ABSTRACT

The United States Opioid Crisis: A Bioethical Review of Policy from

Two Perspectives with a Consideration of Opioid Use Among Pregnant Women

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The United States has experienced a public health crisis in which opioid use, dependency, and overdoses have led to social strain and economic loss, leading to a developing body of research that looks into how to address the issue. In this response, there have been developments in treatment methodology as well as policies enacted in attempts to ameliorate the effects of the crisis. This thesis provides a history of the opioid crisis and pain management perspectives, taking a particular look at the intersection of opioid use among pregnant women. What follows is a bioethical review of policy from two frameworks: principlism and Catholic bioethics. Principlism appeals to the bioethical principles of beneficence, non-maleficence, justice, and respect for autonomy. The Catholic bioethics framework uses concepts of participation in change and common good bioethics, as described by Catholic ethicist Lisa Sowle Cahill. The final part of this work weaves together considerations from both frameworks to set out ethical criteria that could shape future policy and research on opioids and pregnancy. These evaluative criteria are aimed at offering a positive proposal for future change, with special consideration of how to protect pregnant women experiencing opioid dependence.

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THE UNITED STATES OPIOID CRISIS: A BIOETHICAL REVIEW OF POLICY FROM TWO PERSPECTIVES WITH A CONSIDERATION OF OPIOID USE AMONG PREGNANT WOMEN

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began. I am also thankful for the Medical Humanities Program which has afforded me the opportunity to be in classroom spaces where we consider the intersections of medicine, faith, philosophy, and history. This program is where I found my calling and has inspired me to devote my life to attending to the spiritual needs of sick patients and their families. I am also thankful to Baylor University Honors College for stirring the minds of its students to ask, seek, and find in their pursuit of knowledge. Their support has been ever-present on this journey.

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INTRODUCTION

Chapter 1 begins this work with an exposition of the history of the American opioid crisis. The complicated nature of this public health crisis is illuminated as I detail the concurrent changes to opioids themselves, perspectives on pain management, and policy that mutually influenced each other (sometimes through luck and circumstance, other times through intentional decisions of agents involved). I also reserve space in this chapter to look at the intersection of opioid use and pregnant women. This vulnerable population will be of particular interest in this work, for it is undeniable that infants, fetuses, and pregnant women should be counted among the most vulnerable casualties in this epidemic, and so a focus on how policies have and will continue to affect them will help us be alive to important ethical considerations in health policy formation.

Chapter 2 then proceeds into bioethical analysis of policies regarding opioid use and their application to pregnant women. I start with an explanation of the principlism framework, as defined by Tom Beauchamp and James Childress in *Principles of Biomedical Ethics*. This framework appeals to the four principles: beneficence, nonmaleficence, distributive justice, and respect for autonomy. It is acknowledged that principlism has come up against heavy critique and it certainly has its downfalls. However, I argue that it also has under-discussed merits in application to the opioid crisis, which is demonstrated in my evaluation of certain policies and procedures and the ways in which they have violated ethical principles.

Chapter 3 is an appeal to Catholic bioethics for a second bioethical analysis of the same subject. This framework primarily differs from principlism in its consideration of

both individuals and communities, but also differs since it is derived from a religious worldview. I draw on the work of Catholic ethicist Lisa Sowle Cahill to lay out a framework of participation in change, consideration for community systems, and a common good ethic. Again, the bioethical framework is used to evaluate certain policies and procedures to highlight where ethical violations have occurred within opioid crisis responses, and to consider this in contrast with what it would look like to embody the values prioritized in Catholic social ethic when encountering pregnant women with opioid dependency.

Chapter 4 provides a brief set of ethical criteria to use in future development of policies. This positive proposal is aimed towards effecting positive change in a way that respects various ethical principles previously delineated in the work. The chapter does not aim to write any one particular *policy* for future change. In fact, I acknowledge that complicated nature of the opioid crisis means that one sweeping action or one cover-all policy will not be sufficient for addressing the issue. Rather, I aim to provide criteria for policymakers' consideration that can help newly formed policies come into alignment with ethical principles and protect the population that has served as the focus point of this work: pregnant opioid users.

CHAPTER ONE

History of the Opioid Crisis and the Intersection of Opioid Use Among Pregnant Women

To address the history of the United States opioid crisis necessitates that various aspects of the phenomenon are tackled in tandem. The concurrent pathways of drug evolution, pain evolution, and policy evolution all contribute to what was first declared by the U.S. government on October 26, 2017 as a "public health emergency" by Eric D. Hargan, the Secretary of the United States Department of Health and Human Services (HHS).[1] The determination was then renewed in April of 2019 by Secretary Alex M. Azar II and again in April of 2022 by Acting Secretary Xavier Becerra.[2,3] The nature of this crisis is that the changing of the drugs themselves has occurred alongside the changing culture regarding what pain is and what medicine's role may be for treating it. Policy has subsequently aimed to create innovative, timely, and appropriate solutions for the societal, governmental, and health-related issues that have arisen because of the opioid crisis, though existing interventions seem to lack sufficient power to tackle the situation.

Certainly, medicine has found ways to utilize opioids for their analgesic properties in ways that facilitate pain relief for patients who face pain due to illness, surgery, or treatments. Clinical practice guidelines aim to help clinicians provide

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[1] Department of Health and Human Services, "Determination That a Public Health Emergency Exists," October 26, 2017.

[2] Department of Health and Human Services, "Renewal of Determination That a Public Health Emergency Exists," April 15, 2019.

[3] Department of Health and Human Services, "Renewal of Determination That a Public Health Emergency Exists," April 1, 2022.

adequate pain care for those who may greatly benefit from opioids while effectively communicating about their benefits and risks.[4] In the realm of cancer pain, great strides are being made to ensure that cancer patients are receiving adequate pain relief while maintaining a sensitivity to the risk of opioid misuse in the present culture.[5,6,7] Opioids play an integral role in pain medicine and have allowed for incredible advancements to be made in restoring health to those whose pain interferes with many aspects of their lives, so their importance in the discipline of medicine is quite appreciable.

Still, we have seen a cultural trend towards aberrant usage of opioids and diversion of prescription drugs. Due to these cultural changes, the prescription and use of opioids has vastly changed in the United States from their original intended uses.[8] The result has been a crisis for which empirically informed and policy-based responses have been attempted.

In this chapter, I detail the recent history of opioid development, use, and policy governing use in order to set the stage for the evaluation of policies pertaining to opioid

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[4] Deborah Dowell et al. "CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022," *MMWR Recommendations and Reports* 71, no. 3 (2022): 1-95.

[5] Eric Goodlev et al. "Managing Cancer Pain, Monitoring for Cancer Recurrence, and Mitigating Risk of Opioid Use Disorders: A Team-Based, Interdisciplinary Approach to Cancer Survivorship," *Journal of Palliative Medicine* 22, no. 11 (2019): 1308-1317.

[6] Joseph Arthur and David Hui, "Safe Opioid Use: Management of Opioid-Related Adverse Effects and Aberrant Behaviors," *Hematology and Oncology Clinics of North America* 32, no. 3 (2018): 387-403.

[7] Sriram Yennurajalingam et al. "Predicting the Risk for Aberrant Opioid Use Behavior in Patients Receiving Outpatient Supportive Care Consultation at a Comprehensive Cancer Center," *Cancer* 124, no. 19 (2018): 3942-3949.

[8] Whereas opioids originally were specified for the relief of cancer pain, two studies in the 1980s led physicians to believe that opioids were not as addictive as they actually were. This caused a shift in the use of opioids for other purposes, such as for chronic noncancer pain. For more information on the historical context of this shift, see: Marcia Meldrum, "The Ongoing Opioid Prescription Epidemic: Historical Context," *American Journal of Public Health* 106, no. 8 (2016): 1365-1366.

use in pregnancy in chapters to come. Section I explains the evolution of the drugs themselves. The drugs were developed and are legally prescribed primarily as treatments for pain. Section II describes societal and cultural shifts in understanding pain and discusses how this shaped the use and prescription of opioids. Section III then lays out the history of policies developed to address opioid use in America. What emerges is a picture on which American ideals of pain have changed, while new drugs have been created and come with great harms, all while policy has evolved to attempt addressing key issues at many levels of the United States opioid crisis.

I. The Chemical Evolution of Opioids

Opioids are a class of drugs derived from the opium poppy, a flower that is known to have been around since the Neolithic Period and which diffused around Western Europe from 5600 to 4000 BCE and can now be grown in most regions of the world regardless of the environment.[9] Since their earliest appearances, opioids have been used for their analgesic and often euphoric properties, landing themselves a place in the spheres of medicine, culture, and religion. More than mere medicines, they have played a significant role in constructing the fabric of human life. In ancient Sumerian culture, historical accounts tell of opium's use being linked to religion and mysticism. Since it was long before a scientific understanding existed for how opium works to relieve pain, the use of the drug was understood to have roots in the spiritual realm, as it produced an ethereal euphoria not susceptible to scientific explanation for the Sumerians. Research on Sumerian writings even indicates that they may have used the Sumerian word for "joy"

[9] Aurélie Salavert et al. "Direct Dating Reveals the Early History of Opium Poppy in Western Europe," *Scientific Reports* 10, no. 1 (2020): 20263.

interchangeably as the word for "opium."[10] In China between the 15th and 18th centuries, opioid use found its way out of the imperial class and into the mainstream culture. This move of opium into commonplace culture came by the Chinese seafarers who brought opium along with them on their travels to and from Southeast Asia. "Opium dens" began to spring up as sites where patrons could buy and smoke opium, demonstrating its role in social and cultural life. Both tobacco and opium provided a recreational activity that people could come together to partake in. Opium dens were unfortunately also highly connected to the prostitution trade. The sale of sex and the sale of opium became one in the same in the institution of the opium dens.[11]

Thomas Sydenham, a pivotal figure in 17th century English medicine and colloquially known as 'The English Hippocrates,"[12] notoriously wrote that "among the remedies which it has pleased Almighty God to give man to relieve his sufferings, none is so universal and so efficacious as opium."[13] This *universal* and *efficacious* substance has been leveraged for its analgesic properties and has landed it a central place in the scientific laboratory.

Over time, opioids have been chemically modified in order to instantiate various properties for their use in medicine. The result is many broad classifications of opioids based on how they have been tinkered with. Examples include natural opiates, which are

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[10] Michael Brownstein, "A Brief History of Opiates, Opioids Peptides, and Opioid Receptors," *Proceedings of the National Academy of Sciences* 90, no. 12 (1993): 5391-5393.

[11] Yangwen Zheng, "The Social Life of Opium in China, 1483-1999," *Modern Asian Studies* 37, no. 1 (2003): 1-39.

[12] Kenneth Dewhurst, *Dr. Thomas Sydenham (1624-1689): His Life and Original Writings* (Berkeley and Los Angeles: University of California Press, 1966), vii.

[13] Sydenham quoted in: Howard Smith and Steven Passik, *Pain and Chemical Dependency* (New York: Oxford University Press, 2008), 3.

directly from the resin of the opium poppy; opium esters, which are often derivatives of morphine; semi-synthetic opioids, such as hydrocodone (Vicodin), oxycodone (often used in the form of OxyContin), and buprenorphine; fully synthetic opioids, such as fentanyl and tramadol; and endogenous opioid peptides which actually are produced naturally in small amounts in the human body.[14,15] These are all characterized by their ability to bind to various classes of opioid receptors in the nervous system, thereby allowing them to alter the pain response. They tend to work particularly well on the receptors of the brain and spinal cord.[16]

Some of this chemical evolution of opioids has occurred deliberately as scientists took to the laboratory, hypothesis in-hand, attempting to create new derivations of a drug.[17] Even then, discoveries have occurred that were not intended. In fact, the attempt to craft "the perfect opioid" resulted in one of the particularly disastrous moments in opioid evolution. While morphine had been used in patient pain management for decades, scientists wanted to look at it in new and innovative ways to attempt to make a morphine derivative that was just as effective, but non-addictive. In 1897, German chemist Felix Hoffman took up this initiative while on a short stent working for the Bayer Company.

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[14] "Opioids," *Johns Hopkins Medicine,* Accessed March 14, 2023, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/opioids.

[15] "Opioids: Commonly Used Terms," *Centers for Disease Control and Prevention*, January 26, 2021, https://www.cdc.gov/opioids/basics/terms.html.

[16] Ian Zagon, Michael Verderame, and Patricia McLaughlin, "The Biology of the Opioid Growth Factor Receptor (OGFr)," *Brain Research Reviews* 38, no. 3 (2002): 351-376.

[17] An example of an intentional hypothesis taken to the lab was the isolation of morphine by German pharmacist Friedrick Serturner. Serturner's understanding of opium pharmacology and the usefulness of its properties compelled him to isolate the morphine compound, which was "pure and therefore of predictable therapeutic action." For more on the development and influence of morphine, see: David Courtwright, *Forces of Habit: Drugs and the Making of the Modern World* (Harvard University Press, 2001), 36-39.

While his objective was to make non-addictive codeine from morphine, the result was an acetylated morphine compound that was actually extremely addictive and three times more potent than regular morphine. He had created heroin, a now illicit drug that has become one of the most commonly abused opioids of the modern age. Though the Bayer company had not been successful in their objective, they continued to commercialize the drug and trademarked it in 1895 under the name Heroin. It was promoted as a cough suppressant and a pain reliever in childbirth, though its users would soon come to find out that it would have one of the highest addiction rates of all drugs.[18,19]

Since then, heroin has been made illegal in the United States for it is widely accepted that it is so highly addictive and sufficiently dangerous that is should be banned.[20] Even with governmental control of substances, a secondary market certainly exists where drugs are illegally sold and circulated.[21] Heroin is still a substance in full force in America and is often sought after when a person fails to obtain a prescription for opioids. Efforts to curb opioid prescription in the 2010s actually contributed to a large

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[18] "Felix Hoffman," *Science History Institute,* December 8, 2017, https://www.sciencehistory.org/historical-profile/felix-hoffmann.

[19] "Felix Hoffmann, the Man Who Invented Aspirin and Heroin," *OpenMind BBVA,* February 8, 2021, https://www.bbvaopenmind.com/en/science/scientific-insights/felix-hoffmann-the-man-who-invented-aspirin-and-heroin.

[20] The Uniform Controlled Substances Act of 1990 promulgated a more uniform control of narcotics and dangerous substances. It promoted that "familiar substances such as heroin and cocaine" needed to be regulated as Schedule I drugs, implying that they have "high potential for abuse" and "no currently accepted medical use in treatment in the United States." The act acknowledged that "laboratories, both legal and illegal, work on discovering new drugs all the time" and that this necessitates a frequent re-evaluation of the drug schedules as more potentially dangerous drugs develop. For more on the Uniform Controlled Substances Act of 1990, see: Richard Braun, "Uniform Controlled Substances Act of 1990," *Campbell Law Review* 13, no. 3 (1991): 365-374.

[21] The Uniform Controlled Substances Act of 1990 also was "drafted with the goal of avoiding encumbrances on legitimate prescriptions, while preventing diversion into illegal markets of controlled substances which may be legitimately prescribed." See: Richard Braun, "Uniform Controlled Substances Act of 1990," *Campbell Law Review* 13, no. 3 (1991): 365-374, 368.

uptick in heroin-related deaths due to it being cheaper, more widely available, and more potent.[22]

Another change in the chemical evolution of opioids came with the creation of OxyContin, known often as "hillbilly heroin" in Appalachia in particular and rural America more generally. Though oxycodone was lab-created in the 1960s, it was first marketed by Purdue Pharma and approved by the FDA in 1995. By adding a time-release ingredient to the mix, OxyContin became a popular extended-release pain medication that rose to popularity in prescription medicine. With it came greater levels of addiction and higher frequency of overdosing. It is a drug that is often diverted, meaning that it often is prescribed to one person but then shared or sold to others, an act which is illegal in the United States. Though Prescription Monitoring Programs (PMPs) attempt to keep database records of opioid prescriptions across state lines, errors in reporting and categorizing the drugs correctly often result in the futility of this resource in flagging aberrant usage or diversion.

Today, a common phenomenon being witnessed is the illicit market for producing and selling fentanyl which is a fully synthetic opioid that is known to carry serious adverse effects. Unlike many other opioids that are prescribed and then diverted, the market for fentanyl is largely rooted in the illicit manufacturing of the substance.[23,24]

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[22] Lindsy Liu, Diana Pei, and Pela Soto, "History of the Opioid Epidemic: How Did We Get Here?" *Poison Control: National Capital Poison Center*, Accessed March 15, 2023, https://www.poison.org/articles/opioid-epidemic-history-and-prescribing-patterns-182.

[23] Ibid.

[24] Described as a "fentanyl outbreak," fentanyl has steadily become a new norm in the world of opioid use. The phenomenon of fentanyl-adulterated and -substituted heroin (FASH) describes the intersection of heroin and fentanyl use, describing as well how accessibility to fentanyl has altered what heroin use in the U.S. looks like. There is a correlation demonstrated between heroin overdose and availability of fentanyl. Synthetic opioid-related overdoses have been causing a large wave of U.S. drug-

While fentanyl is used in the medical sphere, the supply and demand dynamics of uncontrolled use have led to it being synthesized and sold illegally. Extremely potent, medically useful, and yet widely available and inexpensive, fentanyl has become a dangerous player in the opioid crisis. [25]

The variability of types of opioids available today creates a challenge when it comes to the medical understanding of each type. Doctors no longer are only concerned about how to taper someone off of morphine. They now must consider what to do with heroin, methadone, fentanyl, and oxycodone-addicted patients as well. They also face the challenge of understanding drug-to-drug interactions when a person is using opioids with other substances or is utilizing more than one type of opioid.

As opioids have chemically evolved, there have been some notable discoveries contributing to the treatment of addiction and overdosing which count as scientific discoveries regarding opioids, since many treatments constitute opioids themselves. Buprenorphine, methadone, and naloxone have all played a central role. Buprenorphine and methadone are themselves opioids, though they can be used to tandemly address pain and opioid withdrawal without the euphoric effects that are commonly a part of opioid use. By using methadone and buprenorphine as replacements for a patient's usual opioid,

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related deaths, though fentanyl-related deaths are rising across the globe. For more information about fentanyl and its role in the U.S. opioid supply, see: Daniel Ciccarone, "Fentanyl in the US Heroin Supply: A Rapidly Changing Risk Environment," *International Journal of Drug Policy*, no. 46 (2017): 107-111.

[25] Former Assistant Secretary for Health for the U.S. Department of HHS Dr. Brett Giroir discusses the dangers of synthetic opioids like fentanyl and carfentanyl, noting that while it is used in medical practice, the dosing is much smaller and is clinically managed. He cites the shocking statistic that the street value of 254 pounds of fentanyl, enough to kill 20% of the American population, is only $3.5 million. For his interview on the state of opioid abuse in America, see: "The Opioid Epidemic and Emerging Public Health Policy Priorities," October 31, 2019, in *Moving Medicine,* produced by the American Medical Association, podcast, https://www.ama-assn.org/delivering-care/overdose-epidemic/opioid-epidemic-and-emerging-public-health-policy-priorities.

patients can begin a journey towards detoxification from opioids entirely.[26] Naloxone has been another substance with great implications for treating opioid dependence. It is a substance used in emergency treatment of a known or suspected opioid overdose, reversing the actions of the opioids through its antagonistic properties. Marketed in nasal spray form as Narcan, naloxone can be rapidly administered and has shown remarkable success in reversing an overdose, landing is a central role in emergency medicine. Due to its utility in reversing opioid overdose, the FDA has approved it to be used over the counter and efforts have been made to make the drug more widely available for pharmacies and first responders.[27]

II. The Evolution of the Definition of Pain

To understand the use of opioids in medical practice in the 20th century especially, we need to appreciate the evolution of the conception of what opioids, when legally prescribed, are meant to treat: pain. Before the 19th century, pain itself was viewed as a an "existential phenomenon associated with aging" and a sign of one's vitality.[28,29] Though means to ameliorate pain have long been adapting and changing, it was not until

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[26] Repeated use and abuse of opioids only grows one's addiction to the euphoric effect. Therefore, buprenorphine offers a beneficial option for mediating these behaviors of addiction and dependence, allowing OUD patients to control their opioid use without risk of abuse. This deters illicit opioid use and facilitates "socially resilient and supportive environments" for opioid users. The causal link between euphoric effects, further addiction advance, and continued opioid use means that these replacement drugs can interrupt the causal chin and allow for eventual weaning. More information about the legislative response relating to buprenorphine can be found at: Mark Jones et al. "Government Legislation in Response to the Opioid Epidemic," *Current Pain and Headache Reports* 23, no. 43 (2019): 1-7.

[27] James Hodge et al. "Innovative Law and Policy Responses to the Opioid Crisis," *The Journal of Law, Medicine, and Ethics,* 47 (2019): 173-176.

[28] Mark Jones et al. "A Brief History of the Opioid Epidemic and Strategies for Pain Medicine," *Pain and Therapy*, no. 7 (2018): 13-21.

[29] Marcia Meldrum, "A Capsule History of Pain Management," *Journal of the American Medical Association* 290, no. 18 (2003): 2470-2475.

the 1990s that the United States healthcare system came to see so many of the changes that have contributed to what we today call the opioid crisis.

In 1995, Dr. James Campbell gave his presidential address to the American Pain Society describing pain as something that could be assessed as a vital sign. Similar to the way that a patient's blood pressure, heart rate, temperature, respirations, height, and weight are objectively recorded at each doctor's visit, information about a patient's pain could also be objectively collected and recorded.[30] This idea of pain as the "fifth vital sign" took root and soon enough, the Veterans Health Administration (VHA) was in support of the movement. The Joint Commission (TJC) came to endorse it as well and they subsequently developed a series of toolkits and to treat pain in a more standardized way.[31] Under the guise of the Hippocratic mandate to "do no harm" and the notion of pain as an objective vital sign, patients could report pain and expect their providers to respond in a rather consumeristic model of the patient-provider relationship. Even when they did not know how to respond appropriately, providers felt pressure to address pain adequately which meant that they turned to prescribing opioid medications as an "efficient response to their patient's vital sign."[32] As medical providers hoping to aid patients in their times of pain and suffering and to ease the pain when it was possible, this response made sense.[33]

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[30] James Campbell, "APS 1995 Presidential Address," November 12, 1995, Century Plaza Hotel, Los Angeles, CA, https://fbaum.unc.edu/teaching/articles/Campbell1996Pain.pdf.

[31] Natalia Morone and Debra Weiner, "Pain as the 5th Vital Sign: Exposing the Vital Need for Pain Education," *Clinical Therapeutics* 35, no. 11 (2013): 1728.

[32] Ibid., 1729.

[33] The Declaration of Montreal, a 2010 statement released by the International Association for the Study of Pain, maintained the moral duty of physicians to attend to the relief of suffering and pain. It affirmed that having access to pain treatment is a fundamental human right. See: International Pain Summit

At the same time, there was beginning to be a shift in the type of pain that opioids were being used for. Whereas providers had consistently and solely used opioids for malignant cancer pain, they began to use opioids as analgesics for non-malignant chronic pain. Descriptions of the medications themselves were changing and marketing played a key role in this shift. Before, the typical use of these medications was for the sort of patient who was experiencing pain due to chemotherapy for cancer treatment. However, pharmaceuticals began to market these drugs as viable options for patients experiencing either explainable or unexplainable chronic pain.[34] Today, we still see this general use for chronic pain, especially after injury or surgery. An example of this is seen in the docuseries "Dopesick" on Hulu in which a young girl working in the mines experiences a workplace injury. Set in the 1990s, it portrays the time period when OxyContin was first marketed. When she continues to feel chronic pain due to the accident, the doctor prescribes her OxyContin and when she becomes more and more addicted, she turns to heroin.[35] Prescription opioids like OxyContin were dishonestly marketed for this type of analgesic use, though opioids were not originally intended for this type of pain and no strong evidence had yet shown how opioids could be used for non-malignant pain.[36]

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of the International Association for the Study of Pain, "Declaration of Montreal: Declaration that Access to Pain Management is a Fundamental Human Right," *Journal of Pain and Palliative Care Pharmacotherapy* 25, no. 1 (2011): 29-31.

[34] Mark Jones et al. "A Brief History of the Opioid Epidemic and Strategies for Pain Medicine."

[35] Danny Strong, *Dopesick,* directed by Barry Levinson, Michael Cuesta, Patricia Riggen, and Danny Strong, (2021; Los Angeles: 20th Television), Hulu Miniseries.

[36] Art Van Zee, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy," *American Journal of Public Health* 99, no. 2 (2009):221-227.

In the years since TJC's endorsement of Pain as the Fifth Vital Sign, the influence of both the VHA and TJC has led to the commonplace nature of pain assessment in clinics and hospitals across the nation. Their toolkits, standards, and training guidelines made way for the "pain score" as a quality measure for inpatient pain assessment. However, the push for greater acknowledgement of pain by using the language of "vital sign" was defective in creating systems of "comprehensive pain evaluation, examination, and management."[37] Dr. Natalia Morone and Dr. Debra Weiner argue that the Pain as the Fifth Vital Sign movement "created provider awareness without preparedness" and "exposed serious deficits in provider education and training in pain assessment and management as patient's report of pain level has become commonplace in clinical practice."[38] They argue that the "piecemeal incorporation of pain topics" in medical education and the "deficit of clinical skills" for pain management led to the overreliance and overprescription of opioids for pain management.[39] They call for a more comprehensive look at pain that does not "box it into a vital sign," thereby diminishing its complexity.[40]

In short, accusations of improper pain management, the conceptualization of pain as the fifth vital sign, and the changing use of prescription opioids came together to create a nationwide phenomenon of increased prescribing of opioids for non-malignant chronic pain. In the moment, and with the inaccurate marketing schemes of big pharmaceuticals,

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[37] Natalia Morone and Debra Weiner, "Pain as the 5th Vital Sign: Exposing the Vital Need for Pain Education," 1731.

[38] Ibid., 1728.

[39] Ibid., 1729.

[40] Ibid., 1730.

medical professionals began to prescribe opioids more widely than ever before in what we now, in hindsight, describe as the phenomenon of over-prescribing.[41] What is notable is that there was not just an increase in the number of prescriptions for opioids, but also an increase in deaths by opioids. There was an almost fourfold increase of opioid deaths from 1999-2008 and opioid deaths continue to be on the rise, despite current initiatives and regulation on prescribing.[42]

Therein lies part of the nature of the problem. The increased nationwide dependency on opioids comes with harmful societal effects: increased crime, familial disruption, homelessness, abuse, and the most salient marker that we can empirically account for: death.

The CDC estimates that there are 136 fatal opioid overdoses each day in the United States, or about 49,000 deaths per year.[43] Crime rates are shown to be causally connected to opioid use because of the need to procure substance, the influence of intoxication, participation in illicit market activities, and victimization, where the opioid user becomes an "easy target" to potential offenders due to vulnerabilities conferred by intoxication.[44] It has been shown that opioid misuse during the opioid crisis has been treated more as a medical disease than other drug epidemics, allowing for a different response in the criminal justice system. The United States has attempted to prioritize "the

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[41] Marcia Meldrum, "Opioids' Long Shadow," *AMA Journal of Ethics* 22, no. 8 (2020): E729-734.

[42] Mark Jones et al. "A Brief History of the Opioid Epidemic and Strategies for Pain Medicine."

[43] Johanna Maclean et al., "The Opioid Crisis, Health, Healthcare, and Crime: A Review of Quasi-Experimental Economic Studies," *The Annals of the American Academy of Political and Social Science* 703, no. 1 (2022): 15.

[44] Ibid., 36-37.

provision of treatment rather than punitive measures or incarceration" but not all changes in the judicial system have relaxed the enforcement of drug crime.[45]

Opioid use has been shown to increase both violent and nonviolent crime, while the reduction of the supply of prescription opioids has been associated with decreasing violent crime.[46] Expansion of treatment availability has also been shown to decrease "violent and financially motivated crimes."[47]

Other social effects are being seen, such as the disruption of children's living situations. In areas of high opioid overdose rates, children are less likely to live with two married parents and are more likely to live with adults other than their parents. With children more likely to live with cohabitating unmarried parents, with a single parent, or with adults other than their parents, they become "disproportionately vulnerable to instability and material hardship."[48] It also has been demonstrated that foster care entries attributable to parental drug use increased by 147% from 2000 to 2017. While drug use related placements are not new to the foster care system, the rapid increase due to opioid use and opioid overdose was overwhelming to child welfare agencies.[49] While child removal can be necessary at times, given a particular family situation, removal is a

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[45] Ibid., 37.

[46] Ibid., 39-40.

[47] Ibid., 39.

[48] Monica Caudillo, Andres Villarreal, and Philip Cohen, "The Opioid Epidemic Has Disrupted Children's Living Arrangements," *Syracuse University Lerner Center Population Health Research Brief Series*, no. 95 (2023): 1-4.

[49] Jennifer Matjasko et al., "Strengthening Communities: A Qualitative Assessment of Opportunities for the Prevention of Adverse Childhood Experience in the Wake of the Opioid Crisis," *Journal of Child and Family Studies* 31, (2022): 1145-1157.

traumatic childhood experience which many drug-using adults actually cite as their own reason for initiating substance use.[50]

Homelessness has also been exacerbated by the opioid crisis. Since poverty and lack of affordable housing tend to drive homelessness, and evidence suggests that the opioid epidemic has only worsened these determinants, it seems that the opioid crisis continues to have negative effects through the increase of housing insecurity.[51] The connection between opioid use and homelessness seems to rest in the higher unemployment rates that those abusing opioids are more likely to face.[52]

This short compilation of data and facts regarding the social harms brought forth by the opioid crisis serves to briefly demonstrate how complicated and far-reaching the impacts of the opioid crisis truly are.

III. The Evolution of Opioid Policy

Since both opioids themselves and the national attitudes about pain management have changed, the United States has found itself facing a public health crisis. The United States has a long history of making reform and changes regarding substance abuse, and opioids have been no exception. A vast array of policies controlling the sale, marketing, and legality of opioids have arisen from the perceived need for governmental intervention in drug availability and use in America. Both the general public and the government sector have acknowledged that we need implementable policies and guidelines to regulate

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[50] Ibid.

[51] Andrew Sullivan and Changwe Park, "Do Federal Grants for Medication-Assisted Opioid Treatment Reduce Homelessness?," *The Annals of the American Academy of Political and Social Science* 703, no. 1 (2022): 285-302.

[52] Ibid.

and change how the United States government controls opioids. Here I provide a brief general history of United States policy regarding opioids.

In the early 20th century, America began to see an uptick in heroin manufacturing and usage which led to negative societal outcomes and it became apparent that there needed to be regulation on opioid use. As a response to increased illicit use of heroin and iatrogenic morphine, the United States 63rd Congress enacted the Harrison Narcotics Act of 1914, a federal law to address heroin and morphine dependence in America.[53] The goal of this act was to limit overall opiate use by regulating and taxing the production of opiates and coca products. It also governed the marketing and sale of narcotics so that it was illegal to use or possess narcotics without a prescription. The act required pharmacies and physicians to keep records of their prescriptions, leading to the avoidance of prescribing. Before the Harrison Narcotics Act, there was little to no record-keeping of who was using substances, what they were using, how much they were using, and how often they were using. This drive to start keeping prescription records for opioids was a step in the right direction. The goal was to discourage physicians and patients alike from relying too heavily on opioids and to keep what narcotic transactions were occurring within the "legitimate medical channels."[54]

The problem with the Harrison Narcotics Act was that, for all of its effort to decrease illicit drug use, the outcome was an increase in street drug use because of the inability to get prescriptions. This stimulated the black market for drugs and sparked the debate over "the legal and medical propriety of maintenance" therapy which "set in

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[53] Marcia Meldrum, "A Capsule History of Pain Management."

[54] David Courtwright, "Preventing and Treating Narcotic Addiction – A Century of Federal Drug Control," *The New England Journal of Medicine* 373, no. 22 (2015): 2095-2097.

motion a public health catastrophe by creating durable precedents against maintenance."[55] The Harrison Narcotics Act in conjunction with the Eighteenth Amendment created a prohibitory status on drug sales, thus criminalizing many of the actions of pharmacists, physicians, and drug users themselves.[56]

Still, throughout much of the 20th century, opioid-related death remained fairly low. It was certainly unlike how it is today. A report looking at long-term trends in deaths of despair demonstrated that drug-related deaths were on a long-run decline from the early 1900s through the 1960s, when illegal drug use increased. Drug-related deaths also increased in the 1980s due to the crack cocaine epidemic and then continued to skyrocket in the 2000s with the opioid crisis.[57] Even in recent history, the amount of opioid-related deaths per capita has continued to rise, from 33.3 deaths per million population in 2001 to 130.7 deaths per million population, a 345% increase overall.[58] Some of the drugs that are considered major players in the opioid crisis, such as oxycontin, heroin, and fentanyl were already around back then but did not play as large of a role as they do today. The reason that these opioids remained at low-level usage throughout most of the 20th century can be attributed to the hesitancy of physicians to prescribe them. The notion that they were still highly addictive and still meant for isolated cases of pain, such as cancer-

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[55] Ibid.

[56] Tarnell Brown, "From Harrison to Volstead: How Prohibition Laid the Foundation for the War on Drugs," *The Library of Economics and Liberty,* September 2, 2020, https://www.econlib.org/from-harrison-to-volstead-how-prohibition-laid-the-foundation-for-the-war-on-drugs/.

[57] United States Joint Economic Committee- Republicans, "Long-Term Trends in Deaths of Despair," *United States Congress Joint Economic Committee,* September 5, 2019, https://www.jec.senate.gov/public/index.cfm/republicans/2019/9/long-term-trends-in-deaths-of-despair.

[58] Tara Gomes et al., "The Burden of Opioid-Related Mortality in the United States," *Journal of the American Medical Association Network Open* 1, no. 2 (2018): 1-6.

related pain, deterred physicians from prescribing them more widely or outside of those contexts. The ramping up of prescription pain medication usage that has led to the crisis today can be attributed to the changing understanding of medicine's responsibility for pain management and the establishment of large pharmaceuticals who rapidly learned how to market their products with generation of revenue as their primary goal.[59,60,61]

Therefore, it took over a hundred years since the introduction of heroin to medical practice, eight decades after the Harrison Narcotics Act, five decades after oxycodone became available in the United States, and four decades after the invention of fentanyl for the opioid crisis to explode. The escalation was concurrent with conception of pain as the fifth vital sign, the call for physicians to better treat pain, and the introduction of inaccurately marketed drugs like OxyContin. Misinformation spreading through scientific journals downplayed the dangers and addictive properties of opioids. Based on two retrospective publications in the 1980s that said that there were low rates of addiction and misuse associated with opioids, the *Annals of Internal Medicine* published a paper in 1990 that stated that the "therapeutic use of opioid analgesics rarely results in addiction."[62] Though we now know this to be untrue, it was the basis for many physicians to increase opioid prescribing.

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[59] Mark Jones et al. "A Brief History of the Opioid Epidemic and Strategies for Pain Medicine."

[60] Jonathan Marks, "Lessons from Corporate Influence in the Opioid Epidemic: Toward a Norm of Separation." *Journal of Bioethical Inquiry* 17, no. 1 (2020): 173-189.

[61] Art Van Zee, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy."

[62] Quoted in, Mark Jones et al. "A Brief History of the Opioid Epidemic and Strategies for Pain Medicine."

Moving into the 21st century, the Drug Addiction Treatment Act of 2000 was the first act to be passed to address the issue of opioid dependence.[63] It was designed to increase access to medications that treat opioid dependence and, though it lacked much of the structure needed to be proactive in addressing Opioid Use Disorder (OUD), its goal to support those needing treatment for OUD was a worthy cause.[64] The FDA had not yet approved buprenorphine and naloxone, crucial medications for treating OUD and overdoses. Their approval came in 2002.[65]

However, again there were problems with enacting a law to address problems with opioids in the United States. TJC, in a response to the efforts of the VHA, published standards for pain management in medicine at about the same time as the Drug Addiction Treatment Act of 2000. These standards for pain management were stricter than ever before and called for quantitative pain assessment. Physicians felt pressure to comply with these standards; if pain was not being treated adequately in their clinics and hospitals, they ran the risk of having their federal funding pulled. Therefore, in an effort to better assess pain, these standards only pushed a more liberal prescription of opioids

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[63] United States 106th Congress, "H.R.2634 – Drug Addiction Treatment Act of 2000," July 27, 2000, https://www.congress.gov/bill/106th-congress/house-bill/2634.

[64] Opioid Use Disorder is defined by the Diagnostic and Statistic Manual of Mental Disorders, Fifth Edition (DSM-5) as a disorder that involves many behaviors related to the use and procurement of opioids. It may involve taking larger amounts of opioids or taking them for a longer time period than intended, unsuccessful efforts to control or restrain use, or continued use despite knowledge that there is a persistent physical or psychological problem that is likely to have caused abuse of the substance. The DSM-5 also includes criteria that describe how OUD can be diagnosed by social and psychological impact. If a great deal of time is spent procuring the opioids, use causes failure to fulfill major obligations in work, school, and home, or opioid use exacerbates or causes interpersonal problems, there may be reason to diagnose a patient with OUD. Exhibiting tolerance and/or withdrawal from opioids are also diagnostic criteria. For the complete list of DSM-5 Criteria for the diagnosis of OUD, see: American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders: DSM-5* (Arlington, VA: American Psychiatric Association, 2013), 541.

[65] Mark Jones et al. "A Brief History of the Opioid Epidemic and Strategies for Pain Medicine."

that would have unintended consequences in the coming years.[66] The Drug Addiction Treatment Act, therefore, had a difficult time curbing opioid addiction and death by increasing access to OUD medications since the phenomenon of overprescribing was occurring simultaneously.

Another attempt at increasing access to treatments for opioid dependence occurred in 2006 with the Reauthorization Act.[67] It outlined a structure of increasing the maximum allowable number of buprenorphine patients a physician could have, attempting to get more patients with opioid dependence on a replacement therapy. This greatly enhanced access to treatment for OUD patients.

While not explicitly enacted to address the opioid crisis in America, President Barack Obama's 2010 Affordable Care Act (ACA) had implications for opioid dependence prevention and treatment.[68] The ACA was designed to expand Medicaid to provide more comprehensive care for Americans who rely on government aid for medical care, with the hope of seeing an overall reduction in the number of uninsured patients in America. With its enactment, we witnessed an uptick in the treatment of OUD, especially using buprenorphine replacement therapy. A majority of these treatments were occurring in regions where OUD disproportionately affects the population, such as in rural Appalachia and in states like West Virginia. Still, due to the nature of Medicaid in

[66] This relationship between TJC's standards, physician's prescribing patterns, and the Drug Addiction Treatment Act is all described by Mark Jones (ibid.).

[67] Ibid.

[68] Ibid.

America and the ACA itself, the uptake of treatment was uneven, with substantial differences based on race, ethnicity, rural status, and diagnosed comorbidities.[69]

The potential for the ACA to put a dent in the progression of the opioid crisis was certainly possible but yet again, concurrent evolutions in how pain was understood continued to prevent the policy from making significant headway. The Declaration of Montreal (2010) by the International Association for the Study of Pain stated that relieving pain and suffering was a moral duty of physicians. It affirmed access to pain treatment as a fundamental human right.[70] While the promotion of pain relief and suffering relief as a duty of the physician was not inherently incorrect or unimportant, it propagated the pressure for physicians to rely on opioids as a method for pain relief and prescriptions continued to rise.[71]

Probably the most notable policy-related response to the opioid crisis was the Opioid Crisis Response Act (OCRA), which was passed in 2018. The design of this policy intended to bolster and distribute significant funding to prevent further explosion of the opioid crisis. It was intended to be implemented on federal, state, and local levels as a response to the 2017 declaration by the Secretary of the Department of HHS.[72]

Among its objectives were reducing opioid supplies, enhancing treatment and recovery services, protecting youth and their families, and developing opioid alternatives.

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[69] Brendan Saloner et al., "The Affordable Care Act in the Heart of the Opioid Crisis: Evidence from West Virginia," *Health Affairs (Project Hope)* 38, no. 4 (2019): 633-642.

[70] For more information about the Declaration of Montreal and the International Association for the Study of Pain, see Footnote 33.

[71] Mark Jones et al. "A Brief History of the Opioid Epidemic and Strategies for Pain Medicine."

[72] James Hodge, Chelsea Gulinson, and Drew Hensley, "The Opioid Crisis Response Act: Looking Ahead, Ignoring the Present," *Jurist Legal News & Commentary*, September 22, 2018, https://www.jurist.org/commentary/2018/09/james-hodge-opioid-responseact/.

This necessitated funding towards multiple goals and the strengthening of many different types of programs to meet them. This included law enforcement, drug disposal services, recovery centers, community programs, and research on new non-addictive pain management options.[73]

Though it aimed to invent and employ a timely response to the opioid crisis, OCRA arguably had many downfalls. Some argue that it was not immediate enough and did not target the true roots of the crisis. The goal seemed to be saving lives in the present moment which, though a worthy goal, did not reform any of the existing structures that continued to enable the crisis. It is argued that OCRA never had enough funding to begin with to be able to achieve it's intended goals and therefore, gravely failed at raising up systems to fight the opioid crisis at all.[74] A look into OCRA's (s2680) budget reports show that the proposed budgets did not properly align with actual spending, another downfall of OCRA's implementation.[75,76]

These various policies enacted to address aspects of drug usage and opioid dependence in America have all attempted to reduce the impact that opioids are having on society, but they have continually run up against problems and shortcomings. It seems mandated standards about what physicians must address with regards to patients' pain and conversations on moral obligations to treat pain have clouded some of the

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[73] Ibid.

[74] Ibid.

[75] Congressional Budget Office, "Congressional Budget Office Cost Estimate: S.2680 Opioid Crisis Response Act of 2018," July 11, 2018, https://www.cbo.gov/system/files?file=2018-07/s2680.pdf.

[76] Department of Health and Human Services (SAMHSA), "2021 Report to Congress on the State Opioid Response Grants," Accessed April 1, 2023, https://www.samhsa.gov/sites/default/files/2021-state-opioid-response-grants-report.pdf.

conversations on designing truly effective policies for the opioid crisis. Not only that, but the lack of funding and lack of implementable structure has caused their unsuccess.

IV. The Opioid Crisis: What's the Big Deal?

Societies and individuals all have problems and fail to achieve ideals of health and wellbeing. What is it about the opioid epidemic that is so concerning? What makes it special, if it is? Many proponents of recreational drug use or proponents of opioids for pain management argue that there is not a true problem at hand. I argue against these proponents, as there is something particularly troublesome about the explosion of opioid use, especially illicit use, in the United States. A comparison with another analgesic, ibuprofen, may help us understand the nature of this subject.

What if, instead of an opioid crisis, we had an explosion of ibuprofen usage across the United States? In this hypothetical situation, people would be taking this drug at much higher rates than we presently see. Sales would be up, though since it is an over-the-counter medication, there would not be such a thing as "illicit" use. Overall, we might see general improvement in pain management, patient satisfaction, and people's ability to maintain their quality and stability of life. How is this any different than the widespread use of opioids in our country? While we wish that these two situations, the real opioid epidemic and the hypothetical ibuprofen epidemic, were more comparable, they are simply not the same.

It is the addictive nature of opioids and the adverse social effects that we see from them that raise the red flag of concern. If everyone were taking ibuprofen at unprecedented rates, improving their overall pain control, allowing for the pain epidemic to concurrently be addressed, and without social structures suffering as they do with the

opioid crisis, the uptick in use and diversion would be *no big deal.* However, that is not how opioids work and that is not the nature of the opioid crisis. What we have on our hands is no uptick in ibuprofen usage; we have a real and pressing crisis in our country.

The adverse social effects caused by the opioid crisis in our country are shocking. Many studies show how damaging this problem has been to family life, the job market, and social and economic welfare. The mortality rates alone are disquieting. Opioid-involved overdose deaths have continued to rise: 21,089 in 2010, to 47,600 in 2017, to an alarming 80,411 in 2021.[77] Opioids specifically were the culprit for 75% of all drug-related death in America in 2021.[78] It is not just the number of users and deaths, though, that are problematic. While they are indicative of the how opioids affect the nation, these statistics alone do not always capture the social and economic impact due to the opioid crisis.

The U.S. Congress Joint Economic Committee (JEC) analyzed data about burden and loss due to the opioid crisis and determined that the opioid epidemic cost the United States nearly $1.5 trillion in 2020. This analysis used a methodology which considered costs for the persons experiencing OUD or opioid overdoses and the costs incurred by society, such as criminal justice costs. This economic toll of $1.5 trillion dollars reflects the healthcare costs, crime-related costs, lost productivity costs, and the valuation of quality of life and overall lives lost. It is another reminder of the multifaceted impact of

[77] “Drug Overdose Death Rates,” *National Institutes of Health- National Institute on Drug Abuse,* February 9, 2023, https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates, Figure 3.

[78] Ibid., Figures 1 and 3.

this epidemic on the United States.[79,80] From 1999 to 2015, opioid dependency caused labor force participation rates to decrease among prime-age males and females by 1.4 and 1.8 percentage points, respectively. Because of this change, in 2015 alone there were 2 million prime-age individuals in the United States who were absent from the labor force due to opioids.[81] This decline in the number of people in the labor force cost the economy over 27 billion work hours and $1.6 trillion in economic output over the course of 16 years (1999-2015).[82] This public health crisis has social and economic ramifications that run far deeper than we often see.

To answer the question, "What is the big deal about the opioid crisis?" we must consider the social impacts described above. Opioid use, while it has its place in appropriate pain management techniques in biomedicine, has impacts on American life that run deeper than just an increase in people taking a certain suite of medications. These impacts on society form the basis for the bioethical considerations that will follow in later chapters.

V. The Intersection of Use Among Pregnant Women

Because of the deleterious maternal and fetal effects shown to be caused by opioid use during pregnancy, the intersection of Opioid Use Disorder (OUD) and

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[79] United States Joint Economic Committee- Democrats, "The Economic Toll of the Opioid Crisis Reached Nearly $1.5 Trillion in 2020," *United States Congress Joint Economic Committee,* September 28, 2022, https://www.jec.senate.gov/public/index.cfm/democrats/issue-briefs?ID=CE55E977-B473-414F-8B88-53EB55EB7C7C.

[80] Curtis Florence, Feijun Luo, and Ketra Rice, "The Economic Burden of Opioid Use Disorder and Fatal Opioid Overdose in the United States, 2017," *Drug and Alcohol Dependence* 218, (2021): 1-7.

[81] Ben Gitis, "State-by-State: The Labor Force and Economic Effects of the Opioid Crisis," *American Action Forum*, September 12, 2018, https://www.americanactionforum.org/project/opioid-state-summary/.

[82] Ibid.

Substance Use Disorder (SUD) among pregnant women has become a particular area of interest for many scholars.[83] Centers for Disease Control (CDC) data shows that among the 13,365 deaths from opioid overdoses among women in 2016, 56% were women of reproductive-age.[84] While this fact alone says nothing about how the opioid crisis has been affecting pregnant women and their offspring, it highlights the reality of just how great of an impact opioid use *could* have on the population of women who may possibly become pregnant. While opioid use has certainly skyrocketed among many populations, it is particularly on the rise among reproductive-age women. The number of pregnant women with OUD presenting at the hospital for delivery quadrupled from 1999 to 2014.[85] As a result, a great deal of research has gone into understanding the relationship between pregnant women, opioid use, and short-term and long-term impacts on their children.

As the number of pregnant women with OUD has risen, so has the number of neonates diagnosed with Neonatal Opioid Withdrawal Syndrome (NOWS).[86] While the

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[83] Substance Use Disorder (SUD) is a broader umbrella term referring to unhealthy dependence on one or many various substances, including opioids. The general diagnostic criteria from the DSM-5 indicate that taking more of a substance than originally intended, or for a longer time than originally intended, with persistent or unsuccessful attempts to cut down and control use of the substance may well be indicators of SUD. It also includes the social and psychological impacts, such as failure to fulfill roles in home, school, and work, and interpersonal problems caused or exacerbated by use. SUD, when specified, can refer to dependence on opioids (OUD) but also includes disorders of using alcohol, inhalants, stimulants, cannabis, tobacco, and other substances. For more information on SUD diagnostics, and for the associated specific disorders, see: American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders: DSM-5.*

[84] Amalia Tobon, Erin Habecker, and Ariadna Forray, "Opioid Use in Pregnancy," *Current Psychiatry Reports* 21, no. 118 (2019): 1.

[85] Ibid., 1.

[86] Neonatal Opioid Withdrawal Syndrome (NOWS) and Neonatal Abstinence Syndrome (NAS) are often used interchangeably, or at least as similar terms. Both are describing withdrawal symptoms as they occur in newborns. Just as SUD describes a broader range of disorders that includes OUD, NAS describes the prenatal exposure and postnatal withdrawal from a variety of substances whereas NOWS is specifically describing prenatal exposure and postnatal withdrawal from opioids. While NAS implies maternal opioid use, it should be reserved for describing the clinical symptoms of the neonates experiencing substance withdrawal and not their mothers' experience. The symptoms for NAS can often

rate of NOWS diagnoses was at 1.2 per 1000 births in 2000, it rose to 20 per 1000 births by 2016.[87] Opioid use during pregnancy has been associated with a number of adverse outcomes, such as toxemia, third trimester bleeding, maternal mortality, and preterm birth, making it highly dangerous for the mother.[88] A nationwide sample showed that women with any sort of opioid use had a significant increase in the odds of an in-hospital maternal death compared to women with no opioid use.[89] A number of adverse effects are also observed in neonates, such as small, gestational age, low birthweight, reduced head circumference, sudden infant death syndrome (SIDS), and respiratory complications.[90] Maternal-fetal research has been challenging due to the confounding variables at stake, as well as the diversity of illicit and treatment drugs used, leading to mixed results on what the short-term and long-term impacts are on infants, children, and young adults who experience opioid exposure in utero. The effects of illicit opioid use versus treatment-related opioid use have been challenging to disentangle. Still, it seems that there are potential cognitive and motor effects, as well as impacts on development and vulnerability to future adversities for infants exposed to opioids during fetal development.[91]

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include tremors, seizures, overactive reflexes, excessive fussiness/inability to be consoled, breathing difficulties, diarrhea, temperature regulation problems, and nutritional difficulties. See: Prabhakar Kocherlakota, "Neonatal Abstinence Syndrome," *Pediatrics* 134, no. 2 (2014): e547-e561.

[87] Amalia Tobon, Erin Habecker, and Ariadna Forray, "Opioid Use in Pregnancy," 3.

[88] Ibid., 2.

[89] Ibid., 2.

[90] Ibid., 2.

[91] Ibid. 2-3.

Great strides have been made to look at what medical resources there are for assisting women experiencing OUD during pregnancy. Medication Assisted Treatment (MAT), where replacement opioids are given in a safe and monitored manner, remains the standard of care.[92] MAT is shown to lead to higher abstinence rates from illicit drugs as well as better treatment engagement rates.[93] Since using illicit drugs in relapse can be incredibly dangerous – risking exposure to bloodborne pathogens, soft tissue infections, and overdose death – it is easily understood that MAT is a highly preferable option. Debates continue over whether detoxification from opioids should be considered as a treatment option for pregnant women. However, discontinuing opioids while pregnant is highly dangerous due to the challenges associated with withdrawal on the developing fetus, making it ethically risky for clinicians to suggest a course of treatment that involves detoxing.[94]

In addition to MAT, which is a pharmacological treatment plan that allows use of safe opioids to prevent withdrawal or relapse, non-pharmacological interventions are also being researched for their effectiveness. One such approach, known as the Eat, Sleep, Console Model, encourages environmental variations, breastfeeding, soothing, and social techniques for NOWS babies in the NICU.[95] The results have been encouraging, showing

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[92] Medication-Assisted Treatment (MAT) is defined as "the use of medications in combination with counseling and behavioral therapies, which is effective in the treatment of opioid use disorders (OUD) and can help some people sustain recovery." Buprenorphine, methadone, and naltrexone are the three FDA-approved medications to be used as replacements in MAT but are shown to be most effective when used in conjunction with counseling and psychosocial support. MAT is not a one-time treatment, but a continual process that a patient engages in to move towards and sustain recovery. See: "Information About Medication-Assisted Treatment (MAT)," *U.S. Food and Drug Administration,* February 14, 2019, https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat.

[93] Amalia Tobon, Erin Habecker, and Ariadna Forray, "Opioid Use in Pregnancy," 5.

[94] Ibid., 5.

[95] Ibid., 3.

decreased hospital stays (average 22.4 days to 5.9 days), decreased infant morphine use, and decreased hospital costs.[96] Non-pharmacologic interventions can also help support the mother and infant socially, such as with breastfeeding which has been shown to decrease severity of NOWS symptoms and enhances attachment and immunity.[97]

It has also been identified that OUD during pregnancy is often happening concurrently with other challenges such as poor nutrition, inadequate prenatal care, poverty, other chronic medical problems, and domestic violence.[98] Ethical concerns arise when considering that these situations happen in conjunction with opioid use and that they impact access to treatment. Social stigma, violent relationships, lack of adequate childcare, and high rates of coexisting mental health issues can all raise existing barriers to seeking treatment in a successful manner.

Women-centered and multidisciplinary care has been the response to these concerns. The Substance Abuse and Mental Health Services Administration (SAMHSA) has advocated for psychosocial assessment and support plans in conjunction with MAT as the first-line defense.[99] Part of this response has used contingency management (CM) as a method "based on the principle of positive reinforcement," used to modify behavior in a "positive and supportive manner."[100] CM relies upon incentive structures like monetary vouchers, affecting the environment of autonomous choice. Perhaps violating

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[96] Ibid., 3.

[97] Ibid., 6.

[98] Ibid., 1.

[99] Ibid., 5.

[100] Ibid., 5.

bioethical principles surrounding the protection of free decision-making, it should still be noted that CM used as an attempt to improve birth weight in a group of women on MAT proved to be no more effective than the non-incentivized control group. Other studies have shown no benefit of either fixed or scaling incentives on abstinence and treatment retention rates.[101] Doing research on this vulnerable group can prove difficult, especially given concerns about violating the principle of equipoise and coercion.[102] Therefore, gathering more data through qualitative interviewing may be the most viable avenue to learning more about what in fact benefits this population.

The American College of Obstetricians and Gynecologists (ACOG), informed by research on opioid use disorder in pregnancy and speaking as the authority on standards for the profession, notes that the most important role an obstetrician-gynecologist (OBGYN) can play is to be a professional who recognizes substance abuse as it appears in their patient population and to act to intervene, getting the patient connected to appropriate resources. ACOG and SAMHSA identify the methodological approach to this role as "SBIRT: Screening, Brief Intervention, and Referral to Treatment." This is an evidence-based and community-based screening protocol to "identify, reduce, and prevent problematic use and dependence on alcohol and other substances." [103] Ultimately, the ACOG indicates that optimal care for pregnant women experiencing OUD is best achieved through the identification of their multi-faceted needs (medical needs, mental

[101] Ibid., 5.

[102] Benjamin Freedman, "Equipoise and the Ethics of Clinical Research," *New England Journal of Medicine* 317, no. 3 (1987): 141-145.

[103] "Committee Opinion No. 711: Opioid Use and Opioid Use Disorder in Pregnancy," *The American College of Obstetricians and Gynecologists,* (2017): 83, Box 1.

health conditions, social service needs, etc.) and making appropriate referrals to specialized multidisciplinary care.[104]

Identifying the intersection of opioid use and pregnant women as an area where ethical issues may arise, the American College of Obstetricians and Gynecologists (ACOG) put out a Committee Opinion to lay out an ethical framework for "optimizing care of patients with substance use disorder" and for "resolving common ethical dilemmas related to substance use disorder." [105] The Committee Opinion reads as a list of recommendations supported by appeals to the four principles, which will be addressed in Chapter 1. Recommendations include equitable routine screening for all people, ethical attitudes towards SUD patients, informed consent, and familiarity with legal requirements.[106]

Lastly, it should be acknowledged that specialized policies have arisen to determine how physicians should legally proceed with pregnant patients who are found to be using opioids, or opioid patients who are found to be pregnant. The ACOG's ethical guidelines for OBGYNs include the responsibility to be highly familiar with the legal requirements of his or her state or city, especially regarding reporting mandates.[107]

Two types of policies related to substance use in pregnancy have been identified in a study published on the effects of punitive and reporting state policies on rates of Neonatal Abstinence Syndrome (NAS). *Punitive policies* were identified as those which

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[104] Ibid., 83.

[105] "Committee Opinion No. 633: Alcohol Abuse and Other Substance Use Disorders: Ethical Issues in Obstetric and Gynecological Practice," *The American College of Obstetricians and Gynecologists,* (2015): 1529.

[106] Ibid., 1529-1530.

[107] Ibid., 1530.

"criminalize substance use during pregnancy, consider it grounds for civil commitment, or consider it child abuse or neglect." *Reporting policies* were identified as those which require reporting if prenatal substance use is suspected.[108] The study set out to see if there was an association between punitive and reporting policies and rates of NAS, which was determined to be a responsive variable that would indicate an increased or decreased rate of maternal opioid use.[109] The study found that "the odds of NAS among neonates living in states with punitive policies were significantly greater than among neonates in states without such policies but found no association of reporting policies with odds of NAS."[110] It concluded that punitive policies were associated with greater rates of NAS, indicating higher levels of maternal opioid use, likely because of the way that these policies discouraged women from seeking SUD treatment and prenatal care due to the criminalization of SUD while pregnant.[111] A policy which does the opposite of its intended goal (to reduce the effect of substance use on neonates) is not considered successful. The authors suggested that policy makers take note of the results of the study and focus on primary prevention through reporting policies rather than punitive policies as an ethical, effective, and appropriate approach to substance use among pregnant women.[112]

[108] Laura Faherty et al., "Association of Punitive and Reporting State Policies Related to Substance Use in Pregnancy with Rates of Neonatal Abstinence Syndrome," *Journal of the American Medical Association Network Open* 2, no. 11 (2019): 3.

[109] Ibid., 2.

[110] Ibid., 7.

[111] Ibid., 2.

[112] Ibid., 9.

This cross-section of opioid use and pregnant women is particularly troubling from a social-political and moral perspective, namely because of the direct adverse effects on unwilling others: the children involved.

V. Ethical Analysis

The rest of this work will be an ethical analysis of the current standards and policies regarding opioid use among pregnant women, with a consideration of how opioid use among this population leads to adverse societal effects.

In the case of ethics, it is accepted that what is legal is not always morally correct. This has held true in many situations, as in the case of slavery. What people believe and do also is not always normatively sound. While it is ideal that society would enact policies, laws, and regulations that are in accordance with normative ethics, it is not always so. It would take another (and very different) thesis to propose a model for policy that stands a chance of being corrective and pragmatically feasible in the present context. But before such work can be undertaken, it would be worthwhile to have in hand a set of ethical criteria along which we could evaluate policy models and specific proposals as better or worse – criteria that take seriously our history and details of the present situation.

From two perspectives on bioethics – principlism and Catholic bioethics – I will provide an ethical analysis of this subject and will conclude with some evaluative criteria to consider as we move forward addressing opioid use among pregnant women.

CHAPTER TWO

Bioethical Review from the Perspective of Principlism

I. Principlism

Tom Beauchamp and James Childress first penned *Principles of Biomedical Ethics* in response to the *Belmont Report* (1976) and the bioethical injustices that had been taking place in the sphere of American biomedical research on human subjects.[1] While their original work has undergone many updates and further editions of the text have been produced, the framework of principlism continues to rest on the four principles: beneficence, non-maleficence, respect for autonomy, and justice.[2] These principles were identified by the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* as guidelines for proceeding with human *research,* and not clinical practice directly, but they have come to be accepted in

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[1] The origins of the field of biomedical ethics are worth reading about. While more complicated that may be explained here, there was a great connection between injustice in biomedical research on human subjects and the academic development of the field by leaders such as James Childress, Tom Beauchamp, Albert Jonsen, and others. For a collection of chapters that explain the creation of the *Belmont Report* and its connection to the four biomedical principles, see: *Belmont Revisited: Ethical Principles for Research with Human Subjects,* ed. James Childress, Eric Meslin, and Harold Shapiro, (Washington, D.C.: Georgetown University Press, 2005).

[2] What is a principle? Beauchamp and Childress claim that principles are practical moral norms which serve as "starting points and general guides for the development of norms of appropriate conduct" and which should be supplemented with paradigm cases, data, experience, and other tools of judgement (2). While this may seem like a limitation to using the principles, this is no defect but rather a reminder that we must use discernment when applying such general guidelines to action and policy formation since "moral analysis is part of good policy formation, not merely a method for evaluating existing policy" (8).

Principles are general guides that offer substantive guidance in developing more specific rules and policies. They do not tell us definitively what we should do in any case or policy-making decision. However, they can help steer us into a wise and worthwhile direction. Whereas other moral theories depend upon nonoverridable rules, the principles are not unbending and may and must be specified and weighed in various circumstances. For more information on the place of principles, see: Tom Beauchamp and James Childress, *Principles of Biomedical Ethics,* Fifth Edition, (New York: Oxford University Press, 2001).

the clinical sphere of healthcare ethics. These principles were thought to be highly relevant, though not completely exhaustive, and were able to be utilized as a practical tool for conducting ethical research on humans.[3]

It should be acknowledged that the model of principlism as a way of doing bioethics is not perfect and has many limitations. Many have argued that the principles themselves are not sufficiently grounded and that principlism appeals to concepts that are not in themselves agreed upon. In other words, one might say "while I understand what respecting autonomy should look like, why am I to value the respect for autonomy as a principle to begin with?" Another limitation of principlism is that the principles themselves often come into conflict and there is no straightforward way to "order" or "balance" them. Even Beauchamp and Childress do not specify the prioritization of any one principle over another. In the case of weighing beneficence and non-maleficence, they assert that there is "no rule in ethics [favoring] avoiding harm over providing benefit in all circumstances."[4] It seems that we are left with principles that are often in unresolvable conflict and "lack any systematic relationship to each other."[5]

I agree that principlism has its downfalls. However, for the purposes of this chapter, the principles are sufficient for the bioethical analysis of opioid-related policy and its effects on pregnant women. An analysis of how these principles were applied or

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[3] Department of Health and Human Services, "The Belmont Report," April 18, 1979, https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report.

[4] Tom Beauchamp and James Childress, *Principles of Biomedical Ethics,* 115.

[5] The strongest critique of Beauchamp and Childress' concept of the four principles has come from K. Danner Clouser and Bernard Gert, who argue that the principles do not function as claimed and that their conflicts with one another are not only unavoidable, but also unresolvable. Clouser and Gert go as far to say that use of the principles is replaces any moral theories or rules that have been previously relied upon for dealing with moral problems in medicine. See: K. Danner Clouser and Bernard Gert, "A Critique of Principlism," *The Journal of Medicine and Philosophy* 15, no. 2 (1990): 219-236.

how they have fallen short still allows us to see some potential problems in policy and provides sufficient grounding for the claims that follow. Despite the critiques of principlism, they can be used here since the goal is deducing criteria for consideration (Chapter 4) through "specification" of each principle as it pertains to opioid policy.[6]

II. The Principles

It is important to first take inventory of what principlism entails. Principlism derives its moral grounding from appeals to a set of principles. There are four central principles of this model, though there may be more principles than just these four that we might consider when examining the extent to which policies and procedures are ethically permissible. The principles are as follows: respect for autonomy, beneficence, non-maleficence, and justice. Each of these principles must be defined in a particular manner, else we run into confusion about what one may mean when invoking some of these broad and multi-defined terms (i.e., "justice" could have a vast array of meanings with innumerable applications).

- **Respect for Autonomy**: said to be the most central of the four, this principle necessitates respect for people's intrinsic right to make choices for themselves. Medical practitioners and policies should respect the individual's claim to self-determination and the individual's right to have informed and rational information, whether or not the individual will consequently align with the choice

[6] "Specification" is a particular technique put forth by Henry Richardson for making "our general norms specific for a particular context or range of cases." Through this process, the abstract principles grow in content so that they are better able to guide action for particular cases. See: Tom Beauchamp and James Childress, *Principles of Biomedical Ethics,* 15-18.

that the provider or policymaker would make for them.[7, 8] From respect for autonomy, we derive the procedure of informed consent which includes information, comprehension, and voluntariness.[9]

- **Beneficence**: more than merely avoiding harm, this principle calls those providing healthcare to "treat persons autonomously" and "contribute to their welfare."[10] It is in beneficence that we find a positive obligation to do good unto others. It is the root of promoting welfare in biomedicine and healthcare. Generally, positive beneficence requires agents to provide benefits and follows these general rules: [11]
    - Protect and defend the rights of others
    - Prevent harm from occurring to others
    - Remove conditions that will cause harm to others
    - Help persons with disabilities
    - Rescue persons in danger
- **Nonmaleficence**: embodied by the Hippocratic promise to *do no harm*, this principle is rooted in the negative duty to not cause any undue suffering or pain. This includes the moral duty to not kill. It can be challenging to distinguish

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[7] Tom Beauchamp and James Childress, *Principles of Biomedical Ethics,* 57-58.

[8] Albert Jonsen, Mark Siegler, and William Winslade, *Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine* (New York: McGraw Hill Education, 2015), 49-50.

[9] Department of Health and Human Services, "The Belmont Report," April 18, 1979, https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report.

[10] Tom Beauchamp and James Childress, *Principles of Biomedical Ethics*, 166.

[11] Ibid., 167.

beneficence and nonmaleficence due to the intertwined relationship between doing good and avoiding harm.[12]

- **Justice**: often understood as *distributive justice,* this principle deals with the fair and unbiased allocation of resources, opportunities, services, and benefits.[13] It can particularly be of note for situations where disadvantaged people lack access to a medical good or a medical benefit simply because of their social status, race, economic profile, etc., which is distributively unjust.

III. Argument from Secularism and Pluralism

As I mentioned in the introduction, this thesis will evaluate current policy and offer suggestions for shaping future policy using two different frameworks: the principlism framework and the Catholic bioethical framework. While I expect the Catholic bioethical framework will have a great deal to say about social responsibility and religious obligation in ensuring ethically sound policies and systems, the principlist account is not built to issue judgments from the theological perspective and would be stretched to its limits to say something informative. So, we will put these issues to the side temporarily in this chapter.

This chapter addresses the bioethical review from the framework of principlism, so we must consider what this framework has to offer in light of the subject at hand. This framework will be an argument from secularism and pluralism. It must be acknowledged that the United States is an increasingly pluralistic nation. We require an ethical framework that prescinds from any particular faith, and principlism can serve that

[12] Ibid., 113-115.

[13] Ibid., 226.

purpose. It is what Bernard Gert, Charles Culver, and Danner Clouser would term a "common morality."[14] In their work entitled "Bioethics: A Systematic Approach" which aims to integrate moral philosophy into practical, clinical medicine, the three authors present a compelling case for this type of morality and promote the idea that a theory should express what the common folk believe.[15] This commonsense morality appeals to the pluralistic and multi-faith context in which the United States opioid crisis exists. Despite the controversial nature of medical decision-making and drug use in America, this is a "moral system implicitly used" and while it does not provide an answer to every moral problem, is a common ground from which we may operate.[16]

IV. Opioid Policy and the Principles

Respect for Autonomy

The requirement to respect autonomy cannot be met merely by ensuring that autonomous decision-making is preserved. It also includes attending to features of the environment that can erode people's capacity for making autonomous decisions. Preserving autonomy, under this view, then involves non-coercive environments and systems in which people are empowered and respected in their own choices. The autonomous environment embodies the acknowledgment of a "person's right to hold views, to make choices, and to take actions based on personal values and beliefs,"

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[14] Bernard Gert, Charles Culver, and K. Danner Clouser, *Bioethics: A Systematic Approach,* Second Edition, (New York: Oxford University Press, 2006), vii.

[15] Ibid., 22-23.

[16] Ibid., 22.

assurance of the person's understanding, and preservation of the person's voluntariness in acting.[17]

One situation in which a respect for autonomy has been compromised is in the way that policy has pigeonholed physicians into taking certain actions regarding prescribing opioids. Policies have arisen requiring physicians to meet certain guidelines in pain management. While it is important to have standards governing *what* is addressed when it comes to pain and *how*, these policies often had negative outcomes on how patients were treated. In particular, we can look at the push for "pain as a fifth vital sign" that resulted in increased prescribing of opioids in the 1990s due to physicians' fear that their federal funding would be withdrawn for not meeting pain management guidelines.[18] Physicians perceived that the uptick in prescribing was not proportional to the true need for opioids in their patient populations but regulations caused a change in how they chose to act. In this case, it appears that *both* patients and physicians lost out on the chance to make autonomous choices. System-wide pressures caused by policies to meet certain guidelines allow for autonomy to potentially be compromised.

Another area where the respect for autonomy can be forsaken is in incentive structures. If a policy incentivizes certain activities (even ones that we may deem as good), then consideration must be given as to whether or not it preserves people's right to self-determination. People may even act outside of what they truly want to do because there is an incentive on the table, or a sort of gain that they *need*. This manipulation then gets people to comply with policies and regulations without full autonomous choice

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[17] Tom Beauchamp and James Childress, *Principles of Biomedical Ethics*, 63-64.

[18] Natalia Morone and Debra Weiner, "Pain as the 5th Vital Sign: Exposing the Vital Need for Pain Education."

because when given “options,” they perceive the option attached to the incentive to be the only viable option.

A recent randomized clinical trial studied how financial incentives affected women with OUD and a high risk for unintended pregnancy in their choice to utilize contraceptives. One group received financial incentive to attend follow-up visits that included urine screening for pregnancy and ensured proper use of the contraceptive. The incentive was scaling, increasing at each consecutive follow-up visit. The participants received the money whether or not they had actually been following the birth control method properly. The study cites the increase in maternal opioid use and the subsequent increase in NAS as costly phenomena in which contraception among women with OUD and a high risk of unplanned pregnancy would help reduce the cost burden of these phenomena.[19]

This study and any system in which incentivization is employed require further consideration about respect for autonomy. This study seemed to not cross a line of adding undue pressure to get women to participate or comply. Since the goal was to make sure women had access to contraceptives and access to the proper information about how to use them by utilizing a follow-up appointment system, and since the women were compensated independent of their compliance, it seems that there was not undue influence. However, respect for autonomy always requires consideration about influence, coercion, manipulation, and nudging.[20]

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[19] Sarah Heil, Heidi Melbostad, and Alexis Matusiewicz, “Efficacy and Cost-Benefit of Onsite Contraceptive Services With and Without Incentives Among Women With Opioid Use Disorder at High Risk for Unintended Pregnancy,” *Journal of the American Medical Association Psychiatry* 78, no. 10 (2021): 1071-1078.

[20] “Nudging” is term proposed by Thaler and Sunstein, which they define as “any aspect of the choice architecture that alters people’s behaviors in a predictable way without forbidding any options or

Autonomy is not just about being informed and getting to make your own choice. It also relates to the *conditions* that surround the choice and the right to self-determination. Stigmatization is a condition that can surround policies and procedures and impede the respect for autonomy that is due to all patients. When a certain stigma is strengthened by a policy, we may see respect for autonomy for those populations of people beginning to diminish. For example, consider policies that villainize pregnant opioid users. In Minnesota, South Dakota, and Wisconsin, substance abuse during pregnancy is grounds for civil commitment. In seventeen other states, civil child welfare statutes consider substance abuse during pregnancy to be child abuse.[21] While there are certainly necessary steps that should be taken to help both mother and child in the event of opioid use during pregnancy, these states' policies facilitated greater stigmatization about unfit motherhood, pregnant drug users, and the relationship between opioids and mental health. The stigmatization, discrimination, and fear of punishment that arises from these types of policies engenders avoidance of healthcare and proper treatment, creating further barriers for an already vulnerable population.

To see the detrimental effects of stigmatization in medicine, consider the well-known phenomenon of describing patients as "non-compliant." Often, if a physician note

significantly changing their economic incentives" (6). Proponents of nudging argue that it utilizes human psychology only on the level of "shallow cognitive processes" and improves decision-making by changing the way that are options are presented but does not change the options themselves and therefore, can be used ethically in a way that preserves autonomy.

For Thaler and Sunstein's concept of "nudging," see: Richard Thaler and Cass Sunstein, *Nudge: Improving Decisions about Health, Wealth, and Happiness* (New Haven: Yale University Press, 2008).

For a clear explanation of arguments *for* and *against* nudging, see: Andreas Schmidt and Bart Engelen, "The Ethics of Nudging: An Overview," *Philosophy Compass* 15, no. 4 (2020): 1-13.

[21] Rebecca Stone, "Pregnant Women and Substance Use: Fear, Stigma, and Barriers to Care," *Health & Justice* 3, no. 2 (2015): 1-15.

about a patient uses this label, this has the effect of removing certain avenues for treatment or conversations about social determinants of health. This is an example of a way in which autonomy of opioid users may be violated, on the part of the physician who removes their agency through bias.[22]

Distributive Justice

In the context of the United States opioid crisis, distributive justice is one of the most violated bioethical principles with regards to funding, policy, and creating solution systems.

First, it should be acknowledged that the origins of the opioid crisis cast a shadow on current policies for treating opioid dependent patients from the perspective of justice. Current practices and policies can be traced back to practices of misleading marketing and incorrect information. While this itself was not inherently a violation of distributive justice, many of the consequences of the corrupt marketing schemes and misinformation led to practices that were unjust. Because the facts about many opioids were withheld, misrepresented, or completely lied about, people began to utilize drugs that were not appropriate for them, or which had side effects that they did not know about.[23] This practice was not fair and the corrupt marketing schemes did wrong by everyone who then utilized that product or unknowingly advocated for it. Moreover, this impacted various groups differently, leading to inequities in health outcomes. For example, United States

[22] For a simulation demonstrating the effects of labeling a patient as "non-compliant," see: Waseem Sous et al., "Use of a Simulated Patient Case and Structured Debrief to Explore Trainee Responses to a 'Non-Compliant Patient,'" *BMC Medical Education* 22, no. 842 (2022): 1-8.

[23] What is being referenced here is primarily Purdue Pharma's promotion and marketing of OxyContin. Marketing schemes purposefully misrepresented the addiction risks of oxycontin and encouraged physicians to increase prescriptions of the drug. See: Art Van Zee, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy."

military veterans and older adults were two vulnerable populations who were more affected by particular marketing messages.[24] Studies also show that areas with lower county median household incomes, higher unemployment rates, and less income inequality have been associated with higher dosages prescriptions and an overall higher total number of prescriptions of morphine than other areas.[25] The demographics impacted by the opioid crisis lead us to conclude that it is often vulnerable populations who are more likely to be impacted negatively.

As the opioid crisis began to explode in the 1990s and in the early 21st century, a whole collection of responsive policies was enacted as a way to address the crisis at hand. While they often promised funding and resources to be allocated to various programs, a comparative look at the proposed budgets versus the actual spending documents showed that there was great discrepancy between plans and their implementation. Not only that, but differences across state lines meant that states where the opioid crisis was causing the greatest damage were not privy to the resources or funding necessary to implement innovative solutions. If the intent of distributive justice is to preserve the fair allocation of a particular resource, opportunity, or service for those who need it, independent of extraneous factors, then the downfalls of opioid crisis response budgets seem to be a profound example of distributive justice being violated. Revisiting the Opioid Crisis Response Act (OCRA) of 2018 gives us an example of this. Hodge, Gulinson, and Hensley cite that OCRA's Congressional Budget Office report estimated that $8 billion

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[24] Hanna Yakubi, Brian Gac, and Dorie Apollonio, "Marketing Opioids to Veterans and Older Adults: A Content Analysis of Internal Industry Documents Released from *State of Oklahoma v. Purdue Pharma LP, et al*.," *Journal of Health Polities, Policy, and Law* 47, no. 4 (2022): 453-472.

[25] Chao Zhou, Ning Neil, and Jan Losby, "The Association Between Local Economic Conditions and Opioid Prescriptions Among Disabled Medicare Beneficiaries," *Medical Care* 56, no. 1 (2018): 62-68.

would be given to various federal agencies to carry out OCRA's plans. They then compare the $8 billion for opioid crisis efforts to the $26 billion spent annually on HIV/AIDS programs, and also point out that the opioid crisis caused $504 billion in economic costs (a 2015 estimate). They conclude that "the nation's worst public health crisis requires significant resources, not Congressional 'pocket change,' for public health prevention and response efforts."[26] Not only this, but the authors point out that imbalances exist with regards to *where* OCRA's funding was proposed to go. A considerable amount of the proposed budget was to be focused on non-treatment related endeavors such as drug courts and law enforcement which, while meaningful, can be thought of as an unjust distribution of funds that could better be used for further expansion of treatment availability.[27]

Beneficence & Nonmaleficence

While beneficence and non-maleficence are two separate principles, their interrelatedness allows us to consider them in tandem. When beneficence is violated, it is often due to a misperceived idea of a "good" that in effect, actually does not bring good or even brings harm.

There have been many policies that have had an initial intent of instilling positive change, aiming to do good for both communities and individuals facing the harms of opioid addiction. Unfortunately, many of these have had unintended consequences that

[26] James Hodge, Chelsea Gulinson, and Drew Hensley, "The Opioid Crisis Response Act: Looking Ahead, Ignoring the Present."

[27] Ibid.

have caused net harm. Policies that affect *access* to opioids or healthcare in general are of particular note when considering violations of beneficence and non-maleficence.

There is general consensus among healthcare professionals against punitive approaches for substance use in pregnancy which increase fear and discourage women from seeking prenatal care and addiction treatment care. Instead, professionals push for supportive policies which increase access to care and reduce barriers to care. However, many states have adopted laws which enforce punitive action on pregnant or postpartum women with substance use disorders. Not only do these laws seem to create a gap between principles and practices surrounding opioid users, they also disproportionately affect black women and women living in poverty.[28] Recommendations for respecting beneficence and upholding nonmaleficence include "comprehensive, coordinated, evidence-based, trauma-informed, family-centered care" rather than punishment and criminalization for pregnant and postpartum women struggling with substance use.[29]

It should be noted that there is a unique consideration for understanding beneficence and nonmaleficence as they relate to pregnant mothers. It seems that we *can* limit the actions or options for pregnant mothers to a certain extent because, unlike in other situations, the people who stand to be protected (the unborn) are different from those who are restricted (mothers). This sort of soft paternalism promotes that since those

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[28] Laura Faherty, Bradley Stein, and Mishka Terplan, "Consensus Guidelines and State Policies: The Gap Between Principle and Practice at the Intersection of Substance Use and Pregnancy," *American Journal of Obstetrics & Gynecology MFM* 2, no. 3 (2020): 3-4.

For particular article cited by Fahery, Stein, and Terplan which investigates the intersection of race, pregnancy, and opioids, see: Khiara Bridges, "Race, Pregnancy, and the Opioid Epidemic: White Privilege and the Criminalization of Opioid Use During Pregnancy," *Harvard Law Review* 133, no. 3 (2020): 770-851.

[29] Ibid., 4.

who require protection (unborn) are not voluntarily able to protect themselves. [30,31,32] However, these limitations all take place in the context of weighing beneficent and nonmaleficent outcomes. For example, while it may be appropriate to limit a pregnant woman with OUD by only recommending MAT as an option for treatment, since the option to detox would cause harm particularly to the fetus, it would not be appropriate to suggest abortion for women experiencing SUD. While these may seem like extremes, it demonstrates how medical benefit and harm must be considered when developing ethical approaches to treating women experiencing OUD.

V. Principlism and the Ethical Responsibilities of Obstetrician-Gynecologists

Interestingly, the professional ethical responsibilities of obstetrician-gynecologists (OBGYNs) for treating alcohol abuse and SUD in pregnant patients are based around the four-principle system described in this chapter. These ethical recommendations are put forth by the ACOG. [33]

Justice

The ACOG recommends routine screening "applied equally to all people, regardless of age, sex, race, ethnicity, or socioeconomic status." This can be through questionnaire screeners or conversation and not just through lab testing. They also echo

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[30] Gerald Dworkin, "Paternalism," *The Stanford Encyclopedia of Philosophy,* September 9, 2020, https://plato.stanford.edu/archives/fall2020/entries/paternalism/.

[31] Gerald Dworkin, "Paternalism," *The Monist* 56, no. 1 (1972): 64-84.

[32] Gillian Lockwood, "Pregnancy, Autonomy, and Paternalism," *Journal of Medical Ethics* 25, no. 6 (1999): 537-540.

[33] "Committee Opinion No. 633: Alcohol Abuse and Other Substance Use Disorders: Ethical Issues in Obstetric and Gynecological Practice."

the recommendation asserted previously that punitive measures should be avoided, as they disproportionately affect different patient populations. [34]

Respect for Autonomy

Maintaining the autonomous environment for pregnant SUD patients includes providing proper information. OBGYNs are expected to notify patients if a legal or medical obligation exists to test patients for SUD and make a reasonable effort to obtain informed consent. The ACOG upholds the value of the patient-provider relationship and expresses an ethical obligation to protect patient autonomy, confidentiality, and integrity within legal limits regarding disclosure of SUD, which is best accomplished by including only accurate and medically necessary information in each patient's medical record. Physicians should be very familiar with the legal requirements of their state or city regarding reporting mandates. [35]

Specific to the situation of pregnant women, there is an ethical responsibility to pregnant and parenting patients with SUD to discourage the separation of parents from their children solely based on substance use disorder, whether suspected or confirmed.[36]

Beneficence

OBGYNs are ethically obligated to treat their patients with dignity and respect, despite their struggles with substance use. This allows them to form a "therapeutic alliance" in which the OBGYN can act for the patients' good. OBGYNs also are

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[34] Ibid., 1531.

[35] Ibid., 1531.

[36] Ibid., 1533.

expected to familiarize themselves with the resources available locally and statewide so that they can increase patient access to helpful resources through appropriate referrals. [37]

Non-Maleficence

It would be unethical for OBGYNs to practice medicine under the influence themselves. They hold a responsibility to safeguard patients by seeking guidance from professional aid if they identify SUD within themselves or their colleagues.[38]

OBGYNs should also only follow current best practices for controlled medications. This is to avoid inadequate or inappropriate treatment of pain and to avoid the harms that arise from the misuse or diversion of prescription medications. [39]

Summary

Principlism stands out as a valuable framework for making assessments about the state of opioid-related policies and responses in a way that honors our pluralistic and secular American society. It is evident that many violations of the four principles have been made and our ethical criteria in chapter 4 may help us see how to avoid such mistakes in the future. The next section will provide analysis from a religious framework.

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[37] Ibid., 1530.

[38] Ibid., 1534.

[39] Ibid., 1532.

CHAPTER THREE

Bioethical Review from the Perspective of Catholic Bioethical Teaching

I. Moving from Principlism to a Theological Framework

Chapter 2 evaluated policies arising out of the opioid crisis from the framework of principlism, acknowledging both the potential shortcomings and the potential benefits of such a system. The feature of particular interest was that principlism proceeded from a pre-faith worldview, allowing a common ground to be found amidst the pluralistic and multi-faith society represented in the United States where agreement on bioethical issues can be challenging to achieve.

The goal of this chapter is to appeal to a theological bioethical framework to evaluate responses to the opioid crisis. In particular, this will depend upon a Catholic social ethics framework derived from two works of Lisa Sowle Cahill, a contemporary Catholic ethicist.

While we can reach some of the same conclusions about mid-level ethical claims without addressing theological bioethical principles, this framework distinctively offers grounds for a more comprehensive and deep critique of the current social situation regarding the opioid crisis and beginning of life. It propels us to consider a social ethic that stimulates an active response towards social change and promotes social wellbeing, and it prompts us to evaluate our culture and social systems not only in terms of the outcomes they produce but also in terms of the intentions they shape.[1]

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[1] Different philosophical models exist with vastly different functions, not all of which are appropriate for policy-development, allocation of funds, social justice reform, public health crises, etc. Each model brings its own advantages and disadvantages to the table. Here it is important to note that

II. Catholic Bioethics

Lisa Sowle Cahill has been researching and contributing to the field of Catholic ethics and bioethics for over forty years. Studying under the supervision of James Gustafson, an American theological ethicist, she works at the intersections of Catholic church teachings, sexuality and gender, and bioethics. The primary works that I will rely upon are her book *Theological Bioethics: Participation, Justice, and Change,* which outlines how bioethics in the Catholic sector is meant to be engaged with social justice and a desire to participate in positive change, and the 2004 Père Marquette Lecture in Theology entitled *Bioethics and the Common Good*, which provides insight as to what a creative and collaborative approach can mean for engaging in prudential actions that seek a common good for all people.[2,3]

While there are many prolific writers who have voiced their frameworks for approaching theological ethics, the Catholic Church itself has written extensively to make known its perspectives on these issues. Within the *Catechism of the Catholic Church*, believers are urged to do good, avoid evil, love God and love neighbor, and thereby live a moral life that bears witness to the dignity of others.[4] The teaching emphasizes that the acting agent can order his or her *intentions*, which matter greatly, and that all should be

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principlism is helpful for the context of our pluralistic American society. It allows for an appeal to broad principles that can be further specified for the topic of interest: the United States opioid crisis and opioid use among pregnant women. However, principlism has much less to say about social responsibility and what we own one another, which Cahill's work will be able to illuminate.

[2] Lisa S. Cahill, *Theological Bioethics: Participation, Justice, and Change* (Washington D.C.: Georgetown University Press, 2005).

[3] Lisa S. Cahill, *Bioethics and the Common Good* (Milwaukee: Marquette University Press, 2004).

[4] Catholic Church, *Catechism of the Catholic Church: Revised in Accordance with the Official Latin Text Promulgated by Pope John Paul II,* Second Edition, (Washington, D.C.: United States Conference of Catholic Bishops, 2016), para. 1706.

oriented towards the ultimate end of loving God.[5] For example, one might choose to give money to charity because their intentions were ordered towards the end of loving God. However, they could perform the same action of giving money to charity with the intention of receiving honor, favor, or acknowledgment for their philanthropic deed.

Even then, the *intention* alone of doing good does not make an action "good or just." [6] The *Catechism* conceptualizes "justice" as a moral virtue represented by a "constant and firm will to give their due to God and neighbor" and is given meaning in the Sacred Scriptures of the Holy Bible to include "right thinking" and "uprightness" of conduct towards one's neighbor.[7] The concept of "charity" is represented by a love of God for His own sake, as well as a love of others for the sake of the loving God.[8] Therefore, the theological virtues of justice and charity within the Catholic framework are understood to be social in nature because they involve a right relationship with both God and neighbor. This framework thus prompts us to look both inward and outward, and to acknowledge the complex relationship between those two dimensions of human life.

The Catholic bioethical framework that is derived from Catholic social thinking embodies participation, a care for charity and justice, and a desire for change, all centered upon aiming towards a common good. "Social justice" seems to be a concept that found its roots within the Catholic church, so it is fascinating to make connections to the contemporary setting. While a passion for social justice or a desire to participate in social change are often associated to the more politically liberal and less religious sectors of

[5] Catholic Church, *Catechism of the Catholic Church*, para. 1752.

[6] Ibid., para. 1753.

[7] Ibid., para. 1807.

[8] Ibid., para. 1821.

American society, Cahill's perspective stirs Christians of today to consider what it looks like to participate in societal (and even global) change. A theological bioethical framework that puts participation, justice, and change at the forefront invokes a new meaning on what it means to seek "Thy kingdom come, Thy will be done, on earth as it is in Heaven."

III. The Problem and the Solution: A Bioethics of the Common Good

Invited to give the 2004 Père Marquette Lecture in Theology, Cahill desired to revisit the 1973 and 1975 lectures given by two of her greatest theological mentors, James Gustafson (1975), who was her doctoral dissertation director, and Richard McCormick (1973).[9] In this lecture, *Bioethics and the Common Good*, Cahill set out to describe a Catholic bioethical framework which holds the common good as the guiding principle, therefore inspiring consideration of the communal whole rather than the individual alone.

Cahill writes that "the Catholic concept of the common good has always tied person and society together by insisting that the intrinsic sociality of persons demands their interdependence, communication, solidarity, and co-responsibility." [10] When considering how this practically plays out, it is important to note that this approach highlights the participation and decision-making role of *all* people within a group. This means that it incorporates preferential options for the poor[11], aims to meet basic needs of

[9] Cahill, *Bioethics and the Common Good,* 7.

[10] Ibid., 9.

[11] A "preferential option for the poor" is a specific term within liberation theology and Catholic social ethics. It involves the idea put forth in Old Testament law that the Christian faithful have an obligation to be mindful of the poor and to assist them. With the poor as a vulnerable group, the "preferential option for the poor" requires Christians to show preference for helping the "powerless

life, and attempts to eliminate illnesses which are avoidable in the present state of modern medicine.[12]

As predecessors to Cahill in the field of theological ethics, McCormick and Gustafson identified problems with the practicability of a common good morality: namely, proportionalism. Proportionalism is a theory that combines consequentialist and deontological theories to consider both *intent* and *consequence* of actions and implies that deciding to what extent we should respect the principle of the common good involves knowing if there is a proportionate reason to do so. While McCormick and Gustafson acknowledge that, even in the common good framework, "the needs and interests of some persons may have to be overridden in the process," they argue that within proportionalism it can still be challenging to balance the common good for many with the "value of *every* person to be affected by a decision."[13] Surely, this is the great problem of balancing the individual effects with the communal effects which plagues many moral theories.

Cahill's solution includes a conceptualization of the "good" that she believes helps in approaching this problem with proportionalism. The good should always aim at avoiding some greater evil, should allow self-preservation of the acting agent, and should aim towards loving one another even when it necessitates that the active agent will his

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individuals who live on the margins of society." This term derives its meaning from Matthew 25 in particular, where Jesus Christ associates himself with the poor and vulnerable and urges his followers to care for "the least of these." See: Kira Dault, "What is the Preferential Option for the Poor?," *U.S. Catholic*, January 22, 2015, https://uscatholic.org/articles/201501/what-is-the-preferential-option-for-the-poor/.

[12] Cahill, *Bioethics and the Common Good,* 9.

[13] Ibid., 17.

own self-sacrifice.[14] The corrective to proportionalism is not to weigh goods and evils against one another because, in fact, evils of some members of a group will impact the goods of other members of another group. In other words, we cannot parse out what to do by weighing individuals' goods and evils alone. Our communitarian nature makes this too complicated. We can consider individual goods and evils, but not apart from the individuals' relationships to the community.

Perhaps another issue to be faced in the practicability of a common good ethic is that of systems failures. A common good ethic necessarily requires a social system in which choices, policies, procedures, and practices can take place. In the application of a common good principle, we remember that "distorted structures and social practices can force even the virtuous agent to make choices that reflect the brokenness of the choice's social context."[15] This is exactly what will be discussed in subsequent sections as we assess how responses to the United States have taken place in structures that can so often "mediate brokenness and conflict."[16] Attempting to preserve the common good is a process that *takes place* in a "network of institutional and structural relationships" which come bearing their own "narratives, symbols, and meanings" that may in fact be antithetical to the common good.[17] While upright moral agents are certainly important, upright institutions and systems are just as important; it is through them that "we touch the good of distant others."[18]

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[14] Ibid., 18.

[15] Ibid., 24.

[16] Ibid., 24.

[17] Ibid., 26.

[18] Ibid., 26.

Cahill's common good ethic is dependent upon justice as a moral principle, but is justice conceptualized differently than in the framework of principlism. For Catholic teaching, justice is characteristically linked to subsidiarity and solidarity.[19] *Subsidiarity* is a political and social teaching of the Catholic church which maintains that "a community of a higher order should not interfere in the internal life of a community of a lower order, depriving the latter of its functions, but rather should support it in case of need and help to coordinate its activity with the activities of the rest of society, always with a view to the common good."[20] It calls for an appropriate stratification of power sharing.[21] *Subsidiarity* does not negate the importance of larger structures such as the federal government but rather adheres to the cooperative responsibility that *both* local units of society and larger associations, such as the federal government, hold in aiming for the good of communities. The federal government, in this approach, acts as a higher authority with the duty to "right imbalances in local preferences and practices but not to dictate undue top-down approaches to all smaller, local units."[22] The second component of justice is *solidarity*. This is defined as a "firm and preserving determination to commit oneself to the common good" and is the social analogue to charity. [23] This commitment is aimed towards preserving the dignity and good of *both* the individual and the community, which are inseparable from one another.[24]

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[19] Ibid., 59.

[20] Catholic Church, *Catechism of the Catholic Church*, para. 1883.

[21] Cahill, *Bioethics and the Common Good,* 60.

[22] Ibid., 47.

[23] Ibid., 60.

[24] Ibid., 57.

Ultimately, Cahill notes that "this process, even if undertaken collaboratively and in good faith, can never completely eliminate the reality that some *moral conflicts* cannot be resolved in such a way that the good of all persons and the common good are commensurately served, or kept in balance."[25] What, then, do we do in this situation? Primarily, we acknowledge that these moral conflicts arise in and must be solved in their particular contexts. We acknowledge that the ranges of questions arising in policy formation are best addressed with "middle-level thinking" and a concern for the principles of distributive justice, solidarity, subsidiarity, and a preferential option for the poor.[26] Lastly, while it may be an unsatisfactory proposal to some, we acknowledge that sometimes moral conflicts may occur that are simply too complicated for the envisioned common good approach. In attempting to satisfy obligations to the good of both individuals and of social systems, we may have to settle for a solution "analogous to the good we truly desire."[27] We may do well to heed this advice when it comes to approaching policy formation related to the opioid crisis, acknowledging that it may not be possible to achieve a truly *ideal* approach but that we might still be able to pursue analogous goods. In doing so, we move towards a creative, collaborative, and prudential approach to realizing humanity's common good, with a vision for God as the ultimate good of all.[28]

[25] Ibid., 64.

[26] Ibid., 65-66.

[27] Ibid., 66.

[28] Ibid., 77.

IV. The Perspective: Participation, Justice, and Change

The second work of interest by Cahill is a work called *Theological Bioethics: Participation, Justice, and Change* which elucidates the perspective that Catholic thought takes on the participatory and public nature of bioethics. In the introduction to her work, she cites Catholic theologian and contributor to the Second Vatican Council, Edward Schillenbeeckx, who said that "On the basis of Jesus' message, parables, and his praxis of the reign of God, we see how the biblical concept of God is essentially bound up with a praxis of persons who liberate their fellow human beings, just as Jesus did before us."[29] To care about justice and liberation is not a passive application of church doctrine, but rather is an affirmation of the incarnation of God in Christ as representative of His identification with "the poor, oppressed, and finally executed innocent individual."[30] In other words, Schillebeeckx speaks of a faith tradition that is enlivened to be active in change because of the example set forth in Jesus Christ. With its "commitments to the dignity of persons, common good, and subsidiarity," Catholic social teaching provides a normative stance that is not only "morally desirable" but is also possible.[31]

Cahill's perspective of *participation, justice, and change* is again a framework that is contextually dependent and meant to be applied to whole social systems, reminding us that "individual bioethical decisions cannot be and never have been separated from social ethics."[32] No matter what theological or philosophical perspective one takes, a look at the current state of affairs with regards to healthcare access in the

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[29] Cahill, *Theological Bioethics: Participation, Justice, and Change*, 2.

[30] Ibid., 2.

[31] Ibid., 4.

[32] Ibid., 3.

United States is enough to remind us that we are a part of systems in which the conditions need radical change.[33] A system which calls life-saving measures for the poor "extraordinary" but not for the rich is one which must be assessed for virtue and value flaws.[34] These questions of distributive justice, healthcare access, and social reform are extremely important in the consideration of the disproportionate effects of the opioid crisis on regions of varying socioeconomic status.

A potential critique of using Catholic social ethics is that it proceeds from a Christian worldview, a belief system which not everyone in the United States holds fast to. I have alluded to the notion that we can rely upon the tenets of frameworks because of the moral values that they promote (common good, subsidiarity, a care for the poor, etc.) without affirming some of the premises that they are derived from (the incarnation of Christ, the validity of the Biblical text, the sovereignty of God, etc.). Cahill proposes that the *participatory* bioethics she is describing is one that "operates simultaneously in many spheres of discourse and activity, from which it is possible to affect the social relationships and institutions that govern healthcare."[35] Even in the pluralistic state of American public discourse, Cahill's *participatory* bioethics can be "conservative or progressive, right or left, pro-life or pro-choice, market oriented or social-welfare oriented, or some combination of any of these."[36]

Again, Cahill visits the concept of *subsidiarity* which describes a model for participation in theological ethics. This principle, developed in multiple papal texts,

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[33] Ibid., 133.

[34] Ibid., 120.

[35] Ibid., 24.

[36] Ibid., 24.

defines a “reciprocal relationship between higher and lower organizations and their governments” and involves intervention of governing authorities “when necessary for the common good.”[37] It calls for an evaluation of the political arrangements represented within society and consideration of their adequacy for different social concepts. When appealing to it properly, the principle of subsidiarity governs the appropriate expansion and contraction of power at various levels of government in order to foster the common good. I will later show how democratic critique often challenges the principle of subsidiarity. However, Cahill affirms that the two are not necessarily at odds and that “the idea of participatory democracy provides an essential complement to the theory of deliberative democracy” since it attempts to make progress through “instigating social change from the bottom up and by explicitly involving worldview claims.”[38]

Next, I will consider how Cahill’s theological bioethics of participation, justice, and change in the context of aiming towards the common good is reasonably applied to policy and systems surrounding the United States opioid crisis.

V. Theological Bioethics and the Opioid Crisis

i. The United States as a Democratic Republic

A key feature of applying the framework I just discussed to the opioid crisis is matching the political structure we have to an appropriate response for the crisis. The principle of subsidiarity and commitment to political inclusion both independently support a participatory ethic: the people who should take care of the community should be those who are in the community. The leaders of communities are ideally coming from

[37] Ibid., 45.

[38] Ibid., 51.

those communities, representing the voices of peoples in those communities, who demonstrate political prudence and have knowledge about local resources, equipping them to be the most fitting advocates for community-level change.

If we affirm that the opioid crisis is a phenomenon with impacts that are characteristically different from one community to the next, it makes sense that we would affirm that the greatest lever for change is to address the crisis at the community level, factoring in federal intervention when fitting and necessary to attain the common good.

The opioid crisis has certainly been a nationwide phenomenon, but regional variation should be acknowledged.[39] There have been disproportionately high prescribing rates identified in counties in Appalachia and in southern and western states. Studies have also shown that *smaller* urban, suburban, and rural cities tend to have higher rates of abuse of prescription opioids. Differences were observed with respect to gender in rural and urban areas. In rural settings, opioid abuse and dependence affected males more than females for every age group observed. However, in urban settings, females aged 13-18 experienced a much greater rate of opioid abuse and dependence than males aged 13-18. It seems that regional differences are especially distinct when comparing rural and urban settings in America. However, mere population size has not been shown to be a good indicator of a city's opioid problem, since certain large cities are less affected than others while certain small cities have been greatly impacted by opioid abuse while others remain relatively unaffected.

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[39] FAIR Health Inc., "Peeling Back the Curtain on Regional Variation in the Opioid Crisis: Spotlight on Five Key Urban Centers and Their Respective States," *Health Policy and Services Research,* (2017): 1-28.

Fascinatingly enough, recent studies show that there is even regional variation in the frequency and manner in which opioid-related deaths are talked about on the news and social media. Since both the news and social media can contribute heavily to public perception and attitudes, this variation is quite interesting. [40, 41]

These regional variations can be challenging to address given the democratic republic structure of the United States government. Dilution and distortion of public opinion happens as you scale up a republican democracy, a well-known critique of the political theory itself.[42,43] It makes for less inclusion of the community level. This is exactly what Cahill implies when discussing the principle of *subsidiarity.* What is needed is a re-ordering or a re-orientation of the levels of influence in the United States to be able to more powerfully affect change.

What the opioid crisis looks like in different regions is inherently different, and therefore both the *allocation* of funds and *how* money is used should display regional differences. Presently, much of the approach has been to work out federal policies that are pushed onto all of the states, even though the opioid crisis looks different from state to state. Attempting to bring the entire issue under one set of federal guidelines has proven to be unsuccessful. A prior look at budget reports versus actual spending

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[40] Yulin Hswen et al., "Evaluation of Volume of News Reporting and Opioid-Related Deaths in the United States: Comparative Analysis Study of Geographic and Socioeconomic Differences," *Journal of Medical Internet Research* 22, no. 7 (2020): 1-8.

[41] Lidia Flores and Sean Young, "Regional Variation in Discussion of Opioids on Social Media," *Journal of Addictive Diseases* 39, no. 3 (2021): 316-321.

[42] James Madison's *Federalist No. 10* considers some of these critiques of the democratic republic theory, noting how to manage majority versus minority opinions, protection against factions, and the impact of wealth on matters of public interest. To read the entire work, see: James Madison, *Federalist* No. 10, in *The Federalist Papers,* ed. Clinton Rossiter (New York: New American Library, 1961), 77-84.

[43] Will Friedman, "Deliberative Democracy and the Problem of Scope," *Journal of Public Deliberation* 2, no. 1 (2006): 1-31.

demonstrated that there has been poor proportioning of funds (budget proposals) and poor usage of funds (actual spending reports) that have violated ethical principles. While the nature of the American government system is that certain powers are held by the federal government while others a reserved to states and cities, the concept of subsidiarity implies that there should be change effected at the proper levels of society. The nature of the opioid crisis suggests that the community level is the most appropriate level for this particular issue.

ii. Avoiding Top-Down Policy Formation

Social responsibility gets diluted with top-down policies. If the policies are such that they cannot be implemented given the resources and capital of localities, then that are not going to do the social good that they are aimed to do.

While the Catholic theological bioethics framework is inherently communitarian in nature, it does still maintain a great deal of responsibility for the individual to act within his or her society. When imagining what this means for reform of health-related phenomena, such as the opioid crisis, Cahill reminds us that all spheres of influence must be firing on all cylinders: "Reform of the healthcare system requires the cooperative action of state and federal governments and legislation, civil society and local organizations, and the individual commitment of every citizen and voter."[44]

Cahill's idea represents a more nuanced relationship that takes place between individuals and groups. The intentional individual actions afforded by a culture and social system are implicated – there is a complex, dynamic, interrelated network of social institutions like the AMA and ACOG, hospital networks, individual hospitals, and

[44] Cahill, *Bioethics and the Common Good,* 47.

clinics, on the one hand, and individuals who comprise them on the other. These mutually influence and shape each other. This relationship of individuals to larger systems can be violated in terms of seeking a common good. For example, if I am a physician in a hospital system where pharmaceutical company representatives are allowed to incentivize certain actions, that will change the kind of intentional choices I make (ex: incentives for prescribing certain medications, offering specific treatment options, resources, etc.). Another example arises if I am a physician practicing medicine in a state which prosecutes opioid users who are pregnant. This state-level policy impacts my intentional individual choices, and I cannot act well in treating my pregnant opioid-using patients. It seems that my moral responsibilities are affected by the social-political context.

This complicated interrelatedness of the individual and the group can make it hard to discern *how* policies should be developed, *who* they should aim to effect, and *what* they should require of different levels of society. I believe that Cahill's common good ethics and concept of participation in change both imply favoring *bottom-up* policy formation rather than *top-down* policy formation.

This means that a policy not crafted with the input of actual pregnant mothers would be a violation of ethical requirements on the social ethic framework presented by Cahill and others. Pregnant women are already a vulnerable population, before even considering opioid dependence. The unborn are also paradigmatically vulnerable as a group. The participatory bioethics promoted by Cahill and the Christian commission to "care for the least of these" both necessitate care for the well-being of the most vulnerable to be prioritized and protected. The way that the opioid crisis has affected not only pregnant women, but other vulnerable populations, means that one-size-fits-all

policies have largely been ineffective. Not only that, but our lack of attention to these populations is a sort of “norming” that involves crafting policies that inherently leave our or exclude those who fall outside of the norm. This attempt to apply one sweeping policy that will effect change has consistently run up against regional and demographic variation of the opioid crisis. A bottom-up approach which involves the participation of those most affected at the community level seems to be preferable.

iii. Realism About Policy Formation

Lastly, Cahill’s Catholic bioethics framework is helpful insofar that it is realistic about the limitations of policy formation. The most ideal resolution is to find a plan which will bring about an end to this crisis, but there is no one policy or plan which will do that. That is not realistic. Hoping to do so places us in a moral quandary about what we are able to do to help those in need and about how to be effective in change. Rather, what we might have to settle for is small, yet effective, calculated steps in the right direction. These steps, if thought out critically, will do some good and contribute to the overall greater common good that we so greatly desire.

Cahill uses phrasing that refers to accepting a good that is “analogous” to the one we truly desire.[45] If not a complete resolution to the opioid crisis, there must be some sort of intermediate good we could accept. However, a problem arises when considering how we would measure whether or not small steps of change are positive ones. It also would be challenging to assess whether these small steps are contributing on the whole to the larger goal.

[45] Cahill, *Bioethics and the Common Good,* 66.

The challenge remains in determining what constitutes an *effective* small, calculated step. However, based on this framework of a common good and participation in change, it seems that there are certain things that should definitively be prohibited. For example, if a small portion of wealthy people (perhaps physicians specifically) are the only ones able to put in their input on policy, or they are the ones in charge of allocating funds earmarked for opioid crisis related resources and programs, this cannot be a right step forward. While they may decide to do something "good" with the influence that they possess, they violate ethical requirements of transparency and justice for those most affected to be involved in decision-making. So, while it may achieve more subsidiarity than before, it still may be impermissible and an indicator of *improper* small steps.

To evaluate whether a small, calculated step is actually being effective in moving towards a goal, we also must know what dimensions of value we can evaluate a policy on in the first place. We might look at who is participating, how it loops in vulnerable populations and seeks their input in evoking change, how it improves subsidiarity (how it moves influence between different levels of government/society), etc. These all might be helpful markers for evaluating effectiveness through means which are not simply empirical.

We are still left with a challenge in coordinating all of the analogous goods and small steps into a move towards the common good. It also does not perfectly help us know which things to prioritize first (ex: should we address issues of subsidiarity or justice or short-term health benefits first?). However, these are matters of prudence.

The last chapter will lay out some further ethical criteria to consider which may help in this issue.

CHAPTER FOUR

A Positive Proposal: Considerations for Future Development

Hopefully, the sum of this work thus far has demonstrated that there have been grave bioethical violations in the past regarding opioid crisis related policy and procedures. It is a worthwhile project to move forward in such a way that avoids further violations, and which attempts to find more innovative solutions to this public health emergency. While the opioid crisis is an issue that will not be remedied by any one policy or by one sweeping action, it can be changed in ways that it has not been changed before if we were to take some different steps than the ones we have taken before.

This last chapter aims to delineate a set of criteria that may be considered when proposing new policies or plans. I make no attempt to write a policy myself, for that is both outside of the scope of my expertise and too complicated to propose here. However, the history of the opioid crisis (Chapter 1), evaluation from the framework of principlism (Chapter 2), and the evaluation from the framework of Catholic bioethics (Chapter 3) have all provided sufficient information to be able to synthesize a set of evaluative criteria to use when developing new policies that help avoid the ethical violations of the past. These criteria are aimed at offering a positive proposal for future change, with special consideration of how to protect pregnant women experiencing opioid dependence. A potential benefit of centralizing these criteria, even though they are derived from two different ethical frameworks, is that they allow us to better able to consider best outcomes for many different stakeholders involved, whether it is policymakers, physicians,

pregnant opioid users, others requiring treatment for OUD and NAS, or even the general public.

Evaluative Criteria for Future Development

i. Consideration of Proposed Policy Versus Real Implementation

An ideal policy regarding solutions to the opioid crisis will consider the difference between how it is proposed and accepted and how it will be carried out in reality. There is often a difference between what is written within a policy and then how it is interpreted, carried out, understood, and how it effects change.[1] Chapter One demonstrated how many policies related to the opioid crisis had a specified goal but a very different effect, such as the Harrison Narcotic Act which intended to decrease illicit drug use by monitoring prescriptions and imposing taxes but actually increased street drug use.[2]

[1] Perhaps the most salient recent example of this occurred within the federal court with *Dobbs v. Jackson Women's Health Organization.* While this was a judicial ruling and not directly and act of policy formation, the point still stands that the *proposed* change was different from what has occurred in *actuality*. The overturn of *Roe v. Wade* with the *Dobbs* decision made abortion illegal in the United States. Laying aside whether or not abortion itself should be legal or illegal, it should be acknowledged that the *intent* of the *Dobbs* decision is different from what has happened since. It not only influenced state policies on abortion, but has changed what is involved in medical education, has impacted the vulnerable women impacted by intimate-partner violence, and has called into question other medical practices as the medical community redefine what "abortion" really means. Many physicians have experienced great fear of losing their medical licenses. For this example, the point to be made is that a good policy will consider not only what it substantively indicates, but other effects that may arise secondarily to its enactment, as much as it can foresee these changes.

For more on the impact of *Dobbs* on medical education, see: Biftu Mengesha, Nikki Zite, and Jody Steniauer, "Implications of the *Dobbs* Decision for Medical Education: Inadequate Training and Moral Distress," *Journal of the American Medical Association* 328, no. 17 (2022): 1697-1698.

For more on the impact of *Dobbs* on women experiencing intimate-partner violence, see: Elizabeth Tobin-Tyler, "A Grim New Reality – Intimate-Partner Violence after *Dobbs* and *Bruen*," *New England Journal of Medicine* 387, no. 14 (2022): 1247-1249.

For the unintended effects of *Dobbs* on women with cancer, see: Jane Meisel et al., "When the Personal Becomes Political: The Impact of the Dobbs Decision on Women with Cancer," *American Cancer Society Journals* 129, no. 2 (2022): 171-174.

[2] David Courtwright, "Preventing and Treating Narcotic Addiction – A Century of Federal Drug Control."

It is understandably challenging to predict effects of policies not yet instated, but ethical policymaking should strive to heavily consider what unintended consequences may arise out of the policy. This includes consideration of possible political, social, economic, and public health ramifications.[3]

ii. Compliance with a Deeper Policy Analysis Method

The book *Policy Analysis for Public Decisions* by Duncan MacRae and James Wilde offers one of the most popular methods for evaluating public policy and invites individuals to engage in a civic duty to consider the ethical basis for the policy.[4] Their work is aimed at making the reader a more "informed citizen" and places "*systematic ethics* at the center of the field."[5]

MacRae and Wilde's method, "The Elements of Policy Analysis," is a five-step process. It involves the following steps: (1) Definition of the Problem, (2) Criteria for Choice, (3) Alternatives, Models, and Decisions, and (5) the Cycle of Policy Analysis. [6] While it is unlikely to be valuable to highlight the whole framework here, some elements may be particularly valuable.

First, the "definition of the problem" step may be quite helpful when it comes to opioid related policy. This step requires "a clear statement of the problem you propose to

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[3] An example of this type of consideration of unintended consequences comes from Jim Stone's article on advance directives. This paper lays out the way in which the formal documentation of living wills and other advance directives, because of their often confusing and nebulous structure and writing, can actually lead to a host of unintended consequences which were not specifically part of their creation. The same concept is applied here in the context of policymaking regarding opioids. See: Jim Stone, "Advance Directives, Autonomy, and Unintended Death," *Bioethics* 8, no. 3 (1994): 223-246.

[4] Duncan MacRae and James Wilde, *Policy Analysis for Public Decisions* (North Scituate: Duxbury Press, 1979), xiii.

[5] Ibid., xvi.

[6] Ibid., 7-12.

analyze."[7] This is often able to be achieved by noticing deficiencies in the situation. Once deficiencies are identified, the definition of the problem may be improved by considering alternative definitions to what have been identified in the past.[8] In keeping with ethical obligations to move towards a common good, proper definition of the problem allows for better determination of appropriate responses in which we can "propose policies that are both right and effective and use our scarce resources on problems that are important and that offer genuine hope for remedies."[9]

The layered history given in chapter 1 reminds us just how complicated the opioid crisis is. In that respect, "definition of the problem" is likely to be challenging and there may not even be one overarching problem that can be identified. However, ideal policies for the opioid crisis will do their best to utilize data, community perspectives, and historical evidence to understand what it is that they aim to achieve. They will more fully define their goals so that they can affect deeper, more lasting change. For example, rather than identifying the problem as an increase in opioid-related deaths, perhaps policymakers may attempt to define the problem more specifically by opioids' economic impact, their intersectional impact on vulnerable populations, or by their social impact on the welfare of children.

The other component of MacRae and Wilde's method that is particularly insightful for opioid-related policy is the fifth step, "The Cycle of Policy Analysis." This is the step that occurs *after* an initial policy has been put into effect. It involves

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[7] Ibid., 17.

[8] Ibid., 17.

[9] Ibid., 23

evaluation of impact by using the information that is generated following the policy's implementation. Under this view, policies are meant to be dynamic, not static. The cycle of policy analysis necessitates that policies undergo changes that either improve them or help them act towards their intended goal (if they do not have positive impact following implementation).

This would be particularly helpful with opioid related policy since it has often been witnessed that these policies' intended goals have not been met. This criteria in which policy is continually reviewed, re-evaluated, and revised is a necessary part of making sure that opioid policy is within the ethical expectations of the four principles and that it is promoting a common good by invoking participation at the community level.

iii. Decriminalization and Destigmatization

Previous chapters have highlighted just how detrimental the criminalization and stigmatization of drug use can be, especially the criminalization and stigmatization of *pregnant* opioid users who are then often deterred from seeking care. From the data on how negative the impacts of these processes are, I propose this criterion as incredibly necessary for the protection of especially vulnerable populations, like pregnant women. In crafting new policy and law, policymakers and lawmakers should seek those which decriminalize and destigmatize drug use among pregnant women and rather, forward those "supportive" policies which increase access to treatment and resources and promote the adequate care for pregnant and postpartum women experiencing OUD.[10]

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[10] Laura Faherty, Bradley Stein, and Mishka Terplan, "Consensus Guidelines and State Policies: The Gap Between Principle and Practice at the Intersection of Substance Use and Pregnancy."

This ethical criterion can be derived from both the principlist and catholic social ethic justifications. On the principlist side, it is evident that criminalization and stigmatization have altered the autonomous environment of pregnant women experiencing OUD. When criminalization for their actions is threatened, they perceive that seeking healthcare for both their pregnancy and their drug use is no longer a viable option. In that manner, the environment surrounding free choice is tainted and people no longer have access to the choice they might desire, namely the choice to seek adequate healthcare. The physical and psychological harms that come by these mothers and their babies due to this phenomenon are also violations of beneficence and nonmaleficence; they neither obtain the good they require (proper care) and are not protected from harm (adverse outcomes for mother and baby).

This also then creates challenges for distributive justice. As described earlier, criminalization and stigmatization disproportionately affect different regions, races, ethnicities, and circumstances. In doing so, they re-enforce barriers to equitable care and a just distribution of healthcare resources.

A catholic social ethic justification pushing for decriminalization and destigmatization of drug use among pregnant women is derived mainly from the notions of Christian charity and preferential options for the disadvantaged. In the commission for Christians to seek a common good by showing particular care to those are disadvantaged, there is an invitation to see the needs of pregnant women in hardship and to meet them charitably. It seems that violations to the social ethic promoted here occur when pregnant opioid users are faced with punitive, stigma-creating responses rather than supportive, resource-building responses.

iv. Maintaining the Autonomous Environment

While every ethical consideration that has been highlighted thus far in this work is incredibly important, if there was one that needed to be pointed to in particular for its role in this specific topic, I think that it would be respect for autonomy as described in chapter 2. I stated there that respect for autonomy includes, but is not limited to, informed consent, respecting patients' wishes, and allowing them to make their own choices. It also includes preservation of the autonomous environment. This involves heavy consideration of where coercion, undue influence, nudging, and incentives are being used and analysis to discern if there is a violation of the autonomous environment in doing so.

I make no definitive claims about what level of influence may be acceptable, though it does seem that "nudging" or forms of "soft paternalism" may be permissible in the case of pregnant mothers experiencing OUD. However, I assert that it is of the utmost importance that policymakers and lawmakers look into all possible violations of autonomy that may be conferred by the policies and laws which they develop.

Take for example a policy which overall looks to be appropriate. It includes increased funding towards access to OUD treatment, drug education programs, and social supports such as foster care. This policy outlines that the funding for this will be allocated at the state level so that each state can utilize data on how the opioid crisis has particularly affected its communities and act accordingly to proportion the funds to the needed and appropriate programs. However, this theoretical policy, in its support of foster care, also supports the separation of mothers and babies if the mother is found to be using opioids while pregnant. It asserts that it will bolster foster care because it affirms that opioid-dependent women are unfit for motherhood and that, in most cases, they

demonstrate an inability to care for their children. Perhaps this seems like an unrealistic stipulation of a policy and while it is only theoretical in nature, opinions and perceptions of this nature can easily fall into policy if not careful. A policy which would discriminate against pregnant opioid users by encouraging separation from their children due to unfitness would surely alter the autonomous environment. Not only would it generate fear and likely induce the phenomenon I have previously discussed in which pregnant opioid users avoid care due to policies like this, but it would also greatly restrict the autonomous environment of pregnant women.

This theoretical policy demonstrates the nature of forceful action and its violation of the ethical principle of autonomy. While it may be easy to agree that future policy development should stay far away from this type of influence, it is less clear as to whether other types of influence, incentives, and interventions should be allowed. Good policy formation will flesh out further how these methods affect the autonomous environment and will aim to preserve it at all costs.

CONCLUSION

If anything can be concluded after the whole of this work, it is that the opioid crisis has been an incredibly complicated phenomenon which continues to raise ethical, religious, social, political, and economic questions for the United States.

The two frameworks which have been referenced in this work have provided a great deal of help in considering how we might move forward in making positive change regarding the opioid crisis, as well as how we might protect those who are disproportionately and most gravely affected. Principlism was incredibly helpful due to its pre-faith origins and ability to be specified from more general rules to specific implications for addressing opioid use policy. A respect for the autonomous environment was seen as a key feature of this framework. However, principlism was challenging to adapt between individuals and communities. Cahill's participatory and common good ethic was then the corrective for this problem. Participation in change and communal care for a common good are distinctives of this framework which allow it to have a greater authority on dictating community responsibility in policy formation.

The combination of these two frameworks and the critiques of opioid policies which were derived from them then allowed for a compilation of evaluative criteria. Certainly, more criteria than were listed here could be given. However, it seems that ideal policymaking for opioid crisis related solutions will consider the difference between proposed policy and its actual implementation, will follow a cyclical policy analysis model which revisits and revises existing policy, will push forward the task of

decriminalizing and destigmatizing drug use, especially among vulnerable populations, and will aim to preserve the autonomous environment.

Compliance with these ethical guidelines does not ensure perfect policy *formation*, nor does it ensure perfect policy *implementation*. It certainly does not promise a one-size-fits-all fix to the opioid crisis in America. However, it does offer a positive proposal of guidance that may be particularly fruitful in future endeavors to reduce the economic, social, and political impact of the opioid crisis on the United States.

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