of the day, Dr. Rush believed that health and disease were related to an imbalance of the four humors: blood, phlegm, black bile, and yellow bile. His methods of curing acute drunkenness involved practices now considered harmful, such as bloodletting, purging, and blistering. His view on chronic drunkenness was groundbreaking. He was the first physician to advocate for complete abstinence from any form of alcohol. He proposed a “multiple pathway” model for treatment that is not unlike modern models of treatment for substance use disorders, although some of his remedies – including inflicting guilt or shame and witnessing the death of another drunkard - would be considered highly unethical in today’s terms.108

Other treatment methods emerged during this time. Aside from the temperance movement – which began in the early 19th century – other methods were introduced into society to “cure” alcoholism. These included reform clubs such as the Washington Society, which were precursors to modern mutual aid groups.109 The 19th century also saw the introduction and subsequent growth of institutions dedicated to the treatment of alcoholism. “Inebriate homes” provided minimal level treatment, while “inebriate asylums” were larger, medically directed facilities. The New York State Inebriate Asylum opened in 1864 and is considered the first alcohol rehab center. Keeley alcoholism cures were also introduced. Dr. Leslie Keeley opened more than 120 “Keeley Institutes” in North America and Europe. These institutes consisted of addiction cure centers and proprietary home cures, such as bottled “Double Chloride of Gold Cures for Drunkenness.”110 Private “sanitarias” were also developed for more affluent clientele. Although the inebriate homes and asylums did not last, the movement to create such
specialized institutions also triggered a movement towards professionalization of
drug addiction treatment. In 1870, 14 physicians, trustee and individuals associated with
ingebriate asylums met in New York City to establish the American Association for the
Cure of Inebriates. It was the first professional organization within the addiction
treatment field. After the inebriate homes and asylums closed, alcoholics were sent to
drunk tanks, hospitals, and insane asylums.

It is important to note that while the idea that certain substances are inherently
addictive was systematically worked out for alcohol first, it applies to other substances as
well. Heroin, morphine, and other drugs classified as opiates are all derived from one
plant – the opium poppy. It was well known in ancient Mesopotamia, although initial
references to it only date to 3400 B.C. Ancient Sumerians referred to the bright red
opium poppy as the “joy plant.” It was used as a sleep aid, analgesic, to calm children
and in some instances as an anesthetic during surgery. As the industrial revolution
ushered in during the 19th century and international trade expanded, addiction itself
(regardless of the drug) became a global health problem. In the 18th century – around the
time that people were formally recognizing the addictive qualities of alcohol – large
numbers of Chinese citizens became addicted to opium, and the Chinese government
tried to combat this by suppressing opium sales and ultimately opium use. This result of
this led to two conflicts known as the Opium Wars.

In other parts of the world, other types of addictions were emerging. Laudanum
was created by Paracelsus in the 16th century and was widely used in the Victorian Era. In
the early 19th century, German Fredrich Surtuner isolated morphine from opium, which
then went on to become a very popular pain killer – especially during the American Civil
War.\textsuperscript{115} Its use during that war caused upward of 400,000 soldiers to develop an addiction. This era also saw a rise in the use other substances such as cannabis, heroin, and cocaine – primarily found in concoctions known as “patent medicines.” These medicines claimed to be panaceas for any and all ailments, when in fact many of them initiated or exacerbated addiction. This was not isolated to those hoping to make a profit off other people’s ailments. The founder of psychoanalysis Sigmund Freud thought that a newly isolated substance known as cocaine could be used as a way to wean the addicted off of morphine.\textsuperscript{116} Instead, its abuse also became widespread.

Addiction to opiates was not as overt as alcohol. While it was not criminalized in the 19\textsuperscript{th} century, its use was certainly shrouded in uncertainty and stereotype. The prominent images of opiate use during this time were those of the woman addicted to patent medicines or laudanum or negatively connotated images of addicts at a Chinese opium den.\textsuperscript{117} While the disease concept of alcoholism extended to opium and morphine thanks to the work of addiction experts like T.D. Crothers, it was still highly stigmatized and therefore largely hidden. However, treatments were available for those willing to seek them out. These focused on narcotic withdrawal and included sudden cessation of the drug (known as going “cold turkey’ because of the predominance of “goose bumps” during the withdrawal process); titration of the ingestion of the drug to the point of zero consumption over a short period of time; prolonged titration wherein the patient took less of the drug over a period of weeks to months.\textsuperscript{118} The cold turkey method was not as successful and more life threatening than the other two – which were still quite painful, and also involved taking tonics, stimulants and various other pharmacological agents to boost the immune system and relieve pain. These treatments were only administered in
private practice, which alienated a large population of individuals with opiate addiction who could not afford them. Exclusivity in treatment was also prevalent for alcoholics. This phenomenon was only exacerbated by events in the 20th century that changed the landscape of addiction and addiction treatment.119

At the turn of the 20th century, those in the popular press embraced a disease-oriented conceptualization of addiction, which in turn lead to growing support for medical treatment. This support began to wane as legislation restricting access to legal and legitimate forms of opium for treatment of addiction began to gain traction in federal court. In 1914, the Harrison Anti-Narcotic Act was passed. It made it difficult – if not impossible – for anyone who was a known addict to obtain opiates. In 1916 a Supreme Court ruling made it so that addicts would be required to have a prescription to legally possess narcotics. In 1922 the Supreme Court ruled that it was a violation of the Harrison Act to prescribe narcotics to an addicted patient regardless of purpose. This changed the perception/status of the addict from patient to criminal and lead to the incarceration of over 25,000 physicians from the period of 1914-1938.120

Despite this, there were many types of treatments introduced in the early part of the 20th century, many of which were in response to ongoing and emerging addictions. Alcohol and opiates continued to plague people not just in the United States, but worldwide. There was also a rise in the number of addictions to hallucinogenic and synthetic drugs due to technological advances. At the turn of the century there was an attempt to isolate “anti-alcohol” antibodies in order to create a vaccine for alcoholism. This ultimately failed. Later in 1909, Charles Townsend introduced the “Towns Treatment” - a medicinal and behavior modifying treatment regimen for opioid and other
addictions. The science of eugenics also bled into addiction treatment, with some state laws allowing the sterilization of individuals who “would produce children with tendency to disease, deformity, crime, insanity, feeble-mindedness, idiocy, imbecility or alcoholism.” Morphine maintenance clinics were later created in communities in response to the Harrison Act as an attempt to treat morphine addiction. They were later closed due to legal threats by the Treasury Department. This led to what is known as “medical detoxification” which didn’t treat the addiction itself but rather assisted with withdrawal. Dr. Thomas Ratigan Jr. (illegally) administered morphine to addicts in his Public Health Institute because – as he noted – there were no formal treatment programs available at the time. He was considered ahead of his time, as 35 years later the introduction of what we know as methadone clinics - whose maintenance methods mirrored his own - were introduced in the United States.

The Federal Government became involved in addiction towards the end of the prohibition era (1920-1933). In 1929 Congress passed the Porter Act, which allocated money for the U.S Public Health Service for two “narcotic farms”: one in Lexington, Kentucky and the other in Ft. Worth, Texas. These “farms” were constructed to house and rehabilitate addicts and drug offenders. Some patients/inmates were there voluntarily, while others were transferred from other facilities due their addiction status. They were provided with three phases of treatment: withdrawal, convalescence, and rehabilitation. Therapy came in many forms. Many of these inmates were also research subjects – used by the American Research Center to test the effects of any and all types of opiate on the human body. As other forms of treatment became more popular, the use of Narcotic Farms began to decrease, and they died out in the mid to late 1950s.
Outside of these walls other forms of treatment emerged. The reality was, outside those walls there was little to no access to treatment for addiction. By 1930 most of the institutions for “drying out” alcoholics had closed and overcrowding in hospitals and asylums made it near impossible for any type of addict to get treatment. At the same time a new method of managing addiction became popularized. While mutual support groups were not new in the realm of addiction, one in particular found itself at the right place and time to grow exponentially and thrive: Alcoholics Anonymous. In 1935, Dr. Robert Smith and Bill Wilson founded Alcoholics Anonymous (AA), a mutual aid group that uses therapy, group therapy and group accountability to elicit change from its members. It is based on the principles of a Christian-based self-help group known as the Oxford group. The addition of the 12 steps, meetings and sponsors distinguished them from the Oxford group and helped make AA a prolific organization. While it is spiritual in nature, there are AA groups that cater to certain religions (including lack thereof).

Currently there are over 30 other 12-step programs based on this model for myriad addiction and other health-related issues (such as sexual assault survival). Other mutual aid groups that are secular in nature began to emerge later on in the 20th century in response to the desire for a non-spiritual alternative. These include Women for Sobriety, Self-Management and Recovery Training (SMART) Recovery, Secular Organizations for Sobriety (SOS) and Life Ring Secular Recovery. The famous Minnesota Model – which gained traction in the 1950s – was also derived from the AA model of abstinence and was/is used to treat myriad forms of addiction even today.

By the mid-20th century, focused efforts by the United States on a national and global level all but eradicated illicit drug use in many parts of the country. Although the
illicit use of well-known drugs dwindled, the availability of new and exotic drugs changed the landscape of illicit drug use. The counterculture of the 1960s produced a rise in marijuana usage, despite its being outlawed by the government in 1937. Considered illegal since 1917, cocaine also gained traction throughout the 1970s, ultimately peaking in 1982 with 10.4 million known users. A cheaper form of cocaine known as “crack” was created in the 80s, causing the US to “crack down” on its use, which lead to a decline in users. First synthesized in 1938, Lysergic acid diethylamide (LSD) was a hallucinogen introduced by the government in the 1950s as a “truth drug” and initially tested on the military. It became popular with the counterculture movement in the mid to late 1960s. Although its popularity waned, the emergence of “rave” culture in the 1990s revitalized its use. America’s addiction to opiates has a long history, but in the mid to late 20th century a rise in the use of heroin occurred during the Vietnam War, where 10 – 15% of American soldiers came home addicted to the drug. Another wave of opiate addiction also began in the late 1990s and can be attributed to the misuse of (expensive) prescription opiates, ultimately leading some to turn to heroin to feed their substance use disorder.

The proliferation of these drugs not only lead to an increase in illicit drug use, but to the creation of policy related to their use/abuse/treatment as well as the introduction of new methods of treatment. The Halfway House Association was founded in 1958. Halfway houses were a different path to recovery, and provided safe, recovery-focused housing for individuals who were suffering from substance abuse problems. In 1960, E.M. Jellinek further promoted conceptualization of alcoholism as a disease, promoting insurance companies to start reimbursing for its treatment. Methadone was introduced
in 1964 and approved by the FDA to treat heroin addiction in 1972. Narcan was also approved by the FDA during this time (1971), which was initially used for opiate inhibition. In 1994 it was approved for use in the treatment of alcoholism as well. This was a step up from the use of antidispotropic medicines such as Antabuse, which merely sensitized the body to alcohol. ¹³³

During the latter part of the 20th century, policies were introduced that would go on to shape the future of diagnosis and treatment of addiction. In 1970, Comprehensive Drug Abuse Prevention and Control Act was signed into legislation relegating certain substances to 5 schedules, classified by the potential for abuse and creating a new system for classifying/stigmatizing drug use. In 1987, the American Medical Association started considering all addictions. It was then that they passed legislation identifying alcoholism as a “complex disease that merited the serious concern of all members of the health profession.” This was done in part because of the difficulties encountered in third-party reimbursement because of their previous endorsement in 1956 of alcoholism as an illness, not a disease state. ¹³⁴

The beginning of the 21st century is bringing changing attitudes towards certain types of drug use. The “War on Drugs” and “Just Say No” campaigns of the 1970s and 1980s are considered failures, and even politicians admitted illicit drug use at some point in their lives. Smoking tobacco – once a highly popular and at one time in history medically promoted habit – has slowly waned in favor. ¹³⁵ Many cities across the U.S have made it increasingly difficult to do so indoors, and corporations are even discouraging – if not outright banning – people from doing so. On the other hand, alcohol is seeing more rigorous laws enacted in order to deter driving under the influence. People
are increasingly in favor of legalizing marijuana – both for medicinal and recreational use. A 2017 Gallup poll showed 61% of Americans in favor of legalizing marijuana, compared to 12% in 1969. What is also changing is the potency of such medications – cocaine, alcohol, marijuana, and heroin have gotten stronger over time. Other man-made substances such as OxyContin, oxycodone and fentanyl have also increased in potency, thus making the potential for addiction and deaths related to their use higher. The response to this has been a frontal assault from a pharmaceutical, clinical, public health and policy standpoint.

For instance: although Medication Assisted Treatment (MAT) (which involves not only the use of FDA approved medications, but counseling and behavioral therapy) is not a new practice in the fight over addictions, it has gained considerable ground in use during the latter part of the 20th century and into the 21st. The approval of a newer MAT drug for opiate addiction (2002) known as Suboxone or buprenorphine eliminated the exclusivity of going to methadone clinics, as specially trained doctors may prescribe it from their private practice. This is especially relevant in a time where opiate addictions are at an all-time high. The Mental Health Parity and Addiction Equity Act of 2008, couple with the Affordable Care Act of 2010 are making it easier to access these types of care for addiction. As society and technology progresses, science and clinicians are beginning to recognize both the ubiquitous and unique nature of addiction and are creating new theories and treatment models (such as the P.R.I.M.E Theory of Motivation) for addiction. Newer fields of study such as pharmacogenetics and pharmacogenomics may allow doctors to predict and more precisely prevent and treat such addictions.
Such advancements cannot, however, prevent those who might benefit from heightened awareness of addictions from doing so. As was the case with heightened health concerns of the past, the emergence of issues such as opioid use disorders and other ailments also trigger an influx of false promises. The scope of this is not limited to those who would sell counterfeit or tainted drugs—it has expanded to those promising addicted individuals and their families false hopes of recovery.

In the May 20, 2018, episode of *Last Week Tonight*, host John Oliver delivered a powerful critique of the drug rehabilitation industry in the United States. In his monologue he points out that the industry currently lacks federal, state, and municipal oversight and regulation and therefore creates an environment where vulnerable people and families can be taken advantage of—much like the “snake oil” salesmen found throughout history. The current penal system is also not equipped to deal with opioid use disorders in a manner other than a criminal one—which not only exacerbates the courts but also perpetuates the cycle of use, overdose, and death.\(^\text{140}\) However, in order to address these issues, it is important to examine some of the root causes.

The United States has seen a sharp increase in the amount of recovery treatment centers and sober living homes over the past decade. Much of this can be linked to the Mental Health Parity Act and the Affordable Care Act; two well-meaning laws that inadvertently created a new market for fraud and abuse. By requiring that mental health issues be covered by insurers and nullifying the pre-existing condition as a reason for denying coverage, more people than ever are seeking treatment for their SUDs.\(^\text{141}\) According to recent data from National institute on Drug Abuse, the drug and alcohol rehabilitation industry is a rapidly growing industry worth over 35 billion dollars a year.
in the United States. There are now over 14,500 specialized treatment facilities now in operation across the country, and countless sober living homes (SLH) as well. This influx towards treatment is also in response to the growing opioid epidemic – once declared a National Emergency - that continues to morph into progressively more dangerous territory with regards to how OUD is initiated and thus, how it is treated. The current concern with fraud and opioid related treatment was not unforeseen, as concerns about the burgeoning opioid crisis and its influence on health care fraud was flagged several years ago by people whose business is fraud. However, it wasn’t until 2017 that those at the federal level (DOJ) started prosecuting opioid related scams.

The problem with recovery treatment centers (RTC) themselves begins with lack of regulation and oversight. While there are some regulations in place to help protect patient safety in RTCs, they are not uniform and may be more limited depending on the state. This lack of oversight makes patients with SUDs and their families especially vulnerable to deceptive business practices, insurance fraud, patient neglect, and malpractice. Even those who manage and work in RTCs are not regulated in many states – meaning that in some states, as long as you aren’t receiving federal funding you can open up a facility without any type of scrutiny.

The treatment methods are also largely unregulated. While SAMHSA provides funding to states for substance abuse services, compiles lists of evidence-based treatment facilities and regulates methadone providers, the broader industry itself is not subject to its regulation. This means that unethical providers can provide treatment that is not evidence-based, or often provide false claims surrounding the treatment methods they use. These providers may also claim that they provide evidence-based treatment, but they
often lack data that support such statements.\textsuperscript{147} For instance, in the \textit{Last Week Tonight} episode on treatment centers, one former patient of a treatment center in California references “equine treatment” – which in this instance merely involved petting horses. The data on its efficacy in addiction therapy is currently limited.\textsuperscript{148} This then opens up the potential for patients to go from treatment center to treatment center, only to relapse again and again because of the lack of well-tested.

Recovery Treatment Centers and Sober Living Homes also engage in fraudulent business practices, such as conducting and billing insurance providers for unnecessary or excessive procedures like urine drug testing, which have high pay out or reimbursement rates. Here again the lack of regulation and oversight in the industry leaves the person with a SUD vulnerable to abuse, as some RTCs and SLHs have patients do upwards of 5 tests a week while they stay there, which by some accounts means upwards of $7,500 per week per person with a SUD.\textsuperscript{149} This is especially true for SLHs, which have minimal oversight of any kind, and are often hotbeds for drug use and distribution. The owners (who are not regulated) benefit from the patients by means of financial kickbacks and withholding any real treatment from people there trying to recover. The practice of bouncing people from home to home or treatment center to treatment center and benefitting from fraud became so ubiquitous to South Florida treatment centers the term “Florida shuffle” was coined to describe it.\textsuperscript{150}

The problem is only exacerbated by the fact that the system is difficult to manage – even for those with exceptional health literacy.\textsuperscript{151} A majority of those who are looking for treatment on their own (61\%) use the internet to search for facilities, a practice which has recently been shown to favor treatment centers owned by conglomerates who do not
specialize in evidence-based treatment methods and have been categorized as “shady” by some standards.\textsuperscript{152} This was brought to the attention of executives at Google who ceased allowing certain algorithms to be used in rehab center searches, because they frequently funneled people to ads that gave false addresses or were associated with call centers that used aggressive business tactics to steer patients away from higher quality care that was often more affordable and convenient.\textsuperscript{153} Television ads for treatment have also been found to be aggressive and to inflate the success rates of the providers, all the while equating luxury with successful treatment.

Recovery Treatment Centers and Sober Living Houses are but two aspects of recovery that warrant scrutiny. Understanding the precarious relationship between drug use, addiction, and the criminal justice system, it is easy to see why the treatment industry has not caught up with the science of treatment. Since the Harrison Tax Act in 1914, criminalization of drug use and addiction therapy means that advances have been slow to catch on, including evidence-based treatment methods that can benefit those struggling with addiction.\textsuperscript{154} It is important to examine the criminal justice system as it is with regards to its views on addiction, as well as how it is handling in the court system.

The NIDA estimates that half of those incarcerated in the United States criminal justice system abuse or suffer from substance use disorders. Roughly 1 in 5 of those in prison are in there specifically for a drug related offense. However, only a minimal number of incarcerated individuals suffering from a SUD receive any form of treatment while they are in the system.\textsuperscript{155} Many of these individuals are left to suffer from withdrawal and run the risk of dying from the effects of it, depending on the drug from which they are withdrawing. Alcohol withdrawal in particular is especially dangerous
without medical supervision. There are other concerns for these individuals as well. Incarcerated individuals who have a SUD that goes untreated while they are in jail or prison have an alarmingly high relapse rate - 95% within 3 years. They also have higher levels of recidivism, as most repeat offenders have a SUD. Many of these individuals have not been diagnosed as such, and therefore do not seek treatment outside of prison. What’s also alarming is that those individuals with untreated addiction are at a greater risk of dying from an overdose after release, with the highest risk being within 2 weeks post release, at a rate 13 times greater than non-offenders with a SUD.

Evidence shows that those who are incarcerated with a SUD have a greater chance of recovery after release if they start a treatment program in prison. Indeed, models such as the prison Therapeutic Community (TC) do exist in a limited number of facilities in the United States and abroad. These programs allow those who are incarcerated with a SUD separate times and facilities for recovery. Prison TCs differ from other models of treatment by their focus on recovery, overall lifestyle changes, and the emphasis on the “community” as the impetus for change. In this instance, the “community” involves fellow inmates and faculty staff. Research on those who have participated in prison TC have lower recidivism rates than those who did not. Also – those who participated in community TCs were also less likely to relapse and re-integrated into the community better than those who did not participate. However promising this model may seem, there is one key thing to consider: almost no facilities have MAT, which may assist individuals with detox-related symptoms that will help them transition back into the community without the risk of relapse. It is typically cognitive based therapies and motivational interviewing – in addition other purely
behavioral based therapies. Individuals with opioid addiction in particular reduce the odds of relapsing and potentially dying from an overdose benefit greatly from MAT with drugs such as Suboxone, naltrexone or methadone, yet only one state in the United States has passed laws that make such drugs available to inmates with a SUD. 160

Another way in which the criminal justice system attempts to address the issue or criminality and SUDs is through what are known as drug courts. Drug courts are “specialized court docket programs that target criminal defendants and offenders, juvenile offenders, and parents with pending child welfare cases who have alcohol and other drug dependency problems.” 161 They vary in target population (although primarily focus on adults), program design and service resources, but primarily follow a model of care that involves screening and assessments, judicial interaction, monitoring and testing for substances, sanctions, and incentives as well as treatment and recovery services. The model is implemented by a variety of community members and stakeholders – including magistrates, law enforcement, social workers, legal representatives, and community corrections workers. Here again, limitations exist.

As in prison, MAT is not available in over half of the over 3,000 drug courts in the United States – despite the evidence that supports its use.162 Only 21% offered methadone-to-abstinence programs and only 18% offered methadone maintenance programs. Many will not allow anyone to come through their drug court if they are currently using any form of opiate (most of which, drugs used in MAT are).163 Drug courts are meant to be less punitive, but often incarcerate individuals who relapse at rates higher than they would if the individual would not have entered the drug court system, which again leaves individuals with SUDs at higher risk while incarcerated and upon
release. As with in-patient rehabilitation industry – drug courts are not regulated. Judges are not required to have established experience with addiction or its treatment to set up a drug court in their municipality. This has the potential to be dangerous when dealing with individuals who may be deeply affected by the effects of their SUD, especially when adopting a model of treatment that denies potentially life-saving MATs. In California, a patient died from lack of MAT during their time in drug court, and the state subsequently passed a law requiring its drug courts to offer it.

These issues with the criminal justice system stem from views about the ingestion of certain substances deemed illicit as well as subsequent legislation that also criminalized certain aspects of treatment for SUDs related to their use. Countries across the globe are beginning to adopt viewpoints of drug use that decriminalize the act itself and attempt to divert individuals with a SUD towards a model more directly involved in treatment without fear of punishment. Although the United States is catching onto this idea, it is only in small pockets and again subject to federal sanctions, which are still focused on criminality. Until that changes, it is important to focus on improving the outcomes for individuals going into treatment – regardless of the locale. A consideration of the ethical issues related to individuals with a SUD in treatment is necessary so ethicists can consider what can be done to ensure they benefit from treatment.

4bii. Ethical Problems and Practical Solutions

Before a discussion about practical solutions occurs, it is important to analyze some of the ethical issues surrounding some of the treatment currently available in Substance Use Disorder Treatment Centers, Sober Living Homes, and the U.S. Criminal
Justice System. Once there is an understanding of some of these issues, possible solutions to address them can be addressed. For this section of the chapter, tenets of principlism as discussed by Beauchamp and Childress will primarily be used.

Principlism’s focus on the moral principles of autonomy, nonmaleficence, beneficence and justice can also help providers and decision makers assess the ethical issues in the treatment and recovery industry. Autonomy is primarily exercised in healthcare through the practice of informed consent, which is permission given by a patient (or their caregiver) with “full understanding of the treatment and its consequences” and with “full knowledge of its risks and benefits.”¹⁶⁸ In the case of individuals with a SUD going into treatment or sober living homes, this form of autonomy is questionable. If a patient is going into a treatment without a full understanding of the benefits of said treatment, it is not considered informed consent by Beauchamp and Childress’ definition.

Evidence based practice (EBP) incorporates research culled from multiple studies regarding the efficacy of treatment methods, clinical expertise and client preferences and values.¹⁶⁹ Without these elements, no proof exists for their use in certain types of treatment. Therefore, without proof of effectiveness of certain types of treatment, true autonomy cannot be achieved in certain substance use disorder treatment centers and should be cause for ethical concern. On the episode of Last Week Tonight that featured the fraud and abuse in rehab centers, one gentleman discussed his equine therapy and had “no idea” how this was beneficial to his recovery.¹⁷⁰

This also leads to concern about beneficence and nonmaleficence. Beneficence requires that treatment benefit the patient. While this may seem similar to the discussion

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about autonomy, there is a difference. Autonomy requires that the patient be properly informed about the potential benefits and burdens of treatment, while beneficence merely addresses the issue of whether there is a benefit to the patient from treatment. In this case, the treatment given in a treatment facility of sober living home should be beneficial to the patient. Again, treatments like equine therapy which – while they do benefit some patients – have no evidence of being beneficial to those with a SUD. Other practices that occur in some facilities are also questionable as to their benefit. For instance, in some facilities, it is not uncommon to test patients’ urine up to five times a week for drugs. This practice is commonly done for financial gain and not to the benefit of the patient. In fact, it is common in sober living homes for drug use to continue while living there, until the patient’s benefits run out and they are released – only to relapse and begin the cycle over again – which leads to the next principle of nonmaleficence.

Nonmaleficence requires that providers “first do no harm” or inflict the least amount of harm possible to their patients. This is incompatible with a system that knowingly takes advantage of individuals who are suffering from a SUD who likely do not understand how to navigate the system and who may be unfamiliar with the benefits of evidence-based practices versus other types of treatment. For instance, even the former Deputy Drug Czar of the United States, Dr. Tom McClelland, had no idea where to begin finding treatment for his son who became addicted to opiates in 2015. The possibilities for those with less familiarity of the system seem grim in this instance – especially when there are mechanisms in place such as referral services and “junkie hunters” who are merely looking for financial kickbacks. The “Florida Shuffle” – a practice that cycles those with a SUD in and out of rehab at the detriment to addicts and the financial gain of
rehab services – is one such unethical practice preying on lack of knowledge.\textsuperscript{175} The lack of regulation in this part of the industry only exacerbates this problem by making it easier for those who can take advantage of people to do so – as was common in other eras.

As an ethical principle, justice requires equitable access to treatment, as well as equitable forms of treatment. Although the Mental Health Parity and Addiction Equity Act, paired with the ACA made it easier for people with insurance to get treatment for mental health and substance use disorders, it leaves part of the population without insurance to go without treatments – some of which can cost upwards of $73,000 for a 30-day treatment session.\textsuperscript{176} It also doesn’t cover those who may work one or more part time jobs that do not qualify for insurance through their employers and yet may still make too much to qualify for Medicaid or Medicare. Another part of the population also goes without because of lack of insurance or other resources for care: the homeless; a large portion of which are on the streets because of a substance use disorder, or who have succumbed to the disease whilst living on the streets.\textsuperscript{177}

Moral distress is another issue that affects individuals in and around the substance use disorder treatment industry. A phenomenon that was at once only addressed as something that pertained to nursing working in high stress situation, it refers to moral dilemmas that occur when a nurse or other health professional “knows the right thing to do, but institutional constraints make it nearly impossible to pursue the right course of action.”\textsuperscript{178} This could mean someone in administration who does not agree with some of the treatment or practices occurring in a treatment facility, or an aide in the facility who is having a similar moral conflict and who has less authority to do anything to change the system. The consequences of which may be a decrease in level of care, caregiver burnout
or rapid turnover. This can be detrimental to a patient’s care – SUD treatment centers notwithstanding.\textsuperscript{179}

It is also vital to address the unique ethical concerns of those in the United States who are individuals with a SUD going through the criminal justice systems, as the concerns within this system are unique compared to the concerns of those outside of it – be it through incarceration or the drug court system. This is a result of several issues, including the unique situations many criminals find themselves in – including homelessness, recidivism and psychosocial issues that may or may not be related to their criminality. Many rights of prisoners are stripped upon entrance into the penal system – the greatest of which is autonomy.\textsuperscript{180} There are often limited options (or resources) for proper detox or MAT, nor is there always a choice about the types of treatment offered to inmates (either in jail or prison). These typically differ from one jurisdiction to the next, and many personnel do not believe that tax dollars should go towards their use.\textsuperscript{181} What is offered is often mandated and limited to what the county or state offers (although as previously mentioned, there are some prisons that offer a Prison Therapeutic Community). While 12 step programs are offered within the walls, the options surrounding these are also limited, and often do not provide individuals who may not desire a religious-based program with alternative options.\textsuperscript{182} They are also coercive, which also goes against the principle of autonomy and informed consent. This also applies to programs offered in drug courts. It is up to the magistrate who presides over them. Only recently have states started to offer treatment such as methadone maintenance or MAT during pre-trial periods or while in drug courts after some in the system died without access to them.\textsuperscript{183} This strips the individual with and SUD of the option to find
treatment which works best for them, as MAT regimens are not a one-size-fits-all remedy for detox and rehabilitation.

This leaves the ethical question about the principles of beneficence and nonmaleficence in treating individuals in the penal system. What is offered is often mandated and limited to what the county or state offers and begs an analysis of ethical versus unethical treatment of prisoners in jails, prison, and drug court situations. It also creates concern about justice. It is understandable that some rights are vanquished upon committing crime, but it also requires that inmates retain some form of human dignity – including their right to access to medical care, and if necessary, treatment for SUDs.

The absence of equal access in prisoners or criminals in comparison to civilian counterparts may be considered “par for the course” for being a criminal, but there has to be a standard of care for everyone in the justice system – which is currently lacking. It is also important to keep in mind that many who enter the criminal justice system are already at a disadvantage because of overrepresentation of minorities and impoverished, who likely lacked resources outside of it. And certainly, moral distress is also a concern in the criminal system. From those who may be working in jails and prisons, to those working in the courts themselves who are trying to exact change and help people get back on their feet but may be limited in their ability to do so by laws and regulations that seemingly are not keep up with modern medicines approach to substance use disorder.

There are some practical ways in which these issues can be addressed. These include policy changes – both at the federal and states level – as well as the use of methods for improvement within treatment centers that already exist. Implementation
science, quality improvement and regulation are but a minor but necessary step towards improving the lives of people seeking recovery. The lack of oversight in sober living homes and treatment centers, drug courts, as well as the lack of consistent access to evidence-based SUD treatment in the U.S. criminal justice system lends itself to the need for laws and regulations to be implemented to address these inconsistencies. After a national emergency regarding the opioid crisis was declared in October of 2017, the President's Commission on Combatting Drug Addiction and the Opioid Crisis published a report with 56 recommendations on how to address the current public health issue surrounding opioid use and misuse.\textsuperscript{186} This included policy recommendations that addressed concerns about regulation and reimbursement of evidence-based programs for SUD treatment, as well as the need to address personal and societal biases towards individuals with a SUD. It also addressed the need for MAT in the criminal justice system – in drug courts, pre-trial, during incarceration and afterwards.\textsuperscript{187} Other states are addressing issues in the criminal justice system on their own by providing MAT and other opiate based treatments to all inmates in need.\textsuperscript{188}

The report itself did not, however, address SLHs specifically.\textsuperscript{189} What is promising though are states such as Arizona and New Jersey that – in the interest of providing more oversight - have subsequently begun passing their own legislature to do just that.\textsuperscript{190} In May of 2018, Florida Senator Marco Rubio introduced a bill known as the Sober Home Fraud Detection Act that would require HHS to publish known indicators of fraudulent practice in SLHs – although as of April 2019 no further action has occurred on that bill.\textsuperscript{191} The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018, addressed the issue of
fraud and recovery by increasing penalties on kickbacks and overprescribing of opioids specifically, while and making addiction treatment more accessible to some. It did not provide for any expanded SUD treatment.\textsuperscript{192} While this is progress, it is essential to pass legislation that more aggressively confronts not only the root of substance use disorders but the outdated policies that allow the fraud and abuse to continue.

Other micro level practices can have an impact on the experiences and outcomes of patients seeking SUD treatment. Research has shown that evidence-based approaches to substance use disorder treatment such as pharmacological therapies (such as MAT) psychosocial therapies (such as cognitive behavioral therapy) and/or integrated therapies for people with co-occurring disorders have positive effects on substance use disorder and problems associated with it.\textsuperscript{193} Despite the evidence to support their use, integration of such therapies into community settings lags behind the science. The reasons for this gap include lack of knowledge or resources as well as system and financial disincentives.\textsuperscript{194} A new science has emerged that examines processes and factors associated with successful incorporation of evidence-based practices into various settings: implementation science. Implementation science uses a variety of conceptual frameworks and scientific data to not only implement certain treatment settings and evaluate their effectiveness, but to also examine the providers, organizations and systems within which a recipient receives treatment to see what areas may require improvement.\textsuperscript{195} Implementation outcomes that are studied include: \textit{implementation} – which pertains to outcomes at an organizational level (fidelity, cost); \textit{services} – which include quality indicators endorsed by the National Academy of Medicine (as efficiency
and disparity) and a patient dimension – which relates to outcomes such as drug and alcohol use as well as consequences and function.\textsuperscript{196}

While research in this field on the application of implementation science/research to substance abuse treatment centers is minimal, journals such as the \textit{Journal of Substance Abuse Treatment} are eager to see new data on the applicability of implementation science in substance abuse treatment centers, drug courts and correctional facilities. With new enthusiasm emerging for the of EBPs in SUD treatment not only on the policy end of the spectrum, but in the healthcare field as well, the prospects for IR are promising.\textsuperscript{197} Progress in this area will allow implementation researchers to address some of the ethical issues that have emerged at all levels, and possibly prevent them from ever occurring in the first place.

While implementation research is intended for the introduction of EBPs into treatment centers, another practice is intended for the improvement of services already in place. In 2006, the IOM recommended that institutions implement QI strategies for improving SUD treatment.\textsuperscript{198} One method for improving EBPs is Continuous Quality Improvement (CQI). CQI is a “planned approach to transform organizations by evaluating and improving system to better achieve outcomes.”\textsuperscript{199} Originally designed for use in the U.S. manufacturing industry to improve quality and productivity in those sectors, CQI is now being adopted in health care systems to improve the quality of care. Studies that have adapted CQI methods such as the “Plan-Do-Study-Act” intervention to healthcare settings provide evidence that CQI can improve health outcomes. These improvements were not only for the recipient of care, but providers and staff as well. Studies that applied CQI methods specifically to community-based treatment settings
supported this evidence as well. Application of CQI methods to places already integrating EBP into their treatment centers, drug court practices and correctional facilities may benefit from doing so and see better overall outcomes for individuals with a SUD.

This section examined the history of substance use, abuse, and treatment and some of the ethical considerations that come along with it. While the use and abuse of certain substances is not a new phenomenon, the way in which we view and treat those who use them to excess has evolved over time. One thing that is consistent over time, however, is the propensity for people to try and take advantage of those individuals seeking a healthier living. Fraud is rampant in the substance use disorder treatment industry in the form of financial kickbacks and promises of cure by methods for which there is no evidence of success. Treatment centers and sober homes lack regulation, and the criminal justice system is inconsistent in their treatment of individuals with a SUD. It is essential that all of the issues brought forth are addressed at a macro level through state or national legislation and at a micro level through the use of implementation science and quality improvement methods. This has the potential not only to improve the health of individuals with SUDs in residential, outpatient treatment, and the criminal justice system, it has the potential to improve the overall health of their families and the providers guiding them through their treatment.

4c. Ethical Concerns in Research on Subjects with a Substance Use Disorder

Clinical trials are an essential element of the healthcare process. Knowledge gained from clinical research allows researchers to not only develop screening and diagnosing tools, interventions for the treatment and prevention of disease it also
generates understanding and appreciation of the unique experiences of subjects. One of
the biggest obstacles to clinical trials is getting people to participate. In many clinical
trials, incentives are offered to induce participation. There is an ongoing debate as to the
ethical nature of offering incentives in exchange for participation in clinical research.
However, with the rise in opioid use disorder (OUD) over the past decade, there is a
heightened sense of urgency in research on interventions for those with an OUD. These
and other related studies necessitate individuals with an OUD and/or another substance
use disorder. This development has elicited ethical concerns about research on this
population. This paper will examine an ethical framework specific to human subjects
research and ethical concerns surrounding the use of incentives, with particular attention
paid to vulnerable populations such as those with a SUD. Potential solutions to concerns
surrounding the inclusion of individuals with a SUD and suggestions for future research
will also be explored and discussed.

4ci. Ethical Considerations in Human Subject Research

Research conducted with the goal of gaining knowledge for the purpose of
improving health and the individual and structural level needs to consider the ethical
challenges inherent with doing so on other human beings. The primary concern of
contemporary researchers and ethicists is that such research is done in such a way as to
avoid exploitation and minimize risks. Traditional Western bioethics often measures
ethical standards using a framework popularized by the work of Beauchamp and
Childress. Ezekiel Emanuel et. al introduced a more comprehensive framework for use
in assessing the ethical nature of clinical research. This framework is helpful when
discussing elements of research that are considered controversial yet often necessary, such as the use of incentives.

Autonomy/respect for persons, beneficence/nonmaleficence and the principle of justice are the pillars of (western) bioethical thought. However, as Emanuel et al. point out, existing guidelines are flawed—particularly with regards to research ethics. They are often reactionary in nature, with a focus on recent transgressions then an exhaustive examination of potential ethical problems. They are also myopic and reductive in nature, often deferring to other broader guidelines for direction. Emanuel et al. also argue such guidelines suppress the contributions of large portions of the population such as pediatric patients. In order to address these deficiencies, Emanuel presents a more comprehensive framework to guide the ethical conduct of clinical research. Following these eight principles helps minimize the possibility of exploitation, simplifies identification and assessment of problems, and may assist in the creation of possible solutions. Each principle has benchmarks that elucidate each principle, along with practical considerations.

The first principle refers to the collaborative partnership that is necessary for ethical clinical research. This refers to the relationship between the researcher and the participant, communities involved, research sponsors, and policy makers to ensure that the research meets the needs of the community, respects their values and cultural traditions and is beneficial. It requires partners, collaboration, mutual respect, fair benefits for the community in which the research is being conducted and fair distribution of agreed upon benefits amongst all partners. Upholding this principle requires
identification of suitable community representatives throughout all phases of the research, from planning to dissemination of the results.

Clinical research must also have social value, meaning that it must be beneficial to those participating, the community and overall society.205 Prior consideration of the social value of research can save resources and eliminate unnecessary risks. This requires the researcher to identify to whom the research will be valuable – not only in the short term but future beneficiaries as well – and at what level of society this benefit applies. It is also necessary to identify the potential value for each type of beneficiary. For example, if the research benefits local health or that in another area. It is also necessary to produce ways to enhance the social value of the research by developing collaborative partnerships as a means to disseminate findings and further develop the research. It is also important to consider how the research affects current health infrastructure in the community in which it is conducted (so as not to undermine existing systems.206

Ethical research also requires scientific validity, which includes the requirement that said research provides data that is reliable and valid. Otherwise, the research has no social value and may subject participants and other partners to unnecessary risks. This can be achieved by considering the internal and external validity of the study, while also considering other accepted research standards (re: sample size, outcome measures, proper use of statistical analyses). The research design must also consider the ease with which the data can be interpretable and be useful in the context of health-related issues. Entitlement to medical studies in the research must also be considered, with a “methodologically compelling” justification required as to why participants might not
be. In such research it must be ensured that denial to such healthcare services does not put the participant at risk.

*Fair participant selection* is necessary to minimize exploitation – especially of those populations historically targeted for less favorable or high-risk research studies. Participants should be chosen on the basis of the research objectives and no other factors such as ease of access or other criteria that may identify them as vulnerable or easily exploited. Fulfilling this principle requires that the study population be that ensures scientific validity. The target population should not include individuals who may be put at undue risk – for instance those with a health condition that may be exacerbated by participation. Participants should be chosen in a way that maximizes the social value of the research and possibly benefit them as well. Vulnerability based on a variety of factors (age, gender, health status) must be assessed and safeguards put in place to mitigate these factors.

Ethical clinical research requires that it offer participants and other partners a favorable risk-benefit ratio – or in cases of research where the risk outweighs the benefits, ethical standards require that the risk be justified by its social value. This principle is upheld through identification of all possible risks of conducting the research, assessment of all benefits associated with the research, and through a comparison of the risks to benefits to assess the proportionality of risks to benefits and consider whether high risk research is justifiable through its purported social value.

Independent review in clinical research upholds its ethicality by minimizing concerns related to conflict(s) of interest and providing public accountability. It is imperative that standards and procedures established by regulating bodies be adhered to
for such an independent review. Such reviews should be independent of the research, and any member with a conflict of interest should be excused from that particular review process. Members of this independent committee should have some type of expertise related to research/research protocols. Such a process should be transparent so as to bring about communal understanding. All scientific and ethical considerations must be addressed during the first and any subsequent reviews as necessary or required by law.  

In Emanuel’s framework, seven benchmarks must be met to fulfill the informed consent principle. Recruitment procedures and incentives must be consistent with and respectful of cultural, political, and social practices of the potential participants and their community. Any disclosure forms or procedures must take these into consideration.

Procedures must also be in place to properly obtain consent for those who are unable to do so (i.e., minors) or other supplementary consents (i.e., spouses, community leaders). Assurances must be made that consent procedures are acceptable within the context of the local community, and all potential participants must understand their right to leave the study if/when they see fit to do so.  

Respect for persons not only refers to the process of obtaining informed consent, but the behavior of the researcher to participants (and their communities) throughout the research process. This is first achieved by monitoring the health and well-being of the participants before and after administering an intervention. Adverse effects may occur physically or mentally which may affect participant health in the short and/or long term. Adhering to patient confidentiality is also necessary and being honest with participants about the extent to which you can keep their data private. Researchers must also respect the right of participants to withdrawal from the study at any time they see fit.
Clinical research relies on the voluntariness of human subjects to participate, as well as a respect for and adherence to all principles of research ethics throughout the process. Once the Institutional Review Board (IRB) or other appropriate governing body has properly approved the research protocol and design, the practical aspects of research must begin - starting with the recruitment process. Successful recruitment of participants is one of the singular most daunting parts of clinical research. Many studies do not meet their recruitment goals. This happens for multiple reasons. The researchers may have set unrealistic recruitment goals or used inadequate recruitment strategies. The criteria created for inclusion or exclusion may be too narrow or the materials provided for the study may be inaccurate. Sponsors may have done an inadequate job of recruiting suitable members of the medical community to conduct the trial. Studies have shown that doctors may also be culpable insofar as they neglect to refer or recruit patients for clinical trials simply out of ignorance that they exist. One of the primary reasons people do not participate in clinical trials is because they are unaware of their existence. Other reasons given include: no foreseeable benefits from participation; lack of access; potential disruption of day-to-day living; fear, distrust or suspicion of research based on personal or historical injustices; perception of insensitivity of recruitment practices – particularly in historically underserved populations and cost/insurance related concerns.

What is often ignored in research is the reasons why people do participate. Research on survey participation suggests three main reasons: altruistic (participation fulfills a social obligation or to do so helps others); survey-related reasons (the topic is interesting); and egoistic reasons (monetary reasons or they like to). Groves, Singer and Corning also outline what they call “leverage salience theory” of participation which
posits that those with higher interest in community involvement participate in survey research at a higher rate than those with a lower interest. However, the role of incentives in motivating research participation is well-documented and requires consideration. Two meta-analyses of experiments using mail, face-to-face and telephone interviews shows that incentives are more effective at attracting participants than in those experiments where there was no incentive advertised or provided. Incentives in the aforementioned data sets were identified as either monetary (e.g., gift card, cash, or check) or non-monetary (e.g., childcare, transportation, groceries, sports tickets). Both analyses also showed that money is more effective than non-monetary incentives as an inducement to participate. This finding is also true in clinical research settings. Although this is practice is ubiquitous throughout clinical research, the ethicality of it remains a topic of controversy.

Proponents of providing financial incentives for individuals taking part in clinical research cite the need to boost the number of individuals who participate in trials as one reason. As previously mentioned, many research trials fall short of their projections, and although some may participate for altruistic reasons, many would not do so otherwise. In line with the research of Groves Singer and Corning, those with higher interest in the research are less influenced by such incentives than those with less interest. This is also true in reference to socioeconomic statues – financial incentives exerted more influence on those who are disadvantaged socioeconomically than those who are not. Payments are also seen as a way to provide a fair share to the benefits for the risk of sharing personal health data for which they are being paid. This upholds the favorable risk-benefit ratio principle of ethical research. Some proponents also see financial
payments as one form of appreciation given to participants for their involvement in the research. Another thing to consider is that for some populations, the provision of no incentives or non-monetary incentives further stigmatizes and reinforces economic disadvantages, which violates respect for persons by assuming members of a population considered “vulnerable” are incapable of exercising “good” judgement when making personal decisions about their health if offered monetary inducements.

Opponents of offering payment to individuals in exchange for their participation in research trials contend that it has the potential to be coercive and/or cause undue inducement to participate. Federal regulations in the United States, as well as other international codes of ethics for research stipulate that “consent to participation in research should be obtained in a manner that minimizes the possibility of both coercion and undue inducement.” Coercion is “the use of force, intimidation or threat to make someone comply with a demand or threat.” Undue inducement is when external factors influence the decision-making capacity of an individual. In the case of clinical research, it would be incentives, but more specifically monetary ones. Most agree that offering payment for research is not coercive, because no one is threatening individuals with harm by offering them financial incentives. There are concerns about the threshold for what constitutes inducements as undue – and as of now there is no consensus. It is generally agreed that if a prospective participant is strongly motivated by financial incentives, their decision making maybe impaired, thus violating the principle of informed consent and potentially the social value of the research should certain populations who may be motivated financially for various reasons be left out. Generally speaking for an inducement be considered “undue,” and therefore ethically problematic, payment must be
large enough to induce a person to take risks they wouldn’t accept with a smaller payment.²³⁰

Secondly, opponents of financial incentives also discuss the possibility of exploitation. For instance, if researchers offer meager incentives to certain demographics of individuals whom they know will likely take advantage of it due to their economic or social situation (e.g., college students, citizens of low-income countries or low wage workers), they are engaging in a form of exploitation. This not only violates the fair participant selection principle, but the favorable risk to benefit ratio and collaborative partnership principle as well. There is also the risk that children may be exploited by their parents for monetary incentives.²³¹

A third ethical concern with offering financial incentives is what is known as biased enrollment. The prospect of financial gain from enrolling in clinical research may be more enticing to an individual from a lower SES, therefore clinical studies may attract more from economically disadvantaged backgrounds than those of the middle class or higher SES. This can affect both the generalizability of the results and create a situation in which those with higher SES benefit from research done on those from a lower SES.²³²

Despite the disagreement on whether or not to provide financial incentives in research, it is generally agreed that populations that are considered vulnerable to coercion, undue inducement, exploitation, and biased enrollment should be protected throughout the course of the research process. Policies and safeguards exist in research as a direct result of the treatment of vulnerable populations for the benefit of those with the power to do so. In considering the ethical issues with providing or omitting incentives from clinical research, ethicists often turn their focus from that of the “average person” to
the person who is vulnerable. This allows ethicists, researchers, and IRB members to consider how such incentives might influence the decision-making skills of those who have or continue to experience disadvantage.

The issue of vulnerability proposes a unique challenge to those who wish to include incentives as part of the research process. What defines a population as vulnerable is not universal, nor is it stagnant. However, for the purpose of this paper vulnerable is defined as membership in a population that is susceptible to receiving injuries; open to attack or damage; and/or capable of being physically or emotionally wounded.233 Vulnerability applies not only to individuals, but to groups, communities, and countries. Resnik identifies vulnerability specific to research subjects as vulnerability to impaired decision making, risk-taking and potential for exploitation. Unless there is a legitimate scientific reason for including vulnerable groups in research, studies will often exclude such populations.234 Examples of vulnerable populations include: children, prisoners, the homeless, senior citizens, racial and sexual minorities, those who are physically or mentally disabled, economically disadvantaged and the educationally disadvantaged. Major ethical references such as the Nuremberg Codes, the Belmont Report and the Declaration of Helsinki were all created in response to events surrounding the abuses of vulnerable populations, therefore it is important to consider some of the ethical concerns research designers must consider before deciding whether or not vulnerable populations should be included in or excluded from studies.235

Proper informed consent requires full disclosure of information, full comprehension of the information and that any decision is made voluntarily and free from coercion. Current methods of informed consent do not ensure that this takes place –
even in the general population. In a systematic review of the literature by Falagas et. al, it showed roughly one-third of participants didn’t have a clear understanding in the area of risks, benefits, randomization, study aims, withdrawal, and voluntarism in research studies. This is particularly worrisome in vulnerable populations such as children, the educationally disadvantaged or economically disadvantaged who often have lower health literacy and poorer comprehension of such research dimensions. Marginalized populations may also assess information from the informed consent process differently. In vulnerable countries where pharmaceutical research is often conducted, language barriers and differences in the concepts of autonomy and informed consent may also inhibit the fulfillment of this principle. The risk for therapeutic misestimation may also occur with improper informed consent, which is when subjects overestimate the benefits of study or when they underestimate the potential risks associated the study. Incentives are also an ethical issue for some, because economically disadvantaged populations may be unduly induced into providing consent – particularly in studies where the incentives are monetary in nature. This also applies to surrogates of mentally disabled adults or parents of children who enroll those for whom they are responsible in studies for economic gain, regardless of risk.

Inadequate informed consent creates a new ethical problem: higher risks because of either participants’ lack of understanding from a subpar process or because of the possible influence of incentives on their decision-making. Not only does the informed consent principle require research design and execution to mitigate these risks, but the scientific validity and favorable risk-benefit ratio principles require this as well. In vulnerable populations in particular, where decisions may be made under duress for a
variety of reasons (lack of access to health care, economic hardship, social pressure to participate) there is a need to ensure that risks of participation are minimized, and benefits are amplified to the extent possible – not only for individual participants but for the local communities as well.\textsuperscript{241} This is especially true in vulnerable countries that are continually exploited for the resource of research participation and other vulnerable populations whose contributions are at risk of being exploited for the sole benefit of others.\textsuperscript{242} Otherwise not only is there the risk of the development of experimental mistrust from vulnerable populations, but the principles of collaborative partnership and social value are left unfulfilled.

Researchers must also understand that although there is a chance that incentives might influence a person’s decision to participate in clinical research, not all incentives are monetary in nature. The provision of health care of any kind prior to, during and after clinical research can be considered an incentive for a person belonging to a vulnerable population who might not otherwise receive it. Here again it is the responsibility of the research designer and IRB reviewers to consider the care plan for participants after the research is completed so as not to cause harm to them and the community long term, or risk violating the principle of respect for participants as outlined by Emanuel.

Research on vulnerable groups have generally similar ethical concerns, but one group in particular raises concerns that are singular to the nature of their vulnerability: individuals with substance use disorders. Not only is there controversy surrounding their inclusion in clinical studies, but ethical considerations about the impact of the use of incentives in this population is of particular interest to ethicists and researchers because of the unique impact it can have on the individual and overall research outcomes.
Individuals with a SUD are considered a vulnerable population, requiring “special protection” and “additional safeguards” in clinical research. They are considered vulnerable in the context that their disease puts them at risk for poor physical, psychological, and/or social health. Those with a SUD may also belong to other vulnerable groups such as those with mental illness, the economically disadvantaged, the homeless and/or racial, ethnic, and sexual minority groups, exacerbating their risk of exploitation.

There are several ethical concerns about including individuals with SUD in clinical research. One of the foremost are the ethical issues in obtaining informed consent. This requires participants have both the cognitive capacity to understand the risks and benefits of participation, but also the volitional capacity to decide to do so. Many studies on addicts and injectable drug users (IDU) show that they generally have the capacity for comprehension and to give consent. The challenge here is assessing whether or not those with a SUD are providing free and internally uncoerced consent to participate – purely due to the nature of the addiction itself. The “brain disease” of addiction pervades the thinking of some bioethicists who insist that individuals with a SUD are incapable of making free and autonomous choices about participation in research studies – especially those that involve the administration of their drug of addiction, although there are studies out there that suggest otherwise.

Some bioethicists also suggest that only those who have entered or intend to enter treatment have the capacity to freely consent to participate in studies involving administration of drugs, but that assumes abstinence is the only competent choice and that treatment is voluntary. Other ethical considerations regarding capacity in
individuals with SUDs focus on two issues: concern that intoxication or withdrawal symptoms may impair (although temporarily) attention, cognition and recall; and the thought that consequences of long-term drug use on cognitive skills may limit understanding necessary for proper informed consent, thus violating the informed consent principle of Emanuel’s framework.248

Individuals with a SUD often engage in illegal activities associated with the misuse of prescription drugs or the use of other illicit substances. Examples of such activities include (but are not limited to): driving while intoxicated, selling illicit substances, diverting prescription drugs, violence and crime while using drugs and/or alcohol or with the goal of financing their continued drug/alcohol use. This raises another issue: privacy and confidentiality of personal data. Some study participants may face criminal charges if research data was linked to individuals by law enforcement.249 Respect for participants requires that confidentiality procedures be put in place to protect privacy. Considering the sensitive nature of this issue, the United States does have some assurances available, such as the Certificate of Confidentiality, which protects such data from federal or state subpoena. It does not however, protect from voluntarily disclosure by researchers, nor is it an option for international research.250

Other privacy concerns include the use of geospatial mapping in data collection about “hot spots” for illicit drug use, which may not only risk confidentiality concerns, but expose researchers and participant to undue harm (violating the favorable risk-benefit ratio in the meantime).251 Innovations in technology also allow mapping of the human genome, which can be used to identify different disease states (or the potential for them). Exposure of personal genetic data may also pose unwanted risks to a participant if it is
linked to a participant. Such data can be exploited by health companies, insurers and possibly employers.\textsuperscript{252}

Concerns also exist about the effect of interview or survey research on vulnerable populations like those with a SUD, who may have lived experiences marked by violence and abuse. The assumption is that by investigating the personal histories of those with a SUD, researchers are “re-traumatizing” or “re-victimizing” them, therefore inflicting undue harm and violating the favorable risk-benefit ratio principle. This assumption is persistent, despite research that suggests that those who have experienced past trauma(s) may find talking through such experiences as beneficial and cathartic\textsuperscript{253}

One of the most pervasive concerns with having individuals with a SUD in clinical research is the ethicality of providing financial incentives for their participation. Research with these individuals typically have more difficulty with recruitment and retention than the general population because of problems with generalizability, transient nature of some of the population, employment instability and comorbid health/psychosocial problems.\textsuperscript{254} The success of monetary incentives is established, and the concern about the influence of undue inducement on informed consent well-documented. However, there is a stronger reluctance to use them in this particular population because of the belief that financial incentives will be used to purchase drugs, alcohol, or other illicit items (guns, knives etc.), which may put the subject at further risk of harm (a challenge to the favorable risk-benefit ratio principle).\textsuperscript{255}

While some studies suggest there is a relationship between financial payments and drug use, the only controlled study found that neither the means of payment nor the amount had any significant effect on drug use.\textsuperscript{256} Financial incentives were primarily
used to pay for household items and bills, while gift cards were used on gift and luxury items because of the limited flexibility of their use. Qualitative research done by Bell and Salmon reveal that participants are aware of these concerns and note that those who assume that money will be used to further drug use are “judgmental” and “degrading.” This was also true for studies that provided gift cards and non-monetary incentives as “inappropriate” and felt exploited by stereotyping and assumptions made by researchers about how the incentives would be used. Respondents in another study noted that regardless of such tactics, “if [we’re] going to get high, we’re going to; the money doesn’t matter.” However, they derided the assumptions by the researchers on the impact of incentives on their desire or ability to acquire their drugs of addiction and chastised them for trying to control how they used their incentives, stating it is “none of [their] business.”

Despite the existence of research that refutes held beliefs about capacity, informed consent, participation-induced re-traumatization and the influence of financial incentives, apprehension and uncertainty still exists with regards to this particular population. This is likely due to the stigma associated with SUDs which is pervasive throughout society, and commonly cited as a barrier to equity in healthcare. Fortunately, healthcare providers recognize the impact stigma has on healthcare delivery and are now taking measures to address it.

4cii. Solutions and Suggestions for Future Research

Growing research shows that subjects with a SUD not only engage in research for reasons similar to the general population, they also generally use monetary and other incentives in a responsible manner. Despite this knowledge, controversy surrounding the
practice of providing them with monetary incentives still exists.\textsuperscript{261} What is troubling about this is that these attitudes tend to be formed without a proper understanding of the realities of having a SUD. Those in healthcare and those who make decisions about what is permissible in research often rely on prevailing stereotypes about these disorders when designing and approving clinical research instead of empirical facts.\textsuperscript{262} Stigmas attached to SUDs have historically impeded engagement with healthcare providers, including those conducting clinical research.\textsuperscript{263} Therefore, it is necessary to educate and train providers to reduce stigma at the individual and structural level.

Canadian sociologist Erving Goffman defines stigma as the “situation of the individual who is disqualified from full social acceptance.”\textsuperscript{264} Stigmas set an individual or group apart from “normal” society, thus inviting stereotyping, prejudice and negative actions and behaviors towards those who possess the “mark of disgrace.”\textsuperscript{265} In health care facilities this may manifest overtly in behaviors such as denial of care, provision of sub-standard care, physical and verbal abuse or covertly in making certain individuals wait longer or passing off patients to other colleagues.\textsuperscript{266} In clinical research, this can manifest itself through practices such as prohibiting active users from participating in research, requiring treatment as part of participation or prohibiting/limiting the use of financial incentives.\textsuperscript{267}

Stigma occurs at various levels: individual, interpersonal and structural. Individual stigma manifests itself in the act of concealment or self-stigma (internalization of social views about the stigmatized condition) while interpersonal stigma reveals itself in the interactions between stigmatized individuals and the non-stigmatized.\textsuperscript{268} Structural stigma recognizes the influence of institutions and cultural ideologies in perpetuating
stereotypes and discrimination. Institutional policies that overtly restrict the opportunities for stigmatized individuals and dominant social norms that devalue certain identities or status contribute to structural stigma (e.g., Jim Crow laws or bans on same sex marriage). Health-related stigma in particular relates to groups that are devalued, rejected, and excluded on the basis of a socially discredited health condition. As such, substance use disorders rank as some of the most stigmatized health conditions.

In light of research that has increasingly focused on documenting the problem of health-related stigma and its effects, governments and other professional organizations have started to shift their attention to its management and prevention. A systematic review of the effectiveness of interventions for reducing stigma by Livingston et. al (2011) showed that, although the data is limited, available interventions show promise for meaningful change in stigmas related to substance use disorders at each level of stigma: therapeutic interventions such as group-based acceptance and commitment therapy can reduce self-stigma. Social stigma can be addressed with motivational interviewing, and at a structural level, contact-based training and education-based training for medical student and other professionals can also be effective. However, many of these interventions were done at a singular level and focused on substance use disorders in particular. While effective, it is myopic to only consider one form of health-related stigma if we are to address it at a magnitude sufficient to reduce it throughout healthcare and alleviate the problems associated with stigma in all aspects of clinical research.

To address this issue, Stangl et. al have developed what is known as the Health Stigma and Discrimination Framework, which is intended to be a “broad, orienting” framework to enable interdisciplinary researcher to standardize measures of stigma,
compare outcomes and create more effective interventions for multiple health issues.\textsuperscript{273} Unlike other interventions, its focus is on the stigmatization process as it occurs across the socio-ecological spectrum, which varies across economic contexts – meaning it’s applicable to low, middle and high income countries.\textsuperscript{274} This differs from other interventions which have often been used in primarily high-income countries.\textsuperscript{275} While contemporary interventions often target driving forces of stigma or policies that perpetuate it, more effective interventions such as the one proposed would include components at multiple socio-ecological levels. Data on health-related stigma would also be collected and monitored at a program, facility, and national level. This could then be used by researchers and program evaluators for assessment of interventions and modification of training and policies regarding stigma reduction.\textsuperscript{276}

The goal of this framework is for practical application to address not only historically stigmatized conditions such as SUDs, but the intersectionality of certain diseases and other statuses that conflate a number of health-related issues, including those found in designing and conducting clinical research.\textsuperscript{277} Micro-level interventions such as those analyzed by Livingston et. al. are shown to be effective, but until the issue of health-related stigma is addressed at a structural level, there will continue to be instances of incongruity with regards to education on stigma and the influence that has on if and how vulnerable populations such as those with a SUD will be allowed into clinical research.\textsuperscript{278} These inconsistencies only perpetuate stigma and violate ethical principles such as fair participant selection and informed consent.

Stigma reducing interventions are not the only way in which clinical research can promote the inclusion of individuals with a SUD and alleviate health-related stigma.
present in the designing and implementation process. Institutional Review Boards often rely on the principles set forth by the Belmont Report and Beauchamp and Childress’ principlism when reviewing research proposals. The Common Rule establishes safeguards to further protect vulnerable populations, but these safeguards are considered “vague” and only impose additional burdens on IRB committees and investigators who want to protect a population but may not know how.279 The Emanuel Framework undoubtedly provides more clarity for clinical research, but for populations such as those with SUDs who often engage in risky behaviors, principles such as those aimed at harm reduction may provide further guidance towards not only protecting subjects involved in clinical research who may be active users, but ensures they too are able to contribute to research that benefits them and their communities.

Harm reduction refers to interventions that are aimed at reducing problematic health-related behaviors.280 Although there is no single definition or standard of practice for implementing a singular harm reduction approach, it is broadly described by Harm Reduction International (HRI) as:

“Policies, programs and practices that aim to reduce the adverse health, social and economic consequences of the use of legal and illegal psychoactive drugs without necessarily reducing consumption”281

The harm reduction model is not exclusive to substance use disorders, even though its roots in the United States extend as far back as the 1900s when narcotics maintenance clinics were available.282 The focus of harm reduction in individuals with a SUD in particular is not on the drug use itself, but the negative consequences associated with it. Often found in treatment programs, harm reduction has gained traction in other healthcare settings.283 This led to the desire to not merely define harm reduction policies,
programs, and practices in the context of substance use disorder, but to specify and define harm reduction principles that can be operationalized for use with a broader healthcare audience. It is also the goal of those in harm reduction that such principles become incorporated into standard practice of all healthcare providers – not just those who engage with populations that with to improve the health outcomes of their patients.²⁸⁴

Hawk et. al conducted research using mixed methods on an HIV clinic providing harm reduction-informed services.²⁸⁵ Interview with patients and staff yielded qualitative data which was then used to refine harm reduction concepts and develop harm reduction principles that can be generalized to other healthcare settings. These principles include humanism, pragmatism, individualism, autonomy, incrementalism, and accountability without termination.²⁸⁶ Humanism describes the way in which providers value, care for, respect and dignify patients as individuals. It posits that it is important to recognize that people do harmful things for a reason; that these behaviors provide some benefit for the individual and those benefits must be assessed in order to understand the balance of benefit(s) and harm. This can be done by provision of friendly, non-judgmental services that are attentive to the needs of the individual. Pragmatism reflects the idea that no one will ever achieve perfect health behaviors. This approach means that for this individual, abstinence may not be a priority or goal, and a range of supportive approaches that do not focus on moral or societal standards should be available. Individualism reflects the notion that each individual presents with their own needs and strengths and therefore need a variety of intervention options. The principle of autonomy acknowledges the value of education and intervention suggestions from providers but highlights the importance of individual choices with regards to care. Patient-provider relationships are vital and
shared-decision making the ideal. *Incrementalism* acknowledges that any positive change is a step towards improved health and recognizes that regression is a part of this process. It highlights the value of positive reinforcement and encourages celebration of success – no matter how “minor.” *Accountability without termination* provides that patients are responsible for their own health choices and their consequences, but they are never “fired” from care.287

On its surface it may not seem like harm reduction principles (HRP) are applicable to clinical research, but a consideration of some of the barriers to participation and retention clarify the potential for their adaptation and incorporation into research design and practice. For instance, one of the barriers discussed throughout research is the potential for informed consent to be compromised in individuals with and SUD due to current or long-term substance misuse.288 Humanism as a principle requires lack of moral judgement and the provision of services that are responsive to the patient’s needs. The goodness of fit model for informed consent is ideal for this concern, and one way in which researchers can fulfill this principle. The goodness of fit model modifies traditional informed consent by requiring researchers to consider the principles to be responsive to the abilities, values, and concerns of subjects and/or their surrogates and be aware of their own competencies and obligations. Instead of following a checklist of requirements for formal informed consent, researchers conclude what elements of informed consent are necessary and create a procedure that best conveys these concepts and garners understanding.289 This tailored informed consent process can also fulfill the *individualism* principle which necessitates that providers tailor messages, interventions and treatment options to address the spectrum of needs of each individual.290 There are some
proponents that believe extending the window of consent and withdrawal of consent will also empower active users to exercise autonomy, which in the context of harm reduction emphasizes the relationship between the patient and provider, exemplified by patient-driven care.\textsuperscript{291} In the context of clinical research, the relationship between the subject and researcher is vital, but ultimately the subject has to have both the power to consent and the ability to withdrawal consent at any time and for any period of time (retroactively) – especially if their state of intoxication fluctuates, as may be the case in certain types of studies such as ethnographic research.

Another HRP that can be incorporated into clinical research is the principle of pragmatism – understanding that none of us will ever achieve perfect health behaviors and therefore not requiring them. Some ethicists maintain that a person does not have the capacity to make an informed decision about drug use without first making the decision to abstain and enter treatment.\textsuperscript{292} The principle of pragmatism acknowledges that the moral ambiguity of harm reduction but allows for a range of supportive approaches to provide safe consumption. In clinical research this translates to providing incentives regardless of how they might be used. It could also mean providing supplies for those that may use during the study, not only to acknowledge their choice without judgement but to ensure their safety and mitigate risk.

Accountability without termination is vital for recruitment and retention purposes. It is also a way to fulfill the fair participant selection principle proposed by Emanuel. Studies involving subjects with a SUD will often do drug testing to see if a patient is using. Even studies such as Phase I clinical trials will test to ensure that no illicit drugs are present.\textsuperscript{293} On the surface it seems to make sense for certain studies to exclude illicit
drug users so that a “sterile” study can be done of the safety, efficacy, and side effects of new drugs. However, with an estimated 20.3 million people with a SUD in the United States alone (and increasing numbers globally), research on the effects of the interaction of certain illicit substances - and licit ones like alcohol and prescription opiates – is warranted. Therefore, the principle of accountability without termination may be invaluable in some types of clinical research which previously punished users by either excluding them from a trial once their SUD was discovered in the recruitment process or “firing” them from the trial after a failed drug screen. Carter and Hall posit that neuroscience may be one of many fields that may benefit from allowing drug use during studies as a means to learn how their use affects motivation, learning, memory, and decision-making.

Although relatively new in conception, these principles have the potential to be another way to be more inclusive in clinical research – regardless of the health condition. The use of interventions for reducing stigma also shows promise, but there are limited studies on how this might work in clinical research settings. More research is necessary to assess stigma in research development and execution. There is also a paucity of qualitative data on stakeholder perceptions regarding the inclusion of individuals with substance use disorder in clinical research, aside from those that focus on providers and stigma. There is an equally limited amount of research available regarding the perceptions of research designers and other persons of power in clinical research on the inclusion of financial incentives.

Qualitative research offers insight into human thoughts, feelings and behavior that are lost in survey research methods. If we want to learn more about why individuals in
positions of power in clinical research are apprehensive about providing financial
incentives to individuals with a SUD and how their attitudes might be changed on the
matter, it is important to conduct in-depth research that qualitative methods afford. Such
research can also contribute to the further development of the *Health Stigma and
Discrimination Framework* developed by Stangl and her colleagues by not only exploring
where these attitudes stem from in these particular settings and in these particular
individuals, but by also allowing for an assessment of various stigma reduction
interventions in various professional environments.

The research proposed would involve people in the positions of power in the
development and execution of research: funders, researchers, clinicians, IRB members
and anyone else involved in writing, approving, and conducting research. These are the
people who exert influence on how research studies are carried out. They are the ones
who exercise the authority to include certain populations and exclude others; to allow for
financial incentives or not; and set the rules for participation and retention. Recruitment
would require a targeted approach: sending letters to IRBs and clinical research facilities,
as well as physicians’ offices that assist in the research process. This may prove more
difficult in countries where IRBs and other governing bodies related to research are
sparse or non-existent. Nonetheless inclusion of data from anyone associated with the
execution of research in such locations could prove beneficial to future research
development.

Literature suggests that anywhere from 12 to 30 interviews would be ideal, with
numbers over 30 approaching saturation. However, it would be prudent to consider
separating the numbers into groups of each type of participant so as to gather as much
data from different viewpoints as possible. A mixed methods approach would benefit this type of research. Semi-structured interviews would be used to interview participants on their attitudes about using financial incentives for research involving individuals with a SUD to gain insight into why they think that way. For instance, these interviews might glean data on whether or not ethical guidelines are the sole influence on their decision-making process and behavior towards individuals with a SUD or reveal whether or not other structural or personal factors are involved. Introduction of an educational intervention would be done in a group setting to disseminate it to as many people as possible at a time.

In studies of staff who worked in addiction treatment, it was found that even the most experienced staff members were not comfortably familiar with protections related to informed consent, but when educational interventions were introduced, they improved correctness related to informed consent significantly. This approach may provide the same benefits with regard to stigma and SUDs. Attitudes would then be reassessed immediately post intervention via semi-structured interviews and again at a later time via either telephone follow-up surveys or written surveys. Questions at follow up will include those on the impact of the educational piece on their role in the research process. And while financial incentives are but only one part of the process, the role of stigma has its part to play in the attitudes surrounding its use in drug/alcohol using populations. This data can then be used to help intervention designers assess, create, and improve upon available stigma interventions and inform proponents of the Health Stigma and Discrimination Framework in development practical ways to proactively intervene and
reduce or eliminate such stigma before it starts. A larger benefit is that this research can inform interventions for other highly stigmatized populations as well.\textsuperscript{300}

This section serves as an exploration of principles that may be more apt for exploring ethical issues in clinical research, which is vital to the propagation of vital clinical research across the globe. Emanuel’s Framework provides more clarity for addressing issues not only related to the research process but the design process as well. Attention was paid to issues related to the use of incentives – financial incentives in particular – during the recruiting process. Individuals with substance use disorder garner much more scrutiny with this practice out of unfounded fears that they will use them to further substance misuse and cause themselves and other further harm when in fact, empirical research shows these concerns to be largely unfounded. Much of these fears are based on stereotypes that stem from stigma attached to substance misuse. Potential solutions to extinguish such stigma, therefore opening up more opportunities for people living with a SUD to contribute to clinical research, lie in the introduction of various standard educational interventions. These would be designed specifically for people creating and executing clinical research. The integration of harm reduction principles into the research process is also suggested as a means of reducing risk while allowing people who may be active users to participate. Further empirical research on the effectiveness of such interventions in this population is also necessary so that they can become standard to global research practices.

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Chapter Five: Conclusion

In the years since the Opioid Crisis was declared a public health emergency, initiatives at the community, state, national and global levels have emerged. In the United States, the National Institutes of Health awarded $945 million for grants, contracts, and cooperative agreements across 41 states through the Helping to End Addiction Long-term Initiative (HEAL) Initiative. The aim is to improve chronic pain treatment while reducing the rate of opioid use disorders, the incidence of overdose in those with an OUD while promoting long-term recovery efforts. Select examples of legislation that has been passed since declaring the opioid crisis as a public health emergency in 2017 include H.R. 3692, which would enable clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists to prescribe buprenorphine, which is one type of MAT used to treat opioid dependence; existing federal law limits the types of providers who may prescribe it. The HEAL Act authorizes federal funding for services provided outside IMDs to Medicaid beneficiaries who are pregnant or postpartum and receiving substance use disorder services at an IMD. H.R. 5009, known as Jessie’s Law, would require a patient’s history of substance use disorder to be prominently displayed in a patient’s medical records so that all of a patient’s providers are aware and can make the most appropriate clinical decisions. H.R. 5002, the ACE Research Act, would provide the National Institutes of Health with new authority to conduct research on the prevention, diagnosis, or treatment of diseases and disorders, or to respond quickly to a public health threat, such as the opioid epidemic. The SCREEN Act would provide funding to the FDA to support the development of non-opioid, non-addictive options for pain treatment.2
On the international level, the United Nations Office on Drugs and Crime (UNODC) continues to award grants to support youth-centered activities in low and middle income countries to support substance use disorder prevention and awareness in schools and local communities. The WHO recently revised The International Standards for the Treatment of Drug Use Disorders, in conjunction with the UNODC to support the development and expansion of effective, evidence-based and ethical treatment for drug use disorders, especially in low to middle income countries. The publication includes principles for organizing treatment services for substance use disorders and describe the main components of treatment systems.

However, these efforts have been mired by the COVID-19 pandemic, which began in late 2019. The virus that causes COVID-19 is thought to spread mainly from person to person, through respiratory droplets produced when an infected person coughs, sneezes, or talks. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. While some individuals are asymptomatic or suffer mild symptoms, others may experience more severe reactions, up to and including death. The rapid spread of COVID-19 caused many jurisdictions to implement mitigation strategies such as social distancing, quarantines and lockdowns. This in turn had an adverse effect in the incidence of substance use disorders, the incidence of overdose related to illicit drug use and the rates of cardiac arrests and deaths in individuals who presented with concomitant illnesses; in this instance SUD and COVID-19. A recent study of hospital outcomes shows that hospitalizations and death rates of COVID-19 patients were all elevated in people with recorded SUDs compared to those without (41.0% versus 30.1% and 9.6% versus 6.6%, respectively). These outcomes are
more pronounced in minority and socioeconomically disadvantaged communities. The pandemic has also affected drug trafficking both in the means of moving drugs (affected by disrupted supply chains) as well as their cultivation and use. Rising unemployment and reduced hours can impact workers in areas affected by lockdowns and travel bans, causing them to be more vulnerable to drug use and to turn to illicit activities to secure an income. The pandemic has also created opioid shortages, which may result in people seeking out more readily available substances such as alcohol, benzodiazepines or mixing with synthetic drugs – creating more harmful patterns of substance use. Limited access to safe injection or syringe exchange programs during this time also impact the spread of HIV/AIDS and Hepatitis C.

Substance abuse costs the United States alone over $600 billion annually. Treatment reduces associated health and social costs by far more than the cost of the treatment itself. For example, the average cost for 1 full year of methadone maintenance treatment is approximately $4,700 per patient. In the United States, the predominant alternative to treatment is often incarceration, which is significantly more costly, costing on average $24,000 for 1 full year of incarceration. Of course, the total costs to the individual with a substance use disorder and society go beyond the financial. Other costs include higher unemployment levels, lost productivity, higher cost and incidence of drug-related crimes, domestic violence, divorce rates and the incidence of homelessness. Deaths from overdose are also on the rise, as accessibility to sensible opioid and non-opioid chronic pain treatments remain scare and inequitable at best. Unborn children and their mothers are also affected on a physical, social, and economic level, while the use of
illicit opioids or other injectable drugs and lack of access to needle exchanges or safe injection sites impacts the rates of HIV/AIDS Hepatitis C.\textsuperscript{12}

Despite what we know about what is necessary to address the opioid crisis and other substance use disorders, changes to the social and economic determinants associated with substance use and misuse are not a simple fix. However, research on substance use disorders recognizes the power of stigma to deter individuals with a substance use disorder from engaging with the healthcare system. Stereotypes can influence public policy in terms of restricting the rights of persons with behavioral disorders.\textsuperscript{13} Such perceptions are influenced by knowledge about these disorders, the degree of contact or experience that one has had with people with substance use disorders, and media portrayals. What is encouraging is the knowledge that these perceptions are also strongly influenced by social norms concerning the attribution of cause, or blame, for mental and substance use disorders, and the perceived dangerousness or unpredictability of people with these disorders. Such norms can – and often do – change as a result of local and national legislation and through the influence of people in authoritarian positions.\textsuperscript{14} United Nations Office of Drug and Crime Executive Director acknowledged in an open session of the Commission on Narcotic Drugs the importance of positive attitudes and respect in administering effective treatment and care for individuals with a substance use disorder, highlight the need to “[overcome] the stigma often attached to SUDs.”\textsuperscript{15}

To successfully improve the health outcomes of people with substance use disorders, it is critical to shift to a more comprehensive and integrated approach to ethics and the provision of healthcare which is captured in a public health ethics framework.
The purpose of this analysis is to approach the issue of substance use disorders from the perspective of public health as opposed to a criminal justice one. In this respect, this dissertation explored the ethical justification for modifying current delivery systems and the criminal justice system itself to treat individuals with substance use disorders like anyone else presenting with a chronic illness, as opposed to using punitive measure in order to curb abuse and misuse. The socioecological model allows for further analysis of the issues present in systems at various levels (personal, community, organizational and policy level). Such an approach requires the recognition that healthcare organizations are best suited to implement interventions to improve patient outcomes and that governmental actors can and should recognize the moral failings inherent in the criminal justice system with regards to individuals with substance use disorder(s). Together, these concepts provide an ethical framework to call for greater transparency and a nationwide implementation of evidence-based practices designed to improve outcomes and avoid preventable harm.

The argument builds by first acknowledging the widely accepted understanding of substance use disorders as a public health issue. This foundation provides a mechanism to adopt a similar organizational approach to call for more standardized form of care for individuals with substance use disorder. One that can be found not only in clinical practice settings, but also research environments and daily living. The dissertation first explored the extent of the problem from an historical perspective, mapping out the evolution of drug misuse, treatment, and prevention. This included a discussion of how circumstances surrounding a chronic pain crisis helped shape the opioid crisis, which was declared a “public health emergency” in 2017. Chapter two critically assessed substance
use disorder as a distinctly public health issue, as opposed to one of criminality and moral failing. To provide a context for understanding the extent to which substance use disorder affects people’s lives over their lifetime, chapter three provided a glimpse at pivotal moments from birth to death in which a person, their family and even their progeny may be affected by substance use disorder. This analysis studied issues related to maternal and pre/postnatal concerns related to opioid use disorder, possible effects of genetic testing on IWSUD and end-of-life obstacles that may present themselves for people with substance use disorders. A key argument here is that punitive measures such as incarceration are not only financially costly, but place unnecessary burdens on IWSUD, often hindering any hope of recovery. Chapter four, then, examines the issue of substance use disorders on a global scale. This is done by examining undertreatment of chronic pain as a catalyst for the opioid crisis, while further exploring what defines an issue as a “global bioethical problem.” Rate of chronic pain, as well as comorbidities associated with chronic pain such as depression, unemployment and other physical and social psychological concerns are also explored. Of particular significance to this dissertation’s central argument. This chapter critically examined the ethical obligation to not only develop a global standard of care for chronic pain, with careful consideration of the inequities present in low to middle income countries with regard to healthcare access, but to address issues surrounding substance use disorders (trafficking, dispersion, use) with a more unified approach. Next, the substance use disorder treatment industry as a whole is explored. What is gleamed from this discussion is that the width and breadth with which the standards of care differ is immense. Many treatment centers have little to no regulation, and a staggering number of them engage in practices that are not only unorthodox, but unproven. This supports the
need for a more standardized system of regulating and monitoring such facilities. This chapter also provided a look at ethical frameworks for bioethical research. Ezekial Emanuel introduced an expanded version of previous principles and benchmarks to provide a more modern and extensive way to determine if human subjects research is ethical.\textsuperscript{17} Harm reduction principles as developed by Hawk, Coulter, Egan et. Al developed for clinical settings were also introduced as a possible method for including individuals with substance use disorder into human subjects research and providing a means by which they can participate on more egalitarian manner, with an emphasis on the need for stigma reduction.\textsuperscript{18} Through this analysis, it is clear that healthcare organizations and governmental agents need to assume greater responsibility as far as health outcomes for individuals with substance use disorders is concerned. Specifically, as moral agents, such entities have a moral and ethical obligation to develop evidence-based practices that are less punitive and reduce public harm. In this way, this dissertation uses public health ethics as a mechanism to advance normative methods to improve quality of care for this particular population, which in turn can affect the health, safety, and well-being of others as well.

Critics of methods such as harm reduction and decriminalization point out that doing so won’t allow people with a SUD to hit “rock bottom” and may inadvertently promote more drug use or overdoses.\textsuperscript{19} While the evidence on decriminalization may be scarce because few countries have done so, harm reduction is a practice that has been around for a while, albeit in different forms (such as the HIV/AIDS epidemic of the 1980s).\textsuperscript{20} Evidence from previous health crises point to its effectiveness, and while decriminalization is a newer concept, countries that have implemented laws that still
allow persecution of illegal drug activity but create a safer environment in which to obtain and use drugs of choice of shown reductions in the about of overdose deaths, as well as new users. While opponents point out the entrenched nature of punitive measures for substance use and misuse these are merely issues that need to be addressed when updating the healthcare and criminal justice systems—not reasons why such methods cannot succeed. A daunting task, but one that can be achieved if people in the public and in public service are willing to take the necessary measure to adopt and adapt. If anything, the opioid crisis and the amount of policy and procedural changes have come as result have shown us that this is something that can be achieved, if society agrees that there is a need to do so. Unfortunately, it often comes at the cost of human lives.


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