2019

The Regulatory Transformation in Using Medicinal Cannabis to Treat Disease in the United States

Kevin Rubin
Walden University

Walden University

College of Social and Behavioral Sciences

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Kevin M. Rubin

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Review Committee
Dr. Christopher Atkinson, Committee Chairperson,
Public Policy and Administration Faculty

Dr. George Larkin, Committee Member,
Public Policy and Administration Faculty

Dr. Linda Day, University Reviewer,
Public Policy and Administration Faculty

Chief Academic Officer
Eric Riedel, Ph.D.

Walden University
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Abstract

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Kevin M. Rubin

MPA, Walden University, 2008

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Doctor of Philosophy

Public Policy & Administration

Walden University

May 2019

Abstract

Therapeutic benefits of medicinal cannabis are well documented in the treatment of a variety of medical conditions. There is not, however, a nationally consistent delivery system, which has prevented many patients from realizing these benefits. Using policy feedback theory as the foundation, the purpose of this general qualitative study was to better understand how state-level regulatory efforts in medicinal cannabis may provide guidance on formulating national public policies that are beneficial to patients. This study compared 3 core tenets of NORML, an authority in the cannabis industry, against the policies of 3 states with exemplary state medical cannabis programs. The tenets included access to whole-plant cannabis, wide latitude for doctors to decide treatment regimens, and the right to cultivation for personal use. Data collected from publicly available documents such as legislative archives, state government websites, cannabis coalition groups, and media coverage of medicinal cannabis legislation were deductively coded and subjected to a cross-case analysis procedure. Findings indicated a lack of full alignment with NORML's core tenets as well as significant gaps between research on the efficacy of medical cannabis and the regulatory systems governing delivery within the states. Future policy makers may consider these results in devising nationwide legislation to research and recognize the medicinal use of cannabis, thus addressing the identified need for a uniform delivery system in the US for patients in need of cannabis for medical purposes. This study may contribute to positive social change through recommendations to federal legislators for creating a national government model for patient access to medicinal cannabis.

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Chapter 1: Introduction to the Study

Introduction

The purpose of this research study was to address the need for an increased understanding about the possibilities of developing a delivery system for medicinal cannabis for the treatment of diseases in the United States. Medicinal cannabis, consisting of dried leaves and flower buds from a natural plant, has therapeutic use for treating chronic and debilitating ailments. According to Seamon et al. (2007), "Marijuana contains more than 460 active chemicals and over 60 unique cannabinoids. The major active ingredient in marijuana is tetrahydrocannabinol (THC), which is primarily responsible for its therapeutic and psychoactive effects" (p.1038). Medical cannabis merits consideration as a relevant option in the United States for those patients suffering with specific diseases. This study is critical to understanding the possibilities of a formal delivery system for patient access that is considered an acceptable practice as determined by patient and physician and not restricted by federal law. Therefore, the potential social implication of this study is that information may help patients requiring medical cannabis for disease treatment find ways to access, purchase, possess, and use cannabis to treat their disease without the fear of potential criminal prosecution under federal law.

Background

The use of medicinal cannabis and the possibilities of a delivery system in the United States can provide benefits for patients suffering from certain diseases. According to Reinarman et al. (2011), marijuana is useful in treating seizures, muscle spasms, headaches, anxiety, nausea, vomiting, depression, and diarrhea. Moreover, it has also

proven to improve appetite, sleep, and concentration. In addressing medical cannabis's therapeutic effectiveness, Lucas (2012) claimed its use lessened chronic pain and allowed patients an opportunity to reduce their use of pharmaceutical opiates. Additionally, Moeller et al. (2015) noted the increase in the number of health care professions who recognize the benefits and use of medical cannabis, also finding that pharmacy students support cannabis legalization for medicinal use. Moreover, Bonn-Miller, Boden, Buscossi, and Babson (2014) provided information on oncology palliative care patients who used medical cannabis and experienced a reduction of nausea, vomiting, and pain as well as decreased suffering from diminished spasticity and intraocular pressure.

A public political debate over medicinal cannabis as a treatment of disease in the United States has resulted in proposals to Congress for new regulations. For example, introduction of the Legitimate Use of Medicinal Marijuana Act of 2014 was to allow state officials to legally move toward an appropriate use of medical marijuana without fear of federal criminal prosecution. Also proposed was the Respect States and Citizens' Act of 2017 introduced in the House of Representatives. If enacted, this bill would have amended federal law by decriminalizing the possession, distribution, and cultivation of state-regulated medical marijuana. In this case, the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 et seq. would no longer supersede state law, thus allowing for the therapeutic use of medical marijuana.

However, the results of *Gonzales v. Raich* (2005) influenced future public policies and laws regarding the emerging issue of medical cannabis and federal regulation. This case has precedence, so currently proposed policies would need to override the court's

decision and change federal authority. The authority vested in Congress by Article I, §8, of the United States Constitution (Constitution) sets the precedence as "to make all Laws which shall be necessary and proper for carrying into execution its authority to regulate Commerce with foreign Nations, and among the several States includes the power to prohibit the local cultivation and use of marijuana in compliance with California law" (*Gonzales v. Raich*, 2005), thus establishing case law precedence for medicinal cannabis. The majority opinions held that the Controlled Substances Act of 1970 (CSA) prohibits the possession and/or manufacture of medical cannabis. Authority falls under the Commerce Clause regarding this issue, and California statute does not exceed the authority of Congress.

This study allowed me to address the gap in knowledge regarding the lack of and possibilities for a delivery system development allowing U.S. patients to use medicinal cannabis for the treatment of diseases. The information from this study is critical and may be helpful in the creation of a formal delivery system of medicinal cannabis as a best practice across state lines, since federal law currently does not recognize the medicinal properties of cannabis.

Problem Statement

Researchers have well documented the therapeutic and medicinal benefits of cannabis (Hill, 2015; Webb & Webb, 2014). Cannabis is useful in treating seizures, muscle spasms, headaches, anxiety, nausea, vomiting, depression, diarrhea, and multiple types of pain (Lucas, 2012; Reinarman et al., 2011). Researchers also support that many patients do not respond to existing pharmacological treatments and could benefit greatly

from the use of medicinal cannabis (Koppel et al., 2014). Currently, the federal Controlled Substances Act, Title II, of the Comprehensive Drug Abuse Prevention and Control Act of 1970, which prohibits local cultivation and use of marijuana, governs medical cannabis.

The general problem is the United States does not have a formal delivery system for accessing medicinal cannabis, as federal law does not recognize its medicinal properties. With changes in state policies since the 1970s and growing research on the medicinal value of cannabis, it is necessary to revisit the possibilities for a delivery system of cannabis for the treatment of diseases in the United States. More than 30 states are exploring this emerging issue by establishing or implementing laws legalizing the delivery and use of medical marijuana for qualified patients.

Purpose of the Study

The purpose of this research study was to address the need for an increased understanding concerning the lack of and possibilities for the development of a medicinal cannabis delivery system for use in the treatment of diseases in the United States. As the United States does not currently have a formal delivery system for medicinal cannabis, research at the state level would facilitate exploration of initiatives and system possibilities. For example, patients whose physicians provide written recommendations could legally obtain medicinal cannabis as treatment for disease. Therefore, patients could possess, transport, and conduct activities related to medical cannabis within the confines of their state's medical cannabis laws. The patient's quality of life will improve

by mitigating chronic illnesses and/or diseases by using cannabis as a viable treatment option without fear of arrest or federal criminal prosecution.

Virginia Republican Morgan Griffin introduced H.R. 4498 on April 28, 2014, legislation known as the Legitimate Use of Medicinal Marijuana Act, in an attempt to reclassify cannabis under the federal CSA from a Schedule 1 to a Schedule 2 drug. This would have eliminated existing restrictions on medical cannabis research and provided greater freedom to authorize cannabis treatment by physicians. In addition, the Act would have prohibited the federal government from interfering with a patient's access to medicinal cannabis in states where it was legal. If the bill had passed, it would have amended federal law by decriminalizing the possession, distribution, and cultivation of state-regulated medical cannabis. As a result, the FFDCA (1938) would no longer supersede state law, allowing for the therapeutic use of medicinal cannabis.

Introduced in the House of Representatives on February 14, 2013, was another legislative bill known as the States Medical Marijuana Patient Protection Act. According to this Act:

> [N]o provision of the Federal Food, Drug, and Cosmetic Act shall prohibit or otherwise restrict an entity authorized by a state or local government, in a state in which the possession and use of marijuana for medical purposes is legal from producing, processing, or distributing marijuana for such purpose. (States Medical Marijuana Patient Protection Act, 2013)

To this effect, I employed a qualitative cross-case analysis to fill this identified gap in research and legislation surrounding the delivery of medicinal cannabis. Through

the inclusion of National Organization for the Reform of Marijuana Laws' (NORML; 2019) three core tenets, the goal in this research study was to compare perspectives of other state practices. The core tenets of NORML's patient-centric, evidence-based medical cannabis program include (a) patient access to the whole plant, (b) a list of qualifying medical conditions, (c) and patients' legal options to cultivate for personal use in their private residence (NORML, 2019). I used policy feedback theory as a base and triangulated policy practices. While the literature includes related issues like the legalization of cannabis at the federal level or the rescheduling of cannabis under the CSA, researchers have not included the lack of and possibilities for a delivery system development for U.S. patients to use medicinal cannabis. This study was necessary because states have already implemented different types of medical cannabis programs, policies, rules, and regulations; thus, it addressed this research gap.

Research Question

RQ: How do state-level regulatory efforts in medicinal cannabis provide guidance on formulating national public policies that are most beneficial to patients in the United States?

Theoretical Framework for the Study

The theoretical lens for framing this research study was Mettler and SoRelle's (2014) policy feedback theory. According to Mettler and SoRelle and Sabatier and Weible (2014), this framework is applicable for addressing the formation of policy and for conducting an examination of the dynamics of and societal response to policies. For example, the court's decision in *Gonzales v. Raich* (2005) influences current and future

laws regarding the emerging policy issue of medicinal cannabis and federal regulation. Although this case established precedence, legislators are currently putting forth policies intended to override the court's decision and eventually change federal law. Researchers support these changes with cases of patients with numerous medical issues who used state-approved medicinal cannabis with positive results and no serious side effects (Webb & Webb, 2014). Finally, it appears that public opinion has shifted over the last several decades toward a greater social acceptance of state laws regulating medical cannabis (Koppel et al., 2014).

Nature of the Study

In this study, I used a qualitative method to compare and contrast regulatory cases across states. Qualitative research was most appropriate to understand the lack of and possibilities for a delivery system in the United States for the use of medicinal cannabis in the treatment of diseases. With a qualitative approach, the researcher assesses information and knowledge gained from a particular audience through case studies. Data collection for this study occurred through a review of legislative records, memos, state government websites, cannabis coalitions, and documents available on medicinal cannabis programs. I conducted a cross-case analysis comparing three exemplary state-implemented medical cannabis programs for common and dissimilar elements and subsequently compared these programs to three of NORML's patient-centric, evidence-based medical cannabis program core tenets: (a) patient access to the whole plant, (b) an expansive list of qualifying medical conditions, and (c) the patients' legal option to cultivate plants for personal use in their private residence (NORML, 2019). I engaged in

Internet-based and hard copy data collection to compare patterns and ideas regarding current and future regulatory efforts and policies for medicinal cannabis in the United States and to show how existing policies impact equal access. With this type of research design, I allowed for a detailed description of the phenomena by each of the study entities, including mitigation of personal bias, identification of particular experiences, creation of units of themes and patterns for statements, and individual case descriptions.

Definitions

Policy: Course of action at all levels of government (and individuals) adopted or proposed through a government body (Sabatier & Weible, 2014).

Marijuana: A green/brown mix of dried flowers, stems, leaves, and seeds from the flowering tops of the hemp plant, *Cannabis sativa* (National Institute on Drug Abuse, 2017). These tops contain cannabidiol, cannabinol, and isomeric tetrahydrocannabinols (Marijuana, 2017).

Medical or medicinal cannabis: Cannabis products (plant or extracts) ingested for the treatment of symptoms caused by an illness (National Institute on Drug Abuse, 2017).

Using medicinal cannabis/marijuana for the treatment of diseases: Consumption for medicinal and/or therapeutic reasons. The California State Legislature Medical Marijuana Research Act of 1999 allowed the Center for Medicinal Cannabis Research to conduct clinical trials of smoked cannabis in the United States. As a result of this systematic research, researchers supported the idea of utilizing cannabis as treatment in selected pain syndromes and muscle spasticity caused by injury or diseases of the nervous system (Center for Medicinal Cannabis Research, 2017).

Assumptions

The regulatory transformation in using medicinal cannabis to treat diseases in the United States may have suffered from the lack of a formal delivery system to patients because federal law does not recognize cannabis as medicinal. For this study, I assumed past federal regulations were successful in preventing equal access to medicinal cannabis used by patients to treat diseases within the United States. The success of past methods used by federal regulations for different issues can guide the transformation of regulations on medical cannabis to help establish a formal delivery system for future success in treating diseases in the United States.

Another assumption was that regulatory transformation and a formal delivery system are the best methods for changing regulations for the treatment of diseases in the United States. Given the lack of central direction from the federal government, other bills, memoranda, and state laws served as policy laboratories to promote medicinal cannabis use and regulate some form of delivery system. In this study, I used a cross-case analysis to measure three exemplary state-implemented medical cannabis programs against a benchmark of three of NORML's patient-centric, evidence-based medical cannabis program core tenets. I assumed NORML would be the best source of information for determining regulations and a formal delivery system that provides equal access to all patients needing medical cannabis.

Scope and Delimitations

The current regulations for medicinal cannabis delivery systems have impacted the regulatory transformation in using this product to treat diseases. This cross-case

analysis facilitated comparison of three states that have implemented exemplary medical cannabis programs against three of NORML's medical cannabis program core tenets. NORML was the benchmark as a leading authority in medical cannabis regulations. I identified the three states that have implemented exemplary medicinal cannabis programs as an ideal sample population because each has established compelling, yet unique programs and served as a model for others states' regulatory efforts. Currently, regulatory inconsistencies exist among the states that have implemented medical cannabis programs, and the result has been a plethora of different medical cannabis policies.

Limitations

In a qualitative research inquiry, rules regarding sample size are fluid (Patton, 2015). The sample size necessary to generate meaningful qualitative data via in-depth inquiry for this study was relatively small. Consequently, the data collected could be too limited for the purpose of generalization. However, according to Patton (2015), the logic and power of purposeful sampling lie in selecting information-rich cases for an in-depth study. First, this sample population represented those states leading the medical cannabis regulatory efforts. Furthermore, all states lacked a model to follow, and therefore they have become inconsistent in their regulatory policies. States that implemented policies after the three states in this sample partially followed the patterns and practices of those three exemplary programs, but they also implemented unique regulations largely driven by politics. The inconsistency has created a range of different medical cannabis policies that warrants further research.

Significance

In this research study, I identified how perceptions of regulatory efforts regarding medicinal cannabis shape policies in the United States and the gaps in the regulatory systems that govern delivery. I also reviewed existing research supporting the value of medicinal cannabis. Through these efforts, this study may lead to positive social change by potentially improving the lives of ill individuals who could benefit from treatment with medicinal cannabis. Although clear policies governing medicinal cannabis exist at the federal and state levels, practical implications from this research include policy recommendations for incorporation of evidence-based research about the use of medical cannabis for the treatment of disease. Furthermore, the significance of this study is that it may provide additional data to aid in improving systems of government oversight for current and future programs and policies. In terms of implications for social change, this study's findings could result in better and more consistent future public policy regarding the establishment of a systematic delivery system of medicinal cannabis for the treatment of specific diseases.

Summary

In this study, I sought to use a qualitative cross-case analysis to explore regulatory transformation for the use of medicinal cannabis to treat diseases in the United States. The use of medicinal cannabis is growing. Individual state regulatory changes over the last several decades have increased as a result of well-documented therapeutic research on the medicinal benefits of cannabis treatment for diseases. However, the CSA, which prohibits local cultivation and use of marijuana, regulates medical cannabis in the United

States. The United States does not have a formal delivery system for accessing medical cannabis. Exploring the lack of and possibilities for a delivery system for medical cannabis usage was essential. The results of this study may spur regulatory transformation that will help qualified patients throughout the United States legally access, possess, and cultivate medicinal cannabis to treat their diseases without the fear of federal criminal prosecution. Chapter 2 provides an overview of researchers who have explored United States policy and evidence-based research regarding medicinal cannabis use, including current and potential future government oversight policies.

Chapter 2: Literature Review

Introduction to Literature Review

This chapter includes an exhaustive review of existing literature that addresses the need for an increased understanding about the lack of and possibilities for the development of a formal delivery system for accessing medicinal cannabis for the treatment of disease in the United States. The goal was to gain insight into policy recommendations that incorporate evidence-based research on the use of medicinal cannabis for the treatment of disease, along with improving systems of government oversight for current and future policy. This chapter includes the theoretical framework and history of medicinal cannabis, contemporary uses of medicinal cannabis for therapeutic benefits, the statutory basis for delivery systems currently established by the United States government, and the delivery systems currently established by foreign governments for medicinal cannabis. The theory most appropriate for the framing of this proposed research was the policy feedback theory that, according to Mettler and SoRelle (2014), provides a look at the formation of policy and an examination of the dynamics and societal response to policies. I conducted a thorough analysis of existing literature supporting the history of medicinal cannabis, the contemporary uses and therapeutic benefits of medicinal cannabis, and gaps between the regulatory system governing the delivery of medicinal cannabis and research supporting the value of medicinal cannabis for the treatment of disease in the United States.

Literature Search Strategy

The review of literature for this research study involved myriad search terms and resources related to *policy, policy feedback theory, marijuana, cannabis, medical* or *medicinal cannabis,* and *medicinal cannabis for the treatment of disease*. I used these keywords and key terms as a guide to peer-reviewed journals, books, articles, and documents from the following sources: Walden University library, the NORML website, and state and federal laws, regulations, and policies. The search engines used for this literature review included ProQuest, EBSCOhost, ProQuest Dissertations & Theses Global, and Sage. The extensive number of research inquiries yielded an exhaustive overview of the current body of literature concerning the problem and purpose of this study.

Policy Feedback Theory

The social paradigm of policy design pertains to groups either positively or negatively through the interpretation of policy creation. The multifaceted theory of policy subsystems leaves people to depend upon heuristic processes and thinking. Analytic familiarity and knowledge becomes paramount because much of public policy involves fundamental processes (Weible et al., 2011). Theories concerning public policy can serve as frameworks to improve understanding of the policy process. Furthermore, the policy sciences are cornerstone to the framework most applicable to this research study. Empirical researchers can support policy design and collective achievements to facilitate problem-solving that influences policy processes in the overarching policy feedback theory (Weible et al., 2011).

The systematic approach to allocate benefits to the policy recipients (target groups) appears in social groups versus individual acuities (Maltby, 2017). Developed by Mettle and SoRelle (2014), policy feedback theory served as an appropriate theoretical foundation for this study because of the interpretative effects of the problem and purpose statements. The existing policy for medicinal cannabis delivery systems leaves patients unable to travel across state lines with cannabis in their possession (Interstate Commerce Act of 1887, 49 U.S.C. § 3-22). The complexity of medicinal cannabis regulatory efforts and existing policies that impact patients in the United States aligns with policy feedback theory. Social groups endure the impact of existing laws and policies. In this regard, an enhanced understanding of the lack of and possibilities for the development of a delivery system is needed. The United States does not currently have a formal delivery system for medical marijuana.

Theoretical Overview

Upon policy enactment, implementation aids in developing structure while providing benefits to groups of people. Policy feedback theory encompasses the importance of policy design and its impact on political agendas and groups of people (Mettler & SoRelle, 2014; Sabatier & Weible, 2014). The cornerstone of policy feedback theory are historical aspects, which reveal that past pledges create cumulative returns that lead to enduring efforts (Cairney, 2012; Pierson, 2002). The policy feedback theory is broad in focus, thus applicable to the cross-case analysis between the states chosen for this study in comparison to NORML's three tenets.

The concept of policy feedback theory encompasses policy feedback and its various effects. As policy feedback theory is an implicit defined theory, a causal postulation exists supporting the validation for the effects of any given policy. As Sabatier and Weible (2014) asserted, the meaning of citizenship affects future policies and results from the power of groups, political agendas, and systems of governance. In line with policy feedback theory, an individual's preferences and decisions are largely molded by policies. While a variety of policy theories exist, the policy feedback theory draws upon three distinct components: the independence of the three NORML tenets, the connection between these three concepts, and the correspondence resulting in policy evolution. This theory is largely tautological and relies heavily on knowledge acquisition (Sabatier & Weible, 2014). Furthermore, the levels of analysis and scope are implicit, describing how policies form policymaking and subsequent politics (Sabatier & Weible, 2014). With more than 30 states having established laws legalizing the use and possession of medicinal cannabis for the treatment of disease, a need exists for an improved delivery system. The policy feedback theory is appropriate for an overview of the established policies on medicinal cannabis for the treatment of disease and the need for a sound delivery system (Mettler & SoRelle, 2014).

Other Theories

Given that personal experiences are pertinent in forming political beliefs and attitudes (Mettler & Soss, 2004), "the term 'policy feedback' describes the process through which public policies shape political outcomes, which in turn either reinforce or undermine the policy itself" (Lerman & McCabe, 2017, p. 626). Policy feedback theory

provided the strongest theoretical foundation for the comparison and analysis of the development of delivery systems for U.S. patients in need of medical cannabis for the treatment of disease. As such, other theories are not applicable and fall short, since policy feedback theory is best suited for this cross-case analysis.

Just as new policies impact the creation of changing politics, they also shape social group incentives, capacities, and resources. The institutional analysis and development theory serves as a framework that stems from the action of people and their associated goals to develop policies (Lerman & McCabe, 2017). The institutional analysis and development theory was not ideal for this cross-case analysis because of its focus on a single action or situation that provokes adaptive decisions and constant adjustments over time. The advocacy coalition framework was also not appropriate for this study because of its focus on process emergence as a result of competition or conflict over time (Sabatier & Jenkins-Smith, 1993); in turn, this process involves long periods of political conflict or attempts to mediate agreements. In addition, the punctuated equilibrium theory did not fit this research study because of its view of policy from an empirical view. According to the punctuated equilibrium theory, like people, the political system is unable to consider all issues simultaneously, and therefore, introductions of subsystems are a means to exercise parallel processing. The reason this theory is not applicable is because it is inherently conservative yet predisposed of sporadic radical change (Sabatier & Weible, 2014); therefore, the punctuated equilibrium theory becomes irrelevant amid the periodic changes that occur within the political system.

Policy feedback functions most strongly among individuals and/or groups whose understanding of politics writ large may still be somewhat limited. Another benefit policy feedback theory offered this study was that research in support of the delivery of specific policy information may also stimulate opinion formation in individuals with lower levels of civic or policy knowledge (Lerman & McCabe, 2017). Using the policy feedback theory as a foundation for this cross-case analysis, I sought to explore how regulatory efforts concerning medicinal cannabis create policies that benefit U.S. patients.

The reason for selecting this theory over others was the need to consider heuristics to assist in reasoning due to the complexity and purpose of the study. Heuristics allows for efficiently allocating attention, thereby simplifying incoming stimuli for better interpretation and understanding (Weible et al., 2011). However, the boundaries set with policy provide some degree of structure, albeit a broad focus in the nature of this study: the development of an improved delivery system for medical cannabis for U.S. patients. With more than 30 states having established laws to legalize medicinal cannabis, the structure provided by the policy feedback theory facilitated support of individuals and groups who may not be privy to the intricate details of policy. Furthermore, because the United States does not have a formal delivery system for medicinal cannabis, patients are limited in access of necessary medicine.

Policy Feedback Theory Evolution

Whether internal of external, changing conditions impact the dynamics of a policy's subsystem (Sabatier & Weible, 2014). As such, policy change is the result of conditions that warrant evolution. Alterations to socioeconomic conditions shift advocacy

alliances and make changes in policy possible. The process of policy feedback theory is change and effect, with public policy fundamentally dependent upon implementation. The feedback element functions as a result of changes within the policy components that then lead to policy design changes, subsequently creating or strengthening existing social structures and groups. Through the policy feedback theory, the demand arises for subsystem contributions. Policy feedback theory stems from the adage that "policy creates politics" (Mettler, 2002; Mettler & SoRelle, 2014: Nowlin, 2016).

As Soss and Schram (2007, as cited by Maltby, 2017) posited, the chief strength of policy feedback theory is the ability to impact people's lives in concrete and direct ways. The two dominant approaches concerning policy theories come from policy analysis scholars and policy process scholars. The benefit of the policy feedback theory is that it rests between these two positions (Mettler & SoRelle, 2014). Another key concept is that policy should be more apparent in groups of individuals who find their lives targeted by the issue. Furthermore, analytic knowledge is only one aspect, albeit a limiting one to some extent, as bias may creep in when simplifying a phenomenon (Weible et al., 2011). Therefore, the empirical-based approach to the policy feedback theory supports the need for the development of an improved delivery method for medicinal cannabis for U.S. patients.

As past policy interactions, federal and state laws and policies also contradict one another. Federal law and state law have established precedence, yet such precedence has prevented development of such a system. The irregular policy action, policy precedence,

and political environment are in conflict, and with federal law superseding state law, there is no uniform cannabis delivery system.

History of Medicinal Cannabis

The theoretical framework and history of medicinal cannabis provide a foundation for this study, demonstrating how political factors, propaganda, and regulatory efforts have impacted medicinal cannabis over time. Further, theoretical underpinnings support the progression of public policy regarding the use of cannabis for medicinal purposes. The use of medicinal cannabis from the 1930s to date has notably advanced in status and regulation.

Prior to the 1930s, physicians used medicinal cannabis as a common course of treatment for chronic pain (Hall, 2015; McKenna, 2014). For instance, in 1887, doctors introduced medicinal cannabis as a daily treatment plan for individuals suffering with chronic migraine and/or headache pain (Baron, 2015; Greenwell, 2012; Hill, 2015). In 1890, the president of the British Medical Association advocated for cannabis and its medicinal value for the treatment of numerous illnesses, specifically migraine and neuralgia, over a 30-year period (Baron, 2015; Hill, 2015; Warf, 2014). In 1915, Sir William Osler, considered the father of modern medicine, argued that cannabis was likely the most satisfactory remedy for the treatment of migraines (Baron, 2015).

Furthermore, in 1916, Dr. Dixon, a professor of pharmacology at several prestigious universities, noted therapeutic benefits of medicinal cannabis in the treatment of migraine headaches (Baron, 2015; Carter, 2013; Kuddus, Ginawi, & Al-Hazimi, 2013). According to Baron, American pharmacopeias included cannabis for the

prevention and treatment of headaches during this time. Additionally, numerous other well-known physicians advocated for medicinal cannabis as treatment throughout the 19th and 20th centuries (Baron, 2015; Horowitz, 2014). For example, the president of the New York Neurological Society Dr. William Osler advocated extensively for the medicinal use of cannabis for the treatment of headaches. The following is review of changes that occurred with regard to medicinal cannabis during the 1930s.

In the 1930s, amid favorable political factors, prominent members of the business community were able to mitigate and eventually eliminate the use of medicinal cannabis as a therapeutic treatment of illness and disease (Horowitz, 2014; Kuddus et al., 2013). They did so through the use of propaganda portraying cannabis as a drug abused by low-income and minorities (MacDonald & Pappas, 2016). According to Baron (2015) and Routh (2017), efforts included a campaign overseen by Harry Anslinger and the Federal Bureau of Narcotics, a scare tactic associating medicinal cannabis use with psychosis, deterioration of mental capacity, and violent crimes. What resulted was the creation of the Marihuana Tax Act of 1937, enacted despite opposition by the American Medical Association (Routh, 2017).

According to Baron (2015), a substantial tax on both the medical cannabis and hemp industries reduced its growth, given the potential for hefty fines and criminal prosecution for noncompliance; political powers and protests from the medical community were not enough to prevent the prohibition of medicinal cannabis. In 1941 came the removal of medicinal cannabis from the United States Pharmacopoeia and

National Formulary. Moreover, legislative changes by the federal government in the 1970s did not help medicinal cannabis.

The phenomenon is a lack of consistency in public policy and state and federal regulations concerning the use of medicinal cannabis for patients. Policy analysis is a response to practical issues with an understanding of historical cognizance. However, the role that technical information plays in the policy process is only part of the equation (Lerman & McCabe, 2017; Sabatier & Weible, 2014). As Lerman and McCabe asserted, intellectual action rooted in a social process merits address by policy analysis. Policy feedback theory derives from the reality that political learning is largely tied to partisanship and opinion formation drawn from political messaging and secondary sources. As such, public policies are learned via personal experiences, thereby forming policy feedback (Lerman & McCabe, 2017; Sabatier & Weible, 2014). Policy feedback theory is appropriate for this study due to the need for improved understanding concerning the current deficiency and opportunities for the development of a delivery system for the use of medicinal cannabis for the treatment of disease in the United States.

Changes in Medicinal Cannabis During the 1970s

The federal government maintained the removal of medicinal cannabis from the United State Pharmacopoeia and National Formulary in 1941. In 1970, the federal government classified cannabis as a Schedule 1 narcotic under the CSA (Kamin, 2012; Routh, 2017). As a result, the U.S. federal government prohibits the distribution, possession, cultivation, and sale of cannabis. Additionally, physicians cannot prescribe cannabis to their patients due to licensing requirements by the U.S. Food and Drug

Administration (FDA; Kamin, 2012; Routh, 2017). The federal government's classification of cannabis under the CSA defines it a drug with no acceptable medicinal value and a high possibility of addiction. Therefore, "the federal courts have held that a state's adoption of medical marijuana provisions is irrelevant in a federal prosecution under the CSA" (Kamin, 2012, p. 979).

Moreover, groups of individuals within the United States known as "hippies," a culture of recreational cannabis users, increased prior to the regulatory implementation of the 1970 CSA (Hall, 2015). According to McKenna (2014), "hippies" were mainly part of the antiwar movement and included protesters, students, and members of college faculty. The enactment followed the hippie movement, when recreational use became intertwined with the medicinal use of cannabis. As a result, it was very difficult for experts to conduct research and/or give opinions on the effectiveness of medicinal cannabis as a therapeutic treatment for disease (Hall, 2015). Currently, however, the treatment of disease with medicinal cannabis has become a major component of individual state laws legalizing its use.

Current Status of Medicinal Cannabis in the United States

This phenomenon of medicinal cannabis in the US appears often in existing literature and research; therefore, addressing the current status of medicinal cannabis in the United States may also benefit from this review. Currently, more than 30 states are establishing or have implemented state laws legalizing the use of medicinal cannabis for qualified patients (Maxwell & Mendelson, 2016), with studies underway in several more states. Qualified patients are able to possess and cultivate medicinal cannabis without fear

of criminal federal prosecution as long as they remain compliant with state laws, rules, and regulations. Individual states have developed a medicinal cannabis program that allows patients to use and access medicinal cannabis through state- and locally regulated dispensaries (Freisthler & Gruenewald, 2014). Moreover, according to Maxwell and Mendelson (2016), medicinal cannabis regulation differs state by state regarding the criteria of who can recommend and/or prescribe medicinal cannabis and who can become a qualified patient of the program. However, as is apparent by the current politics, public policy, and case law within the United States, there are many regulatory gray areas (Lucas, 2012; Rosenberg, 2015).

For instance, representatives have introduced several legislative bills related to legalizing medical cannabis. Given this political shift, currently there are two legislative bills (H.R. 714 and H.R. 2528) supporting public policy reform by challenging the federal statute through the reclassification of marijuana and/or decriminalization under federal law. On January 27, 2017, H.R. 714: Legitimate Use of Medicinal Marijuana Act (LUMMA) was introduced to legally allow states to identify an appropriate use of medical cannabis without fear of criminal federal prosecution. Also in support of policy reform is H.R. 2528: Respect States and Citizen's Rights Act of 2017 (introduced in the House). If passed, the bill will amend federal law by decriminalizing the possession, distribution, and cultivation of state-regulated medical marijuana. As a result, the FFDCA (21 U.S.C 301) would no longer supersede state law allowing for the therapeutic use of medical cannabis.

Therefore, physicians who provide written recommendations for their patients will be able to legally obtain medicinal cannabis as treatment for chronic illness. Patients will be allowed to possess, transport, and conduct activities related to medical cannabis within the confines of their states' medical cannabis laws. Moreover, according to H.R. 2528 (2017), no provision of the FFDCA shall prohibit or otherwise restrict an entity authorized by a state or local government, in a state in which the possession and use of marijuana for medical purposes is legal, from producing, processing, or distributing marijuana for such purpose. As a result, H.R. 2528 has the potential to allow state-regulated medical cannabis dispensaries and patients to lawfully conduct business. It will allow dispensaries to cultivate, possess, and distribute medical marijuana legally under both federal and state law.

However, influence and regulation continue to stem from *Gonzales v. Raich* (2005) to regulate federal, state, and local laws regarding state-legalized medical cannabis programs. The FDA has the power to regulate and classify controlled substances and/or drugs based on medicinal value and a therapeutic treatment option. Moreover, case law precedent continues to influence the Drug Enforcement Administration (DEA; 2019) and its enforcement of the federal CSA. The Supreme Court of the United States (Supreme Court) held that the power vested in Congress by United States Constitution Article I, § 8, included the power to prohibit the local cultivation and use of cannabis, even though such cultivation and use was in compliance with California law (*Gonzales v. Raich,* 2005). Additionally, this case overruled the State of California's Compassionate Use Act 1996. As a result, state laws regarding the decriminalization of medical

marijuana use for patients who possess state-approved physician recommendations do not receive legal protection under this act because federal law supersedes state law.

In June 2011, James M. Cole, Deputy Attorney General of the U.S. Department of Justice (DoJ), established the Cole Memorandum, creating more gray areas regarding medical cannabis (DoJ, 2013). The memo served as guidance to federal prosecutors concerning the enforcement of cannabis under the CSA. This included updates and guidance for state initiatives legalizing marijuana under state law for the possession and regulation of marijuana production, processing, and sale, including information for law enforcement and DoJ attorneys regarding enforcement efforts and resources. Therefore, as long as the states do not violate federal priorities, the federal government will allow the states to regulate and enforce cannabis under their individual state laws (California Department of Food and Agriculture, 2017; Titus, 2016).

Contemporary Uses of Medicinal Cannabis for Therapeutic Benefits

Until recently, medicinal cannabis was not an option for most patients. Therefore, it is imperative to address gaps in existing literature supporting the need for a formal delivery system of medicinal cannabis for the treatment of disease in the United States for those suffering with a medical or chronic illness. For instance, according to emerging research, cannabis is a viable treatment option for a number of clinical applications. According to NORML (2019), treatment with medicinal cannabis can be for nausea, glaucoma, movement disorders, appetite stimulation, dementia, GI disorders, chronic pain, ALS, and PTSD. In 2010, following clinical trials, the University of California

Center for Medicinal Cannabis Research concluded cannabis should be “first line treatment” for patients with serious illnesses and neuropathy (NORML, 2019).

The struggle for regulatory recognition of the medical cannabis industry is one with extensive resources from the pharmaceutical industry and associated businesses, as all parties seek to maintain a major role in the development of medicinal cannabis. In the face of this legislative lack, pharmaceutical medication abuse is growing at an alarming rate (Substance Abuse and Mental Health Services Administration, 2017). Furthermore, the use of and dependence on pharmaceutical opiates is a critical public and personal health concern (Lucas, 2012; Scavone, Sterling, & Van Bockstaele, 2013). However, according to Lucas, there has been an increase in the use of medical cannabis as a substitute for pharmaceutical opiates. Moreover, the use of medical cannabis can help reduce the tolerance to and/or withdrawal from opiates (Lucas, 2012; Scavone et al., 2013). As a result, medical cannabis has proven therapeutic in clinical settings by lessening patients’ chronic pain and giving them opportunity to reduce the use of problematic pharmaceutical opiates. Furthermore, medicinal cannabis is a demonstrated means of treating symptomology and management of debilitating diseases.

According to Johannigman and Eschiti (2013), Strouse (2015), and Uritsky, McPherson, and Pradel (2011), hospice professionals dealing with terminally ill patients support the use of medicinal cannabis within a hospice facility. Uritsky et al. indicated 90% of hospice care professionals were in agreement on legalization of cannabis, with the majority of participants indicating that cannabis has medicinal benefits. The use of medicinal cannabis within palliative care settings by oncology and advanced practice

nurses is another consideration. For example, patients within this type of environment could be suffering from cancer, a qualifying condition for many state medical cannabis programs. When patients are in oncology palliative care, the use of medical cannabis can reduce nausea and vomiting, control pain, diminish spasticity, and decrease intraocular pressure (Bonn-Miller et al., 2014; Johannigman & Eschiti, 2013). Because continuing this limited and restrictive access to medicinal cannabis has proven both ineffective and counterproductive, I sought to help fill the gap and provide new research that can aid in the regulatory transformation and possibilities for a formal delivery system for the treatment of disease with medicinal cannabis in the United States.

Treatment for Patients Suffering with Terminal or Chronic Illness

According to Cook, Lloyd-Jones, Ogden, and Bronomo (2015) and Webb and Webb (2014), several random trials have shown promising treatment with the use of medicinal cannabis for several illnesses. For instance, patients suffering with multiple sclerosis have shown a reduction in spasms and an improvement in sleep. Cancer patients undergoing chemotherapy have reported a reduction in nausea and vomiting with the use of medicinal cannabis (Bonn-Miller et al., 2014; Cook et al., 2015). Additionally, anorexia and chronic neuropathic pain respond to medicinal cannabis as a means of treatment to stimulate appetite and reduce pain. Druzin (2016), the Medical Director at Oasis Medical Centre in Windsor, Ontario, indicated that patients suffering with neuropathic pain, arthritic pain, and musculoskeletal chronic pain benefit from medicinal cannabis as a viable form of treatment. Doctors at the Centre found using medicinal cannabis beneficial for the treatment of fibromyalgia, nausea, appetite stimulation in

cancer patients, Crohn's disease, and multiple sclerosis (Druzin, 2016). According to Betthauser, Pilz, and Vollmer (2015) and Krumm (2016), the use of medicinal cannabis is effective in treating patients suffering with posttraumatic stress disorder, as cannabis targets neurobiological processes and returns neurotransmitter imbalances to a state of homeostasis (Krumm, 2016).

Statutory Basis for Delivery System Currently Established by the United States Government

In 1996, California voters passed Proposition 215, making California the first state to legalize the use of medicinal cannabis (NORML, 2019; Titus, 2016). Since then, more than 25 states and the District of Columbia have legalized and implemented medicinal cannabis programs. In 2009, DoJ Attorney General Eric Holder issued memoranda outlining medicinal cannabis programs within the United States (Titus, 2016). According to the Ogden Memorandum, the use of federal resources should not be utilized to penalize person(s) who use medicinal cannabis as long as they are in compliance with state-specific medicinal cannabis laws (Titus, 2016). As a result, there is renewed attention on the use of medicinal cannabis as a treatment option. According to Baron (2015), Butler (2013), and Titus (2013), theories of federal "conflict" preemption are roadblocks to state medical cannabis programs, as the federal government has the power to delay legislation implementation. Thus, the Attorney General may sue the state in federal court for an injunction halting the state from implementing and/or providing state-legalized medicinal cannabis programs.

One federal statute regarding medicinal cannabis is the FFDCA: "The term 'drug' means articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man . . . and articles (other than food) intended to affect the structure or any function of the body of man" (21 U.S.C. § 900, 2007). The FDA has the authority to regulate controlled substances and classify each drug according to a "schedule," based on medicinal properties and/or value. Currently, the FDA classifies medicinal cannabis as a Schedule 1 narcotic with no medicinal properties, something echoed by the CSA (1970) in deeming marijuana a Schedule 1 controlled substance. To warrant Schedule 1 classification, a drug must have a potential risk of abuse, lack acceptable safety standards, and have no accepted medical value. As a result, the Drug Enforcement Administration (DEA) is required to complete an investigation and prosecution for violations of controlled substance laws within interstate and international levels (DoJ, 2017).

Gonzales v. Raich (2005) is the most recent case and precedence decided by the Supreme Court regarding the use of state-regulated medicinal cannabis and federal law. According to Article IV, the Constitution and laws made in the pursuance thereof are the supreme law of the land, with federal law governing in case of conflict between federal and state laws. The federal government's continued support of the CSA appears to be relevant given case precedence regarding medical marijuana cases decided by the Supreme Court. According to the CSA, prohibition of marijuana manufacture and possession, as applied to intrastate manufacture and possession for medical purposes under California law, should not exceed Congress' power under Federal Constitution's commerce clause (Art. I, § 8, cl. 3). Therefore, patients living in California who were

otherwise protected under the state's approved medical cannabis program were not able to obtain injunctive and/or declaratory relief from the CSA. As a result, the Supreme Court established precedent with this case and held that the power vested in Congress by the Constitution included the prohibition of marijuana use and cultivation, even if the use and/or cultivation was in compliance with state law (*Gonzales v. Raich*, 2005).

Federal law continues to conflict with new state medical cannabis laws and regulations. As a result, states are challenging supremacy, the concern being whether the federal government will enforce the law of the land. For instance, state agencies have the power to establish and enforce public health and housing standards, regulate utility rates/practices, and govern labor and business activities (Olsen, 2009). Therefore, it is essential to review state regulation such as the Arizona Medical Marijuana Act (2010). The Arizona Department of Health Services was the state regulatory entity granted authority to create the program after passage of Proposition 203. The basic interpretation of the Arizona Medical Marijuana Act is:

> In this chapter, unless the context otherwise requires: 1. "Allowable amount of marijuana" (a) With respect to a qualifying patient, the "allowable amount of marijuana" means: (i) Two-and-one-half ounces of usable marijuana; and (ii) If the qualifying patient's registry identification card states that the qualifying patient is authorized to cultivate marijuana, 12 marijuana plants contained in an enclosed, locked facility except that the plants are not required to be in an enclosed, locked facility if the plants are being transported because the qualifying patient is moving. (A.R.S. 36 § 2801)

Other states have enacted similar regulations regarding the legalization of medicinal cannabis. In 1996, California established the Compassionate Use Act to eliminate state-level criminal penalties for the use, cultivation, and possession of cannabis by patients who obtained a physician's written recommendation indicating the therapeutic benefits from the use of medical marijuana (California Health Safety, 1996, § 11362.5). The Compassionate Use Act affords legal protection to patients diagnosed with any debilitating illness where the medical use of marijuana has been "deemed appropriate and has been recommended by a physician" (NORML, 2019, n.p.). Further support in the literature comes from the experience of foreign governments in developing delivery systems for medicinal cannabis.

Delivery System Currently Established by Foreign Governments for Medicinal Cannabis

Several foreign governments have established a delivery system for equal access to medical cannabis for the treatment of disease. Three of the most noteworthy nations at the forefront of medical cannabis delivery are Israel, Canada, and Australia. It appears Israel is one of the more progressive countries regarding medicinal cannabis, with the Ministry of Agriculture's research organization building a national institute for medical marijuana research. Similarly, Canada has laws in place regarding individual use and access as well as hospital administration oversight and delivery. In 2016, Australia established a delivery system for medical cannabis with federal government oversight.

Israel

In accordance with the State of Israel Ministry of Health and Government Resolution 3609, the Ministry of Health created a government agency, the Medical Cannabis Unit, to oversee the regulation of cannabis for both research and medicinal use (State of Israel Ministry of Health, 2019). In 2016, an additional resolution provided the regulations outlined by the Minister of Health providing qualified patients with equal access and good-quality medical cannabis. The Medical Cannabis Unit also ensures physicians will be able to prescribe the correct dosage as dispensed and accessed at the local pharmacy (State of Israel Ministry of Health, 2019). According to the Health Ministry (2017), approximately 25,000 Israelis have permits to consume medicinal marijuana to mitigate symptoms of cancer, epilepsy, and other diseases, a number that appears to be growing. The Health Ministry published the Green Book documenting the country's system of delivery, with international recognition (State of Israel Ministry of Health, 2019).

Canada

Canada is also at the forefront of the medicinal cannabis industry with an established delivery system and equal access for qualified medicinal cannabis patients. Qualified medicinal cannabis patients, authorized by their health care practitioner, can access medicinal cannabis in several ways (Government of Canada, 2019), including registering with licensed producers, registering with Health Canada to produce a limited amount for personal medical purposes, or designating someone else to produce it for them.

In August 2016, the four-part Access to Cannabis for Medical Purposes Regulations (ACMPR) replaced the Marihuana for Medical Purposes Regulations (MMPR; Ministry of Health Canada, 2017). First, it established a framework for licensed commercial production and distribution of quality-controlled medicinal cannabis in secure and sanitary conditions (2017). Second, it outlined the provisions for individual production amount or designating another individual as the named producer of the medicinal cannabis. The final two parts of the ACMPR outlined transitional provisions, additional amendments to regulations, and Health Canada protocols as of 2016. In a hospital setting, the individual in charge of the hospital can allow the administration, sale, or delivery of medicinal cannabis to a patient or an individual responsible for the patient.

Australia

In October 2016, Australia established a delivery system for equal access to medicinal cannabis for qualified patients. According to the Australian Government Department of Health (2017), the Commonwealth regulates medicinal cannabis products through the Therapeutic Goods Administration (TGA) and the Office of Drug Control, thus overseeing medicinal cannabis products for therapeutic use. Administered by the TGA, the Australian Register of Therapeutic Goods is responsible for importing, supplying, and exporting marijuana from Australia (Australian Government Department of Health, 2017). In addition, the TGA regulates medicinal cannabis products supplied in Australia, with clinical trials conducted in support its use for medicinal purposes.

Undercurrent of Political Rhetoric and Patient Needs

In the political realm, the federal government has established an anticannabis position regarding the therapeutic value of medicinal cannabis. For example, the federal government, under the authority of the CSA decision to override state initiatives, has deemed it appropriate for the DoJ DEA to carry out one of its primary responsibilities through "investigation and preparation for the prosecution of major violators of controlled substance laws operating at interstate and international levels" (DoJ, 2017). Therefore, the politics behind the use of medicinal cannabis for the treatment of disease add further stress to medical practices and administrative processes when physicians try to satisfy patient medical needs. As a result, there is a need for an increased understanding about the lack and development of a delivery system to use medicinal cannabis for the treatment of disease in the United States.

Conclusion

Chapter 2 included an overview of the existing body of literature on the theoretical framework, history, contemporary therapeutic uses, statutory basis for delivery systems, and political rhetoric verses patient needs of medicinal cannabis. The development of policy and regulatory transformation is essential for the establishment of a delivery system when treating disease and improving systems of government oversight for current and future policy within the US. However, in the 1930s research regarding the benefits of medicinal cannabis was not prevalent and therefore did not support cannabis as a form of therapeutic treatment (MacDonald & Pappas, 2016). Furthermore, propaganda and political factors by prominent members of the business community

created stigma and apprehension, negatively impacting medicinal cannabis use and leading to its eventual elimination as a therapeutic treatment of illness and disease within the United States (Baron, 2015; Routh, 2017). Additionally, the federal government established a new precedent in the 1970s, classifying marijuana a Schedule 1 narcotic under the CSA (Kamin, 2012; Routh, 2017). However, as documented in Chapter 2, current medical and scientific researchers provide evidence in support of the medicinal/therapeutic value of using cannabis as a treatment of disease. Over 30 states are establishing or have implemented laws legalizing the use of medicinal cannabis for qualified medical cannabis patients.

Until recently, medicinal cannabis has not been a viable therapeutic treatment option for most patients. Therefore, it is time to address gaps in the literature regarding the need for a formal delivery system of medicinal cannabis for the treatment of disease in the United States. However, the federal "conflict" preemption is a roadblock to state medical cannabis programs (Baron, 2015; Butler; 2013; Titus, 2013), as the U.S. government may to hinder the implementation of legalization referenda by halting states from implementing and/or providing state-legalized medicinal cannabis programs. As a result, this study is an opportunity to change the current underlying anticannabis political influence. A formal delivery system in the United States would be new, as no legislators or government officials have yet implemented such a system for medicinal cannabis and the treatment of disease for improving systems of government oversight for medical cannabis programs and/or policies.

Chapter 3: Research Method

Introduction

Through this qualitative cross-case analysis, I explored how state-level regulatory efforts in medicinal cannabis provide guidance on formulating national public policies that are most beneficial to U.S. patients. I examined three exemplary states with the goal of extracting best practices for adopting a national-level policy. I used three of NORML's patient-centric, evidence-based medical cannabis program core tenets as a benchmark for assessing the merit of each state's medical cannabis policy: (a) access to the whole plant, (b) an expansive list of qualifying medical conditions, and (c) patients having a legal option to cultivate for personal use in their private residence (NORML, 2019). More than 30 states have legalized the use of medicinal cannabis, creating potential conflicts with the federal government (Routh, 2017). The United States does not currently have a formal delivery system for medicinal cannabis, as the federal government has classified medicinal cannabis as without medicinal merit.

NORML, a public-interest nonprofit lobby, has since 1972 advocated for the legal use of medicinal cannabis and provided a model supporting the rights of patients and physicians to use medicinal cannabis for the treatment of disease. NORML is the benchmark for this study because the organization lobbies Congress and state legislatures for more consistent and rational policies. With representatives serving as expert witnesses in legislative hearings, NORML assists and defends the reform of medical cannabis regulations for the treatment of suffering and pain. In addition, the organization provides public access to educational and legal research, including a 50-state legislative tracking

system. As such, NORML is the leading authority in the cannabis industry and was therefore the model for this study.

The purpose of this study was to address the need for an increased understanding concerning the lack of and possibilities for the development of a delivery system to use medicinal cannabis for the treatment of disease in the United States. In this chapter, I provide the rationale for the cross-case analysis design and explain the role of the researcher. I illustrate the methodology for this study, including its context and criteria for selecting participants. After an explanation of the data collection and data analysis processes are issues of trustworthiness and ethical procedures. The information from this research study may be helpful in the creation of a formal delivery system for accessing medicinal cannabis that can be used as best practices across state lines, as federal law does not presently recognize the medicinal properties of cannabis. I used a qualitative cross-case study design to help fill the gap identified as a lack of existing research supporting an optimal medical cannabis delivery system.

Design and Rationale

The goal of this study was to explore the need for the development of a delivery system to use medicinal cannabis for the treatment of disease in the United States. According to Creswell (2013) and Patton (2015), a case study allows a researcher to elicit detailed, rich information about individuals. As the research question called for an in-depth collection of data, including existing and secondary data such as legislative and public databases, websites, and documents, this was the best method for analysis. Patton

argued that every research study can be a case study, because scholars are analyzing social phenomena over time, bounded by time and place.

As an authority in the cannabis industry, NORML served as the post of reference. I analyzed public databases, websites, and documents from a population of three exemplary state medicinal cannabis programs and compared this data with three core tenets of NORML's (2019) patient-centric medical cannabis program: (a) patient access to the whole plant, (b) an expansive list of qualifying medical conditions, and (c) patient having a legal option to cultivate for personal use in their private residence. I sought to build perspectives by using a cross-case analysis and comparing state-implemented medical cannabis programs with a benchmark, authoritative coalition recommended patient-centric, evidenced-based medical cannabis program to analyze ideas and opinions regarding patient access to medicinal cannabis (NORML, 2019). The opinions, laws, and perspectives of each entity helped to answer the following research question:

RQ: How do state-level regulatory efforts in medicinal cannabis provide guidance on formulating national public policies that are most beneficial to patients in the United States?

The use of a qualitative case study design method allows a researcher to gain a better understanding of complex issues using open-ended questions focused on a phenomenon within the context of real life (Baskarada, 2014). A case study research design method involves the study of a single unit to gain a better understanding of the larger class of units (Baskarada, 2014; Patton, 2015). This design enables the researcher to obtain substantial insight into and understanding of the research problem (Baskarada,

2014; Maxwell, 2013). Therefore, a qualitative cross-case analysis research design was most appropriate for this study because it allowed me to analyze three of NORML's patient-centric, evidence-based medical cannabis program core tenets in comparison with three exemplary state-medical cannabis programs. Given the theoretical basis in policy feedback theory, I intended to understand the policy and political experience of three states with remarkable programs and develop professional recommendations. This comparison revealed patterns and ideas regarding current and future regulatory efforts and policies that could benefit medicinal cannabis patients in the United States and illustrate how existing policies without equal access impact quality of life.

According to Grady et al. (2013), using secondary data as a data collection strategy to gather substantive content can result in a substantial amount of data researchers can analyze and use to discover and evaluate unnoticed patterns and outcomes. The use of existing data assisted in the analysis of real-world utilization and effectiveness of medical cannabis programs and policies regarding patient access (Grady et al., 2013). The study did not include a pilot study or an intervention study. Next, I explain the role of the researcher for this study.

Role of the Researcher

My role as researcher in this study was to analyze existing data such as legislative and public databases, state government websites, and documents as the best method for this cross-case analysis. According to Yin (2009), cross-case analysis is a form of case study research in which researches use existing data not dependent upon participant-observer data, resulting in valid, high-quality data. As Owen (2014) argued, the challenge

in conducting a cross-case document analysis is that it requires researcher access to several resources, which helps mitigate potential researcher bias.

Document analysis is one of the four basic types of data collection, allowing the researcher to analyze existing data and seek clarification if needed (Creswell, 2013; Patton, 2015). The document analysis conducted in this study meant I did not have any form of personal or professional relationship with participants. According to Miles and Huberman (1994), it is imperative to avoid bias because it can weaken or potentially invalidate a research study. In this study, neither personal agenda nor bias interfered with the representation of collected data. To ensure the study was free of bias, I suspended tacit knowledge related to the subject. As such, no ethical issues such as researcher's environment, conflict of interest, or power differentials threatened this study, with collected data further supported using proper methodology.

Methodology

I used Sabatier and Weible's (2014) policy feedback theory as the theoretical lens for framing the research. This framework was applicable when analyzing the formation of policy and examining the dynamics and societal response to these policies. To establish the effectiveness of this evidence, I utilized a cross-case analysis and compared three core tenets of NORML's medical cannabis program with three states that have implemented exemplary state-medical cannabis programs. As NORML is one of the leading authorities in the cannabis industry, the three tenets served as the foundation for this cross-case analysis. Rooted in a detailed discussion of politics and policy context, I identified the commonalities and contrasts to determine best practices.

Context of the Study

This cross-case analysis is a regulatory context of three exemplary states to implement medical cannabis policies, as the inconsistency of regulation leaves states to develop their own approaches and processes. As such, the policy feedback theory serves as a foundation for each state's unique approach to policy development and practice. Also analyzed were secondary data regarding the evidence of patient access to the whole plant of cannabis, which included an expansive list of qualifying medical conditions and patients having a legal option to cultivate for personal use in their private residence (NORML, 2019). Legislative and public online databases, state government websites, and documents were the best methods for obtaining secondary data. State government websites provided information on three exemplary state medical cannabis programs and policies. NORML's website and three tenets served as a model, since the organization is the leading authority in the cannabis industry. NORML's model patient-centric medical cannabis program allowed for the cross-case analysis and comparison of policy that includes improved structure and addresses equal access of medical cannabis for all patients. According to Grady et al. (2013), evidence can facilitate the identification and analysis of the efficiency and effectiveness of policy through the presentation of literature.

Data collection came from publicly available documents and websites identified by NORML's patient-centric medical cannabis program and state medical cannabis legislation. The data consisted of documents such as legislative archives, state government websites, media, cannabis coalition groups, and media statements related to

medicinal cannabis legislation and the topic of study. The sources of data included legislative history, state legislative policy records, media from cannabis coalitions, and organizations related to medical cannabis. Similar and/or different factors discovered in this review enabled comparison and contrast.

Upon completion of the cross-case analysis, I summarized differences and made recommendations both in support of and refuting current state medical cannabis policies. A table reveals comparison and contrast of important aspects of these polices, aspects recommended to exclude or include, as well as those that are the same or closely aligned with NORML's model. Recommendations for amendments or alternatives to policy based on this comparison emerged, with patterns and ideas synthesized regarding current and future U.S. regulatory efforts and policies and how existing policies impact equal access of medicinal cannabis.

Criteria for Contributing Cases

The unit of analysis is the focus of qualitative research. The case study sample came from a population of exemplary states to implement medical cannabis programs. I used a cross-case analysis comparing NORML as the benchmark, specifically three core tenets of its patient-centric medical cannabis program. According to Patton (2015), there are no rules for sample size in qualitative inquiry. However, when conducting this type of research study, it is imperative to determine the sample size necessary to provide a sound understanding of the purpose of the inquiry, obtaining credible data, and collecting data within the established timeframe (Creswell, 2013; Maxwell, 2013; Patton, 2015). For this study, using a small population with information-rich cases provided meaningful data and

credibility. Of the existing 33 state medical cannabis programs, three exemplary states facilitated support and defense for the effectiveness of current policies in comparison to quality of patient care amid having no federal model to use as a guide. As such, the inconsistencies have resulted in a myriad of different medicinal cannabis policies.

The most value-oriented, information-rich case studies include current cases that allow a researcher to uncover an accurate, in-depth understanding of patterns or themes (Creswell, 2013). According to Patton (2015), a small sample size may provide substantial breakthroughs and understanding of many types of phenomena. Thus, the sample for this study was three exemplary state medical cannabis programs. Selection criteria were states with medical marijuana legislation in place. One risk therein is that states with future legislation may have improved methods, therefore creating potential bias among existing states. As such, subsequent states enacting policy have had the benefit of witnessing where others have succeeded or failed.

Data Collection

Qualitative data collection may come from multiple types of information and/or data, including observations, interviews, documents, and audiovisual materials (Creswell, 2013; Maxwell, 2014; Patton, 2015). Data collection involved reviewing legislative records, memos, state government websites, cannabis coalitions, and all documents available on medicinal cannabis programs. I compared three of NORML's patient-centric, evidence-based medical cannabis program core tenets—patient access to the whole plant, an expansive list of qualifying medical conditions, and patients having a legal option to cultivate for personal use in their private residence—with three exemplary

state medical cannabis programs (NORML, 2019). Internet-based and hard copy data collection facilitated the identification of patterns and ideas regarding current and future regulatory efforts and policies for medicinal cannabis within the United States and how existing policies impact equal access. I took notes to document my thoughts, determine coding decisions, and form analytical memos. Ensuring a sufficient number of cases is necessary to achieve saturation (Rudestam & Newton, 2007). In this case, the relationship between sample size and saturation came from the use of three exemplary states of the existing 33 that have implemented medicinal cannabis programs. The next step in the data collection process was data analysis.

Data Analysis

The use of coding in support of data analysis enabled me to answer the research question for this study following accumulation of documents, legislation, and notes. Upon review of the NORML's patient-centric medical cannabis program and current state-implemented cannabis programs, coding occurred. This allowed for researcher reflection and the opportunity to edit as needed.

Coding stemmed from the use of NORML's patient-centric medical cannabis program as a benchmark for cross-case analysis comparing state-implemented medical cannabis programs. A selective, or analytical, model of coding or coding scheme was appropriate, as it enables researchers to use one category to compare all data collected (Gerring, 2007; Miles & Huberman, 1994). Analysis of written artifacts and research occurred using selective coding as the specific model and aided in identifying key categories or themes (Burla et al., 2008; Creswell, 2013). The themes that emerged

reflected and determined the sample states' existing policies and alignment, if any, with NORML's three tenets.

To sustain consistency and validity in this cross-case analysis, only one category, NORML, underwent selective coding, with the three exemplary states compared against NORML's guidelines. According to Miles and Huberman (1994), the use of triangulation is helpful for securing corroborating evidence from multiple sources. To ensure reliability and validity of the analyzed data was theme triangulation and review for accuracy by the researcher. The process of documenting the perspective or theme established from the data will help provide validity to the findings. Moreover, some of the information/data gathered from NORML or state medical cannabis programs did follow the predominant theme or pattern. According to Gerring (2007), it is imperative for the researcher to report the negative analysis, thereby giving a realistic assessment of the phenomenon. Therefore, this research study included selective coding, whether the evidence was positive or negative.

The NVivo software database management system was essential for data collection tool effectiveness. NVivo software helps a researcher secure the collected data, making it available via searches and themes. Upon entering the data into NVivo, themes began to materialize, allowing for data exploration and coding. According to Patton (2015), the quality and credibility of qualitative research includes data collection and data analysis, coding data, and identifying recurring themes that help in making meaning and establishing accuracy. This software served as an instrument to ensure study accuracy, as efficiency lies in reducing the time required for grouping data into categories, comparing

data form notes and transcripts, and finding coded themes (Patton, 2015). As a result, NVivo software assisted in the organization of data into relevant clusters, which were essential in the analysis. The issue of trustworthiness appears in the following section.

Issues of Trustworthiness

Trustworthiness of qualitative data increases through the following basic measures: participant criteria, unbiased question, multiple data collection, systematic process and data analysis, and peer review (Fenton & Mazulewicz, 2008). When conducting research for this study, it was imperative to have mechanisms in place to maintain and check for trustworthiness, quality, and credibility of the data obtained. According to Kornbluh (2015), the goal of trustworthiness in qualitative inquiry and findings has four basic elements: (a) credibility to focus on internal validity, (b) transferability focused on external validity, (c) dependability focused on reliability, and (d) conformability.

To ensure credibility and internal validity, qualitative research methods and procedures proved accurate by seeking information, collecting data, ensuring unwarranted data did not appear the findings, and not dismissing any data. Since I explored several data sources and incorporated different perceptions, it was imperative to exercise triangulation. Additionally, ensuring triangulation of the data sources, the documents and policy of NORML's patient-centric medical cannabis program, and several state-implemented medical cannabis programs assisted in a trustworthy interpretation of the data.

External validity comes from the transferability of a substantial amount of information and/or findings from one case study to another (Creswell, 2013; Patton, 2015). Thus, I established external validity of the context regarding the need for an increased understanding about the lack of and possibilities for the development of a delivery system to use medicinal cannabis for the treatment of disease in the United States. Future researchers may use this information, as it is at the forefront of an emerging issue. For the purpose of transferability, a detailed description of the method was necessary. The use of a cross-case analysis in comparing three exemplary state-implemented medical cannabis programs with three of NORML's patient-centric, evidence-based medical cannabis program core tenets created variation within the selection process.

To establish dependability, the researcher must fully document the process of inquiry and responsibility for a documented, traceable, and logical case study (Patton, 2015). To address reliability, I included a descriptive, detailed plan regarding the research design and data collection techniques for the possibility of future study replication, as well as a discussion and evaluation for the effectiveness of the research. Triangulating data provides corroborating evidence and reliability for a research study (Creswell, 2013). The use of different sources in this case study helped to establish a particular theme and/or perspective.

For the purpose of confirmability, a detailed account of three exemplary state-implemented medical cannabis programs and three of NORML's patient-centric, evidence-based medical cannabis program core tenets appears in Chapter 4. Patton (2015)

indicated that it is essential for the researcher to maintain an awareness of potential bias and/or reflexivity such that personal subjectivity of researcher perceptions does not influence the study. Asking a series of specific questions regarding subjectivity of findings will ensure trustworthiness. Furthermore, all data and analysis will be available upon request.

Ethical Procedures

The role as a researcher and agent of positive social change involves following a code of ethics. The means of study execution must be ethical, as it gives validity to the results. Researchers must learn to anticipate ethical issues, resolve them, and ensure there are no human rights violations (Creswell, 2013). This study did not require institutional permission for data collection. Since this study depended upon the availability of public secondary/existing data, there was no need for protections for human participants. Also unnecessary were anonymity and/or confidentiality in data collection.

Throughout data collection and analysis, I projected an impartial tone and showed no bias in the outcome. Furthermore, all documents studied are public records and freely available for review. Subsequently, all data and information used in this study will be available for future confirmation or replication of the research. Because sources could contradict one another, I will disclose any conflicts of interest within the discussion of results.

Summary

Chapter 3 included an explanation of qualitative case study research as a means to obtain information by using a cross-case analysis to collect, analyze, and provide results.

By comparing three states' legislation, I addressed the need for an increased understanding of the lack of and need for development of a delivery system to use medicinal cannabis for the treatment of disease in the United States. This chapter included a description of the purpose of this study and the design and rationale. The role of the researcher in this study appeared along with the methodology, including the context of the study and criteria for selecting participants. Data collection and assessment processes provided include issues of trustworthiness in support of this study. The results of the study appear in Chapter 4.

Chapter 4: Results

Introduction

In this chapter are the results from this qualitative cross-case analysis. The purpose of this research study was to address the need for an increased understanding about the lack of and possibilities for development of a delivery system for medicinal cannabis for the treatment of disease in the United States. As policy design theory supports the concept that groups will either positively or negatively interpret the process of policy development, I used this theory in support of the study. I obtained the case study sample from a population of three states that implemented exemplary medical cannabis programs. I used three of NORML's core tenets of the patient-centric medical cannabis program as the benchmark, as the organization is one of the leading authorities in the cannabis industry. The sample cases for cross analysis were the states of California, Colorado, and Nevada. The research question used to guide this study was:

RQ: How do state-level regulatory efforts in medicinal cannabis provide guidance on formulating national public policies that are most beneficial to patients in the United States?

In this chapter, I describe the setting and demographics and explain the need for this study. Data collection and data analysis occurred in such a manner so as to ensure trustworthiness. I also discuss the themes derived from this study.

Setting

A small population with information-rich cases provides meaningful data and credibility. Of the existing 30 state medical cannabis programs, I used three exemplary

states to support and defend the effectiveness of current policies in comparison to the quality of patient care. However, all states lacked a model to use as a guide, thus having to implement unique policies and regulations. States used were the states of California, Colorado, and Nevada as exemplary cases in comparison with three of NORML's patient-centric, evidence-based medical cannabis program core tenets. There were no conditions that may have influenced participants or interpretation of study results.

The three exemplary states chosen to explore current policies for this study were among the first 10 states to implement medical cannabis programs between 1996 and 2000 (ProCon.org, 2019). Excluded from the study were medical cannabis programs with limited use and/or access. In June 2018, the Network for Public Health Law identified 16 states that had implemented and/or enacted limited access cannabis product laws; thus, none merited inclusion in this study. However, California, Colorado, and Nevada had created a blueprint to which other states could refer when establishing their medical marijuana programs.

California was the first state to legalize cannabis for medicinal purposes, and the existing program serves as a strong advocate for patients. According to Americans for Safe Access (2018), California is the leader in the cannabis industry and is the best place in the country for patients' legal protections and access. The state also removed the sales and use tax on medical cannabis and improved regulations for the manufacture of cannabis products. Since 2014, Colorado has provided safe and legal access to medical cannabis patients. In this, patients are able to easily obtain medical cannabis due minimal zoning regulations, making dispensaries widely accessible. Further, patients can receive

discount medical cannabis due to financial hardship. Nevada has also established a strong medical cannabis program that demonstrates the value of keeping medical and adult use programs legislatively separate. As a result, patients are able to obtain medicinal cannabis with a very high product safety rating. Cornerstone to these participating states is the complex perception of policy subsystems requiring nontraditional thinking, something further supported by policy feedback theory (Weible et al., 2011).

Demographics

I chose the participants of the study due to the exemplary nature of each state's existing programs. Each year, Americans for Safe Access reviews states' medical cannabis program based on how well the current law and regulations accommodate patient needs. California, Colorado, and Nevada scored in the highest percentile for accommodating patient needs when compared to all other states that have implemented a medical cannabis program (Americans for Safe Access, 2018).

Data Collection

I compared the exemplary state medical cannabis programs with three of NORML's (2019) patient-centric, evidence-based medical cannabis program core tenets: (a) patient access to the whole plant, (b) an expansive list of qualifying medical conditions, and (c) patients having a legal option to cultivate for personal use in their private residence. Data collection involved reviewing legislative records, memos, state government websites, cannabis coalitions, and documents available on medicinal cannabis programs and equal access. Information was readily available from each state, with all data easily located and transparent. I compared Internet-based and hard copy data

for patterns concerning existing regulatory efforts and policies for medicinal cannabis. All data collected are available for public view. I took notes in the form of analytical memos, subsequently retaining all recorded all data and researcher notes on a cloud-based system. No variations existed between data collected and the plan presented in Chapter 3 and I encountered no unusual circumstances during data collection.

Data Analysis

In the analysis process, I reviewed three of NORML's patient-centric medical cannabis program's core tenets as a benchmark against California, Colorado, and Nevada's state-implemented medical cannabis programs. I used selective coding to compare one category to data collected (Gerring, 2007; Miles & Huberman, 1994). Using NVivo to inductively move coded units to a larger representation, I entered the three tenets and three participating states' policies into the program for analysis. I used this software as an instrument to maintain accuracy. I examined the data entered, coded via two cycles and analyzed as NVivo produced patterns for the cross-case analysis (results appear in Table 1). The process of coding data included a review/analysis of each coded word, phrase, section, and theme in relation to the research theory. Cases/nodes were clustered into substantive categories to include the three exemplary state policies and NORML's three core tenets. The themes that emerged reflected the participant states' existing policies and alignment, if any, with NORMLs three tenets. I secured corroborating evidence from the three states to ensure accuracy.

Evidence of Trustworthiness

Practices to ensure trustworthiness, quality, and credibility guided this study. According to Kornbluh (2015), achieving trustworthiness in qualitative inquiry and analysis requires the use of four basic factors: (a) credibility focused on internal validity, (b) transferability focused on external validity, (c) dependability focused on reliability, and (d) conformability. Credibility and internal validity emerged from seeking information, collecting data, including no unwarranted data in the findings, and dismissing no valuable data. I made no adjustments from the plan presented in Chapter 3. Because I explored several data sources and incorporated different perceptions, triangulation of NORML's patient-centric medical cannabis program and the three participating states further ensured trustworthiness. I have provided a detailed description of the method to ensure transferability of results. Since all data collected came from publicly available documents, achieving trustworthiness is easier, as future researchers may use this study to further the existing body of literature.

I established dependability and confirmability by documenting the process of inquiry and responsibility, thus making it traceable and logical (Patton, 2015). Future researchers may be able to confirm and replicate the results of this study. I made no adjustments to the descriptive detailed plan regarding the research design and data collection techniques provided in Chapter 3. Trustworthiness also came from maintaining a journal of researcher notes.

Results

The cross-case analysis process led to the results of this study in support of the following research question:

RQ: How do state-level regulatory efforts in medicinal cannabis provide guidance on formulating national public policies that are most beneficial to patients in the United States?

I established themes by comparing NORML's three core tenets against each of the three participating states' existing medicinal cannabis programs. Policy feedback theory further supported this research, as it incorporates policy feedback and the multitude of effects it provides. As Sabatier and Weible (2014) posited, the power of groups affects political agendas, systems of governance, and future policies. Policy feedback theory was appropriate this study as it defends the pattern of an individual's preferences and choices as largely shaped by policies. According to policy feedback theory, researchers address individual concepts and their connection with others, leading to the evolution of policy. This hands-on theory centers on the acquisition of knowledge (Sabatier & Weible, 2014). As such, policy feedback theory supported the customary beliefs denoted by established policies impacting patients who rely on medicinal cannabis for the treatment of disease, thus meriting a sound delivery system in the United States (Mettler & SoRelle, 2014). The following sections provide an illustration of cross-case comparison (results appear in Table 1).

NORML's Core Tenets

Three primary tenets from NORML served as the benchmark in this study. According to the first, access to whole-plant cannabis, "patients must be legally able to obtain and possess herbal formulations of whole-plant cannabis that may be administered via inhalation/vaporization; their therapeutic choices must not be limited solely to orally administered cannabis-derived extracts, oils, or pills" (NORML, 2019, n.p.). Wide latitude for doctors to decide treatment regimens, the second core tenet, means "the approved list of qualifying conditions must be expansive and must allow physicians the option to recommend cannabis therapy for the treatment of chronic pain" (NORML, 2019, n.p.). NORML's (2019) third core tenet, personal cultivation rights, says that "registered patients ought to have the legal option to cultivate personal use quantities of cannabis in their own private residence" (n.p.). I analyzed the three states' existing policies against the benchmark of NORML, as illustrated next.

California Policy and NORML's First Core Tenet

California's policy for access to whole-plant cannabis for medical patients is "the voluntary registry issues ID cards that offer protection from arrest for patients and caregivers in possession of no more than eight ounces of useable cannabis. However, currently there are no possession limits specified; the amount must be "consistent with the patient's needs" that "has been deemed appropriate and has been recommended by a physician" (California Department of Public Health, 2018). When compared to NORML's first core tenet for access to whole-plant cannabis, the results indicate a value match of one. More specifically, the match is not exact, as California's policy has only

partial alignment with NORML's first tenet. California Department of Public Health states that patients:

> [C]an cultivate no more than six mature or twelve immature plants. However, there are no cultivation limits specified under state law, but local ordinances can limit or ban medical cultivation. Furthermore, qualified patients are exempt from state licensing requirements under MMRSA, if they cultivate 100 square feet or less of medical cannabis. Primary caregivers serving up to five qualified patients may cultivate up to 500 square feet of medical cannabis without a state license. Cities and counties retain the right to license, regulate or ban medical cannabis cultivation. (2018, n.p.)

The policy feedback theory represents policies intended to support patients in the United States who need medicinal cannabis and who rely on a sound delivery system (Mettler & SoRelle, 2014). However, current policies in the state of California limiting access, such as local ordinances permitting the regulation or ban of the cultivation of cannabis, restrict patient access. Following cross-examination against the benchmark, a proportion of California's policy align with NORML's (2019) first core tenet, access to whole-plant cannabis.

Colorado Policy and NORML's First Core Tenet

Colorado's existing policy, which includes access to whole plant-cannabis, allows a "Medical Marijuana Registry Identification Card, or that patient's primary caregiver who has been identified on the patient's Medical Marijuana Registry Identification Card, to possess no more than two (2) ounces of a usable form of marijuana" (State of

Colorado, 2018). In comparison to NORML's (2019) first core tenet for access to whole-plant cannabis, the results indicate a value match of one, as Colorado's policy has a limited alignment with NORML's first tenet. Colorado's existing policy limits patient access, with policy feedback theory defending the diverse phenomena of policies and regulatory efforts impacting patient access to medicinal cannabis. When cross-examined against the benchmark, a proportion of Colorado's policy aligns with NORML's (2019) first core tenet.

Nevada Policy and NORML's First Core Tenet

> Nevada's existing policy for access to whole-plant cannabis is:
>
> [T]wo and one-half ounces of usable marijuana and/or a maximum allowable quantity of edible marijuana products and marijuana-infused products as established by regulation of the Division in any one 14-day period. Can only purchase from designated dispensary (can change every 30 days). (Nevada Division of Public and Behavioral Health, 2018, n.d.)

Comparison results to NORML's first core tenet for access to whole-plant cannabis indicate a value match of one. More specifically, Nevada's policy suggests limited alignment with NORML's first tenet. With Nevada's policy limiting access to a 14-day period and the multifaceted factors of policy subsystems, policy feedback theory is paramount, as patients naturally rely on heuristic thinking and trust the social paradigm of policy design. Patients' knowledge and familiarity is crucial, as public policy largely involves fundamental processes (Weible et al., 2011). In cross examination against the

benchmark, a proportion of Nevada's policy matched against NORML's (2019) first core tenet.

As illustrated in Chapter 2, qualified patients may possess and cultivate medicinal cannabis without the fear of criminal federal prosecution as long as they remain compliant with state-established medicinal cannabis program laws, rules, and regulations (Freisthler & Gruenewald, 2014). Each state's regulated programs permit patients to use and access medicinal cannabis through dispensaries regulated by state and local jurisdictions (Freisthler & Gruenewald, 2014). Patients are allowed to possess, transport, and conduct activities related to medical cannabis within the confines of their state's medical cannabis laws. According to H.R. 2528 (2017), no provision of the FFDCA shall prohibit or otherwise restrict an entity authorized by a state or local government, in a state in which the possession and use of marijuana for medical purposes is legal, from producing, processing, or distributing marijuana for such purpose. However, the Supreme Court held that the power vested in Congress by United States Const. Art. I, § 8 overruled the state of California's Compassionate Use Act (1996). As a result, California state laws regarding the decriminalization of medical marijuana use for patients who possess state-approved physician recommendations are not legally protected under this act, as federal law supersedes state law.

California Policy and NORML's Second Core Tenet

California's existing program also includes a wide latitude for doctors to decide treatment regimens, with qualifying conditions including "anorexia, arthritis, cachexia, cancer, chronic pain, HIV or AIDS, glaucoma, migraine, persistent muscle spasms,

severe nausea, seizures and any debilitating illness where the medical use of marijuana has been deemed appropriate and has been recommended by a physician" (California Department of Public Health, 2018, n.p.). In comparison to NORML's (2019) second core tenet providing wide latitude for doctors to decide treatment regimens, results of this cross-case analysis represent a value match of one. More precisely, California's policy suggests partial alignment with NORML's second tenet.

California's specific policy has a focus on qualifying conditions for determining doctors' latitude to decide treatment. As supported by the policy feedback theory, physicians in the state of California have the opportunity to recommend medicinal cannabis to patients with specified conditions. This aligns with the framework of public policy, as patients rely on empirical thinking to decipher the complex subsystems of policy design. In cross-examination to the benchmark, California policy results in a partial match against NORML's (2019) second core tenet.

Colorado Policy and NORML's Second Core Tenet

Colorado's current policy incorporates wide latitude for doctors to decide treatment regimens. The qualifying conditions include:

> [C]hronic nervous system disorders, post-traumatic stress syndrome and debilitating medical conditions are defined as cancer, glaucoma, and infection with or positive status for human immunodeficiency virus. Chronic or debilitating disease or medical condition other than HIV infection, cancer or glaucoma; or treatment for such conditions, which produces for a specific patient one or more of the following, and for which, in the professional opinion of the patient's

> physician, such condition or conditions may reasonably be alleviated by the medical use of marijuana: chronic nervous system disorders; post-traumatic stress syndrome; cachexia; severe pain; severe nausea; seizures, including those that are characteristic of epilepsy; or persistent muscle spasms, including those that are characteristic of multiple sclerosis. (State of Colorado, 2019, n.p.)

In comparison to NORML's (2019) second core tenet for providing wide latitude for doctors to decide treatment regimens, results of this cross-case analysis represent a value match of one. More specifically, a limited part of Colorado's policy aligns with NORML's second tenet.

Colorado's policy has a focus on qualifying conditions for determining doctors' latitude to decide treatment as:

> [C]hronic nervous system disorders or post-traumatic stress syndrome; or debilitating medical conditions are defined as cancer, glaucoma, and infection with or positive status for human immunodeficiency virus. Chronic or debilitating disease or medical condition other than HIV infection, cancer or glaucoma; or treatment for such conditions, which produces for a specific patient one or more of the following, and for which, in the professional opinion of the patient's physician, such condition or conditions may reasonably be alleviated by the medical use of marijuana: chronic nervous system disorders; post-traumatic stress syndrome; cachexia; severe pain; severe nausea; seizures, including those that are characteristic of epilepsy; or persistent muscle spasms, including those that are characteristic of multiple sclerosis. (State of Colorado, 2019, n.p.)

In cross-examination to the benchmark, Colorado's policy reveals a limited match against NORML's (2019) second core tenet, a list of qualifying medical conditions. The intricate subsystems of policy design and the reality that people inherently interpret policy is a social paradigm. Patients rely on familiarity and existing knowledge when viewing policies as positive or negative. As supported by policy feedback theory, patients also rely on their physician for appropriate therapies and medicine; however, current state policies limit both patients and physicians.

Nevada Policy and NORML's Second Core Tenet

Nevada's current policy gives doctors freedom to decide treatment regimens for qualifying conditions including "AIDS, cachexia, cancer, glaucoma, post-traumatic stress disorder (PTSD), persistent muscle spasms or seizures, severe nausea or pain, and other conditions are subject to approval" (Nevada Division of Public and Behavioral Health, 2018, n.p.). In comparison to NORML's (2019) second core tenet, results of this cross-case analysis represent a value match of one. More precisely, Nevada's policy has limited alignment with NORML's second tenet.

Nevada's specific policy focuses on qualifying conditions for determining doctors' latitude to decide treatment, which subsequently affects patients amid the complex process of policy design. As such, policy feedback theory is in support of the idea that individuals largely base decisions on the social constructs of groups, especially concerning multifaceted process of policy creation. In cross-examination to the benchmark, Nevada's policy results in a limited match against NORML's (2019) second core tenet.

According to Maxwell and Mendelson (2016), individual states determine medicinal cannabis regulation with regard to criteria of who can recommend and/or prescribe medicinal cannabis and who can become a qualified patient of the program. Therefore, physicians who provide written recommendations for their patients will be able to legally obtain medicinal cannabis as treatment for chronic illness. Following clinical trials in 2010, the Center for Medicinal Cannabis Research (2017) concluded that cannabis should be "first line treatment" for patients with serious illnesses and neuropathy. As such, medical cannabis treatment continues to be the answer for patients suffering with chronic/debilitating medical conditions (Betthauser et al., 2015; Carter, 2013; Hill, 2015).

California Policy and NORML's Third Core Tenet

> California's current policy incorporates personal cultivation rights, as the patient: [C]an cultivate no more than six mature or twelve immature plants. However, there are no cultivation limits specified under state law, but local ordinances can limit or ban medical cultivation. Furthermore, Qualified Patients are exempt from state licensing requirements under MMRSA, if they cultivate 100 square feet or less of medical cannabis. Primary Caregivers serving up to five Qualified Patients may cultivate up to 500 square feet of medical cannabis without a state license. Cities and counties retain the right to license, regulate or ban medical cannabis cultivation. (California Department of Public Health, 2018, n.p.)

In comparison to NORML's (2019) third core tenet, the results revealed a value match of one. More specifically, a section of California's policy aligns with NORML's third tenet, although limited.

While the state specifies no cultivation limits, local ordinances may dominate. As the policy feedback theory asserts, citizenship results from the power of groups, political agendas, and systems of governance, thus affecting future policies. As such, this theory is in strong support of an individual's preferences and decisions largely molded by policies. In turn, patients in the state of California are limited concerning cultivation rights. In cross-examination to the benchmark, California's policy results in a limited match against NORML's (2019) third core tenet.

Colorado Policy and NORML's Third Core Tenet

> According to Colorado's current policy for personal cultivation rights:
>
> [P]atients (or their primary caregivers) may cultivate no more than six marijuana plants, with three or fewer being mature, flowering plants that are producing a usable form of marijuana. Not more than six (6) marijuana plants, with three (3) or fewer being mature, flowering plants that are producing a usable form of marijuana. Patients and primary caregivers who possess more than two ounces or six plants have an affirmative defense in court after they have been arrested if the amount they have is "medically necessary to address the patient's debilitating medical condition." Patients who have a doctor's recommendation to use medical cannabis but who have not obtained a Registry Identification Card also have an affirmative defense in court. (State of Colorado, 2018, n.p.)

In comparison to NORML's (2019) third core tenet, study results showed a value match of one. More precisely, part of Colorado's policy aligns with NORML's third tenet, although limited.

In cross-examination to the benchmark, Colorado's policy results in a limited match against NORML's third core tenet. Policy feedback theory comprises three distinct aspects: the independence of these three aspects, the role of conjunction between these three concepts, and the solution correspondence resulting in policy evolution. Policy feedback theory is fundamental, as this theory is essentially heuristic while strongly relying on the acquisition of knowledge (Sabatier & Weible, 2014)

Nevada Policy and NORML's Third Core Tenet

Nevada's existing policy defines personal cultivation rights as:

> [T]welve marijuana plants, irrespective of whether the marijuana plants are mature or immature. Limits on home cultivation if patients reside within 25-miles of an operating dispensary. However, patients who are cultivating specific strains of cannabis not provided by a local dispensary may continue to engage in the home cultivation of such strains. Patients who have an established history of cultivating medical cannabis prior to July 1, 2013, also may continue to do so until March 31, 2016. (Nevada Division of Public and Behavioral Health, 2018, n.p.)

In comparison to NORML's (2019) core tenet, the findings determined a value match of one. More specifically, a limited part of Nevada's policy aligns with NORML's third tenet.

Although Nevada's existing policies were to develop structure and provide benefits, policy feedback theory clearly illustrates how the dynamics of policy design impact people on individual and group levels (Mettler & SoRelle, 2014; Sabatier & Weible, 1999). The policy feedback theory supports the intent of policy design is to create increasing returns on prior commitments that also promote continued efforts (Cairney, 2012; Pierson, 2002). In cross-examination to the benchmark, Colorado's policy results in a partial match against NORML's (2019) second core tenet.

As illustrated in Chapter 2, the California Compassionate Use Act (1996) eliminated criminal state-level penalties for the use, cultivation, and possession of cannabis (California Health Safety, 1996). Patients diagnosed with any debilitating illness for which the medical use of marijuana has been "deemed appropriate and has been recommended by a physician" receive legal protection under this Act (NORML, 2019, n.p.). However, the Supreme Court held that the power vested in Congress included that to prohibit the local cultivation and use of cannabis, even though such cultivation and use was in compliance with California law (*Gonzales v. Raich*, 2005). If the legislative bill in support of policy reform, H.R. 2528 Respect States and Citizens' Rights Act of 2017 (as introduced in the House) passes, it will amend federal law by decriminalizing the possession, distribution, and cultivation of state-regulated medical marijuana.

The results of this study have no discrepant cases and are void of nonconfirming data. Table 1 represents values matched against NORML as the benchmark and the states of California, Colorado, and Nevada as the exemplary cases cross-examined.

Table 1

California, Colorado, and Nevada's Provisions in Comparison to NORML

Tenet	California	Colorado	Nevada	NORML
1: Access to whole-plant cannabis	"The voluntary registry issues ID cards that offer protection from arrest for patients and caregivers in possession of no more than eight ounces of useable cannabis. However, currently there are no possession limits specified; the amount must be "consistent with the patient's needs," that has been deemed appropriate and has been recommended by a physician" (California Department of Public Health, 2018).	"Medical Marijuana Registry Identification Card, or that patient's primary caregiver who has been identified on the patient's Medical Marijuana Registry Identification Card, to possess no more than two (2) ounces of a usable form of marijuana" (State of Colorado, 2018).	"Two and one-half ounces of usable marijuana and/or a maximum allowable quantity of edible marijuana products and marijuana-infused products as established by regulation of the Division in any one 14-day period. Can only purchase from designated dispensary (can change every 30 days)" (Nevada Division of Public and Behavioral Health, 2018).	"Patients must be legally able to obtain and possess herbal formulations of whole-plant cannabis that may be administered via inhalation/vaporization; their therapeutic choices must not be limited solely to orally administered cannabis-derived extracts, oils, or pills" (NORML, 2014).
2: Wide latitude for doctors to decide treatment regimens	California's existing program also includes a wide latitude for doctors to decide treatment regimens and provides qualifying conditions to include anorexia, arthritis, cachexia, cancer, chronic pain, HIV or AIDS, glaucoma, migraine, persistent muscle spasms, severe nausea, seizures and any debilitating illness where the medical use of marijuana has been "deemed appropriate and has been recommended by a physician" (California Department of Public Health, 2018).	Colorado's current policy incorporates a wide-latitude for doctors to decide treatment regimens. The qualifying conditions include "chronic nervous system disorders, post-traumatic stress syndrome and debilitating medical conditions are defined as cancer, glaucoma, and infection with or positive status for human immunodeficiency virus. Chronic or debilitating disease or medical condition other than HIV infection, cancer or glaucoma; or treatment for such conditions, which produces for a specific patient one or more of the following, and for which, in the professional opinion of the patient's physician, such condition or conditions may reasonably be alleviated by the medical use of marijuana: chronic nervous system disorders; post-traumatic stress syndrome; cachexia; severe pain; severe nausea; seizures, including those that are characteristic of epilepsy; or persistent muscle spasms, including those that are characteristic of multiple sclerosis (State of Colorado, 2018).	Nevada's current policy includes a wide-latitude for doctors to decide treatment regimens for qualifying conditions. Those qualifying conditions include "AIDS, cachexia, cancer, glaucoma, post-traumatic stress disorder (PTSD), persistent muscle spasms or seizures, severe nausea or pain, and other conditions are subject to approval" (Nevada Division of Public and Behavioral Health, 2018).	"The approved list of qualifying conditions must be expansive and must allow physicians the option to recommend cannabis therapy for the treatment of chronic pain" (NORML, 2014).

Table 1 Continued

Tenet	California	Colorado	Nevada	NORML
3: Personal cultivation rights	The state of California's current policy incorporates personal cultivation rights as the patient "can cultivate no more than six mature or twelve immature plants. However, there are no cultivation limits specified under state law, but local ordinances can limit or ban medical cultivation. Furthermore, Qualified Patients are exempt from state licensing requirements under MMRSA, if they cultivate 100 square feet or less of medical cannabis. Primary Caregivers serving up to five Qualified Patients may cultivate up to 500 square feet of medical cannabis without a state license. Cities and counties retain the right to license, regulate or ban medical cannabis cultivation" (California Department of Public Health, 2018).	Colorado's current policy for personal cultivation rights encompass "patients (or their primary caregivers) may cultivate no more than six marijuana plants, with three or fewer being mature, flowering plants that are producing a usable form of marijuana. Not more than six (6) marijuana plants, with three (3) or fewer being mature, flowering plants that are producing a usable form of marijuana. Patients and primary caregivers who possess more than two ounces or six plants have an affirmative defense in court after they have been arrested if the amount they have is "medically necessary to address the patient's debilitating medical condition." Patients who have a doctor's recommendation to use medical cannabis but who have not obtained a Registry Identification Card also have an affirmative defense in court" (State of Colorado, 2018).	The state of Nevada's existing policy for personal cultivation rights is defined as "twelve marijuana plants, irrespective of whether the marijuana plants are mature or immature. Limits on home cultivation if patients reside within 25-miles of an operating dispensary. However, patients who are cultivating specific strains of cannabis not provided by a local dispensary may continue to engage in the home cultivation of such strains. Patients who have an established history of cultivating medical cannabis prior to July 1, 2013, also may continue to do so until March 31, 2016" (Nevada Division of Public and Behavioral Health, 2018).	"Personal cultivation rights' and is described as 'registered patients ought to have the legal option to cultivate personal use quantities of cannabis in their own private residence" (NORML, 2014).

In response to the research question "How do state-level regulatory efforts in medicinal cannabis provide guidance on formulating national public policies that are most beneficial to patients in the United States?" the assessment results were notable due to the inconsistency across the three exemplary states, which did not fully align with NORML's three core tenets. Furthermore, current policy does not support the lack of access and benefits to patients requiring medical cannabis to treat disease in the United States. Therefore, current state policies do not represent the therapeutic and/or medical value of medical cannabis for patient suffering with diseases in the US. As a result, the

lack of recognition further prevents patients' access and physicians' ability to treat with medical cannabis. Furthermore, policy feedback theory supports the systematic method to appropriate benefits to policy recipients or target groups in groups versus as individuals (Maltby, 2017).

Conclusion

Chapter 4 included the results of this qualitative cross-case analysis research study addressing the need for an increased understanding about the lack of and possibilities for the development of a delivery system to use medicinal cannabis for the treatment of disease in the United States. Three states with exemplary medical cannabis laws—California, Colorado, and Nevada—served as this study sample population. Three core tenets of the patient-centric medical cannabis program of NORML, one of the leading authorities in the cannabis industry, served as a benchmark. The research question "How do regulatory efforts in medicinal cannabis shed light on what is most advantageous in policies that benefit patients in the United States?" guided this study. The policy feedback theory further supported the importance of the need for developing a delivery system to use medicinal cannabis for patients in the United States. A discussion of the setting and demographics illustrated the importance of this study. Descriptions of the data collection and analysis processes provided evidence of trustworthiness, with themes derived as results. Chapter 5 provides an interpretation of the findings.

Chapter 5: Conclusions and Recommendations

The medicinal value of cannabis for U.S. patients suffering from disease is becoming more widely known and increasingly applicable, yet existing laws and policies continue to limit access. The purpose of this cross-case analysis was to address the need for an increased understanding about the lack of and possibilities for development of a delivery system to use medicinal cannabis for the treatment of disease for patients in the United States. The following research question guided this study:

RQ: How do state-level regulatory efforts in medicinal cannabis provide guidance on formulating national public policies that are most beneficial to patients in the United States?

The assessment included an analysis of three exemplary states' existing laws and policies against a benchmark, NORML, the leading authority in medicinal cannabis. I used policy feedback theory for the supporting framework. According to this theory, groups of people naturally interpret the concept of policy as positive or negative based on heuristic thinking, especially concerning the multifaceted subsystems involved. A qualitative cross-case analysis served as the preferred methodology and design because of the nature of participants. Data collected from the sample population and the benchmark case were publicly available documents, so a triangulated cross-case analysis served as the most compelling method to obtain results. The comparison of NORML's three core tenets to policies in California, Colorado, and Nevada showed that patient access to the whole plant of cannabis is restricted, with policies varying from state to state. With this

study, I sought to promote consideration for the development of a delivery system in the United States to use medicinal cannabis for the treatment of disease.

Purpose

The purpose of this study was to explore the lack of and possibilities for the development of a delivery system to use medicinal cannabis for the treatment of disease in the United States. Because the US does not have a formal delivery system for medical cannabis, this study served to support the need for continued research at the state level for initiatives and system possibilities. The comparison of three tenets from the leading cannabis authority, NORML, to three exemplary states' policies allowed me to identify the need for a uniform delivery system to support patients in the United States who depend on cannabis for medical purposes. Patients will benefit from a change in laws and uniform policy for the transportation and delivery system of medicinal cannabis by having access to medicinal cannabis without fear of arrest or federal criminal prosecution. The recommendation is for future policy to reflect the results of this study as substantiation that the development of a delivery system for the use of medicinal cannabis for U.S. patients merits consideration. This would allow patients who rely on cannabis for the treatment of disease to access to legally obtain, possess, and transport cannabis and to conduct activities related to individual needs.

Interpretation of Results

A review of various peer-reviewed articles and secondary data supported the importance of addressing the need for an increased understanding concerning the lack of and possibilities for the development of a delivery system to use medicinal cannabis for

the treatment of disease in the United States. Addressing this need came by comparing three core tenets of NORML's patient-centric, evidence-based medical cannabis program to three exemplary state medical cannabis programs currently implemented. As supported in Chapter 2, when comparing NORML's three core tenets to California, Colorado, and Nevada policies, it is clear that patient access to the whole cannabis plant is limited and varies from state to state.

Interpretation supports policy feedback theory. The power of groups impacts political agendas, systems of governance, and future policies (Sabatier & Weible, 2014). Grounding this study is the idea that policies greatly shape an individual's preferences and decisions. Policy feedback theory supported the customary principles of policies that impact those who rely on medicinal cannabis for the treatment of disease and who are in need a sound delivery system in the United States (Mettler & SoRelle, 2014).

California's policy does not specify means or amount of possession for patients; rather, access must be "consistent with the patient's needs, that has been deemed appropriate and has been recommended by a physician" (Guidelines - Medical Marijuana, 2016, n.p.). According to state policy, Colorado requires a "Medical Marijuana Registry Identification Card, and the patient may possess no more than 2 ounces of a usable form of marijuana" (State of Colorado, 2018, n.p.). Nevada's policy asserts that patients may have access to 2.5 ounces and/or a determined allowable quantity of edible cannabis and/or marijuana-infused product within one 14-day period. Nevada also requires purchase from an elected dispensary (Nevada Department of Public and Behavioral Health, 2018).

As found in this study, each of the three exemplary states met only some of NORML's criteria for an expansive list of qualifying medical conditions. For instance, California's policy offers a wide latitude for doctors to decide treatment regimens, provides a range of qualifying conditions, and also gives physicians allowance for any debilitating illness where medicinal cannabis is been "deemed appropriate and has been recommended by a physician" (California Department of Public Health, 2018, n.p.). Colorado's policy also provides doctors wide latitude to decide treatment regimens, although qualifying conditions are more limited than with California's policy (State of Colorado, 2018). While Nevada presents wide latitude for doctors to decide treatment regimens for qualifying conditions, the state provides limited conditions.

Moreover, state laws restrict allowing patients the legal option to cultivate cannabis for personal use in their private residence, with regulations varying per state medical cannabis regulatory entities such as the Department of Health. For example, California limits a patient's rights to cultivate as:

> [N]o more than six mature or twelve immature plants. Furthermore, Qualified Patients are exempt from state licensing requirements under MMRSA, if they cultivate 100 square feet or less of medical cannabis. Primary Caregivers serving up to five Qualified Patients may cultivate up to 500 square feet of medical cannabis without a state license. Cities and counties retain the right to license, regulate or ban medical cannabis cultivation. (California Department of Public Health, 2018, n.p.)

Colorado's policy is similar, albeit more limited:

> [P]atients (or their primary caregivers) may cultivate no more than six marijuana plants, with three or fewer being mature, flowering plants that are producing a usable form of marijuana. Not more than six (6) marijuana plants, with three (3) or fewer being mature, flowering plants that are producing a usable form of marijuana. (State of Colorado, 2018, n.p.)

Nevada's policy is similar to California's, but with another limitation:

> [The cultivation of] twelve marijuana plants, irrespective of whether the marijuana plants are mature or immature. Limits on home cultivation if patients reside within 25-miles of an operating dispensary. However, patients who are cultivating specific strains of cannabis not provided by a local dispensary may continue to engage in the home cultivation of such strains. (Nevada Division of Public and Behavioral Health, 2018, n.p.)

The results of this study extend knowledge as anticipated in Chapter 2. NORML's three core tenets provide a more broad-based model that includes a willingness to discard traditional policy for patients to have equal access and use medicinal cannabis for the treatment of disease in the United States.

Limitations

This cross-case analysis was critical for U.S. patients, physicians, state laws and policies, future researchers, and federal regulations. This study was important because of increasing attention to the benefits of cannabis for medical purposes and the lack of understanding regarding the need to develop of a delivery system for patients in the United States. The US lacks an existing formal delivery system for medicinal cannabis,

necessitating continued research at the state level to identify initiatives and systems possibilities. This study provided pertinent information regarding the lack of alignment of policies and laws across different states.

I have identified two limitations to this study: sample size and demographics. This small sample population consisting of three exemplary states is not generalizable to a broader population, given that 30 additional state medical cannabis programs did not undergo comparison. The second limitation is due to the particular segment of the population and organization. The use of NORML's three core tenets narrows the model for studying current and future regulatory efforts and policies impacting equal access for medicinal cannabis in the United States.

Recommendations

Recommendations for future research and policy change are considerable, grounded in the strengths and limitations of the existing body of literature as illustrated in Chapter 2. The use of medical cannabis has gained much ground and merits immediate consideration as a relevant option for those suffering with a medical illness. Both in the past and today, medical cannabis has been the answer for patients dealing with disease in the United States. Prior to the late 1930s, physicians could legally provide their patients with a prescription for cannabis.

I make several recommendations for future research. The FDA (2019) does not approve indications for medicinal cannabis; rather, its focus is to evaluate research conducted by drug manufacturers and review data submitted to the FDA to ensure a drug product meets the statutory standards for approval. However, the FDA does not evaluate

or research the cannabis plant for medicinal value (FDA, 2019). The first recommendation is for the FDA to research, study, and evaluate medicinal cannabis and provide its findings to the DEA.

Once the FDA has researched and evaluated the scientific effectiveness of cannabis as a medication with an accepted treatment through the FDA approval process, it can recommend the treatment to the DEA for review. The DEA then has the authority to reclassify medicinal cannabis into a less-restrictive category that would make it more readily available to physicians and patients. The next recommendation is for the revision of the Interstate Commerce Clause to exclude medical cannabis from the legislation. To make this happen, the change would require Congressional approval, a formal legislative action described by Article I, Section 10, Clause 3 of the Constitution. With Congressional consent, the Interstate Commerce Clause would transform federal law and allow for less restrictive businesses practices for medical cannabis dispensaries resulting in greater patient availability. The next recommendation for future study of medicinal cannabis is the reclassification of cannabis as a Schedule 2 or lower. The goal is to implement public policy by reclassifying the use of cannabis for medical purposes. This reclassification will help to improve the quality of life for people suffering from disease within the United States. This recommendation will enable patients and their medical team to devise the necessary treatment plans and medication decisions without the fear of government intervention or criminal prosecution.

The final recommendation for future research is declassification. This would remove cannabis from the CSA entirely and allow patients and doctors to explore

medicinal cannabis and its use for the treatment of any disease deemed appropriate by both patient and doctor. In conjunction with policy feedback theory, people depend on empirical thought processes and rely on the social paradigm of complex policy development. The framework served as a model for this study, as it supported the need to improve understanding of the policy process. The ultimate goal is to educate doctors, citizens, politicians, and government officials regarding the positive therapeutic affect cannabis can have on individual patients and society as a whole. The integration of cannabis into the U.S. medical community will better serve patients with this form of treatment as an option. These recommendations do not exceed the study boundaries, as described previously.

Implications

This study's contribution includes identification of how perceptions of regulatory efforts concerning medical cannabis shape policies that impact U.S. patients. This research is significant because of recognized gaps the perceptions of governing regulatory delivery systems and the existing body of literature focusing on the value of medicinal cannabis. To lead positive social change, the potential to improve the lives of patients in the United States may more readily occur through improved access of medicinal cannabis.

The empirical implications are noteworthy, as acknowledging an alternate solution for a systematic delivery system for medicinal cannabis through change needed to future public policy is a significant step toward constructive social change. Policy feedback theory served to support this study, as the framework centers on the formation

of policy, examination of dynamics, and societal response to these policies (Mettler & SoRelle, 2014). Methodical implications from this study include incorporation of evidence-based research to support policy change for medical cannabis for the treatment of disease. By eliminating current restrictions on medical cannabis, greater liberty is available for physicians to authorize cannabis for the treatment of disease without the federal government prohibiting patient access in those states that have legalized medicinal cannabis.

Amending federal law would decriminalize the cultivation, possession, and distribution of state-regulated medical cannabis. This will result in the FFDCA no longer superseding state law for permitting therapeutic use of medical cannabis. In addition, this will address the legislative bill known as the States Medical Marijuana Patient Protection Act, which reads in part:

> [N]o provision of the Federal Food, Drug, and Cosmetic Act shall prohibit or otherwise restrict an entity authorized by a state or local government, in a state in which the possession and use of marijuana for medical purposes is legal from producing, processing, or distributing marijuana for such purpose. (H.R. 689, 2013, n.p.)

The implications for social change do not exceed the study boundaries. As a result, the implications of this study are significant because they offer additional data that supports the need for improved systems of government oversight for existing and future policies and programs.

Summary

This study was vital to patients in the United States suffering from disease who will benefit from improved laws and policies governing cultivation, possession, and distribution of medicinal cannabis. This change is needed, as physicians are limited in or prohibited from authorizing the use of therapeutic cannabis. This study's problem statement is that the United States does not have a formal delivery system for accessing medicinal cannabis, as federal law does not recognize the medicinal properties of cannabis. Policy feedback theory fully supports the social paradigm of policy design and was therefore the nature of this study. People as groups innately interpret the concept of policy as positive or negative based on heuristic thinking. Furthermore, the results indicated an overarching consensus concerning a lack of attention to consistent policies among three exemplary participant states and NORML, the leading cannabis authority used as the benchmark, which substantiate the importance of this study. The findings of this research support the need for attention to the possibilities for the development of an improved delivery system to treat U.S. patients. With an increase in the number of states legalizing medicinal cannabis, it is important to direct attention to amended regulatory efforts.

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