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State Policies of Medical Marijuana versus Food & Drug Administration Policies of Pharmaceutical Drugs

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Abstract

In the past 22 years, 32 states have legalized and regulated marijuana for medical use. However, marijuana is scheduled as a Schedule I drug according to the federal government. This means that states have no specific regulations to follow for regulating marijuana for medical use. Because of this, states may be risking the safety of medical marijuana patients. Research was conducted to analyze the policies set out by the Food & Drug Administration (FDA) regarding the regulation of a prescription drug. Since the FDA is responsible for the safety and efficacy of prescription drugs, this analysis included what types of risks were mitigated by FDA policies. State policies on medical marijuana were then compared to FDA policies in order to determine if aforementioned risks are being acknowledged and mitigated by states. This research found that states are implementing some policies similar to aspects of FDA regulations, but states are not eliminating nearly as many safety risks that the FDA focuses on eliminating. States are, however, creating additional policies that encompass social issues regarding the legalization of medical marijuana, which the FDA doesn't do, which could be allowing medical safety to be analyzed in a broader social context.

Chapter I. Introduction

The use and acceptance of medical marijuana in the United States is evidenced by an increasing number of states that have passed legislation to legalize its use. While there is a long history of pharmaceutical regulation in the United States, medical marijuana is illegal at the federal level of government. Thus, regulation rests at the state level, where there are significantly different regulatory standards across these states. The level and type of regulation for marijuana as a medication across all states is significantly less than the level of regulation for traditional pharmaceuticals.

Marijuana is considered a Schedule I drug and thus illegal at the Federal level of government. According to the Drug Enforcement Administration, a Schedule I drug is a drug "with no currently accepted medical use and high potential for abuse" (U.S. Drug, 2018). This classification aligns marijuana with drugs like heroin, ecstasy, and lysergic acid diethylamide (LSD). However, in 1996, California passed Proposition 215 which legalized the medical use of cannabis. By 1998, three additional states (District of Columbia, Oregon, and Washington state) had also legalized marijuana for medical use. President Clinton, however, reiterated his opposition to medical marijuana use and threatened to take away the prescribing rights of doctors who suggested medical marijuana use to their patients. A group of physicians in San Francisco, however, challenged this and prevailed in Conant v. McCaffrey. This case prohibited the punishing of physicians or taking their DEA licenses for recommending medical use of marijuana (Conant, 2000). In 2005, during the Bush administration, Gonzales v. Raich ruled in favor of the federal government's ability to enforce federal laws in states that had already legalized medical marijuana, specifically in terms of production and use of homegrown marijuana (Gonzales, 2005). In 2014, during the Obama administration, the Rohrabacher-Farr

amendment was finally passed, after being defeated 6 times since 2001. This amendment describes how the Justice Department is prohibited from spending funds to interfere with the implementation of state medical marijuana laws. The passing of this amendment was the first time in Congress' history that voting swayed to protect medical marijuana patients, and was viewed as a historic victory for those patients.

In the five years since 2014, 11 states have implemented medical marijuana policy. This is a large yearly increase when compared to the 21 states that implemented policies in the 18 years prior to the passing of the Rohrabacher-Farr amendment. Although more states are passing policies regarding medical marijuana, states are not doing so consistently. The Food & Drug Administration (FDA) has a specific protocol for regulating medical drugs. However, due to the duality of legalization in the United States, the FDA is not allowed to regulate the use of medical marijuana and it continues to prove difficult for states to regulate in a standardized manner. While this may prove to be good for policy innovation, it is unclear if the risks associated with the lack of standards should or can be remedied. While there is variation between state policies for medical marijuana regulation, the regulation for pharmaceutical drugs are clear and outlined by the FDA. The FDA uses the Code of Federal Regulations to publish the regulations for regulating drugs for medicinal use.

In this thesis, I will be looking at the difference between the standards of traditional pharmaceutical regulation and the current state of regulation of medical marijuana across a number of states. This is important to study because states currently have no standardization for regulating medical marijuana, which could be jeopardizing the safety of medical marijuana patients. I will identify the goals of different regulatory steps in the traditional processes, and compare these steps to current state regulations of medical marijuana. Through this comparison,

I will identify where current medical marijuana law may be lax, and perhaps inadequately protecting the safety of patients. I will then compare this to what is currently known about the impacts of state legalization to see if any of these potential problems have come to fruition.

The next section will be a review of previous research conducted on the implications of medical marijuana legalization. From this literature, I will identify my specific research questions, outline a methodology for data collection, and describe the data and findings of research. This will be followed by analysis and discussion, as well as research limitations and policy recommendations.

Chapter II. Literature Review

Since medical marijuana is approved as a medicinal drug in many states, it is important to look at the known risks of this type of drug. The purpose of this literature review is to see what studies have been conducted on the risks associated with medical marijuana legalization. It analyzes the most common impacts on society that has been studied thus far, including increased use of recreational marijuana, youth use, public health effects, traffic fatalities, crime and suicide rates, and more.

Methodology

I focused my search results on the implications of implementing medical marijuana laws. Utilizing Google Scholar, research was conducted to find only the implications of medical marijuana once a law or policy was implemented. Some research spanned the United States, while other research only touched a specific group of states, or one single state. Additionally, research spans the whole history of medical marijuana, which is a fairly short timeline (2004-2017). During a preliminary search, I found multiple categories of outcomes studied, including increased use of recreational marijuana, youth use, crime, public health effects, traffic fatalities, suicide, and a change in attitude. Once I discovered the main topics, I delved into them individually. This search included phrases like "legalization of medical marijuana on crime" and "legalization of medical marijuana on suicide rates." All of the statistics of these implications were studied after the implementation of medical marijuana laws and compared to what the statistics were prior to the implementation of the laws. In this review, I have excluded any research that was not exclusively about medical marijuana. This included any papers analyzing effects of marijuana in general, as well as papers discussing implications of legalizing marijuana for recreational use. While some academic scholarship focused on the ethical dilemma and

duality of medical marijuana legislation in the United States, I will not consider the research on ethics, and instead will focus on the seven main categories of study regarding the implementation of medical marijuana laws.

Findings

Summary

The seven main categories of research on the impacts of medical marijuana legalization are: increased use of marijuana, increased youth use (particularly adolescents), effects to the public health system, traffic accidents & fatalities, crime rates, suicide rates and a change in attitude regarding marijuana. A total of 25 articles were found covering these topics. Across the 25 articles, a few revolved around each topic—with the most research being conducted on increased youth use and traffic accidents and fatalities. Table 1 shows the topics covered in each of the articles reviewed. Additionally, Table 2 shows the general findings of each category, while the remaining sections discuss more specific findings for each of these topics.

Table 1: Topics Covered in the 25 Articles Reviewed

	Traffic Citations	**Suicide Rates**	**Public Health Effects**	**Increased Use**	**Youth Use**	**Crime**	**Changing Attitude**	**Potency**	**Pediatric Exposure**
Citation									
Anderson (2013)	x								
Anderson (2014)		x							
Bradford (2016)			x						
Cerda (2011)				x					
Choo (2014)					x				
Chu (2014)						x			
Davis (2016)			x	x					
Friese (2012)					x				
Grucza (2015)		x							
Hasin (2015)				x					
Khatapoush (2004)							x		
Lynne-Landsman (2013)					x				
Masten (2014)	x								
Miech (2015)					x		x		
Morris (2014)						x			
Rylander (2014)		x							
Salomonsen-Sautel (2014)	x								
Salomonsen-Sautel (2012)					x				
Santaella-Tenorio (2017)	x								
Sevigny (2014)								x	
Wang (2013)									x

Table 2: Summary of Article Findings, Based on Categories

Category	**# of Articles**	**Overall Findings**	**Comments**
Youth Use	5	Mixed	No correlation for national sample. Increased use when looking at specific region.
Traffic Incidents	4	Mixed	Lower fatality rates, but higher number of marijuana-positive drivers in accidents.
Increased Use	3	Mixed	Increased use for national sample. No correlation when looking at specific regions.
Suicide Rates	3	Mixed	No correlation in one national study and in regional study. One national study found reduction.
Change in Attitude	2	Positive	Decreased perceived harm.
Public Health Effects	2	Mixed	Lower prescription drug use and increase in hospital admissions.
Crime Rate	2	Mixed	Increase in marijuana arrests, but no correlation to other crimes.

Increased Use

Two articles utilized the National Epidemiologic Survey on Alcohol and Related Conditions to determine if use of marijuana increased after medical marijuana laws were implemented (Cerda, 2011; Hasin, 2015). It was concluded that recreational marijuana use more than doubled after the implementation of policies regarding medical marijuana. In addition, the likelihood of marijuana abuse/dependency increased in states with medical marijuana laws. However, a study conducted in California (Khatapoush, 2004) found no increase of drug use after the implementation of medical marijuana laws. This is likely because of the decreased

sample size. This research demonstrates that policy makers should be aware of potential overuse and abuse of marijuana after the implementation of medical marijuana laws.

Youth Use

Two articles analyzed increased youth use of marijuana across multiple states (Choo, 2014; Lynne-Landsman, 2013). Using surveys, there was no statistically significant difference in marijuana use before and after policy change or implementation. Two other articles conducted surveys in one specific state (Friese, 2012; Miech, 2015). When research was conducted with a narrower sample size of just one state, more statistically significant results were found. In Montana (Friese, 2012), 31% of 8^{th}, 10^{th}, and 12^{th} grade students reported having had used marijuana in their lifetime. Similarly, in California and after the decriminalization of marijuana (Miech, 2015), 25% of 8^{th}, 10^{th}, and 12^{th} graders said they were more likely to have used marijuana in the past 30 days. One study conducted research in the Denver metropolitan area and found that 74% of adolescents had used someone else's medical marijuana (Salomonsen-Sautel, 2012). This research shows how drastically results change based on area and local versus national level data. When looking at national data, the results appear to wash out.

Public Health Effects

The legalization of medical marijuana has impacted the public health system. For example, one study was conducted on how the implementation of medical marijuana policies impacted the use of all FDA-approved prescription drugs paid for by the Medicare Part D program (Bradford, 2016). Using data from the Medicare Part D Prescription Drug Event Standard Analytic file and restricting the analysis to any prescription drugs that treated conditions for which medical marijuana could be a treatment, the author found that medical

marijuana laws caused prescriptions drug use that served as alternatives to fall drastically – with Medicare spending an estimated $165.2 million less than in previous years. In addition, a study in Colorado (Davis, 2016) found that there was an increase in hospital discharges, poison center calls, and decreases in treatment entries after the legalization of medical marijuana.

Traffic Incidents

Two articles used the Fatality Analysis Reporting System collected by the National Highway Traffic Safety Administration to determine if there was a correlation between traffic incidents and the legalization of medical marijuana (Santaella-Tenorio, 2017; Anderson, 2013). Both found that, on average, states with medical marijuana laws had lower traffic fatality rates than states without medical marijuana laws. On the other hand, a study conducted in Colorado (Salomonsen-Sautel, 2014) found that a larger proportion of drivers in fatal motor vehicle crashes were marijuana-positive after commercial availability of medical marijuana increased. Similarly, one study of 12 states (Masten, 2014) found that only a few states—California, Hawaii, and Washington State—had an increased driver cannabinoid prevalence associated with the implementation of medical marijuana laws.

Crime Rates

The implementation of medical marijuana laws has led to changes in crime rate. Two studies were conducted across the United States. One study (Chu, 2014) found that the passing of medical marijuana legislation led to a 10-20% increase in marijuana arrests, while the other study (Morris, 2014) found that medical marijuana laws were not predictive of higher crime rates. In particular, the study found no correlation for increased crime rates of homicide, rape, robbery, assault, burglary, larceny, and auto theft.

Suicide Rates

Three studies were conducted regarding suicide rates after the implementation of medical marijuana laws. Two of them were conducted across the entirety United States, utilizing the National Vital Statistics System (Anderson, 2014; Grucza, 2015). While Anderson (2014) found that legalization of medical marijuana was associated with a reduction in suicide rates of men aged 20-39, Grucza (2015) found that there was no association between medical marijuana policy and suicide risk in ages 15 and older. A third study (Rylander, 2014) was conducted in Colorado and also found that there was no significant correlation between the number of medical marijuana registrants and suicides.

Change in Attitude

Two studies elaborated on the change in attitude regarding marijuana once a medical marijuana legislation was put into place. Both Khatapoush (2004) and Miech (2015) looked at California and noticed that perceived harm of medical marijuana decreased, particularly after the media cover of decriminalization of marijuana.

Other

Furthermore, other categories were mentioned, but not well studied. First, one article analyzed how the potency of marijuana changed after the implementation of medical marijuana laws (Sevigny, 2014). Studying nearly 40,000 marijuana samples that were seized by law enforcement, it was found that potency increased by 0.5% after legalization of medical marijuana. This increased to 1% more potent in states that had retail dispensaries. Secondly, a study analyzed data from hospital emergency departments within Colorado (Wang, 2013). The

study found that there were higher unintentional marijuana ingestions by young children after decriminalization of marijuana.

Discussion

To summarize, this literature review focused on the effects of implementing medical marijuana policies. Some findings were consistent, while others were not. There also was not a large number of articles in any one category. This demonstrates just how new this topic is. Considering the first state to legalize marijuana for medical purposes was California in 1996, limiting the ability of researchers to study the impact of these laws. Overall, the research I found revolved around the societal impacts of implementing medical marijuana policies, such as youth use, traffic incidents, increased recreational use, suicide and crime rates, public health effects, change in attitude, potency, and pediatric exposure. While all of the categories appeared to be under-researched, potency and pediatric exposure proved to be even more so - by only having one study available on each. While this research does address some of the risks associated with medical marijuana legalization, there are many risks that are not considered. This includes safety, efficacy, and potency of medical marijuana. These are things that should be considered when regulating a substance as a medicinal drug. All in all, however, the majority of research appears to be regarding the implications of medical marijuana policies and not much regarding the safety or efficacy.

Three articles analyzed the potential relationship between medical marijuana laws and their implications by examining the importance of policy dimensions, such as registration requirements, home cultivation, and dispensaries, as well as when the particular policy dimensions were enacted (Pacula, 2014; Cohen, 2010; Clark, 2011). There is no standard for

each state to follow, so there is plenty of room for discrepancies and small differences between states' medical marijuana policies.

Chapter III. Research Questions

Given this literature review, it can be seen that there are gaps in the research on the impacts of legalizing medical marijuana. While there was a lack of research on the medical efficacy of medical marijuana, there was also evidence that legalizing marijuana for medical use has a secondary impact on society, including increased use, youth use, public health effects, traffic fatalities, crime and suicide rates, and more. The focus of this research on secondary impacts suggests that regulation of medical marijuana may serve to protect society not from the traditional FDA focus on safety and efficacy, but instead on the above societal impacts. Thus, research for this thesis will focus on answering the following:

1) How does the regulation process of individual states compare to the FDA regulation processes for pharmaceuticals?

2) What might these differences predict about potential issues of safety and efficacy, and how does this compare to current research findings on the issue?

3) Do states take appropriate actions and apply certain steps to mitigate risks that are of most concern?

4) Could the effects displayed in the literature review be mitigated by following FDA regulations, instead of individual states policies?

Chapter IV. Methodology

Study Design & Data Collection

My research design is a comparative study that looks at the way states regulate medical marijuana, as compared to the regulation processes set out by the FDA. This comparison will be made by mapping out the regulations of the FDA and the regulations of the states of study, to find similarities and differences between state & federal regulations.

To begin, I will be looking at the National Conference of State Legislators. This will provide me with a starting point regarding which states have policies and regulations for medical marijuana. Appendix 1 is a matrix that shows which states in the United States have which type of cannabis policy dimensions. This shows policy dimensions such as whether states have or require patient registry or ID cards, if states allow dispensaries, specific medical conditions that medical marijuana can be used for, and whether states will recognize patients from other states. Analysis of state policies will be visually easier to identify from this matrix, allowing for easy comparison across states.

In total, 23 states were selected for study. This included: Arizona, California, Colorado, Connecticut, DC, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. The matrix in Appendix 1 also includes the specific piece of legislation from each state of study that legalized marijuana for medical use. Using this matrix, I looked into each state's specific legislation, adding additional columns to the table that contain how that state legalized medical marijuana and how they regulated medical marijuana. In terms of state legislation of medical marijuana, this refers to a Senate or House bill, an indirect initiated state statute, an initiated state statute, or an initiated constitutional amendment. Some

states have specified the process of regulation in a separate document than that which legalized medical marijuana. For example, Arizona legalized medical marijuana through an initiated state statute, but then had a separate Senate Bill passed to discuss the regulation process of medical marijuana (Americans, 2018). This will also be documented for each state.

Each state specifies which department will be responsible for regulating medical marijuana. This varies dramatically by state and can include the Department of Health, new departments like the Medical Marijuana Authority Division, the Medical Marijuana Commission, or the Office of Medical Cannabis. Some states also utilize the Department of Licensing & Regulatory Affairs. The department responsible for regulating medical marijuana and the specifics of each policy will be documented for each state. While the regulations vary among states, all state regulations do have common threads - including regulations regarding labelling, dispensaries, testing, and which medical conditions medical marijuana applies to. Many of these state regulations are similar to the Food & Drug Administration's regulations for medical drugs.

I will look at 23 states who have legalized and regulated marijuana for medical use. I have eliminated Utah and Alaska in the list of states I am analyzing; while they both have legalized marijuana for medical use, they have non-regulated medical marijuana programs. I also eliminated states that still have pending policies or states that were regulated after 2016, since some data is only available for medical marijuana policies implemented before 2016.

Next, as seen in Appendix 2, I created a second matrix of all states policies versus FDA policies for pharmaceutical drugs. This allows for a comparison of policy dimensions of each state versus corresponding sections of FDA regulations of traditional pharmaceutical drugs. From this matrix, additional tables were created to show which states have, or don't have, more specific regulations within each of those sections. Analysis was conducted to determine if the

gaps in state policies, or FDA policies, are unimportant or critical. This was done by assigning goals or risks to each section.

Chapter V. Results

FDA Regulations

The FDA uses the Code of Federal Regulations to publish their regulations for regulating drugs for medicinal use. The Code of Federal Regulations (CFR) is a codification of general and permanent rules and regulations published by executive departments and agencies of the federal government of the United States (National, 2018). It is published annually and about 10 titles are published on a quarterly basis. FDA regulations are in Title 21; this title governs food and drugs within the United States for three main agencies. Each agency has a chapter within the title. Chapter 1 belongs to the FDA, Chapter 2 belongs to the Drug Enforcement Agency, and Chapter 3 belongs to the Office of National Drug Control Policy. Chapter 1 is then comprised of 1,299 sections, with sections 200 - 370 being dedicated to regulations of pharmaceutical drugs. These sections are reflected below, along with their significance when it comes to regulating pharmaceutical drugs.

Labeling

Part 201 of the CFR is dedicated to regulations regarding labeling. It emphasizes the need for drugs to be labeled with all names of the manufacturers, along with anyone else who has handled the drug in any way, as well as the need for the facility location in which it was manufactured (§201.1). The labeling regulations also include the need for National Drug Code numbers (§201.2). Additionally, the labels must include adequate directions for use and a statement of ingredients in the drug (§201.5, §201.10). The FDA also requires the label to have an expiration date and a lot number (§201.17, §201.18). In general, labeling requirements must include a summary for the safe and effective use of the drug, must be informative and accurate,

not promotional, false or misleading, and have no implied claims or suggestions for use if evidence of safety or efficacy is lacking. While it is true that proper labels give patients the information on how to properly take medications, the primary purpose of labeling is to give healthcare professionals the information they need to prescribe drugs appropriately.

Prescription Drug Advertising and Prescription Drug Marketing

Parts 202 and 203 are dedicated to regulations regarding advertising and marketing, respectively. Some states use advertising and marketing interchangeably, while the FDA has a clear definition of the two. Marketing is the process involving design, creation, research and data mining about how to best align the idea of a product with the target audience. Advertising, on the other hand, is the literal process of making the product known to an audience and is typically the description used to present the product to the general public (Concordia 2019).

The FDA has a set of regulations specifically for advertisements of pharmaceutical drugs. The basics of these regulations include different types of advertisements, including product claim advertisements, reminder advertisements, and help-seeking advertisements. The regulations also include the scope of information that should be included in an advertisement. This can include effectiveness and side effects of the drug. While the specific regulations vary slightly based on the type of advertisement, the majority of the regulations are designed to ensure that there is no false or misleading information on any advertisement. Similar to the labelling regulations, this ensures that information is being portrayed to patients and healthcare professionals truthfully, allowing them to take and prescribe drugs correctly.

Additionally, the FDA has a set of regulations for marketing of pharmaceutical drugs. The purpose of the marketing regulations are to implement the Prescription Drug Marketing Act of 1987 in order to protect the public, and to protect the public against drug diversion by

establishing procedures, requirements, and minimum standards for the distribution of prescription drugs (§203.2). The marketing regulations focus on reimportation, sales restrictions, samples, and wholesale distribution of pharmaceutical drugs. These regulations are put in place in order to protect the general public and their health. Marketing, and advertising, regulations help assure the safety, effectiveness, and security of prescription drugs by allowing people to get the accurate information they need to use prescriptions appropriately and improve their health.

Medication Guides for Prescription Drug Products

Part 208 outlines the regulations for medication guides. Medication guide means FDA-approved patient labeling conforming to the regulations outlined in Part 208 (§208.3). The regulations include the content and format of the medication guide, including how the guide should be written in understandable English, with non-technical and non-promotional wording (§208.20). The medication guide must also include the following headings, followed by a detailed paragraph answering the questions stated in the headings:

- "What is the most important information I should know about {name of drug}?
- What is {name of drug}?
- Who should not take {name of drug}?
- How should I take {name of drug}?
- What should I avoid while taking {name of drug}?
- What are the possible risks or reasonably likely side effects of {name of drug}?" (§208.20)

The regulations also indicate when and how to distribute and dispense a medication guide, as well as exemptions to these regulations (§208.24, §208.26). The purpose of the medication guide is to inform patients and consumers of the prescription drugs of all information regarding the

proper use of the drug. It can be seen, with much more specific regulations here than are found in labelling, that medication guides are more specifically for patients. Therefore, the nomenclature, content, and format are all geared more toward consumers, which can be seen with the very specific headings.

Requirements for Authorized Dispensers and Pharmacies to Distribute a Side Effects Statement

Part 209 outlines the requirements for distributing side effects statements and warnings. This section specifies content and format of the side effects statement. The content must read "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088," and the format of said content must be a clear, single, easy-to-read line with a specified letter type (§209.10). Additionally, the section describes when and how to distribute and dispense the side effects statement (§209.11). The issuing of a side effects statement is important because all medications can cause unwanted side effects. Some side effects are not as severe as others - for example, some medications can cause a simple rash, while others can cause death. Regardless of the severity of a side effect, it is important that all known side effects are disclosed so that patients can be aware of adverse reactions that may potentially occur in their body while taking certain drugs, or if the patient even wants to take the drug in the first place.

Current GMP in Manufacturing, Processing, Packing of Holding of Drugs; General and Current GMP for Finished Pharmaceuticals

Parts 210 and 211 are dedicated to regulations regarding good manufacturing practices (GMPs) during manufacturing, processing, packing and holding of drugs (§210) and for finished pharmaceuticals (§211). Part 210 mainly outlines the current status of GMPs, the applicability of GMP regulations within the pharmaceutical industry, and concludes with some definitions. Part 211, on the other hand, details the specific organization and personnel within a quality control

unit (§211.22 - 211.34), as well as the design, lighting, ventilation, plumbing, maintenance of, and equipment type to be used in, quality control units (§211.42 - 211.72). The section also details production and process control of pharmaceuticals, as well as packaging and labeling control (§211.100 - 211.137). There are also regulations for laboratory controls, including testing, samples, and animals within a lab (§211.160 - 211.176). The section concludes with regulations regarding reporting, including equipment cleaning logs, batch production records, and laboratory records (§211.180 - 211.198). GMPs, and regulations for GMPs, are important in pharmaceutical drug manufacturing because consumers cannot easily detect an unsafe, ineffective, or "bad" drug by looking at it, smelling it, touching it, or even ingesting it. GMP testing is typically performed on small samples within a larger bath to ensure that the rest of the batch is high quality and safe, effective, and "good" for human use.

Drugs; Official Names and Established Names

Part 299 describes the "official name" of a drug. This section is important to standardize what people are calling drugs. While a lot of pharmaceutical drugs tend to have a generic name, in addition to their official name, it would be confusing to have multiple different names for the same drug.

Sections Excluded from State Analysis

Part 205 of the CFR is regulations for state licensing of wholesale prescription drug distributions. The CFR states, "This part applies to any person, partnership, corporation, or business firm in a state engaging in the wholesale distribution of human prescription drugs in interstate commerce" (§205.1). Since each state has different policies on medical marijuana,

there is no interstate distribution, therefore making it fair that this part of the CFR is exempt from being analyzed.

Part 206 of the CFR is imprinting of solid oral dosage form drug products for human use. While medical marijuana is allowed in pill form in many states, this FDA requirement is specifically for pills that are going to be introduced into interstate commerce, stating that "no drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint" (§206.10). With that, and due to the lack of interstate commerce mentioned above, it is fair that this part of the CFR is exempt from being analyzed.

Part 207 of the CFR outlines the requirements for foreign and domestic establishment registration and listing for human drugs, including drugs that are regulated under a biologics license application, and animal drugs, and the National Drug Code. The purpose of this part is to register establishments that manufacture, repack, relabel, and salvage drugs. The FDA keeps record of this, as well as drug listing information, allowing the FDA to have a current inventory of drugs that are manufactured, repacked, relabeled, or salvaged for commercial distribution and where. According to the FDA, "the information facilitates implementation and enforcement of the Federal Food, Drug, and Cosmetic Act and is used for many important public health purposes" (§207.5). States each have their own way of registering dispensaries, and manufacturers or medical marijuana, since states have a variety of different agencies in charge of their medical marijuana programs.

The following parts are not analyzed due to the lack of applicability to medical marijuana: Part 212, regarding good manufacturing practice for positron emission tomography drugs; Part 216, regarding human drug compounding; Part 225, regarding good manufacturing

practice for medicated feeds; Part 226, regarding good manufacturing practice for type A medicated articles; Part 250, regarding special requirements for specific human drugs; and Part 290, regarding controlled drugs.

State Level Regulations of Medical Marijuana

Each state with medical marijuana policies creates their legislation and regulation in a different way. Within the past 22 years, 32 states have legalized and regulated marijuana for medical use. In terms of how that state legalized medical marijuana, 15 states legalized through a Senate or House bill. Similar to the United States government, this means that the Senate or House within the state's legislature proposes the bill and both parties must agree on it. After that, it can be signed by the governor to turn into law. Three states legalized medical marijuana through an indirect initiated state statute, which is initiated by citizens through the collection of signatures. After that, the state legislature can alter it, deny it, pass it, or draft a new copy and post both on a ballot for voters to decide upon. Four states legalized medical marijuana through an initiated state statute, which is similar to an indirect initiated state statute, except it goes directly from the collection of signatures to the ballot for a vote. Three states have legalized through an initiated constitutional amendment, which is similar to the state statute but it directly amends that state's constitution and the exact process varies by state. Some states have specified the process of regulation in a separate document than that which legalized medical marijuana. For example, Arizona legalized medical marijuana through an initiated state statute, but then had a separate Senate Bill passed to discuss the regulation of medical marijuana (Americans, 2018). Approximately half of the states that have legalized medical marijuana, however, also mentioned the regulation process in the same document.

Within the regulation documents, each state specifies which department in each state will be responsible for regulating medical marijuana. This varies dramatically by state. Some states utilize the Department of Health, like Oregon and Hawaii. Other states create new offices and departments that typically fall under the Department of Health. This includes Minnesota, which

calls their new department the Office of Medical Cannabis. Other states, such as Michigan and Connecticut, use the state's current Department of Licensing & Regulatory Affairs. Some states even use the Department of Agriculture, such as Illinois and California. Other states also use a combination of multiple state departments involved in the regulation. While the regulation specifically varies between each state, all states that have regulation do have some common threads - including labelling, dispensaries, testing, and which medical conditions medical marijuana applies to.

Comparison

To some degree, many FDA regulations are reflected within the state regulations. Table 3 shows FDA regulations and states that have policies correspond to different areas of FDA pharmaceutical regulation. The sections below will more specifically discuss which FDA regulations overlap with state policies. Tables 4 through 9 are derived from Table 3, breaking down each FDA policy into a more specific table.

Table 3: Areas of Coverage in State Regulations vs FDA Regulations

FDA Policies	**States**																					
	AZ	CA	CO	CT	DE	DC	HI	IL	ME	MD	MA	MI	MN	MT	NV	NH	NJ	NM	NY	OR	RI	VT	WA
Labeling	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Prescription Drug Advertising	x	x	x	x		x	x				x	x	x	x		x	x		x	x			x
Prescription Drug Marketing		x	x	x							x	x	x				x		x	x			x
Medication Guides for Prescription Drug Products									x		x					x	x					x	
Requirements for Authorized Dispensers and Pharmacies to Distribute a Side Effects Statement				x	x						x		x			x	x	x	x		x		
Current GMP in Manufacturing, Processing, Packing or Holding of Drugs; General																							
Current GMP for Finished Pharmaceuticals		x	x	x		x			x	x	x	x	x	x	x	x	x	x	x	x	x		x
Drugs; Official Names and Established Names	x	x	x	x	x	x	x	x	x	x	x	x	x			x	x	x	x	x	x	x	x

Labeling

The labeling section of the CFR is broken into specific regulations that the FDA is required to follow when regulating pharmaceutical drugs. There is some overlap when it comes to states following these specific regulations in their regulation of medical marijuana. Table 4 shows the specified regulations and which are common, or uncommon, amongst states. All 23 states have regulations regarding the labeling of medical marijuana. 19 of 23 states also require medical marijuana labels to have the name and location of the business manufacturer, packer, or distributor. Additionally, 16 of 23 states have regulations regarding the clear statement of ingredients on the label. Another common regulation is the significance of control numbers. 18 of 23 states require labels to have a control, lot, harvest, or batch number that can be easily tracked back to the manufacturer, distributor, and facility. 13 of 23 states also have regulations regarding the truth and accuracy of all statements on the label. Some less common regulations include the label having adequate directions for use, which was implemented in 7 of 23 states; an expiration date, which was implemented in 10 of 23 states and is optional in Washington state. Specific formatting, which is referred to as "Prominence of required label statements" was implemented in 3 of 23 states. Some aspects of FDA pharmaceutical regulations are not reflected in state policies at all, including National Drug Code numbers and Spanish-language versions of required statements. However, it is understandable that medical marijuana doesn't not have National Drug Code numbers because it is nationally labelled as a Schedule I drug.

In addition to states adopting some FDA regulations, some states have also implemented supplemental regulations. Table 4 summarizes the labeling regulations for each state. Above the colored line is policies found in the FDA standards, while below the colored line are additions made by states not found in FDA standards. This includes regulations such as the printing of patient name or registry identification number on the label, which was implemented in 10 of 23

states; an allergen warning, which was implemented in 8 of 23 states; and the list of all non-organic products used in the cultivation of medical marijuana, which was implemented in 4 of 23 states. 15 of 23 states have added a regulation of labeling the medical marijuana with the specific strain or potency of the marijuana. 17 of the 23 states require the label to have the net weight or quantity of marijuana in the package that is being labelled. Additionally, 13 of 23 states require the label to be not attractive to children, and many states include the complete omission of any pictures or infographics to appeal even less to children.

Table 4: Labeling Regulations of States

	States																						
	AZ	CA	CO	CT	DE	DC	HI	IL	ME	MD	MA	MI	MN	MT	NV	NH	NJ	NM	NY	OR	RI	VT	WA
Name & Place of manufacturer, packer, or distributor	x	x	x	x		x	x	x	x	x	x	x	x	x		x	x	x	x		x		x
National Drug Code numbers																							
Adequate directions for use				x			x				x		x			x		x			x		
Misleading statements		x	x			x			x	x	x		x	x		x	x			x	x		x
Statement of ingredients		x	x	x	x	x	x	x	x	x	x	x	x	x		x	x			x			
Prominence of label statements			x								x			x									
Spanish-language																							
Location of expiration date				x			x	x		x	x	x				x		x	x		x		optional
Significance of control numbers	x	x	x	x	x		x			x	x	x	x	x	x	x	x	x	x		x		x
Additional Policies Added by States																							
Patient's Name or Registry ID Number	x		x	x		x				x	x		x			x	x		x				
Shall not be made attractive to children		x	x				x			x	x	x	x	x	x	x				x	x		x
Allergen Warning		x				x		x		x	x	x		x		x							
Net Weight		x	x		x	x		x	x	x	x	x		x	x	x	x	x	x		x		x
List of cultivation nonorganic pesticides, fungicides, & herbicides			x			x			x												x		
Date of Dispensing			x	x		x	x	x			x	x	x	x		x	x	x	x		x		optional
Strain / Potency				x	x		x				x	x	x	x		x	x	x	x	x	x	x	x

Prescription Drug Advertising and Prescription Drug Marketing

The CFR is broken into both an advertising section and a marketing section. 14 of the 23 states have regulations regarding marketing and advertising. However, seven of the states with advertising and marketing regulations encompass marketing and advertising into one category, as opposed to separating them. Another six of the states only have advertising requirements, and do not mention marketing at all. Oregon is the only state with both advertising and marketing requirements. Montana is the only state with only one advertising regulation, which is that advertising is prohibited. No states have regulations regarding the use of the drug's official name on the advertisement or regulations regarding the ingredients of the drug on the advertisement having to match that on the label. 10 of the 23 states have regulations regarding the truth and accuracy of statements on advertisements, and 5 of the 23 states have regulations outlining different types of advertisements. Only four states have regulations regarding samples of medical marijuana being used for marketing. Of those four, three states have only one regulation: samples for marketing purposes are prohibited. 9 of 23 states do have some type of regulation regarding the maintenance, security, or content of records and receipts, similarly to FDA regulations. No states, however, have any marketing regulations regarding re-importation or sales restrictions.

In addition to states adopting some FDA regulations, some states have also implemented supplemental regulations. In Table 5, all regulations below the colored line are additions made by states. Six states implemented a policy that prohibits advertisements and marketing to be toward minors. Three states do not allow advertisements to encourage the use of medical marijuana for anything other than that states' approved list of debilitating medical conditions. DC has a marketing policy that indicates that dispensaries must have a plan for marketing prior to becoming an approved dispensary.

Table 5: Marketing and Advertising Regulations of States

	States																						
	AZ	CA	CO	CT	DE	DC	HI	IL	ME	MD	MA	MI	MN	MT	NV	NH	NJ	NM	NY	OR	RI	VT	WA
Advertising Guidelines																							
No "unofficial" names														Advertising is prohibited									
Ingredients must match label																							
Types of Advertisements		x											x			x	x						x
Misleading Statements		x	x	x		x	x				x	x							x	x			x
Marketing Guidelines																							
Reimportation																							
Sales Restrictions																							
Samples		x*														x*			x*				x
Wholesale Distribution																				x			x
Request & Receipt Forms, Reports and Records						x					x	x	x	x		x	x		x				x
Additional Policies Added by States																							
Ads cannot encourage use of marijuana for anything other than debilitating medical conditions				x							x									x			
Dispensary application must offer a marketing plan						x																	
No advertising or marketing to minors		x									x	x				x				x			x

x* = while there is a regulation in place, the regulation prohibits samples

Medication Guides for Prescription Drug Products

Of the 23 states being analyzed, only five states have policies regarding medication guides for medical marijuana, which can be seen in Table 6. These states typically refer to them as patient education, or patient information. The FDA only breaks their regulation into two parts: content and format. Their content is quite extensive and while four states have regulations regarding what specifically needs to be in their patient educational materials, the regulations are nowhere near as extensive as the FDA. Only one state requires a specific format, mostly specifying font size and type, and not specifying headings or organization - like the FDA regulations do. Vermont is the only state that has no content or format regulations, but does specifically state that dispensaries are required to provide patient educational materials. Maine and Massachusetts also require the distribution of patient educational materials, while New Hampshire and New Jersey just require the materials to be available for qualifying patients and caregivers.

Table 6: Medication Guide Regulations for States

	States																						
	AZ	CA	CO	CT	DE	DC	HI	IL	ME	MD	MA	MI	MN	MT	NV	NH	NJ	NM	NY	OR	RI	VT	WA
Content									x		x					x	x						
Format																x							
Distributing / Dispensing									x		x											x	

Requirements for Authorized Dispensers and Pharmacies to Distribute a Side Effects Statement

There are nine states that have regulations regarding the distribution of a side effects statement. Similar to the FDA regulations for medication guides, the FDA only breaks their regulations into two parts for side effects statements: content and format. 7 of the 23 states have content regulations, but four of those states only have the content of their side effects section

requiring a statement regarding the limited information available on the side effects of medical marijuana. No states have formatting regulations, while 4 of the 23 states have regulations about how to distribute or dispense the side effects statement.

In addition to states adopting some FDA regulations, some states have also implemented supplemental regulations. In Table 7, the regulation below the colored line is an addition made by states. 2 of the 23 states require any side effects statement to be true, accurate, and not misleading.

Table 7: Side Effects Regulations for States

	States																						
	AZ	CA	CO	CT	DE	DC	HI	IL	ME	MD	MA	MI	MN	MT	NV	NH	NJ	NM	NY	OR	RI	VT	WA
Content					x						x-		x-			x-	x	x	x-				
Format																							
Distributing / Dispensing					x												x	x			x		
Additional Policies Added by States																							
True / Not Misleading				x															x				

x- = while there is a regulation in place, the content states: "There is limited information available on the side effects of medical marijuana"

Current GMP in Manufacturing, Processing, Packing of Holding of Drugs; General and Current GMP for Finished Pharmaceuticals

The GMPs sections of the CFR is broken into specific regulations that the FDA is required to follow when regulating pharmaceutical drugs. There is some overlap when it comes to states following these specific regulations in their regulation of medical marijuana. 18 of the 23 states have regulations regarding GMPs. Table 8 shows the specified regulations and which regulations are common, or uncommon, amongst states. 8 of the 23 states have a general regulation as to how the quality control unit must be organized and 12 of the 23 states have regulations regarding personnel. These regulations vary, as some states have outlined very

specific training, specific onboarding processes, and others have extensive background checks and files on all personnel. The FDA also specifies building or facilities design and maintenance, and 13 of the 23 states have regulations regarding their facilities. However, these regulations are not specific, since some states only specify the sanitation of the building, or describe that the building must be deemed safe by fire and town officials, or be suitable for the manufacturing, packaging, or dispensing of medical marijuana. Similarly, 14 of the 23 states have regulations regarding the equipment used in the facility - however, they are also vague, and most only specify that the equipment should be sanitary. Laboratory controls and record keeping are both common regulations, as 18 of 23 states have regulations regarding them. Since only four of 23 states have a regulation regarding holding/distribution and only 3 of 23 states have a regulation regarding production & process controls, these are much less common amongst states.

Some states have also implemented regulations that go beyond FDA standards. In Table 8, all regulations below the colored line are additions made by states. This includes regulations such as security equipment being on the premises, which has been implemented in 18 of 23 states; specific waste disposal regulations, which has been implemented in 13 of 23 states; and location of dispensaries or other facilities in relation to schools, churches/other places of worship, or pre-designated drug-free zone, which has been implemented in 14 of 23 states. Distance between the medical marijuana facility and off-limits location varies, from a 50-foot radius, to 300 feet away, to 1000 feet away. Some states even include public swimming pools, playgrounds, and day-care facilities in their regulations (NV).

Table 8: Good Manufacturing Practices Regulations of States

	States																						
	AZ	CA	CO	CT	DE	DC	HI	IL	ME	MD	MA	MI	MN	MT	NV	NH	NJ	NM	NY	OR	RI	VT	WA
QC Organization									x	x	x		x			x	x		x				x
QC Personnel			x						x	x	x		x	x		x	x	x		x	x		x
Buildings/Facilities Design and Maintenance			x			x				x	x	x		x	x	x		x	x	x	x		x
Equipment Requirements			x	x		x				x	x	x	x	x		x		x	x	x	x		x
Drug Storage (Containers and Closures)			x	x		x			x	x	x	x	x			x	x	x	x		x		x
Production & Process Controls										x			x				x						
Packaging and Labeling Control		x	x	x		x				x	x	x	x		x	x	x	x	x	x	x		x
Holding/Distribution				x						x	x		x										
Laboratory Controls		x	x	x		x			x	x	x	x	x	x	x	x	x	x	x	x	x		x
Records and Reporting		x	x	x		x			x	x	x	x	x	x	x	x	x	x	x	x	x		x
Additional Policies Added by States																							
Security		x	x	x		x			x	x	x	x	x	x	x	x	x	x	x	x	x		x
Waste Disposal			x	x		x			x	x	x	x	x			x		x	x		x		x
Distance from School		x	x	x		x			x		x		x	x	x	x	x		x		x		x

Official and Established Drug Names

The FDA section regarding established names of drugs specifies that pharmaceutical drugs should use their official name and avoid the use of "other names." 21 of the 23 states being analyzed have regulations regarding the definition of medical marijuana and regulations to avoid the use of street names, and use only the defined definition of medical marijuana in that specific state, which can be seen in Table 9. Nevada and Montana are the only states that do not specify the definition of their medical marijuana.

Table 9: Drug Name Regulations of States

	States																						
	AZ	CA	CO	CT	DE	DC	HI	IL	ME	MD	MA	MI	MN	MT	NV	NH	NJ	NM	NY	OR	RI	VT	WA
Official Name	x	x	x	x	x	x	x	x	x	x	x	x	x			x	x	x	x	x	x	x	x
Avoid Use of "Other Names"	x	x	x	x	x	x	x	x	x	x	x	x	x			x	x	x	x	x	x	x	x

Other Regulations Added by States

In addition to states adopting policies that compare to FDA regulations, states have implemented additional policies related to medical marijuana that focus less on safety and more on the social aspects of medical marijuana. Table 10 shows these additional regulations and which states have implemented a policy for each regulation. 10 of 23 states have implemented a policy regarding the anti-discrimination of employees. This means that states are not allowed to deny employees because of their status as a medical marijuana patient. 11 of 23 states have implemented policies regarding employee drug tests. 5 of 23 states have a policy that they cannot deny or fire employees based on a marijuana-positive drug test, if they are medical marijuana patients. 6 of 23 states have a policy that they can deny or fire employees for a marijuana-positive drug tests, regardless of their status as a medical marijuana patient. 9 of 23 states have a

policy that prohibits the smoking or vaping of medical marijuana in various public places. 9 of 23 states have a policy regarding impaired driving. For five of those states, the policy is zero tolerance – meaning driving under the influence of marijuana, even if one is a medical marijuana patient, is illegal. However, the other four states have a policy that allows medical marijuana patients to have a minimal amount of marijuana in their system while driving.

Table 10: Additional Regulations Added by States

	States																						
	AZ	CA	CO	CT	DE	DC	HI	IL	ME	MD	MA	MI	MN	MT	NV	NH	NJ	NM	NY	OR	RI	VT	WA
Anti-Discrimination Regarding Employees	x			x	x			x	x		x		x		x				x		x		
Anti-Discrimination Regarding Employee Drug Tests	x				x						x		x								x		
Positive Drug Test (Employers)		x	x									x						x		x			x
Prohibits Smoking/Vaping in one or more of the following venues: non-hospitality workplaces, restaurants, bars and/or gambling facilities		x			x				x		x				x					x	x	x	x
Impaired Driving (Zero Tolerance policy)	x				x			x				x									x		
Impaired Driving (minimal amount allowed)			x											x	x								x

Chapter VI. Analysis

State regulations regarding medical marijuana have some variation, particularly when compared to specific sections of the FDA's CFR for pharmaceutical drugs. However, states are implementing additional policies that go beyond the FDA regulations, allowing for the mitigation of additional risks associated with medical marijuana legalization. As seen in the literature review, studies found that safety and efficacy, increased use, youth use, public health effects, traffic incidents, crime rates, and suicide rates were common concerns associated with the legalization of medical marijuana. Many, although not all, of these concerns are addressed in state legislation. This can be seen, for example, with the additional policies added by states revolving around children, such as the distance of facilities from a school and not advertising to minors. These policies are geared specifically toward decreasing increased youth use.

Labeling

Within the labeling section, states have adopted a majority of the regulations already set out by the FDA for pharmaceuticals. The few regulations that are not being adopted include the use of National Drug Code numbers and a Spanish-language version of certain required statements. Since medical marijuana is still illegal on a federal level, it is impossible for states to use National Drug Code numbers. Many FDA regulations regarding labeling are reflected in state regulations. Labeling requirements are important to ensure the product is safe and patients, caregivers, physicians, manufacturers, and dispensaries are getting accurate information about the products. Some states have implemented additional policies including adding the patient's name or registry ID number to the label, as well as an allergen warning, the net weight or quantity, date of dispensing, strain/potency, and list of all non-organic pesticides, fungicides, and herbicides used during cultivation - as seen in Figure 3. The implementation of these policies

adds an additional level of safety to medical marijuana. Considering the reason that the FDA has policies on labeling is to ensure product safety, the states are adding policies to their legislation that is applicable to medical marijuana and continues to ensure the safety of the product. An important added regulation in 13 of the 23 states is that labels cannot be made attractive to children, including the complete elimination of color or cartoons. This helps mitigate the commonly seen risk of increased youth use. More states should adopt a policy regarding the labels being unappealing to children, and the FDA could also learn from this. According to the National Survey on Drug Use and Health from 2014, nearly 6,000 youth reported using prescription pain relievers without a doctor's guidance for the first time (Volk, 2014). Additionally, in 2017, there were 1,031 reported prescription drug overdoses in teens (age 15-24), while there were no reports of teens or young adults dying from a marijuana overdose (The National Institute, 2017). Since it is reported that marijuana overdoses are uncommon, but prescription drug overdoses are common, the FDA could think about implementing policies regarding distance of facilities, pharmacies, etc. from schools and other places that children, teens, and young adults frequent.

Marketing & Advertising

While the FDA separates marketing and advertising regulations into separate sections, states consider them to be the same. With that, the states that have marketing and/or advertising regulations tend to focus more on advertising instead of marketing. Even then, the states focus on the advertisements being true, accurate and not misleading, as well as keeping records of sales and being able to report to the local government if requested. This is important, considering the regulations regarding advertising also revolve around product safety and ensuring that patients, caregivers, physicians, manufacturers, and dispensaries are getting accurate information about

the products. Having true, accurate, and not misleading advertisements is key when it comes to getting accurate information. Routine reporting also plays a key role in product safety, so the fact that states keep records is also important. States also implemented additional marketing or advertising regulations, such as prohibiting advertisements from encouraging use for anything other than that states list of medical conditions and prohibiting advertising and marketing to minors. These regulations mitigate risks that the FDA doesn't focus on, such as increased use and youth use, respectively. As with the labeling requirements, the FDA could adopt similar policies for prescription drugs.

Medication Guides

Medication guides are required by the FDA for every prescription drug. The FDA also outlines how and when the medication guides are to be distributed to patients. However, only five states have a policy regarding medication guides, which they often refer to as patient education materials or patient informational guides. The FDA has very specific content and format for medication guides, giving exact headlines that need to be in the guide and font size. The states have more vague regulations, often neglecting format entirely and having a basic content outline. Medication guides are important to give patients, caregivers, and physicians accurate information about the drug. Since there are differences in strain and potency of medical marijuana, medication guides should be even more necessary and states are highly lacking in this respect.

Side Effects Warning

The data shows that states are lax on requiring a side effects warning, which are required for all drugs by the FDA; only 9 states have adopted a similar policy for medical marijuana. 4 of

the 23 states only have a regulation stating that the side effects warning must read "There is limited information available on the side effects of medical marijuana." Issuing a side effects warning is important so that patients know what could potentially happen while taking the drug. However, the majority of known side effects come about through clinical trials. Since clinical trial data is required for all prescription drugs to be approved by the FDA, it is an important step that states are missing during their legalization of medical marijuana. However, states are not legalizing medical marijuana the same way the FDA legalizes prescription drugs. Instead, states legalize medical marijuana through Senate bills, constitutional amendments, etc., meaning states are less aware of potential side effects.

Good Manufacturing Practices

In terms of good manufacturing practices (GMPs), states have adopted many policies similar to the FDA. GMPs are important to ensure the safety of the product, so it is important that states are following these procedures. There are a few states (Arizona, Vermont) that actually don't have any GMP regulations addressed and these states should absolutely add some, since GMPs are important in product safety. States have also implemented security measures at their manufacturing and/or dispensing facilities, which is important since marijuana is still a Schedule I drug according to the federal government. The security measures ensure that only authorized personnel are entering the facility, adding an extra safety measure to the manufacturing and dispensing of medical marijuana. Additionally, many states added policies regarding waste disposal. Similar to the security measures, disposing of marijuana must be addressed since it is federally illegal. Lastly, another commonly added policy is in regards to facilities' distances from a school, church, place of worship, playground, daycare center, or another already identified drug-free zone. This addresses a concern specific to legalizing medical

marijuana, which is increased youth use of marijuana. Requiring facilities to be distanced from places that are frequently occupied by children could help to mitigate this risk. For the most part, however, states have adopted many aspects of the FDA regulations regarding good manufacturing practices.

Official Drug Names

The FDA regulates the use of official drug names and not using any other names that are not considered "established" for that drug. This is important since it would be confusing to have many different names for the same drug. However, there is no official definition or name for medical marijuana, since there is a slight variation between states. With that, there is no standardization for what is considered to be medical marijuana and what is not. Regulating at the federal level could definitely help in this respect, since the FDA would be able to standardize this definition, allowing for less variation. Along similar lines, there is no consensus between states regarding which medical conditions can be treated using medical marijuana. For example, while most states have a list with similar conditions on them, Maine has no list of approved conditions and physicians are allowed to recommend medical marijuana for any condition they wish (ProCon.org, 2019).

Chapter VII. Discussion and Conclusion

Through this research, it is evident that the FDA outlines important regulations to regulate prescription drugs and that each regulation is in place for a reason, mitigating risks regarding the safety of patients and product quality. States have adopted some regulations in line with FDA regulations, but states have also introduced many additional areas of policy. These new policies mitigate additional risks, particularly in areas that are of high social concern such as increased drug use and youth use. For example, states with additional laws limiting advertising to minors and distancing medical marijuana facilities or dispensaries from schools are taking action to reduce the issue of increased youth use. Medical marijuana is a complex social issue. States can integrate potential solutions to social issues into medical marijuana policies. While states are creating policies for safety reasons and to maintain product quality, they have the opportunity to also integrate policies that address the broader social context, which is something the FDA currently does not do. It is in this respect that policy innovation can really happen at the state level.

Since there is no level of federal standardization considering the illegality of marijuana, states are also creating policies that are vastly different from other states. While some of these discrepancies could be seen as positive policy disagreements, since states are just disagreeing over the scope to which medical marijuana should be regulated (Robert, 2011), the discrepancies should still be remedied since medical marijuana is being utilized as a medication. A remedy to this issue is to reschedule marijuana in a lower drug classification (Schedule II or lower). If that were to happen, the FDA could become involved in regulating marijuana, since it would be allowed for medical use. This would allow for approval of medical marijuana based on scientific

evidence of the benefits or negative effects, from extensive clinical trials that would be required by the FDA for drug approval, as opposed to political considerations.

A commonly suggested idea to mitigate risks like increased marijuana use is to mandate that physicians tell their patients all of the risks of the medical marijuana they are recommending. Several studies (Davis, 2016; Hill, 2015; Grant, 2012) identify that the implementation of medical marijuana laws should come with public education of overdose statistics and other important information, as well as benefits/risks regarding the use of medical marijuana. Additionally, physicians should begin looking deeply into their patients' history before recommending medical marijuana as a treatment, looking particularly at the potential for misuse, abuse, and addiction.

Regarding the future involvement of the FDA in the regulation of medical marijuana, one idea would be for the federal government to reschedule marijuana as a Schedule II, or lower, drug. After that, marijuana would be eligible for use as a medical drug and the FDA would be involved in the regulation of the drug. The FDA requires numerous tests and trials to be conducted in order to determine if a drug is safe and efficacious. The FDA's regulations would create much stricter rules for obtaining, taking, and prescribing medical marijuana. The standardized approach of the FDA could drastically decrease all of the risks felt by the states that have legalized medical marijuana on their own terms and increase the safety of medical marijuana that states are lacking. However, with marijuana's current status, it can be seen that policy innovation is occurring as states build their own policies regarding marijuana for medical use and are allowed to look at drug safety in a broader context. However, without the standardization from the FDA, states are lacking in their general safety policies and potentially risking the safety of their medical marijuana patients.

Limitations

There are some limitations to this research. First and foremost, marijuana is illegal at the federal level. This means that information is fairly limited in general. It also means that states cannot conduct as much research on marijuana. While states can still conduct FDA-approved clinical trials on medical marijuana, the samples must be supplied by the federal government. IN fact, many clinicians have complained that the federally supplied marijuana is of inferior quality, limiting the quality of these studies (Armentano, 2019). Additionally, the topic of medical marijuana is fairly new, so there is – in general – not a lot of extensive research conducted in the area. My research also did not analyze the quality of the regulations been compared to the FDA. While there was overlap between states' regulations and FDA regulations, there was little to no analysis of the quality of the regulations. While I compared which states had which aspects of FDA regulations, there was no analysis into how the state regulations compared to the regulations of the FDA. Therefore, additional analysis could be conducted to determine if the state regulations are on the same level as the FDA or not.

Another limitation while conducting research was the lack of analysis of enforcement of medical marijuana laws. While all states have specific organizations that regulate and enforce medical marijuana, there was no analysis of how this occurs. Many states have multiple departments, or a new branch of a department, serving as the regulator and enforcer of medical marijuana laws. Not studying this could limit research because, while states have these policies in place, it is not specified how states go about ensuring the policies are enacted and done so properly, and up to the standards of the state.

Implications for Future Research

It is clear that additional research should be conducted regarding the implications of state level medical marijuana laws; much of the current research is limited and inconclusive. One noticed absence in existing research was a focus on potency and efficacy. This suggests that more research should be conducted in the realm of clinical trials. States conducting clinical trials on their own terms could allow policymakers to make more informed decisions on medical marijuana policies by using scientific evidence to back up their claims. However, because of the dual legality of marijuana in the United States, this will likely continue to prove to be difficult.

Future research, on the other hand, could utilize information from other countries to make decisions. So far, 21 countries or territories have legalized cannabis fully or partially, for medical or recreational use (MacIver, 2017). Incorporating more countries in a future study could provide insight into the legalization of medical marijuana, as well as potential side effects or analysis of clinical trial studies. Many countries do not have a national agency to regulate clinical trials like the United States, so looking at data from additional countries that have more freedom with clinical trials could provide much more insight and more information than what is known in just the United States.

Further research could be conducted in the realm of what the federal government can and cannot do to states with medical marijuana policies. While patients were given some leeway under the Obama administration, dispensaries are facing penalization by the federal government. For example, the Internal Revenue Service (IRS) has audited multiple dispensaries, referencing on a section of the federal tax code that prohibits companies from deducting expenses related to drug trafficking – alleging that dispensaries owe millions in back taxes. Steve DeAngelo, owner of a dispensary in California that serves more than 100,000 customers and from whom the

federal government says owes $2.4 million, says “No business in America could survive if all of its expense deductions were disallowed. This is not an attempt to tax us. It’s an attempt to tax us out of existence” (Scott, 2012). While states are technically allowed to make their own policies regarding medical marijuana, the federal government may still be making efforts to interfere. Additional research could be conducted to see what impact this has on states’ medical marijuana programs.

Additional research could be conducted regarding the enforcement of medical marijuana laws within each state. Looking at whether, or not, states are abiding by the policies and doing so in a manner that is up to par with the states’ requirements could shed light on the actual impacts of the policies. Analyzing the enforcement process could determine if states are ensuring that policies are where they need to be and can ensure the safety of patients and product. For example, the Colorado Department of Agriculture takes random samples of marijuana, as it does for all crops. By doing so, it discovered 22 cases of pesticide misuse in 2018 (Hoing, 2019). While the process likely varies from state to state, studying how the enforcement occurs could help protect patient safety, ensure product quality, and even keep cultivation facilities and dispensaries sanitary.

Implications for Policy

Recommendation: The federal government should reschedule marijuana as a Schedule II or III drug, so that it can be used for medical purposes.

While marijuana remains a Schedule I drug according to the federal government, states around the United States are deciding to legalize marijuana for medical—and in some cases, recreational—use. This is an intriguing situation, since allowing a substance to be a medicine but also utilized for recreational purposes really complicates the perception of the substance. One article (Clark, 2011) discusses the ethical, legal and medical perspectives in regards to the legalization of medical marijuana. Clark believes that not legalizing medical marijuana denies patients the right to potentially beneficial treatments and to deny them this is a violation of their basic human rights. Additionally, the author looks at the legal perspective – describing how, since marijuana is still classified as a Schedule I drug federally, it becomes difficult to formulate laws at a state level that do not break federal law. This gives perspective into how new policies should be created regarding medical marijuana. Since it is being used as a medical drug, it would make sense for the FDA to begin regulating medical marijuana. This would mean a rescheduling of marijuana as either a Schedule II or Schedule III drug. Changing the status of marijuana would allow physicians to prescribe medical marijuana and mean that the FDA would be responsible for all regulations. Additionally, advocates of rescheduling marijuana look at the economic impact it would have. Legalizing the use of marijuana in the United States would save an estimated $8.7 billion, by reducing government spending for drug enforcement in the criminal justice system (Miron, 2010). Legalizing drugs and taxing them in a way that is comparable to alcohol and tobacco would create additional revenue. Rescheduling marijuana could be a step in the right direction of adopting a better regulatory framework.

Recommendations if the federal government does not reschedule marijuana and states are left to continue making their own policies on medical marijuana: states need to increase the stringency of their regulations to ensure that safety is a higher priority.

There have already been multiple petitions in history to reschedule marijuana. However, the federal government has denied every one of them. The rescheduling process is a long and complicated one. Some complication comes from the idea that rescheduling requires a lot of input from many administrative bodies, such as the President, the Attorney General, the Drug Enforcement Administration, and the Department of Health and Human Services (Rough, 2017). If the federal government continues to deny petitions for rescheduling, the states would remain responsible for the regulation of medical marijuana. On one hand, this could allow states to innovate the way they regulate medical marijuana, allowing them to integrate new policies that could mitigate additional risks that the FDA doesn't currently consider for pharmaceutical drugs. However, it could also mean that states continue on their current path of focusing less on safety. It can be seen that many states do not adopt policies along the same lines as the FDA and, while some do, they are not as detailed or extensive as the FDA. This could mean the addition of health and safety risks, since the standardization is low or non-existent. Not rescheduling marijuana would mean that states need to increase the rigidity of their regulations, in an effort to make sure that safety is a higher priority.

Conclusion

Medical marijuana is a controversial issue. The duality of legislation places marijuana on the federal government's list of Schedule I drugs, while states are legalizing it on a local level. Previously conducted research focused on the risks that occurred after the implementation of medical marijuana laws. My research focused on FDA regulations for pharmaceutical drugs and whether, or not, states have implemented similar regulations in order to ensure the safety of patients and products. The FDA's overarching mission is public health and safety, so FDA regulations are crucial in ensuring those goals are met. While my research found some overlap between state regulations and FDA regulations, it was found that states' regulations are not enough to ensure the safety of medical marijuana products and patients. States are, however, implementing additional policies to mitigate some risks that were found to have occurred after the implementation of medical marijuana laws, including increased youth use and public health effects.

Appendix

Appendix 1: Table Obtained from National Conference of State Legislators and Documentation & Departments Involved in Medical Marijuana Legalization and Regulation

Obtained from National Conference of State Legislators							**Documents and Departments Responsible for Medical Marijuana Legalization & Regulation**			
http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx										
State	**Statutory Language (Year)**	**Patient Registry or ID cards**	**Allows Dispensaries**	**Specifies Conditions**	**Recognizes Patients from other states**	**State Allows for Retail Sale / Adult Use**	**Regulated and Enforced by:**	**Legalization Document**	**Regulation Document**	**Yr**
AZ	Proposition 203 (2010)	Yes	Yes	Yes	Yes, for AZ-approved conditions, but not for dispensary purchases.		Dept of Health Services	initiated state statute	Senate Bill	2010
CA	Proposition 215 (1996) SB 420 (2003)	Yes	Yes (cooperatives and collectives)	No	No	Yes	over a dozen organizations	initiated state statute	Medicinal & Adult-Use Cannabis Regulation and Safety Act	1996
CO	Amendment 20 (2000)	Yes	Yes	Yes	No	Yes	Dept of Revenue, Marijuana Enforcement Division	initiated constitutional amendment	Colorado General Assembly	2000
CT	HB 5389 (2012)	Yes	Yes	Yes			Dept of Consumer Protection, Medical Marijuana Program	House Bill	Same House Bill that legalized	2012
DE	SB 17 (2011)	Yes	Yes	Yes	Yes, for DE-approved conditions.		Delaware Health and Social Services, Division	Senate Bill	Same Senate Bill that legalized	2011

							of Public Health, Office of Medicinal Marijuana			
DC	Initiative 59 (1998) L18-0210 (2010)	Yes	Yes	Yes		Yes		DC Council	DC Council	1998
HI	SB 862 (2000)	Yes	Yes	Yes	No		Dept of Health, Medical Marijuana Dispensary Program	Senate Bill	HB/SB - multiple amendments	2000
IL	HB 1 (2013) Eff. 1/1/2014 Rules	Yes	Yes	Yes	No		Dept of Financial and Professional Regulation, Dept of Health, Dept of Agriculture	House Bill	Same House Bill that legalized	2013
ME	Question 2 (1999) LD 611 (2002) Question 5(2009) LD 1811(2010) LD 1296 (2011)	Yes	Yes	Yes	Yes, but not for dispensary purchases.	Yes	Dept of Health and Human Services, Division of Public Health Services, Medical Use of Marijuana Program	indirect initiated state statute	SB / HB / LD	1999
MD	HB 702 (2003) SB 308 (2011) HB 180/SB 580 (2013) HB 1101-Chapter 403 (2013) SB 923 (signed 4/14/14) HB 881- similar to SB 923	Yes	Yes	Yes	No		Maryland Medical Cannabis Commission	Senate Bill	HB	2003
MA	Question 3 (2012) Regulations	Yes	Yes	Yes	No	Yes	Dept of Public Health	indirect initiated state statute	Same indirect initiated state statute that	2012

	(2013)								legalized	
MI	Proposal 1 (2008)	Yes	Not in state law, but localities may create regulations	Yes	Yes, for legal protection of possession, but not for dispensary purchases	Yes	Bureau of Medical Marijuana Regulation, Dept of Licensing and Regulatory Affairs	indirect initiated state statute	House Bill	2008
MN	SF 2471, Chapter 311 (2014)	Yes	Yes, limited, liquid extract products only	Yes	No		Dept of Health, Division of Health Policy, Office of Medical Cannabis	Senate Bill	Same Senate Bill that legalized	2014
MT	Initiative 148 (2004) SB 423 (2011) Initiative 182 (2016)	Yes	No**	Yes	No		Dept of Health & Human Services	initiated state statute	Same initiated state statute that legalized	2004
NV	Question 9(2000) NRS 453A NAC 453A	Yes	Yes	Yes	Yes, if the other state's program is "substantially similar." Patients must fill out Nevada paperwork. Adults over 21 may also purchase at adult retail dispensaries.	Yes	Dept of Taxation	initiated constitutional amendment	Senate Bill	2000

NH	HB 573 (2013)	Yes	Yes	Yes	Yes, with a note from their home state, but they cannot purchase through dispensaries.		Dept of Health & Human Services, Office of Operations Support, Therapeutic Cannabis Program	House Bill	Same House Bill that legalized	2013
NJ	SB 119 (2009) Program information	Yes	Yes	Yes	No		Dept of Health & Senior Services, Dept of Agriculture	Senate Bill	Same Senate Bill that legalized	2009
NM	SB 523 (2007) Medical Cannabis Program	Yes	Yes	Yes	No		Dept of Health	Senate Bill	Same Senate Bill that legalized	2007
NY	A6357 (2014) Signed by governor 7/5/14	Yes	Ingested doses may not contain more than 10 mg of THC, product may not be combusted (smoked).	Yes	No		Dept of Health	NY Assembly	Same NY Assembly that legalized	2014
OR	Oregon Medical Marijuana Act(1998)	Yes	Yes	Yes	No, but adults over 21 may purchase at adult	Yes	Oregon Health Authority, Oregon Medical	House Bills, Senate Bills	House Bills, Senate Bills	1998

	SB 161 (2007)				retail dispensaries.		Marijuana Program			
RI	SB 791 (2007) SB 185 (2009)	Yes	Yes	Yes	Yes		Dept of Health	Senate Bill	Same Senate Bill that legalized	2007
VT	SB 76 (2004) SB 7(2007) SB 17(2011) H.511 (2018)	Yes	Yes	Yes	No	Yes	Dept of Public Safety			2004
WA	Initiative 692 (1998) SB 5798 (2010) SB 5073 (2011)	No	Yes, approved as of Nov. 2012, stores opened in July, 2014.	Yes	No, but adults over 21 may purchase at an adult retail dispensary.	Yes	Dept of Health & Liquor and Cannabis Board	Initiated statute		1998

Appendix 2: FDA Sections and States that Adopted Similar Policies

FDA Policies	States																						
	AZ	CA	CO	CT	DE	DC	HI	IL	ME	MD	MA	MI	MN	MT	NV	NH	NJ	NM	NY	OR	RI	VT	WA
Labeling	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Prescription Drug Advertising	x	x	x	x		x	x				x	x	x	x		x	x		x	x			x
Prescription Drug Marketing		x	x	x							x	x	x				x		x	x			x
Guidelines for State Licensing of Wholesale Prescription Drug Distributions																							
Imprinting of Solid Oral Dosage Form Drug Products for Human Use																							
Requirements for Foreign and Domestic Establishment Registration & Listing for Human Drugs																							
Medication Guides for Prescription Drug Products									x		x					x	x					x	
Requirements for Authorized Dispensers and Pharmacies to Distribute a Side Effects Statement				x	x						x		x			x	x	x	x		x		
Current GMP in Manufacturing, Processing, Packing or Holding of Drugs; General																							
Current GMP for Finished Pharmaceuticals		x	x	x		x			x	x	x	x	x	x	x	x	x	x	x	x	x		x
Current GMP for Positron Emission Tomography Drugs																							
Human Drug Compounding																							
Current GMP for Medicated Feeds																							
Current GMP for Type A Medicated Articles																							
Special Requirements for Specific Human Drugs																							
Controlled Drugs																							
Drugs; Official Names and Established Names	x	x	x	x	x	x	x	x	x	x	x	x	x			x	x	x	x	x	x	x	x

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