

MEDICAL CANNABIS IN THE UNITED STATES

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MEDICAL CANNABIS IN THE UNITED STATES

A Thesis

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Abstract

of

MEDICAL CANNABIS IN THE UNITED STATES

by

Daniel Francis Scott

In 1970, the federal Controlled Substances Act (CSA) outlawed cannabis in the United States. Since then, advocates have petitioned to have cannabis rescheduled in a less restrictive manner and sixteen states have decriminalized cannabis for approved medical use. This thesis seeks to explain why certain federal organizations have oppositional policy positions on medical cannabis. It questions the common opinion that the conflict over medical cannabis is either a disagreement over scientific facts or a clash between political motivated actors. Instead, it examines motivations of the federal executive organizations tasked with oversight of the CSA in an attempt to understand their policy position on cannabis.

More specifically, this thesis focuses on the policy position on medical cannabis of three organizations: The Drug Enforcement Agency (DEA), The National Institutes of

Health (NIH) and the National Institute on Drug Abuse (NIDA). By examining key documents from each organization, I conclude that the DEA and NIDA support the current Schedule I status of cannabis and the NIH questions this status by determining that cannabis has medical efficacy. I further conclude that the DEA and NIDA demonstrate a paternalistic worldview toward the legal ability to use cannabis as medicine, while the NIH supports the autonomous use of cannabis as medicine provided that a reasoned attempt is made to determine if cannabis use is appropriate.

The ethical position of the DEA and NIDA could explain why these organizations do not support the rescheduling of cannabis and why they will likely oppose future rescheduling attempts. It also has implications for what might be required to change federal policy in this area.

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This thesis is dedicated to the memory of Bernadette Petra (Smith) Scott (1974-1999).

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## Chapter 1

### INTRODUCTION

In 1970, the United States Congress passed the Controlled Substances Act as part of the Comprehensive Drug Abuse Prevention and Control Act. This Act classified cannabis as a Schedule I substance, which outlawed the cultivation, possession, distribution and use of cannabis for any reason, including as medicine. Since then, numerous attempts have been made to petition the federal government to allow the medical use of cannabis by classifying it under a less restrictive schedule. As of 2011, 16 states and the District of Columbia have passed laws allowing the medical use of cannabis despite the federal laws forbidding it.

The purpose of this thesis is to analyze the conflict between federal organizations supporting the use of cannabis as medicine, and those that oppose the use of cannabis as medicine. Both sides in this controversy cite numerous scientific studies and medical analysis which support their arguments, sometimes using the same scientific studies to justify opposing sides in this argument. Law enforcement organizations generally oppose the medical use of cannabis, while medical organizations and advocates for patient care generally support the medical use of cannabis. Analytical studies and policy position papers on this topic generally agree with one side and disagree with the other, frequently using citing the same evidence and scientific studies to justify arguments for opposing viewpoints. I propose that the disagreement is not based in scientific evidence, but in the mission, goals, and underlying ethical perspective of disagreeing organizations. As with

all medical decisions made in the United States, the approval of the use of cannabis as medicine is a balance between medical paternalism and medical autonomy. This ethical conflict lies at the heart of the relationship of citizens and their government, where the government maintains authority for the protection of the common good and the individual expresses the right to self-determination.

Beyond the ethical dilemma and political conflict of the medicalization of cannabis, analysts point to the real-world impacts of this conflict. Almost 500,000 patients in the United States use cannabis as medicine with the approval of both their physician and state law, yet still face the possibility of prosecution, imprisonment and the denial of their ability to self-medicate (ProCon, n.d.). More patients live in the 34 states that provide no protection from local or state prosecution for cannabis use, possession, distribution or cultivation for medical purposes. Professor of Public Policy Mark Kleiman (2011) states that the cost of cannabis prohibition to the United States is high; annually, 30,000 Americans are incarcerated for selling cannabis and 750,000 are arrested for possession. Professor Jon Gettman (2007) states that arrests for production, distribution and use of cannabis comprise 5.54% of all arrests and cost \$10.7 billion in annual law enforcement expenditures. Across the United States, even in states that have decriminalized cannabis for medical purposes, the sick and the dying are imprisoned and denied the medicine they and their doctors believe can improve their quality of life, or even save it.

## Statement of Purpose

In this thesis, I will analyze publications from the two federal executive departments that make policy recommendations to regulate cannabis under the Controlled Substances Act: The Department of Justice and the Department of Health and Human Services. I will attempt to show that recommendations and policies published by these two departments and the various agencies within them directly reflect their respective mission statements and result in a lack of consensus at the federal level regarding the efficacy and risk of the use of cannabis as medicine. For the purposes of this thesis, the terms cannabis and marijuana (or marihuana) will be considered to be interchangeable. In the majority of references, the term cannabis will be used.

The remainder of the thesis is organized as follows: Chapter Two will consist of a review of the background literature, including a discussion of medical ethics underlying medical decisions in the United States, a history of cannabis as medicine in the United States and a discussion of various medical organizations' position on the use of cannabis as medicine. Chapter Three will present the methodology used to compare the policy statements and publications of the different parts of the federal government responsible for the Controlled Substances Act. Chapter Four will present these policy statements and publications. Chapter Five will summarize the findings and their political implications.

I hope that this thesis will provide a framework to better understand the motivations for different actors in the federal government regarding their policy position regarding cannabis as medicine. If this thesis determines that, through the Controlled

Substances Act, the medicalization of cannabis is at a stalemate between opposing organizations in the federal executive branch, I hope that it will inspire alternative action in order to bring about a solution that is fair to both sick individuals and to society in general.

## Chapter 2

### REVIEW OF LITERATURE

Three major topics of discussion will be covered in the review of literature. First, I will present a discussion of ethics underlying medical decisions in a modern, free and democratic society. Second, I will present a history of cannabis policy in the United States. Third, I will present the positions of various medical organizations and other related research on the benefits and harms of the use of cannabis as medicine.

#### Medical Ethics

According to Howard Brody (1981) in *Ethical Decisions in Medicine*, all medical decisions are ethical decisions. Ethics must be considered when humans make decisions that have consequences to others. In this case, governments make decisions on allowing or prohibiting medicines that directly affect individual medical outcomes. These choices between outcomes must be made rationally and with careful consideration of the ethical, scientific and clinical implications. While scientific and clinical evidence is frequently an objective judgment, the rational addressing of ethical questions is not a decision between judging facts as being true or false; it is a comparison of societal and individual values that are used to judge the consequences of alternatives.

The term medical ethics was first used in 1803 by English physician Thomas Percival (Baker, 1999). His writings resonated in both Great Britain and the United States, and inspired the American Medical Association to establish the first code of ethics by any nationwide professional society. This and other medical codes, such as that

adopted by the British Medical Association, expanded upon the traditional notion of serving in a particular profession with honor and virtue and provided guidelines to the medical profession and the doctor's role in caring for the sick and infirmed.

Medical ethics continued to be discussed in the United States in the late 19<sup>th</sup> and early 20<sup>th</sup> Centuries, but a modern interpretation of ethics and ethical behavior would classify these discussions and their resulting codes as medical etiquette (Veatch and Branson, 1976). Publications of the time attempted to further define obligations that doctors had toward patients, focusing upon guidelines for proper medical care, sanitation, and the rising consideration of the disease model. As modern medicine progressed in the 20<sup>th</sup> Century, more serious discussions arose as to the goals of medicine and medical care. Based on the ancient Hippocratic Oath, doctors considered their obligation to be goal oriented and focused on the end result of preventing disease, promoting health, and “doing no harm” to the body (Callaghan as cited in Danis, Clancy, & Churchill, 2002; Brody, 1981).

### Medical Paternalism

Until the 1960's, the dominant ethical consideration in medical practice in the United States was medical paternalism. This was based upon the accepted understanding that members of the medical community are treating physical, scientifically based health problems and that their knowledge on this subject exceeds the knowledge of the patient (Brody, 1981). In practice, medical paternalism restricts freedom of choice and self-determination for the patient's own good (Goldman, 1980). Competent adults may be

unable to act in their own best interest because they are unable to understand consequences and the probability of these consequences occurring (Goldman, 1980). When rational people do not make rational decisions, then paternalistic measures may be invoked to protect the patient from decisions solely due to internal factors, such as depression, ignorance, fear, carelessness, or other uncontroversial irrational motives (Dworkin, 1971). Medical decisions can bring frustration, stress and anxiety, all of which prompt patients to seek relief from the burden of autonomy and to provide tacit consent for medical providers to provide established medical practice (O'Neill 1990). These dictates included the restriction of information to the patient, as the doctor had no tacit responsibility to the patient to tell them or their family the truth. In some cases, complete disclosure could cause fear and depression in a patient that would lead them to make irrational decisions that could interfere with the primary goal of protecting the welfare of the patient (Brody, 1981; Goldman, 1980).

Medical paternalism was first subjected to broad scrutiny during the Nuremberg War Crime Trials after World War II. This event revealed details behind numerous horrific medical experiments conducted by Nazi officials on concentration camp prisoners. At the time, there were no guiding principles in the medical community on medical experimentation. The Nuremberg Code and the Declaration of Helsinki first codified an international understanding of the rights of patients in medical experimentation. These documents became the basis for the modern discipline of bioethics and medical ethics (Brody, 1981).

In the 1960's and 1970's, a sweeping social revolution emphasizing social justice and human rights led people to challenge society's dominant social institutions and values, including the traditional assumptions and ethical premises of health care and medicine (Veatch and Branson, 1976; Brody, 1981). Several famous instances of unethical medical experimentation in the United States helped to create a window of opportunity for society to evaluate health care ethics. Elderly patients were injected with live cancer cells at the Jewish Chronic Disease Hospital. Mentally retarded children were inoculated with hepatitis at the Willowbrook State School. The Tuskegee Study of Untreated Syphilis in Negro Men was conducted for forty years, in which hundreds of the poorest Americans were told that they were being treated for "bad blood", but were simply observed to study the fatal progression of syphilis. These and other occurrences prompted the general public to question the infallibility of the medical establishment and ultimately steered public and professional opinions away from the sole prioritization of medical paternalism (Brody, 1981). The paternalistic goals of medicine were challenged by the humanistic goals of health care (Callaghan as cited in Danis, Clancy, & Churchill, 2002).

Refutation of Medical Paternalism by Albert Goldman (1980) was a cornerstone publication in describing the ethical and moral foundations for this new understanding of medical care (Brody, 1981). Goldman said that minimizing harm through medical paternalism could not be the paramount goal in health policy as this was inconsistent with other areas of American social policy. Goldman further explained that medical care

valued the protection of life, but medical care was evaluated by the ability of the doctor to delay death. The length of life is merely an instrumental value that is used in order to accomplish individual life goals. Instead, Goldman suggests, medical care should value life by prioritizing its intrinsic values, such as free will and self-determination.

Unacceptable limits on autonomy by paternalism must be avoided to maximize patient welfare (O'Neill, 1990).

### Medical Autonomy

Autonomy is a fundamental human value that can be best described as self-legislated action (Christman, 1988; O'Neill, 1990). An autonomous individual is able to exercise free thought, free will and make personal decisions (Benson, 1983). Autonomy is central to the concept of self-governing, that individuals ought to be able to be self-directed in their personal choices and the direction of their lives (May, 1994; Oshana, 1998). It is important to note that autonomy is different from freedom, as an individual could be free to act, but not autonomous in their actions, as autonomy rests upon the individual's ability to decide for themselves as to their best course of action (Christman, 1988). These decisions are predicated upon psychological and social conditions that allow an individual to be autonomous; one must have a legitimate set of self-assessed alternatives from which to choose among free from overt restriction by others (Christman 1991, Waller, 1993).

In the United States, medical decisions and health care delivery generally prioritize personal autonomy, the protection and extension of personal freedoms, and

personal goods over public goods (Callaghan as cited in Danis, Clancy, & Churchill, 2002). Autonomous practice of health care aligns with the traditional American value of self-determination (Ziguras, 2004). Democratic systems are legitimized by autonomous individuals who can freely make decisions. Health care in democratic systems, by extension, is legitimate when they allow participants to freely and autonomously choose among alternative treatment options, including self-care. These health care values, shared by other Contemporary Western societies, encourage patient participation by emphasizing their personal responsibility in their health. This reinforces an individual's self-identity as a political actor and legitimizes his own participation in a free society by empowering moral self-development (Emanuel & Emanuel, 1992). These outcomes are encouraged if systems use a socio-ecological model of health care that appreciates social, economic and environmental factors and mitigates or prevent negative impacts from these factors (Callaghan as cited in Danis, Clancy, & Churchill, 2002; Ziguras, 2004). Ultimately, this approach must encourage equal access to conditions and resources that allow meaningful decision making (Ziguras, 2004).

Brody (1981) states that respect for autonomy is the cornerstone of modern medical bio-ethics. Bioethics in the United States was codified in 1974 with the passage of the National Research Act and the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Five years later, the Department of Health, Education and Welfare released Ethical Principles and Guidelines for the Protection of Human Subjects of Research, commonly known as the

Belmont Report. This statement stressed the values of autonomy, beneficence and justice when conducting medical experimentation. These values have been expanded by the medical community to apply to the ethical evaluation of all medical treatment in the United States, not simply to medical experimentation (Brody, 1981).

#### Balancing Medical Paternalism and Medical Autonomy in a Democratic Society

In *Principles of Biomedical Ethics*, Beauchamp and Childress (1994) emphasize that, in practice, autonomy is not an absolute demonstration of free will and individual choice, but a balance between the individual and society. The individual chooses freely to subject himself to authority. This choice, or consent, must be informed and is never permanent, as the individual has the right to revoke this consent at any time, depending upon the situation that the individual encounters, as each case is considered upon its own merits. The primary instance in which an authority can make decision on behalf of the individual is when the individual is incapable of making an informed choice, incapable of providing informed consent, or if third party effects from an individual's illness necessitate paternalistic intervention, such as immunization or quarantine (Grisso and Applebaum, 1998).

Citizens in a democratic society face limited autonomy and we establish guidelines to draw reasonable boundaries between acceptable and unacceptable paternalism (O'Neill, 1990). Dworkin (1971) emphasizes that moral decisions where paternalism and autonomy conflict are not always simple, especially in a society where many medical decisions are made through an implied consent for medical treatment using

standard accepted medical procedure. In more insidious cases, autonomy is threatened by coercion, manipulation and deception (O'Neill, 1990). Ziguras (2004) also warns that autonomous health care decisions are increasingly shaped by external forces, including governments, corporations, social movements and charismatic individuals. Ultimately, patients should be treated in a manner consistent with what a reasonable person would expect and demand (Husak, 1981).

In most cases, respect for autonomy is considered to be paramount in achieving the fundamental goal of patient welfare, but other ethical paradigms, primarily that of medical paternalism, are still considerations in making medical decisions. As previously discussed, Beauchamp and Childress and other bioethicists acknowledge the balance between the individual and those institutions that the individual chooses to allow authority over him. In certain cases, the practice of autonomy and authority can be incompatible, but the concepts are not incompatible. The balance between these two ethical considerations is represented in the contractual ethical model of the patient-provider relationship. Under this form of ethical contract, each of the two parties agrees to certain terms in their relationship to best serve their role and responsibility (Husak, 1981). Four models of the patient-provider relationship are applied to different medical scenarios: the paternalistic, informative, interpretive and the deliberative models. The model that best demonstrates an ideal relationship is the deliberative model (Emanuel & Emanuel, 1992). This model maximizes patient welfare by helping the patient to understand medical options, helping the doctor to understand the values that the patient

holds, and encouraging a deliberation between the two parties to come to a decision (Emanuel & Emanuel, 1992).

In the last 50 years, our understanding of medical ethics in United States health policy has evolved significantly. Medical decisions were once the exclusive providence of doctors and medical professionals. Today, medical decisions are evaluated by their protection of free will by balancing the two ethical paradigms of medical paternalism and medical autonomy. In the case of cannabis, medical paternalism demands that patients and society be protected from a harmful substance, while medical autonomy demands that patients should be free to medicate in a manner which they and their doctor determines to be appropriate. Drug policy, such as the Controlled Substances Act, should reflect current philosophical interpretations of medical ethics by respecting a deliberative model of autonomy to maximize patient welfare in cases where paternalism is unnecessary to protect the patient or society from harm.

#### What is Cannabis?

Cannabis is one of the oldest psychotropic drugs known to humanity with cultivation and use noted in archeological discoveries from more than 6,000 years ago. There are several species of cannabis, the most common being *Cannabis sativa*, *Cannabis indica*, and *Cannabis ruderalis*. Cannabis contains more than 460 known chemicals, 68 of which are classified as cannabinoids, chemical compounds that are not known to be found in any other plant. One cannabinoid, delta 9-tetrahydrocannabinol, was the first cannabinoid to be isolated and is the primary psychoactive ingredient in

cannabis. It is commonly referred to as THC. Unlike THC, the majority of known cannabinoids has mild to no psychoactive properties and do not lead to intoxication (Hall and Pacula, 2003). Cannabis is most frequently prepared for human consumption from the dried flowers of the plant, commonly referred to in the United States as marijuana. It is usually ingested by smoking but is also consumed orally. As cannabinoids are not water soluble, cannabis preparations are not suitable for injection (Ben Amar, 2006; Hall and Pacula, 2003; Fox Armentano & Tvert, 2009).

Cannabis is the most widely used illicit intoxicant in the United States and in the world. The National Institute on Drug Abuse (2010) reports that more than 93 million Americans over the age of 12 have used cannabis at least once, 25 million Americans have used cannabis in the past year, 15 million Americans use cannabis at least monthly. Approximately 7 million Americans use cannabis at least weekly (Fox Armentano & Tvert, 2009).

#### History of Cannabis as Medicine in the United States

Cannabis has been used for centuries as medicine and an intoxicant in Asia and Africa, primarily in China, Egypt and India (Bonnie & Whitebread, 1999). Medicinal use was first documented in the United States in the 1840s, and in 1851, it was first listed in the United States Pharmacopoeia. Between 1840 and 1900, more than 100 articles in medical journals recommended cannabis (Bonnie & Whitebread, 1999). It was widely used as an analgesic, sedative, and hypnotic for variety of ailments, including spastic conditions, convulsions, tetanus, headaches and labor pains (Bonnie & Whitebread, 1999;

Grinspoon 1971). During this time, there is little evidence of recreational use of pharmaceutical cannabis preparations (Bonnie & Whitebread, 1999). Medicinal cannabis was most commonly delivered as a tincture, an alcoholic solution which was generally imported (Grinspoon, 2001). The medicinal use of cannabis dropped significantly with the introduction of aspirin, the first synthetic analgesic, phenobarbital, the first synthetic hypnotic, and the increasing availability of hypodermic syringes.

In the early 20<sup>th</sup> Century, the widespread, unregulated use of opiates and cocaine led to a demand for paternalistic government regulations to protect the public health from drug addiction. Addiction was viewed as a moral weakness among immigrants and lower social classes who were victimized by a growing pharmaceutical industry. In 1906, Congress passed the Pure Food and Drug Act that required labeling of medicinal preparations containing opiates and cocaine in amounts exceeding medical recommendations (Bonnie & Whitebread, 1999). This was followed by the Harrison Narcotic Tax Act of 1914, which introduced additional restrictions on drug importation and distribution. Neither law viewed cannabis as a harmful drug that required control. During this time, recreational cannabis use became more widespread, leading to its prohibition in most Western states. The first federal controls on cannabis were introduced in the 1937 Marihuana Tax Act, which required registration and taxes on the production and distribution of cannabis. In 1942, cannabis was removed from the US Pharmacopoeia (Bonnie & Whitebread, 1999).

In 1961, The Economic and Social Council of the United Nations (UN) convened a conference to control narcotic drugs and their raw materials through a single instrument, replacing numerous existing international treaties aimed to limit the possession, use, distribution and manufacturing of drugs solely to scientific and medical use. The Convention also established the International Narcotics Control Board. Ninety-seven states participated in adopting the Single Convention on Narcotic Drugs to codify international drug laws to protect individual health and welfare. These laws were established to ensure the availability of narcotic drugs to alleviate pain and suffering and to protect the individual from addiction to narcotics, a “serious evil...fraught with social and economic danger to mankind” (United Nations, 1971 p.1).

The Convention codified a system of drug scheduling to categorize and control substances based upon their accepted medical use and potential for harm from addiction. This system was implemented by the United States in the Controlled Substances Act of 1970.

#### Controlled Substances Act

On October 27, 1970, the United States Congress enacted the Controlled Substances Act as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. This law created a series of regulations to control the manufacturing and distribution of controlled substances at the federal level. All drugs regulated under federal law were classified into regulatory schedules that describe their use as medicine and control their manufacturing, distribution and use. Drugs classified under Schedule I

are not allowed for use as medicine and are the most strictly regulated. Schedule II, III, IV and V drugs are allowed for medical use and have less strict controls. Drugs classified as excluded non-narcotic substances are unscheduled and are commonly known as over-the-counter drugs as they are made available to consumers without a prescription, but are also regulated by the Food and Drug Administration (FDA).

The Controlled Substances Act established three criteria used to determine the schedule in which a drug is placed: efficacy, risk of harm and risk of abuse. Efficacy is the determination that the drug is shown to be effective for medical treatment. Risk of harm is the determination that the drug is dangerous for medical treatment. Risk of abuse is not defined, but is commonly understood to be the potential of the drug to be addictive. The findings required for a drug to be scheduled are summarized in Table 2.1.

Table 2.1 Summary of Controlled Substances Act Criteria

|                                    | Schedule V  | Schedule IV  | Schedule III  | Schedule II   | Schedule I  |
|------------------------------------|---|--|---|---|---|
| Efficacy                           | The drug has a currently accepted medical use in treatment in the United States.  | The drug has a currently accepted medical use in treatment in the United States.   | The drug has a currently accepted medical use in treatment in the United States.                    | The drug has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. | The drug has no currently accepted medical use in treatment in the United States. |
| Potential for Harm                 | The drug has a low potential for abuse relative to the drugs in schedule IV.  | The drug has a low potential for abuse relative to the drugs in schedule III.  | The drug has a potential for abuse less than the drugs in schedules I and II.                       | The drug has a high potential for abuse.  | The drug has a high potential for abuse.  |
| Potential for Abuse/Addiction      | Abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV. | Abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III. | Abuse of the drug may lead to moderate or low physical dependence or high psychological dependence. | Abuse of the drug may lead to severe psychological or physical dependence.  | There is a lack of accepted safety for use of the drug under medical supervision. |
| Examples of drugs in this Schedule | cough suppressants with small amounts of codeine, Lomotil (mixed with atropine to reduce abuse potential)                                       | Xanax, Valium, Restoril, Ambien  | pure codeine under 90mg per dose, anabolic steroids, synthetic THC, ketamine                        | pure codeine over 90mg per dose, cocaine, Ritalin, opium, morphine, PCP, most amphetamines, most barbiturates                                 | cannabis, heroin, LSD, MDMA (ecstasy), GHB, Peyote, Mescaline                     |

(source:DEA Homepage, n.d.)

Regulatory oversight for the CSA is divided between the Department of Justice and the Department of Health and Human Services. Located within the Justice Department, the Drug Enforcement Agency (DEA) has authority to implement the Controlled Substances Act. Determinations for drug safety are delegated to the Food and Drug Administration and the role of scientific research is delegated to the National Institute of Drug Abuse, both contained within the Department of Health and Human Services. The power to amend the CSA is given to Congress and to the Attorney General of the United States. The Attorney General has traditionally delegated this power to the Administrator of the DEA. Petitions for amendments to the Controlled Substances Act must be filed with and accepted by the DEA. If the DEA finds merit with the petition, an evaluation of medical and scientific evidence is held with the DEA making a final ruling on the petition based upon evidence presented at the hearing (Shuglin, 1991).

#### NORML Lawsuit

In 1970, the Controlled Substances Act classified cannabis as a Schedule I controlled narcotic. Less than two years later in 1972, NORML (The National Organization for the Reform of Marijuana Laws) became the first of several petitioners to the Bureau of Narcotics and Dangerous Drugs (predecessor of the DEA) to reschedule cannabis. This led to a series of lawsuits against the BNDD/DEA and the Department of Health, Education and Welfare (DHEW), which later became the Department of Health and Human Services, for their inaction on the petition, which led to numerous appeals to Federal Appeals Courts (Zeese, 1999).

In 1986, the DEA granted NORML's request to schedule an investigative hearing regarding the rescheduling of cannabis from Schedule I to Schedule II. Hearings were held from late 1987 to early 1988. In late 1988, DEA Chief Administrative Law Judge Francis Young recommended that cannabis be rescheduled to Schedule II (Randall and O' Leary, 1998). Late in 1989, the DEA rejected Young's decision. An appeal was filed by both NORML and Cannabis Therapeutics, who won a 1991 ruling that the DEA did not use the proper criteria and standards to reject Young's decision. The DEA reviewed their decision internally, returned with the same ruling to deny rescheduling, and prevailed in a final appeal 1994 that ended this rescheduling attempt twenty-two years after it was first initiated (Randall and O' Leary, 1998).

As a result of this lawsuit, the DEA established a definition for "currently accepted medical use" that would qualify a drug for Schedule II. The five criteria to meet this definition are that the drug must have a known and replicable chemistry, adequate safety studies must be conducted, adequate and controlled studies must prove efficacy, the drug must be accepted by qualified experts, and the scientific evidence for this decision must be publicly available (Randall and O' Leary, 1998).

#### Compassionate IND Program

In 1976, glaucoma patient Robert Randall successfully used the Common Law doctrine of necessity as a defense against cannabis cultivation charges. He petitioned to receive cannabis from the FDA, which resulted in the 1978 establishment of the

Compassionate Investigational New Drug (IND) program. The program was originally limited to a small number of patients with exceptionally rare conditions (Zeese, 1999).

Between 1978 and 1982, 33 states passed some form of legislation to make cannabis available for medicinal use by the seriously ill. Initial drafts of the bills had various provisions centered on making cannabis available on the state level as a prescription drug. The federal government recommended that these states establish state-level research programs through the Compassionate IND. By 1984, 17 states had active state-level INDs for medical cannabis with hundreds of patients. Among these, six states were conducting medical research into the efficacy and safety of cannabis (Zeese, 1999).

In the mid 1980's, the IND program was expanded to include patients infected with the Human Immunodeficiency Virus (HIV). The growing demand for and interest in the use of cannabis as medicine to treat the symptoms of Acquired Immune Deficiency Syndrome (AIDS) resulted in the federal government increasingly restricting access to medical cannabis and in an increased interest in establishing local and state programs to assist patients in obtaining cannabis (Zeese, 1999).

The federal program peaked at 30 patients when it was closed to new applicants in 1991 and all state IND programs were terminated by the federal government in 1992. A small number of patients were grandfathered into the federal program, the rest were recommended to switch to Marinol (Dronabinol), a Schedule III drug that is a chemical form of Delta 9-Tetrahydrocannabinol, one of the many cannabinoids found in cannabis. As of 2008, seven patients remain in the federal IND program.

### State Laws Regulating the Use of Cannabis as Medicine

In 1996, California and Arizona passed statewide ballot initiatives to support medicinal use of cannabis. In recent history, California became the first state to legalize the use of cannabis as medicine with the approval of a physician.

As of 2011, 16 states and the District of Columbia have legalized the use of cannabis as medicine either through ballot propositions or through the state legislature. These states are Alaska, Arizona, California, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, Virginia and Washington.

The website ProCon.org (n.d.) estimates that there are 577,712 legally approved users of medical cannabis in these 16 states. The most common diseases in which cannabis is recommended by physicians are cancer and HIV/AIDS, both of which are progressive, chronic and fatal diseases. Major medical organizations including the American Medical Association, the American College of Physicians, the American Academy of Family Physicians, the American Public Health Association, the American Psychiatric Association, and the American Nurses Association support patients' access to medical cannabis with the approval of their physician (Fox, Armentano & Tvert, 2009; Hazekamp and Grotenhermen, 2010).

### Challenges to the Prohibition of Cannabis as Medicine

The most significant challenge to the status of cannabis as a Schedule I drug is the recent discovery of the endocannabinoid system. During the past 15 years, the scientific

understanding of the biological role of cannabinoids has advanced significantly. The great majority of research conducted in the 20<sup>th</sup> Century investigated the role of cannabinoids in providing temporary relief from disease symptoms. In the 21<sup>st</sup> Century, research is now focusing on the role of cannabinoids to modify or cure diseases and medical conditions (Pacher, Kunos, & Bátkai, 2006). Proponents of cannabis as medicine argue that this new understanding of the role of cannabinoids in human health has not been properly considered by policy making bodies.

The endocannabinoid system is a physiological system that has only recently been discovered and has become a focus of medical research. The endocannabinoid system is believed to exist in all mammals and has been observed in lower vertebrates, including birds, reptiles and fish. The presence in both higher and lower vertebrates suggests that it plays an important biological role in many species as they did not disappear as vertebrates evolved over time. The endocannabinoid system consists of cannabinoid receptors, endocannabinoids and enzymes that synthesize and degrade cannabinoids (Mackie, 2005). Cannabinoid receptors are activated by endocannabinoids, which are naturally produced by the body, or by externally introduced cannabinoids that both naturally occur in plants or are synthetically created pharmaceuticals. They are deactivated by cannabinoid antagonists and regulated by enzymes (Martin and Cone, 1999).

Previous research on the health effects of cannabis incorrectly focused on the interaction between cannabinoids and membrane lipids due to clinical observations that

biologically active ingredients were lipophilic (Lawrence and Gill, 1975). Research on THC conducted in the 1970's demonstrated both strict structural selectivity and stereoselectivity, which indicated that the brain contained undiscovered drug receptors (Hollister, 1974). A cannabinoid-specific receptor was first mapped in the brain in 1988 and later named CB1 (Matsuda, Lolait, Brownstein, Young & Bonner, 1990). Later research revealed two splice variants of CB1, each with unique pharmacology, and a second receptor named CB2 (Munro, 1993). Various evidence strongly suggests that other cannabinoid receptors exist but have not yet been discovered (Wiley and Martin, 2003; Begg, Pacher, Batkai, Ose-Hyiaman, Offertaler, Mo, Liu & Kunos, 2005).

The CB1 receptor is found throughout the brain and the central nervous system and is concentrated in systems that regulate emotions, motor function, memory, pain, digestion, immunity and reproduction. The CB2 receptor is found primarily in the immune system, but is also present in nerve cells in the peripheral nervous system. Its function remains largely undiscovered (Mackie, 2005; Hall and Pacula, 2003).

In light of new scientific evidence that cannabis has therapeutic potential that was not considered under previous attempts to reschedule it under the Controlled Substances Act, the Coalition for Rescheduling Cannabis (CRC) filed another petition to reschedule cannabis in 2002. The petition argues that cannabis has scientifically proven therapeutic potential, is safe for use under medical supervision, and has a lower risk for harm than other drugs currently categorized as Schedule I (CRC, n.d. ).

## Medical Organizations on Medical Cannabis

A number of national and international organizations have published position papers on their findings and recommendations regarding the medicinal use of cannabis. Among these organizations, there is widespread agreement that cannabis shows strong potential for medical use and that additional research is necessary to investigate these claims.

### World Health Organization

In 1997, the Division of Mental Health and Prevention of Substance Abuse of the World Health Organization published *Cannabis: A Health Perspective and Research Agenda*. The purpose of this report is to highlight recent scientific advances in the understanding of actual and potential health consequences of cannabis use for the development of national and international drug control strategies.

The report states that acute and chronic health effects from cannabis use, and from drug use in general, are difficult to measure due to differences in individual experiences and numerous environmental, biological and genetic factors, including the use of other legal and illegal drugs. These contributing influences lead to a risk of oversimplification and implied universality of effects from a particular drug, when effects vary greatly between individuals.

WHO recognizes therapeutic efficacy for cannabis as an antiemetic for cancer patients who are undergoing chemotherapy, as an appetite stimulator for anorexia and weight loss from AIDS wasting syndrome, and as an analgesic. Therapeutic potential for

glaucoma, convulsant and movement disorders, asthma, multiple sclerosis and depression exists, but requires additional evaluation to demonstrate efficacy.

WHO states that the acute health effects from cannabis use include an impairment of cognitive development, of memory, and of psychomotor performance, which increases the risk of injury from accidents. Rare cases of acute psychosis occur, but cannot be directly linked to cannabis use in a causal manner due to frequent comorbidity of mental illness and use of other drugs. Chronic health hazards can include impairment in cognitive functioning, attention and memory, cannabis dependence syndrome, respiratory damage including bronchial injury, inflammation, acute and chronic bronchitis, and exacerbation of schizophrenia. Cannabis use during pregnancy may impair fetal development and increase the risk of rare cancers in post-natal patients.

WHO stresses the need for additional research to better understand cannabis use. Potential areas of research include reasons for use, amotivational syndrome, possible links to schizophrenia and other mental illnesses, pharmacokinetics, dependence, and impacts on the reproduction, immune, cardiovascular and respiratory systems. Additional research is also needed to compare risks of morbidity and mortality from cannabis use in comparison to other legal and illegal drugs in order to accurately schedule it.

#### Institute of Medicine

The Institute of Medicine (IOM) is an independent, non-profit organization that advises policy makers and the public on health and health policy in the United States. In

1999, the Institute of Medicine published *Marijuana and Medicine: Assessing the Science Base*. This publication was commissioned at the request of the Office of National Drug Control Policy (ONDCP) in response to state initiatives allowing the medicinal use of cannabis. ONDCP is a component of the Executive Office of the President with the mission of establishing the national drug control policies, priorities and objectives with the goals of reducing illicit drug use, trafficking and manufacturing, reducing drug-related crime and violence, and reducing drug-related health consequences.

The three areas of focus for this report were the biological effects of cannabis and isolated cannabinoids, the health risks associated with the medical use of cannabis, and the efficacy of cannabis. This report observes that recent scientific advancements in understanding cannabinoids have created great potential for new therapeutic applications for cannabis.

In studying cannabinoid biology, IOM concluded that cannabinoids play a natural role in human biology in a number of biological systems, including pain modulation, movement control, memory and immunity. The body is capable of developing tolerance to cannabinoids which demonstrates a potential for dependence and withdrawal symptoms. When compared with other pharmaceutical and recreational drugs such as benzodiazepines, opiates, cocaine and nicotine, the dependence potential is both milder and on a more limited range. Similarly, withdrawal symptoms are observed to be milder than with other therapeutically accepted drugs. IOM also observed that the effects of different cannabinoids are not well understood and that several cannabinoids are

observed to have therapeutic properties, but lack the psychoactive properties found in THC.

The IOM review of the efficacy of cannabis demonstrated a therapeutic potential for pain relief, control of nausea and vomiting, and appetite stimulation. The efficacy was comparable to existing drugs for similar conditions. Clinical studies of individual patients demonstrated a wide variance in individual response to different therapeutic alternatives, including a subpopulation that does not respond favorably to existing medicines due to strong undesirable side effects. Due to harmful substances that result from smoking cannabis, the future therapeutic value in cannabis most likely lies in alternate delivery systems that do not expose the patient to smoke.

In addition to the physical effects of cannabis, IOM reviewed the psychological effects of cannabis for their potential therapeutic benefits. These psychological effects were shown to have three major areas of influence on the therapeutic use of cannabis. For some patients, especially older patients and those who had not previously used cannabis, the psychological effects of cannabis intoxication were disturbing. This was more common in the oral (eaten) use of cannabis than with inhaled cannabis. Second, the anti-anxiety properties in cannabis made clinical evaluations of its efficacy on movement disorders difficult as disease symptoms were more pronounced for patients with anxiety. Researchers were unable to determine if the therapeutic benefits from cannabis were due to a reducing of symptoms from a unique therapeutic potential or simply from a reduction of anxiety. Third, in medical conditions with multi-faceted symptoms such as cancer and

AIDS, cannabis showed promise in adjunctive therapy as it was able to reduce a variety of symptoms in patients as it simultaneously relieved pain, reduced anxiety, relieved nausea and stimulated appetite.

IOM studied the potential harms from the use of cannabis as medicine. While cannabis is not a completely benign substance, the majority of negative side effects result from the smoking of cannabis, not from the chemical action of cannabinoids on the body. If the physical harm from smoking cannabis is eliminated, the side effects of cannabis are similar to the side effects that are tolerated for other medications that are currently used. IOM observes that this distinction is not made in the majority of past studies on the potential harm of cannabis use and that the harmful side effects of recreational cannabis smoking cannot be cited when attempting to determine the potential harm of therapeutic cannabis use that does not involve smoking.

Acute harms from cannabis use include diminished psychomotor performance, which counter indicates the operation of motor vehicles when under its influence. A small number of patients also experience dysphoria.

The chronic health effects of cannabis are of greater concern to the IOM for its use as medicine. The study divides these effects into chronic effects from smoking cannabis and the chronic effects from exposure to cannabinoids. Cannabis smoking is associated with abnormalities of cells in respiratory tract linings, an increased risk of cancer, lung damage and poor pregnancy outcomes. The study also notes that while cellular, genetic and human studies suggest that cannabis smoke may be a risk factor in

the development of cancer in various areas of the respiratory tract, there have been no studies that have been able to establish a definitive link between the two. Due to the health concerns associated with cannabis smoking, IOM states that smoked cannabis, in general, should not be recommended for long-term medical use. In circumstances where a patient has a terminal illness or has a disease with significantly debilitating symptoms, the long-term risks of disease from cannabis smoking should not be of great concern. IOM states that the future medical use of cannabis lies in the development of cannabinoid based drugs, but the development of these drugs will take place at an unknown time which is likely several years in the future. As there are patients who could benefit from the use of smoked cannabis in the present time, the use of smoked cannabis should be balanced with both an understanding of the efficacy of the drug and the risks for long-term health. Until a safer alternative exists for patients facing chronic illnesses, IOM recommends that patients be allowed to use smoked cannabis for short-term relief.

IOM studied the link between cannabis and drug dependence and drug withdrawal. The study determined that cannabis can have similar symptoms of drug dependence to other drugs of abuse, that cannabis and other drugs of abuse share similar risk factors for drug dependence, and that the great majority of cannabis users do not develop cannabis dependence. It also notes that incidence of cannabis dependence is closely associated with comorbidity of other mental illnesses, especially antisocial personality disorder and conduct disorders.

IOM also examined the hypothesis that cannabis is a gateway drug. This hypothesis is widely cited as a danger of cannabis use due to observations that its use at a young age is indicated in future use of other, harmful drugs and can lead to an increased incidence of drug dependency. Patterns in the progression of drug abuse from adolescence to adulthood have shown that use of cannabis, tobacco and alcohol typically precedes the use of other drugs of abuse and that individuals who use cannabis, tobacco and alcohol in adolescence are more likely to use other drugs of abuse than those who do not use these drugs in adolescence. This has led to the observational hypothesis that cannabis, tobacco and alcohol are gateway drugs, and that their use is more likely to result in the use of other drugs of abuse, particularly illegal drugs such as cocaine, heroin, methamphetamines and psychedelic drugs. IOM found that there is no causal link between cannabis use at any age and later use of other drugs of abuse. The study also notes that any hypothesis of cannabis as a gateway drug does not apply to medical use of cannabis, and that there is no evidence that those who use cannabis medicinally follow the pattern of drug abuse typically observed in those who use cannabis recreationally. The study also addressed the concern that access to cannabis as medicine would increase use of cannabis as a recreational drug in the general population. It concluded that medicinal use of cannabis, if regulated in a manner consistent with other therapeutic medicine would not lead to increased recreational use and that this argument should not be considered when evaluating the value of cannabis as medicine.

In conclusion of their study of cannabis as medicine, IOM makes six recommendations based upon the current understanding of cannabis and the current state of the development of alternative delivery systems for cannabinoids. IOM recommends that research be continued on the physiological effects of cannabinoids on the natural function of the human body, that clinical trials be conducted with the goal of developing safer delivery systems for cannabinoids, that clinical trials be conducted on the psychological effects of cannabinoids, that studies be conducted to better understand the health effects and health risks of smoking cannabis, that clinical trials be conducted on the short-term efficacy of cannabis on patients where a reasonable expectation exists that efficacy exists, and that clinical trials be conducted on the short-term use of cannabis for patients with debilitating symptoms where currently accepted therapies have failed to provide relief.

#### American Medical Association

The American Medical Association (AMA) is the oldest and largest organization of doctors in the United States, with 240,000 members. Its mission is “To promote the art and science of medicine and the betterment of public health” (AMA, n.d.). Throughout the 20<sup>th</sup> Century, the AMA has consistently opposed the classification of cannabis together with other controlled substances such as opium, cocaine and controlled narcotics.

In 2009, the AMA Council on Science and the Public Health (CSAPH) published the resolution Use of Cannabis for Medical Purposes. AMA has four policy positions

regarding the medical use of cannabis: It supports medical research into the use of cannabinoids of serious medical conditions where anecdotal, preclinical or controlled evidence indicates efficacy and the ability to provide treatment or understanding of disease, it urges a review of cannabis' status as a Schedule I drug, it urges the National Institutes of Health (NIH) to facilitate a program to actively support research into the medical utility of cannabis, and it opposes criminal sanctions for doctors and patients who share information regarding treatment alternatives.

The AMA states that medical trials have determined that smoked cannabis is effective as an analgesic in controlling neuropathic pain, improves caloric intake and appetite in patients, and reduces spasticity and pain in patients with multiple sclerosis. Reviews of medical evidence indicate that further research is necessary to determine efficacy in HIV-infected patients with cachexia and neuropathy, patients undergoing antiretroviral therapy who seek relief from nausea, vomiting and peripheral neuropathy, patients undergoing chemotherapy who seek relief from mucositis, nausea and anorexia, in treating postoperative, traumatic or cancer pain, in treating spasticity and pain due to spinal cord injury, neuropathic pain syndromes and central pain syndromes, and in patients with chronic pain and insomnia. In studies of the endocannabinoid system, the AMA recognizes that endocannabinoids play a role in the regulation of a wide variety of organ systems and disease states, including appetite regulation, peripheral energy metabolism, metabolic abnormalities such as obesity, pain, inflammation, gastrointestinal motility and secretion, central nervous system disorders, neurotoxicity,

neuroinflammation, neuroprotection, and mental disorders, including substance use, misuse and abuse.

Adverse effects from the medical use of cannabis, including smoked cannabis, are difficult to determine as few clinical trials have addressed this issue. As effects of cannabis greatly differ between experienced users and inexperienced users, anecdotal evidence of adverse outcomes through short-term, recreational use cannot be applied to those who use cannabis for long-term disease or symptomatic treatment. Studies of short-term use of medical cannabinoids have anecdotally noted adverse events, with less than 4% of these events considered to be serious.

The nonmedical use of cannabis has both acute and chronic health effects. Acutely, smoked cannabis can increase heart rate, decrease blood pressure, and can impair short-term memory, attention, motor skills, reaction time, and the organization and integration of information. Some individuals can experience dysphoria, anxiety, confusion, paranoia, and psychotic symptoms including delusions and hallucinations. Chronic cannabis use can result in substance dependence, which is indicated by increased tolerance and the presence of withdrawal symptoms, including restlessness, insomnia, irritability, nausea and cramping. Dependence is indicated in 4-9% of cannabis users and is more likely to occur in patients with co-morbid psychiatric conditions. Chronic cannabis smoking is associated with symptoms of chronic bronchitis and lung damage, but an increased risk of respiratory disease may only occur synergistically with tobacco smoking. The limited numbers of controlled studies do not find an increased risk of

cancer in the lung, airway or oral cavity, observed an increase in the risk of certain cancers of the testicle, and observed a decrease in the cancer risk for squamous cell carcinoma in the head and neck. Cannabinoids modulate the immune system, but it is unclear if this can have a negative effect on immune response. Chronic cannabis use is associated with changes in mental functioning and neuropsychomotor performance, and subtle impairment of learning. Chronic cannabis use can accompany psychotic or affective mental health outcomes, but it is unclear if cannabis has any role in causing mental disorders or if patients with mental disorders choose to use cannabis for self-management of these conditions.

#### American College of Physicians

The American College of Physicians (ACP) is a national organization of physicians of internists, doctors specializing in the prevention, detection and treatment of illnesses in adults. With 130,000 members, it is the largest medical-specialty organization in the United States and, after the American Medical Association, is the second-largest physician group in the United States. The ACP mission is “To enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine” (ACP, n.d.).

In 2008, ACP published its position paper Supporting Research into the Therapeutic Role of Marijuana, which establishes the ACP policy positions on the use of cannabis as medicine. ACP supports an increase of both programs and funding to allow a rigorous scientific evaluation of the therapeutic benefits, efficacy, dosage and delivery of

both smoked and non-smoked cannabis in comparison to other available treatments. It urges an evidence-based review of cannabis' scheduling based upon its safety and efficacy. It supports the current process of receiving research grade cannabis from NIDA. It strongly urges exemption from federal criminal prosecution, civil liability or professional sanctioning for both physicians prescribing and dispensing cannabis as well as for patients using cannabis under existing state laws.

ACP acknowledges that both existing research and anecdotal evidence supports numerous potential therapeutic uses for cannabis. These medical uses include appetite stimulation, as an antiemetic, as an analgesic, in treatment of neurological and movement disorders, and in treatment of glaucoma.

#### American Nurses Association

The American Nurses Association (ANA) represents more than 3.1 million Registered Nurses in the United States. The ANA mission is "Nurses advancing our profession to improve health for all" (ANA, n.d.). In 2008, the ANA Board of Directors adopted the position statement In Support of Patients' Safe Access to Therapeutic Marijuana to reiterate their support of access to cannabis for medicinal use.

The ANA position supports the education of its membership and other health care practitioners on the therapeutic use of smoked and non-smoked cannabis where efficacy has been clinically determined, further research to confirm the efficacy of cannabis, the reclassification of cannabis from a Schedule I substance into a less restrictive category, and the removal of criminal and civil penalties and professional sectioning for health care

practitioners and patients who prescribe, dispense, administer or use cannabis in accordance with state law.

ANA recognizes the medicinal properties of cannabis are effective in treating a wide range of symptoms in a variety of conditions, including the reduction of nausea and vomiting associated with chemotherapy, appetite stimulation and wasting syndrome associated with HIV/AIDS and cancer, glaucoma, spasticity, pain and tremor in patients with multiple sclerosis, spinal cord injuries or other trauma, and chronic pain. In this Position Statement, ANA echoes the ACP call for research to determine standard and optimal doses and to confirm therapeutic properties, and that this research is hindered by both the federal approval process required to obtain research-grade cannabis and by the categorization of cannabis as a Schedule I controlled substance.

#### American Psychiatric Association

One of the three criteria that places a drug into Schedule I is a determination that the drug has a high potential for abuse. The CSA does not define drug abuse nor does it set guidelines to objectively measure the abuse potential of a particular drug or to compare abuse potential of different drugs.

The Diagnostic and Statistical Manual of Mental Disorders (DSM) is published by the American Psychiatric Association. It provides standardized language that is used in the United States by medical clinicians, medical researchers and by policy makers to define mental disorders, including substance abuse. The current version in use is the Text Revision of the 4<sup>th</sup> edition, published in 2000, and is referred to as the DSM-IV-TR.

DSM-IV-TR (2000) classifies disorders commonly referred to as drug abuse as Substance-Induced Disorders and Substance Use Disorders. Substance-Induced Disorders are acute disorders related to a specific drug and Substance Use Disorders are chronic disorders over a period of twelve months or longer. Substance Use disorders are sub-categorized as Substance Abuse and Substance Dependence, with Substance Abuse considered as a precursor to Substance Dependence.

DSM-IV-TR categorizes Cannabis-Related Disorders as Cannabis Intoxication, Cannabis Intoxication Delirium, Cannabis-Induced Psychotic Disorder and Cannabis-Induced Anxiety Disorder. These are psychoactive effects of cannabis use that can sometimes include paranoia, delirium, hallucination, anxiety, depersonalization, and derealization.

DSM-IV-TR defines Substance Abuse as a series of negative consequences as a result of drug use, including failures to meet major life obligations at work, school or home, substance use in situations that endangers personal safety, recurrent legal problems related to drug use, and recurrent social and interpersonal problems from drug use.

Substance Dependence is a maladaptive pattern of Substance Abuse that includes increased tolerance characterized by diminished effect of the drug requiring use of increased amounts of the drug for the desired effect, withdrawal symptoms, taking the drug in larger amounts or for a longer period of time than intended, unsuccessful efforts to reduce or control substance abuse, significant amounts of time dedicated to obtaining

the drug, interference with important personal obligations from substance abuse, and continued substance abuse despite knowledge of increased physical or psychological problems caused or exacerbated by substance abuse.

Kara D. Volkow, M.D., director of the National Institute on Drug Abuse, states in *Marijuana Abuse* (2002) that NIDA prefers to use the term “drug addiction” when referring to the drug use disorders of drug abuse and drug dependence and considers them to be synonymous.

#### Clinical Trials on Human Subjects

Clinical trials with human subjects are rare when compared with clinical trials for other drugs as the Schedule I classification limits the availability of research quality cannabis in the United States. Two reviews have been conducted that encompass the global history of clinical studies of the therapeutic use of cannabinoids. These studies are peer reviewed, randomized, double-blind, placebo controlled human studies.

In the *Journal of Ethnopharmacology* (2007), Mohamed Ben Amar published a review of studies conducted from 1975 up to and including 2004. During this time, 72 studies were conducted on 3,569 subjects. These studies identified ten pathologies in which controlled studies examined the therapeutic potential for cannabinoids: nausea and vomiting, appetite control, pain, multiple sclerosis (MS), spinal cord injuries, Tourette’s syndrome, epilepsy, glaucoma, Parkinson disease and dystonia. These studies indicated that cannabinoids had therapeutic potential as antiemetics to control nausea and vomiting, as an appetite stimulant in debilitating diseases such as HIV/AIDS and cancer, as an

analgesic and in the treatment of spinal cord injuries, multiple sclerosis, Tourette's syndrome, epilepsy and glaucoma.

In 2010, the journal *Cannabinoids* published the Hazekamp and Grotenhermen review of the most recent human clinical studies conducted from 2005 to 2009. This review consisted of 37 studies with 2,563 patients for pain, multiple sclerosis and spasticity, HIV/AIDS, glaucoma, nausea/vomiting/appetite, intestinal dysfunction, schizophrenia and other dysfunctions including Tourette's syndrome and obsessive compulsive behavior. These studies found therapeutic potential for cannabinoids as an analgesic in chronic neuropathic pain, as an appetite stimulant in chronic diseases and in the treatment of multiple sclerosis.

Clinical studies indicate that cannabis has positive results in treating chronic pain and negative results in treating acute pain. This research found that naturally occurring endocannabinoids produced in the spine prevent acute pain from a number of sources, but become less effective in preventing chronic pain due to inflammation or nerve injury. Several studies concluded that cannabinoid therapy might be effective in chronic pain management where conventional therapies have failed, particularly when using cannabinoids in combination with other accepted therapies. Cannabinoids can be successful in improving spasticity, pain and incontinence in MS patients. Current treatment for MS provides inadequate relief that can be limited by toxicity, resulting in high demand for alternative therapies among patients. Cannabinoids are widely used to relieve symptoms of nausea, anorexia, stomach upset and anxiety associated with both

the disease and with antiretroviral therapy. THC is approved by the FDA for oral use as an appetite stimulant for patients with HIV/AIDS. These studies clearly show positive effects on pain, appetite and weight gain. Studies reinforce past scientific conclusions that cannabinoids are successful in lowering intraocular pressure, the major cause of glaucoma. These studies also note that glaucoma has no known preventive treatment, no known cure and is the leading cause of blindness in the world. Cannabinoid effects on the human gastrointestinal tract were observed but the therapeutic potential in treating intestinal dysfunction are unclear beyond their established use in stimulating appetite and reducing nausea and vomiting.

Both reviews of clinical studies indicate that more research was necessary to determine efficacy, dosage, and route of administration, safety of use compared to other drugs, and which cannabinoid(s) had specific therapeutic potential for specific diseases and conditions.

#### Comparison of Addiction Risk from Different Drugs of Abuse

In 1997, the World Health Organization published A Comparative Appraisal of the Health and Psychological Consequences of Alcohol, Cannabis, Nicotine and Opiate Use as part of the WHO Project on Health Implications of Cannabis Use. In measuring the magnitude of health risks from cannabis use, it concluded that the health risks from cannabis have a smaller impact on global health than tobacco and alcohol use as both the relative risk of harm is lower and the prevalence of use is lower. Particularly important to the scheduling of cannabis is the comparison of harm between cannabis and opioids, as

drugs are scheduled according to their risk relative to other drugs. WHO found that both the acute and chronic effects of opioids that are approved for medical use present far greater health risks to personal and global health than the health effects of cannabis. The risks from opioid use that are not present in cannabis use include fatal overdose, transmission of infection and of fatal diseases including HIV/AIDS, hepatitis and tuberculosis, severe risk of dependence, possibly fatal withdrawal symptoms, shortened life expectancy, and social and emotional problems linked to long-term abuse and addiction (WHO, 1997).

In 2007, The Lancet published *Development of a Rational Scale to Assess the Harm of Drugs and Potential Misuse* presents a model to evaluate the physical harm from drug use (Nutt, King, Saulsbury, & Blakemore, 2007). This study observed that no rational scale exists to place drugs of abuse into regulatory categories such as drug schedules assigned under the Controlled Substances Act in the United States and drug classes under the Misuse of Drugs Act of 1971 in the United Kingdom. The criteria used to assign drugs of abuse into regulatory categories are frequently unsystematic, arbitrary and lacking in scientific rationale, possibly resulting in some drugs being improperly scheduled.

This study ranked common drugs of abuse, both legal and illegal, using a matrix that assigned each drug based upon three categories of harm. These three categories of harm closely match the criteria used under the Controlled Substance Act to schedule drugs.

Each of the three categories of harm was ranked between 0-3, with a score of 0 indicating no harm, 1 indicating some harm, 2 indicating moderate harm, and 3 indicating extreme harm. Each drug was ranked by a diverse group of experts from the fields of chemistry, pharmacology, forensic science, psychiatry, epidemiology, and law enforcement.

Physical safety of a drug is evaluated by acute harm, chronic harm and harm from intravenous use. Heroin, cocaine and barbiturates all had a mean score between 2 and 3, indicating that these drugs have a moderate to extreme potential for harm.

Amphetamines, benzodiazepines, buprenorphine and anabolic steroids had a mean score between 1 and 2, indicating that these drugs have the potential for moderate harm.

Cannabis had a mean score of slightly less than 1, indicating that it has the potential for some harm, but significantly less than other drugs that are therapeutically available and deemed safe enough for regulated use under medical care. According to this study, cannabis is safe for medical use.

#### The Global Commission on Drug Policy

The Global Commission on Drug Policy is comprised of nineteen members, including five former or current heads of state and Kofi Annan, former Secretary General of the United Nations. Members from the United States include former Secretary of State George P. Shultz, who serves as honorary chair, and former Chairman of the Federal Reserve Paul Volcker. It was formed to encourage an informed, science-based discussion on ways to reduce the harm caused by drugs to people and societies.

In 2011, The Global Commission on Drug Policy published The World Drug Report that was highly critical of national and international drug policies pursued over the previous fifty years since the United Nations Single Convention on Narcotic Drugs, which established international policy for eradicating drug production and drug use in supporting the goal of the improvement of the health and welfare of mankind. The Commission asserts that this strategy was based upon limited evidence available at the time and without an understanding of the complexities of drug addiction, drug use and international drug markets. Over the past fifty years, the Commission states that policymaking bodies have ignored evidence and experience that question drug control policies and avoid open scrutiny or debate on alternatives due to ideological perspectives or political convenience. It condemns the United States for being the leading voice in maintaining repressive drug policies and in limiting their review. Instead of improving the health of people who use drugs, the Commission argues that nations both sacrifice the health and welfare of drug using citizens while increasing risks faced by all citizens.

The Commission observes that a core dysfunction in the implementation of drug control systems is the focus on law enforcement and punishment. This focus has created a system dominated by police, border control and military authorities rather than by medical and scientific professionals. In most countries, the vast majority of resources allocated to drug control policies are spent on the enforcement of drug laws and the punishment of drug users, despite repeated studies that demonstrate greater financial and social benefits for communities that invest in health and social programs. The

Commission also argues that the prioritization of law enforcement creates an institutional dynamic that obstructs objective, evidence-based policymaking by creating significant financial incentives in maintaining this focus and promoting the self-interest of law-enforcement agencies.

The Commission agreed on four core principles and eleven recommendations for action. Among these is a call to review the scheduling of certain substances under regulations such as the Controlled Substances Act. The Commission argues that current schedules were established at a time when there was little scientific evidence on which to base these decisions, and that there was little understanding of the relative risk for harm through the use or abuse of these substances. It specifically condemns the flawed scheduling of cannabis as an obvious abnormality that needs to be addressed.

#### Public Opinion on Cannabis as Medicine

Recent polls show that a majority of Americans support the medical use of cannabis. A 2010 Poll from the Pew Research Center for the People and the Press reports that there is broad public support for legalizing medical cannabis, with 73% of those polled report favoring the sale and use of cannabis for medical purposes. An ABC/Washington Post poll in 2010 measured support at 81% (Langer, 2010). A 2010 poll conducted by Quinnipiac University found that 71% of registered voters supported medical cannabis (Newman, 2010). Support for such laws is held by at least a majority of those polled across all demographic groups.

### Summary of Medical Literature

In reviewing the policy statements of both national and international medical organizations as well as past medical research, it is clear that there is widespread agreement among medical authorities that the policies of the United States under the Controlled Substances Act do not agree with current medical opinion. These medical organizations believe that the Schedule I status of cannabis under the CSA is flawed due to evidence that cannabis has medical efficacy while possessing a potential for harm that is equal to or less than the risk of harm from the use of other drugs currently approved for medical use, with respect to potential harm to both to the individual and to third parties. Furthermore, the Schedule I status prevents medical research from providing scientific proof of the efficacy and relative harm of cannabis use in a medical context. While there is evidence of both physical and psychological harm from the use of cannabis, this evidence is largely circumstantial and anecdotal without providing a direct causal link due to the difficulty in conducting research on a Schedule I drug. Furthermore, the evidence of possible harm from cannabis use is largely due to the inhalation of noxious chemicals resulting from smoked cannabis, not from the cannabinoids themselves. The recent discovery of the endocannabinoid system in human anatomy underscores the need for new medical research to be conducted in light of the possibility for new and novel medical uses for cannabis that was not understood by the limited research conducted in the past.

## Chapter 3

### METHODOLOGY

As the literature review in chapter 2 indicates, there is disagreement between the medical community and United States policy regarding the medicinal use of cannabis in the United States. Major medical organizations disagree with the Schedule I status of cannabis due to its potential for medical use and its low risk of harm. In this thesis, I will investigate possible reasons for this disagreement by analyzing the two federal executive departments with regulatory oversight of the Controlled Substances Act, the Department of Justice and the Department of Health and Human Services.

My hypothesis is that the policy position of each department (and its respective agencies, if applicable) will agree with the department or agency mission and goals. I will conduct a qualitative, descriptive study of these two departments to demonstrate a relationship between their policy positions and their guiding mission statements and policy goals by evaluating their support of paternalism and autonomy. The units of analysis will be the two departments analyzed by data collected from their respective position papers, scientific studies, websites and other publications issued by these departments that discuss cannabis, marijuana or marihuana, its use as medicine and its beneficial and harmful effects. After examining hundreds of pages of primary documents published by the United States government over a period of forty years, I determined that an examination of data from these two departments presents the most direct evidence for the policy positions of the United States federal government in the evolution of the

Controlled Substances Act. Other documents examined include publications from the Office of National Drug Control Policy and the nation's Drug Czars, the opinions from the three Supreme Court decisions on medical cannabis, the complete record of the 1997 hearings on medical cannabis in the Senate Judiciary Subcommittee on Crime and Drugs, and a 2010 review conducted by the Congressional Research Service. In each case, the previously mentioned political bodies cite evidence from these two departments as justification for their policy recommendations and judicial decisions. As policy positions change over time in light of both advances in medical evidence and under political guidance from different administrations, I will conduct a cross-sectional study of the most recent publications by these departments as of June 1, 2011.

The federal organizations that will be examined are The Drug Enforcement Agency of the Department of Justice, the National Institute of Drug Abuse of the Department of Health and Human Services, and the National Institute of Health of the Department of Health and Human Services.

#### Evaluation of Mission and Goals

In the first part of my analysis, I will examine the mission and goals of the three previously mentioned federal organizations. The purpose of this analysis is to determine if the underlying values and ethical viewpoint of the organization supports medical paternalism, supports medical autonomy, or balances the two ethical viewpoints. The following criteria will be used to analyze the Drug Enforcement Agency, The National

Institutes of Health, and the National Institute on Drug Abuse for their support of autonomy and paternalism in the medical use of cannabis.

#### Criteria to Evaluate Autonomy

In the Stanford Encyclopedia of Philosophy, Sarah Buss (2008) summarizes the four approaches to personal autonomy based upon the actor's motives: Coherentist, reasons-responsive, responsiveness-to-reason, and incompatibilist. The coherentist approach is strictly internalist, as it respects action if it is compatible with the actor's point of view and long term goals. The reasons-responsive conception recognizes that an actor is motivated to action by reason, even if reason is limited by a lack of complete information about the decision, but the actor is motivated by intuition or learning. The responsiveness-to-reason approach states that an actor is capable of moving beyond personal attitudes and beliefs and can make autonomous decisions based upon higher-order attitudes and practical reasoning. The incompatibilist conception of autonomy states that, by nature, all actions are driven by external forces and actors are simply responding to these forces.

When considering the use of cannabis as medicine, the preceding four approaches to autonomy are respected in the following manner:

Coherentist - allows the use of cannabis if a patient desires to use cannabis

Reasons-responsive – allows the use of cannabis if a patient believes that cannabis will treat the symptoms or cause of a medical condition, regardless of fact

Responsiveness-to-reason – allows the use of cannabis if a patient engages in a reasoned, deliberative attempt to discover that cannabis will treat the symptoms or cause of a medical condition

Incompatibilist – allows the use of cannabis if a patient is powerless to act in his best interest to treat the symptom or cause of a medical condition

In this thesis, these four criteria will be used to determine if an organization respects medical autonomy of a patient to use cannabis as medicine.

#### Criteria to Evaluate Paternalism

In the Stanford Encyclopedia of Philosophy, Gerald Dworkin (2010) summarizes the various normative views describing different situations in which paternalism is justified: Hard vs. soft paternalism, broad vs. narrow paternalism, weak vs. strong paternalism, pure vs. impure paternalism, and moral vs. welfare paternalism. Hard paternalism interferes with action regardless of the actor's intention, while soft paternalism intervenes in an attempt to understand the actor's intention in order to determine if interference is justified. Narrow paternalism concerns only legal authority, while broad paternalism includes institutional authority. Strong paternalism restricts action based upon an assumption of an actor's ignorance of fact, while weak paternalism restricts action if it is incompatible with an actor's values. Pure paternalism only restricts action if it harms the actor, while impure paternalism restricts action if it harms a third party. Moral paternalism protects an actor from corrupting his moral character based

upon societal norms, while welfare paternalism protects an actor from physical or psychological harm.

When considering the use of cannabis as medicine, the preceding ten aspects of paternalism are enacted in the following manner:

Hard paternalism – forbids cannabis use regardless of the patient’s intention

Soft paternalism – forbids cannabis use to determine if it is in the patient’s best interest to allow it in the future

Narrow paternalism – forbids cannabis use based upon legal authority

Broad paternalism – forbids cannabis use based upon medical authority

Strong paternalism – forbids cannabis use because the patient lacks the ability to act in his best interest due to ignorance of medical facts

Weak paternalism – forbids cannabis use because the patient lacks the ability to act in accordance with his personal values

Pure paternalism – forbids cannabis use because it is objectively harmful to the individual

Impure paternalism – forbids cannabis use because it is objectively harmful to third parties

Moral paternalism – forbids cannabis use because it will corrupt his moral character

Welfare paternalism – forbids cannabis use because it will lead to physical or mental illness

In this thesis, these ten criteria will be used to determine if an organization respects medical paternalism in the right of the United States federal government right to deny a patient the use of cannabis as medicine.

#### Evaluation of Policy Position on Cannabis

In the second part of my analysis, I will examine the policy position of each organization on the medical use of cannabis. The purpose of this analysis is to determine if the organization supports the current Schedule I status of cannabis, or if it supports a less restrictive schedule. The criteria for this analysis will be the same three criteria used to schedule a drug under the Controlled Substances Act: the medical efficacy of cannabis, the risk of abuse from cannabis use, and the risk of harm from cannabis use.

#### Paternalism and Autonomy in Drug Scheduling

Using the information in chapter 2, I have created a descriptive model that explains how paternalism and autonomy relate to the scheduling of drugs under the Controlled Substances Act. If a drug is unscheduled, it is available over the counter (OTC) without the approval of a medical provider through a prescription. The decision to purchase and use this drug is completely autonomous, as the patient is free to act without medical approval. The federal government has determined that paternalism is not justified to deny use of the drug as it has determined that the drug has a proven efficacy and a low risk of harm and addiction. This is indicated on the table as (A).

If a drug is classified as Schedule V, IV, III or II, its use is allowed through a balance of paternalism, which is demonstrated in the requirement for a prescription, and

autonomy, where the patient is free to choose to take a drug or to seek alternative treatment, such as other drugs approved for the disease or condition. This is indicated on the table as (A/P).

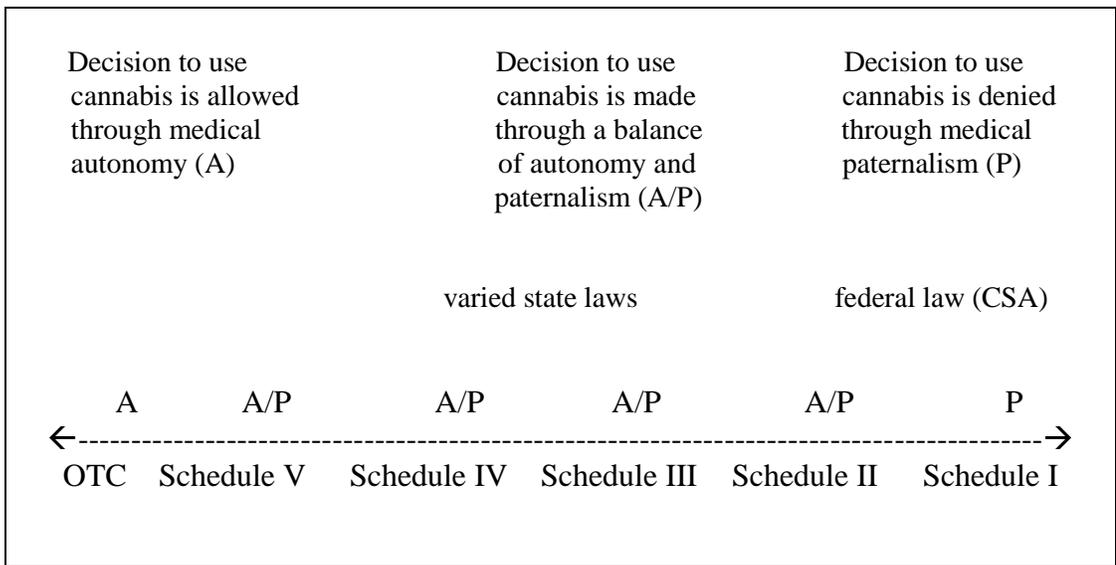
If a drug is classified as Schedule I, its use is legally denied by the federal government through paternalism as the CSA has determined that the drug has no medical efficacy and is unsafe for medical use. This is indicated on the table as (P).

Table 3.1 Paternalism, Autonomy and Drug Schedules

|  |     |  |             |  |             |            |   |
|--|-----|--|-------------|--|-------------|------------|---|
| Decision to use drug is allowed through medical autonomy (A) |     | Decision to use drug is made through a balance of autonomy and paternalism (A/P) |             | Decision to use drug is denied through medical paternalism (P) |             |            |   |
| ←  | A   | A/P  | A/P         | A/P  | A/P         | P          | → |
|  | OTC | Schedule V   | Schedule IV | Schedule III   | Schedule II | Schedule V |   |

When specifically considering cannabis, the federal government currently cites paternalism in denying use for any reason as a Schedule I drug. The states that have passed laws allowing the use of cannabis for medical purposes treat cannabis as if it were Schedule IV or III, allowing its use with the approval of a physician.

Table 3.2 Paternalism, Autonomy and Cannabis Scheduling



Data collected will be presented on a descriptive bipolar scale in Chapter 5 using the models shown in Tables 3.1 and 3.2.

## Chapter 4

### RESEARCH FINDINGS

In Chapter 4, I will present the research findings based upon my analysis of the three federal organizations charged with oversight of the Controlled Substances Act. Each organization will be examined to determine their policy stance on the three criteria used to schedule a drug under the CSA and to determine if their mission and goals support medical paternalism, medical autonomy, or a balance between the two.

#### Drug Enforcement Agency

The Drug Enforcement Agency is a component of the United States Department of Justice. It was created in 1973 by Executive Order to combat drugs on a global level under a single agency. Previous to their inception, federal drug laws were enforced by a number of agencies located in several federal Departments that are responsible for public health, law enforcement, and taxation. The DEA Mission Statement is to enforce U.S. laws regulating controlled substances. One of the nine primary responsibilities of the DEA is to enforce the provisions of the Controlled Substances Act (DEA, n.d.).

#### The Policy Position of the DEA on Cannabis

In July, 2010, the Drug Enforcement Agency published The DEA Position on Marijuana, which states that the proposition of smoking cannabis for medicinal purposes is fallacious. This position paper re-affirms the position of the DEA that smoked cannabis is not medicine nor is it safe to use for any reason. This position is based upon findings of Congress in 1970 that there is no scientifically proven evidence that smoked

cannabis has medicinal value and that the Food and Drug Administration has not approved the use of smoked cannabis for any condition or disease. Every medical condition that proponents of the drug claim can be treated with smoked cannabis already has an existing drug previously approved by the FDA which is proven to be a safer alternative.

The DEA asserts that the medical cannabis movement in the United States is a front for an organized crime lobby who seeks the legalization of cannabis in a manner comparable to tobacco or alcohol. In states where the use of medical cannabis was approved by voters, there is widespread distribution of cannabis to individuals who are not approved for medical use, including to minors. Operations to grow cannabis have resulted in the destruction of public and private property. Recreational drug users lie about medical conditions to medical providers in order to obtain and sell cannabis, placing a heavier burden on local law enforcement to prevent the proliferation of cannabis-related crime. Cities and counties are also burdened by the need to create ordinances to regulate the spread of cannabis dispensaries. As of 2010 in California, one hundred and thirty-two cities and nine counties in California have banned dispensaries, one hundred and one cities and fourteen counties have moratoriums against the opening of new dispensaries, and thirty-six cities and nine counties have ordinances to regulate their business practices.

The DEA further asserts that any legalized cannabis will increase health risks, particularly to children, and will threaten public safety. Increased cannabis use causes an

increase in demand for treatment for drug dependency, in the use of other drugs of abuse, of morbidity and mortality, in delinquent behavior, and in the frequency of driving under the influence. The assertion by cannabis proponents that it is a “soft drug” is false, evident in recent increases in emergency room visits and demand for rehabilitation. These risks are exacerbated by advances in cultivation skills which creates cannabis with higher concentration of psychoactive components.

The DEA states that cannabis use has serious consequences on mental health, particularly in adolescents and teenagers. Reduced blood flow to the brain has been observed in cannabis smokers, possibly leading to abnormalities in the small blood vessels in the brain, high blood pressure and reduced pulmonary function. These abnormalities may explain problems with memory and thought processes observed in other scientific studies. Over time, heavy cannabis users experience diminished cognitive abilities, including memory, speed of thinking, verbal fluency and divided attention. Long term, heavy cannabis use can result in structural abnormalities in the hippocampus, which can influence memory, emotion and aggression, and can result in lower scores on neurocognition tests that measure processing speed, memory and IQ. Acute intoxication in teenagers can result in psychotic symptoms, including hallucination and paranoia. Mental health risks from cannabis use among teenagers include the increase of cannabis use among depressed individuals, exacerbation of depression, anxiety, schizophrenia, and an increase in suicidal thoughts and attempts. Chronic, heavy cannabis use in

adolescence is associated with poorer performance on tests of cognition, verbal memory, attention, psychomotor speed, and planning abilities.

Cannabis use can result in threats to physical health, including an increased risk of fetal damage from prenatal use. The DEA cites that in 2009, the California Environmental Protection Agency added cannabis smoke to their list of chemicals that may cause cancer or reproductive toxicity. Harmful chemicals found in high concentrations in cannabis smoke include ammonia, hydrogen cyanide, nitric oxide, tar, carbon monoxide, toluene, and polycyclic aromatic hydrocarbons. Exposure to these chemicals is particularly higher in individuals who smoke cannabis cigarettes than those who use alternative delivery systems, such as vaporizers. Similar to tobacco smoke, cannabis smoke can increase the risk of a variety of respiratory diseases and conditions, including chronic bronchitis, bullous lung disease, chronic obstructive pulmonary disease (COPD), lung cancer, and impairment of immune response in the lungs. Long-term cannabis use in men has been linked to a significant increase in the risk of nonseminoma, an aggressive form of testicular cancer. A correlation has also been found between cannabis smoking and bladder cancer, cancer of the head and neck, and transitional cell carcinoma in the urinary tract.

Women who smoke cannabis while pregnant may place their child at risk for developmental problems and intellectual development. Prenatal cannabis use can result in lower than average birth weight, adverse effects on nerve cells which may increase later risk for cognitive and motor deficits, and smaller head size, which is linked to later

problems with memory, thinking and behavior. Newborn infants who were exposed to cannabis in the womb have been observed to exhibit behavioral abnormalities, including increased irritability, lower responsiveness to stimuli, and increased crying which may impede mother-child bonding. Cannabis use may also deter the travel and implantation of zygotes, resulting in a failed pregnancy.

Cannabis use was involved in 308,547 Emergency Department (ED) visits in 2007, with the highest rate among patients 18-24 years of age. In 2008, cannabis was indicated in 47,214 ED visits in youth 12-17 years of age, almost 1 in 6 of all ED visits for this age group.

Like any drug of abuse, cannabis use can result in dependency. Withdrawal symptoms have been observed in heavy users. Cannabis has been observed to be a precursor to other drugs of abuse. In general, cannabis use at a young age is seen at a significantly higher rate of individuals who use illegal drugs such as heroin, cocaine and hallucinogens. Adults who were users of cannabis as young adults are also more five times more likely to experience drug dependence.

The DEA position paper also asserts that cannabis use is associated with an increase in delinquent and risky behavior, including driving under the influence. Early use of cannabis by teens is observed in an increased occurrence of violent crimes and property crimes, and increased interactions with and arrests by police. Numerous studies indicate that drivers under the influence of cannabis may be more likely to be at fault for traffic accidents and cause fatal traffic accidents at similar levels to drivers who are under

the influence of alcohol. The National Highway Traffic Safety Administration concludes that cannabis significantly impairs driving through decreased car handling skills, impaired judgment of distance and speed, sleepiness, lack of motor coordination and impaired vigilance.

In summary, the DEA firmly supports the Schedule I status of cannabis under the CSA as cannabis has not been shown to have medical efficacy, has a high potential for abuse and has an unacceptable risk of harm to both the individual and to third parties through its use.

#### United States National Institutes of Health

The Food and Drug Administration is responsible for protecting the public health by assuring the safety, efficacy, and security of human drugs. Within the FDA, recommendations on drug safety and efficacy are made primarily with input from the United States National Institutes of Health (NIH) (FDA, n.d.; NIH, n.d.).

The NIH is the primary federal agency for conducting and supporting medical research. It consists of 27 research institutes and centers and is the single largest source of funding for medical research in the world, funding research at more than 3,000 universities and research institutions.

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. The goals of the agency are: to foster fundamental creative discoveries, innovative research strategies, and their applications as

a basis for ultimately protecting and improving health, to develop, maintain, and renew scientific human and physical resources that will ensure the nation's capability to prevent disease, to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research, and to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science (NIH, n.d.).

#### The Position of the NIH on Cannabis

The US government's most comprehensive review of research into the therapeutic potential of cannabinoids was completed by the National Institute on Alcohol Abuse and Alcoholism of the NIH (Pacher, Kunos, & Bátkai, 2006). This review summarizes more than 1300 published independent studies on the endocannabinoid system. The NIH identified 10 major categories of disease where cannabinoids have been indicated in showing promise in treating either disease symptoms or the progression of the disease itself: diseases of energy metabolism, pain and inflammation, diseases of the central nervous system, nausea and vomiting, cardiovascular diseases, glaucoma, cancer, gastrointestinal diseases, musculoskeletal disorders, and reproductive disorders. Cannabinoids have been used to treat many of these conditions in the past, but are only recently becoming more widely understood through studies of the cannabinoid receptor system in post-mortem humans, in experimentation on laboratory animals and in observational clinical studies on human subjects. Many of these studies also increased

the understanding of the role of endocannabinoids have in normal physiological functions of the central nervous system, the peripheral nervous system and various organ systems. The following is a summary of the medical findings of the NIH on major diseases and conditions that cannabis presents a therapeutic potential for treatment.

### Energy Metabolism

The NIH acknowledges that diseases and disorders of energy metabolism have been treated with cannabis for thousands of years. Endocannabinoids regulate appetite through stimulation of the CB1 receptors located in the hypothalamus and the limbic forebrain. Endocannabinoids are also believed to regulate peripheral energy metabolism which aids in maintaining normal caloric intake through regular feeding. Numerous studies demonstrate success in controlling appetite, both to increase appetite as a treatment for anorexia and to decrease appetite as a treatment for obesity related to metabolic abnormalities. These studies also show promise in treatment of cachexia and wasting syndrome associated with AIDS, cancers, congestive heart failure, chronic obstructive pulmonary disease, tuberculosis, drug addiction, dementia and Alzheimer's disease as well as appetite reduction that is associated with normal aging. Cannabinoids can be successful in treating nonorganic failure to thrive in infants who fail to suckle.

### Pain and Inflammation

Pain and inflammation have also been treated by cannabis for thousands of years in locations such as ancient China, Israel, Greece, Rome and India. Cannabinoids have antinociceptive effects on the central nervous system, spine and peripheral sensory

nerves, which is consistent with the location of the CB1 receptors. Recent evidence indicates activity in the CB2 receptors can be useful in controlling acute and chronic neuropathic pain, especially pain caused by inflammation. Other potential areas of treatment include postoperative, post-traumatic and spastic pain. Cannabinoids have also been shown to have a synergistic effect when used in combination with common treatments including opioids, anesthetics and acetaminophen.

#### Central Nervous System

Diseases of the central nervous system have been an early subject of study for cannabinoid treatment due to the high density of CB1 receptors in the cortex, cerebellum, hippocampus and basal ganglia. These disease and disorder categories include movement, mood and anxiety disorders, processes of memory and learning, and conditions related to brain reward mechanisms. Endocannabinoids provide neuroprotection from neurotoxicity and neurotrauma from acute conditions such as stroke, epileptic seizures and traumatic brain injury, and chronic neurodegenerative disorders such as multiple sclerosis, Parkinson's disease, Huntington's disease, levodopa-induced dyskinesia, tardive dyskinesia, Gilles de la Tourette's syndrome, dystonia, amyotrophic lateral sclerosis, epileptic syndromes and Alzheimer's disease.

While some of the conditions are rare, stroke is one of the leading causes of death and disability in industrialized countries. Likewise, traumatic brain injury is one of the leading causes of death and disability in young individuals. Available pharmacological therapy for both is limited. Modeling indicates that cannabinoids provide both a

protective effect and can be a useful therapeutic tool in promoting recovery from such injuries. Similar successes are predicted in treating spinal cord injury.

### Mental Illness

The distribution of cannabinoid receptors present in varied brain centers that regulate emotion indicate potential in treating various mental disorders. The endocannabinoid hypothesis of schizophrenia states that heavy cannabis use can temporarily create psychotic symptoms that resemble schizophrenia in normal people, that cannabis use can worsen psychotic symptoms in diagnosed schizophrenics, that cannabis use may increase the likelihood of the onset of schizophrenia in people subject to psychosis, that an imbalance of endocannabinoids is observed in schizophrenics, that symptoms are reduced when this imbalance is treated and that postmortem studies observe increased CB1 density in regions of the prefrontal cortex in schizophrenics. This evidence, as well as other clinical evidence, has led to a conclusion that cannabinoid therapy could be a novel treatment for schizophrenia. Mood disorders, such as panic disorder, major depressive disorder and bipolar disorder affect 20% of the worldwide population. The World Health Organization forecasts that by the year 2020, depression will be the second leading cause of premature death and disability worldwide. More than 30% of the population diagnosed with a mood disorder does not respond to current treatment regimens. The high levels of CB1 receptors in the hippocampus, amygdala and prefrontal and anterior cingulate cortex may suggest that endocannabinoids play a key role in the regulation of anxiety and depression. This mechanism is not yet understood and is believed to be

involved with numerous neurotransmitter systems and undiscovered cannabinoid receptors.

### Sleep

Studies on cannabinoids and sleep regulation have shown that they affect sleep patterns, including nocturnal sleep, early-morning performance, memory and sleepiness. CB1 receptors modulate sleep through the light/dark cycle, rapid eye movement, and sleep rebound. When stimulated, these receptors also increase levels of adenosine, a sleep regulatory agent. The causes of insomnia are unknown but are shown to be linked to both mood disorders and chronic disease. Cannabinoids have been shown to increase sleep quality in patients with multiple sclerosis, cancer and chronic pain.

### Nausea and vomiting

Nausea and vomiting are symptoms of a variety of acute and chronic conditions and are a consequence of both chemotherapy and radiotherapy for cancer. Cannabinoids have gained wide acceptance as an antiemetic to control nausea and vomiting and have shown promise in cases where other conventional medications have failed. The exact role endocannabinoids have in emesis is unknown but is suggested that CB1 activation in nerve ending in the digestive tract and in the brainstem suppresses vomiting.

### Addiction

Cannabinoids have recently become a subject of study in their role in controlling the brain's natural reward systems tied to eating, work and sexual activity. Drugs of abuse, such as opiates, nicotine, alcohol, cocaine and psychostimulants lower the reward

threshold for brain stimulation and disrupt normal dopamine levels, leading to addictive actions of these substances. Cannabinoids have also been shown to fulfill the same reward systems with CB1 receptors having a key role in regulating these systems and that repeated use decreases CB1 signaling. Animal experiments have demonstrated that subjects treated with cannabinoids and cannabinoid inhibitors reduce self-administration of opioids, cocaine, alcohol and nicotine.

#### Cardiovascular Diseases

Endocannabinoids and synthetic analogs have been demonstrated to have significant effects on the cardiovascular system. With coronary heart disease as the leading cause of death in the world, therapies to prevent and treat both acute and chronic conditions of the cardiovascular system would be invaluable. Both CB1 and CB2 receptors have a role in cardiovascular regulation, including vasodilatation, hypotension, cardiovascular depression, and bradycardia. CB1 antagonists have been demonstrated to reduce or reverse hypotension associated with hemorrhagic shock, endotoxic shock and cardiogenic shock. Both cannabinoids and cannabinoid antagonists have been shown to increase survival rates through improved endothelial function and improved tissue oxygenation in rodents experiencing cardiovascular dysfunction from a variety of sources, including septic shock, hemorrhage, myocardial infarction, inflammatory reaction and oxidative stress. Cannabinoids have been shown to have a protective effect in preconditioning against both myocardial reperfusion injury and atherosclerosis. CB2 receptors have been observed in the immune response to chronic inflammation and to

atherosclerotic plaques, with administration of cannabinoids resulting in significantly inhibited cardiovascular disease progression. In treating asthma, ingesting cannabis has been demonstrated to increase airway conductance, increase bronchodilation, and inhibit bronchospastic cough. Both respiratory function and pulmonary circulation have been shown to increase with the presence of endocannabinoids for both acute respiratory dysfunction and for respiratory inflammation. This action is believed to be linked to the presence of CB1 receptors located on smooth muscle tissue in the airway and on nerve endings in the lung.

#### Blindness

Cannabis therapy has been indicated as one of the few effective treatments for intraocular pressure that causes glaucoma, the leading cause of irreversible blindness in the United States. Multiple studies have indicated that the CB1 receptor plays a key role in regulating intraocular pressure. These receptors are located in ocular tissues including the retina, ciliary body and choroids plexus. The neuroprotective, anti-inflammatory and antiangiogenic effects on the eye strongly suggest treatment potential in general retinopathy, diabetic retinopathy, and other inflammatory and degenerative eye disorders.

#### Cancer

As previously mentioned, cannabinoid therapy holds great promise in treatment of cancer patients due to its role in appetite stimulation, nausea inhibition, pain control, mood elevation and insomnia. Numerous studies also indicate that cannabinoid therapy might directly inhibit tumor growth by promoting apoptosis in cancerous cells, inhibiting

angiogenesis and limiting cancer cell migration. This is believed to be linked to the role the CB2 receptor plays in immune function. This action has been observed in laboratory studies on numerous forms of cancer, including glioma, oligodendroglioma, glioblastoma multiforme, astrocytoma, neuroblastoma, pheochromocytoma, breast cancer, prostate cancer, colon carcinoma, uterine cervix carcinoma, thyroid cancer, leukemia, lymphoma, lung carcinoma, thyroid epithelioma and skin carcinoma. In some cancers, such as lung cancer, squamous cell carcinoma, bladder carcinoma, glioblastoma, astrocytoma and kidney cancer, cannabinoid treatment is shown to have a bimodal action where low doses cause tumor growth while high doses inhibit tumor growth. Cannabinoid therapy is also believed to show promise in treating cancers that are common in immunosuppressed patients, including non-Hodgkin's lymphoma, Burkitt's lymphoma, Kaposi's sarcoma and cervical cancer in AIDS patients, and various tumors and lymphomas associated with organ transplant recipients.

#### Gastrointestinal Diseases

Cannabinoids are believed to hold strong promise in the treatment of various gastrointestinal disorders. Cannabinoid therapy increases gastrointestinal motility and secretion due to the high levels of CB1 receptors in the gastrointestinal tract. This action is believed to reduce intestinal inflammation, reduce occurrences of gastrointestinal reflux disease through regulation of gastric acid secretion, and to have antiulcer activity. Treatment is also shown to be successful in autoimmune diseases of the gastrointestinal tract such as inflammatory bowel disease, Crohn's disease and ulcerative colitis.

Research on newly discovered CB1 receptors in the liver is showing promise in the treatment of acute and chronic liver diseases such as hepatitis and liver cirrhosis. CB1 receptors in hepatic vascular endothelial cells appear to play a key role in the pathogenesis of liver fibrosis. CB2 receptors inhibit growth of myofibroblasts in hepatic cells and play a role in limiting chronic liver injury.

#### Musculoskeletal Disorders

Cannabinoids are currently used for treatment for various musculoskeletal disorders. The anti-inflammatory and immunosuppressant properties of cannabinoids have demonstrated strong therapeutic potential in treatment of rheumatoid arthritis and other autoimmune disorders, including systemic lupus erythematosus, autoimmune vasculitis, Sjogren's syndrome, and ankylosing spondulitis. This action has been observed in CB1 mediated antihyperalgesic activity in both inflammatory pain and chronic neuropathic pain. Cannabinoid treatment is also shown to block collagen-induced arthritis and to have antinociceptive effects on rats. CB2 receptors are shown to be present in osteoblasts, osteocytes and osteoclasts and involved in the prevention of osteoporosis by regulating bone mass.

#### Reproductive Functions

The endocannabinoid system is present in the reproductive systems of both males and females as well as in pre-implantation embryos. The CB1 receptor in the uterus is involved in embryonic implantation, blastocyst formation, zona hatching and blastocyst formation and can affect the fertilizing capacity of sperm. Research indicates potential in

utilizing CB1 antagonists in the treatment of infertility problems and in maintaining hormone levels necessary for successful reproduction.

In summary, the findings of the NIH do not support the Schedule I status of cannabis under the CSA as cannabis has been shown to have medical efficacy in a number of diseases and conditions, and a therapeutic potential to treat a number of additional diseases and conditions that requires additional medical research for a determination of efficacy. The NIH makes no findings on the risk of harm or abuse, as the Department of Health and Human Services has determined that the responsibility for evaluating these two criteria is under the authority of the National Institute on Drug Abuse.

#### The National Institute on Drug Abuse

The National Institute on Drug Abuse is part of the National Institutes of Health (NIH), a component of the U.S. Department of Health and Human Services (HHS). According to the NIDA website (n.d.), its mission is study the science of drug abuse and addiction by conducting and disseminating multi-disciplinary research to improve prevention, treatment and policy of drug abuse and addiction.

#### The NIDA Policy Position on Cannabis

The most recent NIDA publication on cannabis, titled Marijuana Abuse, was published in 2002. This publication details acute, persistent and long-term health consequences from cannabis use that closely match the definitions of drug dependence described by the DSM-IV-TR in Chapter 2. NIDA states that the use of cannabis can

produce adverse physical, mental, emotional and behavioral changes and is an addictive drug. NIDA states that these consequences can have profound impacts on job performance, educational achievement, life satisfaction, and personal achievement.

Acute consequences of cannabis intoxication include impairment of short-term memory, impairment of cognitive functions, including attention and judgment, impairment of coordination and balance, and stimulation of the cardiovascular system observed through increased heart rate.

Impairment to memory is believed to be linked to an altering of information processing by the hippocampus as observed in laboratory studies on rats. Neuron loss in the hippocampus of rats with heavy exposure to cannabinoids over 30% of their lifetime was shown to be double the natural loss of unexposed rats. Research shows that this adverse impact on attention, memory and learning lasts days or even weeks beyond the period of intoxication. These impacts are observed to end approximately four weeks after cessation of use. Self-reporting from heavy cannabis users indicates their belief that use negatively impacts their career achievements, social lives and personal health. High doses of cannabis, more frequently from oral consumption than inhalation, can result in acute toxic psychosis that includes hallucination, delusion and depersonalization.

Physical health is believed to be impacted by cannabinoid use. Stimulation of cannabinoid receptors in the cerebellum and basal ganglia is believed to negatively impact reaction time, balance, posture and coordination of movement. NIDA reports that this impairment leads to an increased risk of personal injury through accidents, especially

when operating a motor vehicle. Between six and eleven percent of victims of fatal accidents test positive for cannabis, although they frequently also test positive for other drugs, most frequently alcohol. A study conducted by the National Highway Traffic Administration demonstrates that a moderate dose of cannabinoids impairs driving performance with reduced reaction time, visual search frequency, and responses to changes in the relative velocity of other vehicles.

Regular cannabis users report more health problems and higher work absenteeism. Frequent smokers report similar respiratory problems as frequent tobacco smokers, including daily cough and phlegm production, acute chest illnesses, bronchitis, emphysema and an increased risk of lung infection. An increase in heart rate combined with reduction in the oxygen-carrying capacity of blood suggests that risk of heart attack is four times higher within the first hour of smoking cannabis. A statistical analysis indicates a two to three fold increase in the risk of head, neck and lung cancers. Long-term consequences from chronic use that are cumulative and potentially permanent include possible addiction, an increased risk of chronic obstructive pulmonary diseases, and an increased risk of cancers.

### Comorbidity

NIDA considers comorbidity of the drug use disorders of drug abuse, dependence and addiction and other physical and mental illnesses to be a subject of great concern. In the 2008 report *Comorbidity: Addiction and Other Mental Illnesses*, NIDA discusses the

simultaneous or sequential occurrences of multiple diseases and their interactions that can potentially affect their prognosis, development and treatment.

Patients with mood disorders, anxiety disorders, antisocial syndrome or conduct disorders are twice as likely to suffer from drug use disorders. Similarly, patients diagnosed with drug use disorders are twice as likely to suffer from mood and anxiety disorders. NIDA acknowledges that there is no recognized causal link between mental illness and drug use disorders in either direction, but significant risk of harm exists as drugs of abuse can cause users to experience psychosis, mental illnesses can lead to drug abuse through self-medication by patients, and both drug use disorders and mental illnesses are caused by similarly overlapping factors such as brain deficits, genetic vulnerabilities and/or exposure to stress and trauma, especially at a young age.

Genetic disposition has considerable influence on both development of mental illnesses and drug use disorders. This link is believed to involve dopamine activity in the brain, which is involved in drug use, depression, schizophrenia and other psychiatric disorders. Dopamine activity is also involved in the sympathetic and parasympathetic systems of the brain that regulate reactions to stress. The involvement of similar parts of the brain suggests that brain changes from drug use can affect the progression of mental illness, as mental illness can encourage drug use. This predisposition to disease is observed in different manners in which individuals react to drug use, including individual response to a drug experience as a pleasurable or a non-pleasurable experience, the degree to which the effects of particular drugs differ between individuals, and the

duration a drug remains active in an individual. Genetic predisposition to drug use also manifests in risk taking and pleasure seeking behavior that increases the risk of comorbidity of both mental illness and drug use, as well as other risky and potentially dangerous behavior.

NIDA is particularly concerned with the potential for comorbidity from drug use during adolescence. Research shows that early drug use is a strong risk factor for later drug use disorders and possibly for the later occurrence of mental illness. Both mental illness and drug use disorders typically begin to manifest during adolescence. During this developmental stage, brain circuitry that regulates behavioral control, memory, decision making, pleasure and reward are all changing. Drug use while an adolescent is still maturing may enhance vulnerability to a variety of mental illnesses. The link is not direct, but lies in a complex series of precursors to mental illness including genetic vulnerability, environmental influences and personal experiences. A study on the specific link between early use of cannabis and the later onset of adult psychosis demonstrates an increased risk of psychosis when populations that use cannabis at an early age are compared with populations that do not. This risk is only observed in individuals who express a particular gene variant that impacts the way the brain processes dopamine.

In summary, NIDA firmly supports the Schedule I status of cannabis under the CSA as cannabis has a high potential for abuse and has an unacceptable risk of harm to both the individual and to third parties through its use. NIDA has not taken a position on

the efficacy of cannabis, but defers its position to accept the findings of the DEA that cannabis does not have medical efficacy.

## Chapter 5

### ANALYSIS AND CONCLUSION

In Chapter 5, I will present my analysis of the research findings from Chapter 4. As previously mentioned, I have summarized findings from the most recent primary documents from the Drug Enforcement Agency (DEA), the National Institutes of Health (NIH) and the National Institute on Drug Abuse (NIDA). Using these documents, each organization has been analyzed to determine if their mission, goals and actions support paternalism, autonomy, or a rational and deliberative balance between the two, which was shown in Chapter 2 to be the preferred model for doctor-patient relationships. Each organization has also been analyzed to determine their policy position on the three criteria used to schedule drugs under the Controlled Substances Act. I will also summarize the political implications for these results on current and future attempts to reschedule cannabis under the CSA.

#### Autonomy and Paternalism

In examining the Drug Enforcement Agency, the National Institutes of Health, and the National Institute on Drug Abuse, there are marked differences between each organization's approach to autonomy and paternalism. The DEA and NIDA have their missions and goals strongly rooted in the ethical viewpoint of medical paternalism evident through their mission to protect individuals and society from harmful drugs. The NIH, with mission and goals to investigate the negative and positive aspects of drugs and their role in medical care, supports a balance between paternalism and autonomy. This

difference in each organization's ethical viewpoint is evident when evaluated using criteria taken from the definitions of autonomy and paternalism.

#### Evaluation of Autonomy

I have chosen to use the four approaches to autonomy discussed in Chapter 3 as criteria for an organization's position on a patient's autonomous ability to use cannabis as medicine. As discussed in Chapter 4, neither the DEA nor NIDA recognize or respect the autonomous decision to use smoked cannabis as medicine under any circumstance. The NIH, however, could accept the medical autonomy of a patient to medicate using cannabis under the responsiveness-to-reason approach to autonomy. This acceptance would be predicated under the condition that the patient engages in a reasoned and deliberative investigation of the potential benefits and harms of cannabis use in comparison to the effects of the disease or condition from which the patient seeks relief. This acceptance, for example, would be justified in the case of a patient facing a progressive, chronic and fatal disease such as cancer or AIDS where the desire for the immediate relief of disease symptoms outweighs possible future, long term harms from cannabis use which are not likely to be fatal.

Table 5.1 Organizational Evaluation of Autonomy and Cannabis

|                          | DEA | NIDA | NIH |
|--------------------------|-----|------|-----|
| Coherentist              | NO  | NO   | NO  |
| Reasons-responsive       | NO  | NO   | NO  |
| Responsiveness-to-reason | NO  | NO   | YES |
| Incompatibilist          | NO  | NO   | NO  |

#### Evaluation of Paternalism

I have chosen to use the ten aspects of paternalism discussed in Chapter 3 as criteria for an organization's position on paternalistic denial of a patient's ability to use cannabis as medicine. As discussed in Chapter 4, all three organizations view circumstances where paternalistic denial of cannabis use is justified. The DEA and NIDA have a much stricter view of paternalism than the NIH, which has a policy position that could be interpreted as not justifying paternalistic refusal to allow medical use of cannabis in all cases.

Table 5.2 Organizational Evaluation of Paternalism and Cannabis

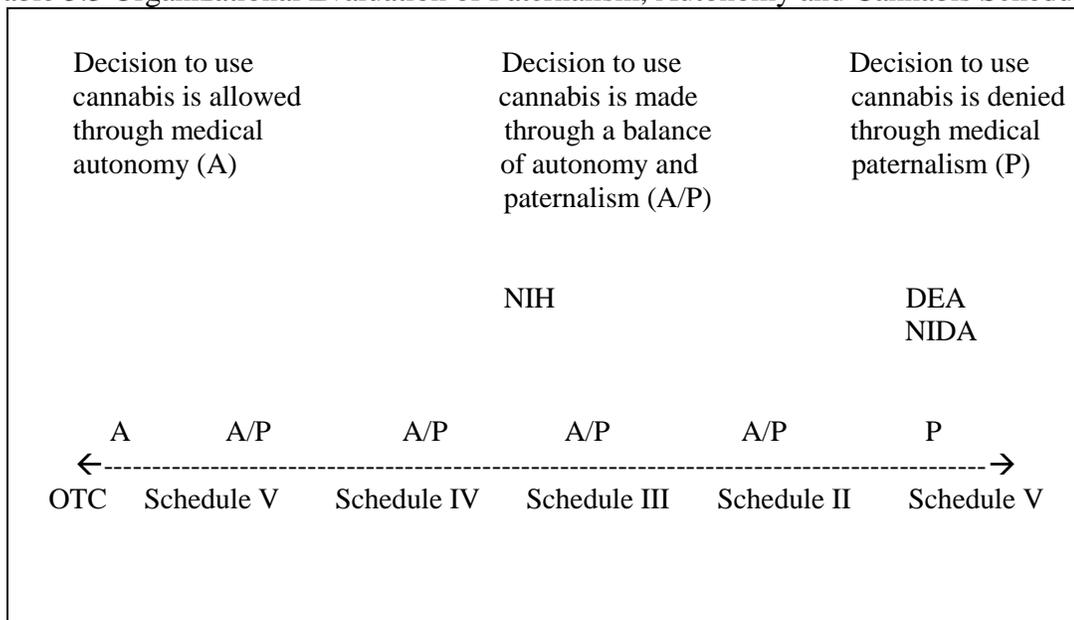
|                     | DEA | NIDA | NIH |
|---------------------|-----|------|-----|
| Hard Paternalism    | YES | YES  | NO  |
| Soft Paternalism    | YES | YES  | YES |
| Narrow Paternalism  | YES | YES  | NO  |
| Broad Paternalism   | YES | YES  | YES |
| Strong Paternalism  | YES | YES  | NO  |
| Weak Paternalism    | YES | YES  | NO  |
| Pure Paternalism    | YES | YES  | NO  |
| Impure Paternalism  | YES | YES  | YES |
| Moral Paternalism   | YES | YES  | NO  |
| Welfare Paternalism | YES | YES  | NO  |

While NIH still maintains that doctors have the medical authority to refuse the use of cannabis for medical use, there are many cases in which it would be allowed, assumedly with certain conditions applied. NIH would not always justify hard or narrow paternalism as a patient's intention may be to use cannabis in light of a reasoned deliberation with medical authority, regardless of legal authority. NIH would not always justify strong or weak paternalism as the patient can be informed of both medical facts and personal values in order to make an informed decision. NIH would not justify pure paternalism as a patient would be allowed to weigh the harms of cannabis use against the

harms of the disease. NIH would not justify moral or welfare paternalism as it does not view use of medicine as a moral issue, nor does it refuse medicine based on objective harm, but on balance of harm from a medicine balanced against the possible benefits a patient would gain from its use. As discussed in Chapter 2, this informed balance of autonomy and paternalism is the preferred model of doctor-patient relationships.

In summary, the NIH research indicates a support for a balance between a patient’s autonomy and the government’s paternalism in making a reasoned and informed decision for or against an individual’s decision to use cannabis. The DEA and NIDA do not support a patient’s autonomy in making a decision to use cannabis as medicine, insisting that governmental paternalism sufficiently supersedes a patient’s desire to use cannabis as medicine or a doctor’s desire to treat a patient through the use of cannabis.

Table 5.3 Organizational Evaluation of Paternalism, Autonomy and Cannabis Scheduling



### Criteria for scheduling under CSA

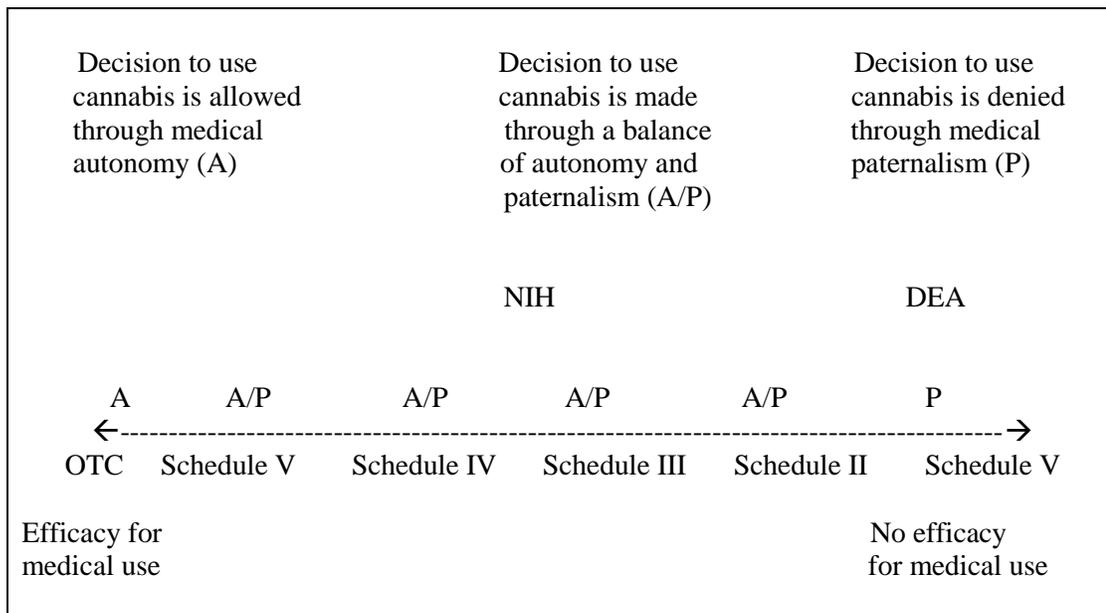
Both the DEA and NIDA argue that cannabis is properly scheduled under the Controlled Substances Act, while NIH strongly disagrees with the scheduling on the criterion of medical efficacy. When considering abuse potential, DEA and NIDA cite the strong potential for abuse and addiction in any cannabis use, medical or recreational, without considering the relative risk of addiction compared to other accepted medical treatments. NIH makes no claims on the risk of abuse or addiction

Table 5.4 Summary of Organizational View of Scheduling Criteria for Cannabis

|   | DEA | NIDA | NIH |
|---|-----|------|-----|
| Cannabis has efficacy   | NO  | N/A  | YES |
| Cannabis has abuse potential that is unacceptable for medical use | YES | YES  | N/A |
| Cannabis is unsafe for medical use                                | YES | YES  | N/A |

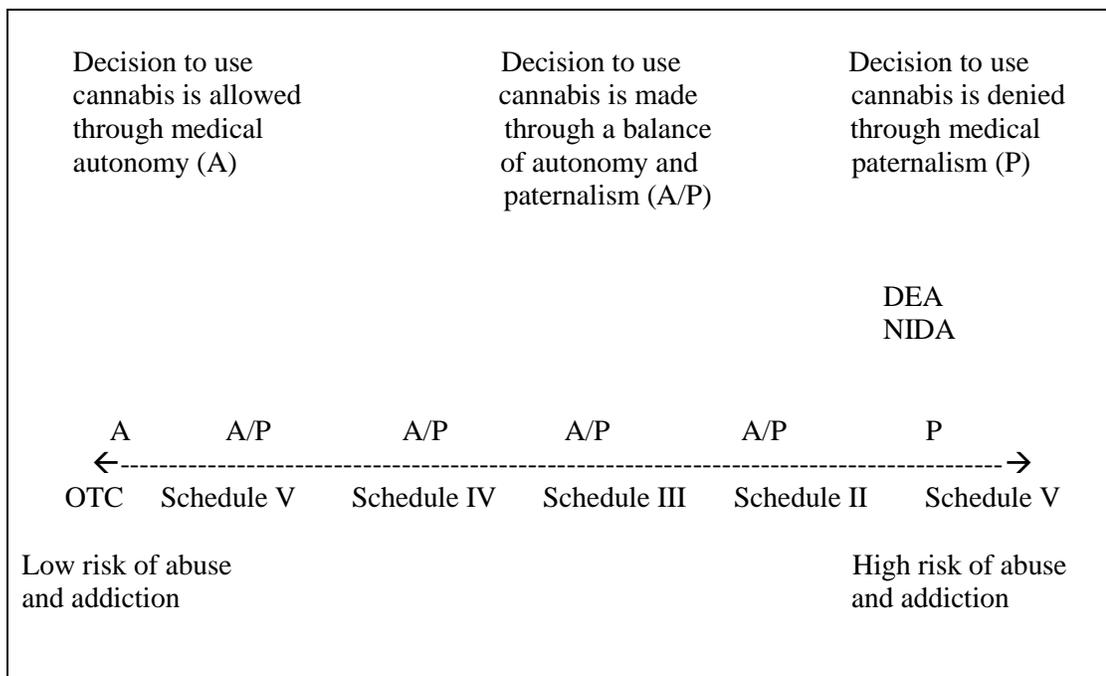
When considering medical efficacy, the DEA and NIDA find no evidence that smoked cannabis has an accepted level of efficacy. NIH finds efficacy for cannabis as an analgesic and an antiemetic for patients undergoing chemotherapy, radiotherapy and anti-viral therapy, and reports the need for additional research into the efficacy for numerous other conditions.

Table 5.5 Organizational View of Efficacy of Cannabis



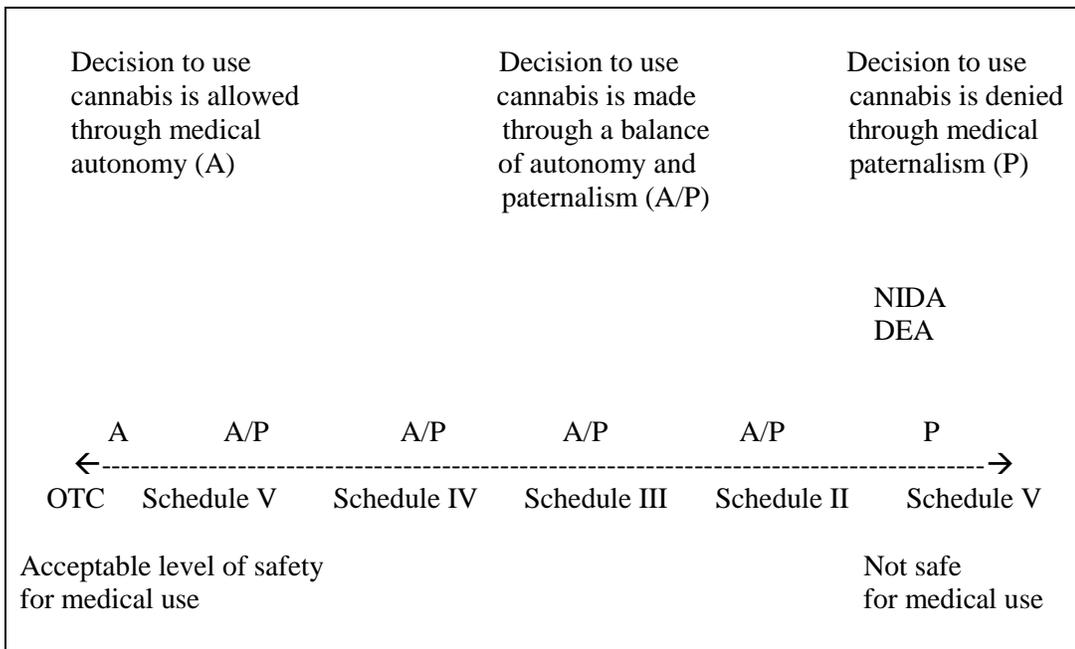
The DEA and NIDA find that cannabis has an unacceptable risk for abuse and addiction when used as medicine.

Table 5.6 Organizational View of Abuse Potential of Cannabis



Similarly, both the DEA and NIDA find no acceptable level of safe medical use for smoked cannabis, while the NIH makes no statement on the criterion.

Table 5.7 Organizational View of Safety of Cannabis



### Ethical Clash over Medical Cannabis

This ethical conflict and clash of mission and goals is evident in the disagreement between different executive branch organizations. In *Understanding & Managing Public Organizations*, Hal Rainey (2003) explains how conflicting goals and missions of executive branch organizations in the United States government results in policy compromise. The executive branch hierarchy presents intensive legal and political constraint for departments and their respective agencies. In order to gain both authorization and appropriation for their actions, they must consider multiple stakeholders who scrutinize policy decisions in light of these missions and goals.

Within this hierarchy, organizations frequently conflict due to ambiguity and multiplicity in their goals. Organizations tend to have value oriented goals with ambiguous definitions, such as the protection of public safety or the promotion of public health, that are debatable based upon different individual and organizational values. Multiplicity of goals, their definitions and the criteria used to measure them also causes conflict between agencies. Conflict between goals can lead to trade-offs between broader goals, e.g. trade-offs between efficiency and equity, individual rights and protection of groups. In the case of medical cannabis, the conflict between the paternalistic goals of the Drug Enforcement Agency and the National Institute of Drug Abuse clash with the autonomous goals of the National Institutes of Health. These three organizations act rationally in defense of their legislated goals, missions and underlying ethical viewpoints.

Historically, this clash of values has resulted in similar drug policy decisions. In *The International Journal of Drug Policy*, Harvard University's Lester Grinspoon (1999) explains that the medical community has conflicted with the federal government since before the creation of the CSA on the safety and efficacy of cannabis. He further states that the risk of harms from a drug is consistently exaggerated while the benefits from a drug are consistently under-emphasized when drug policy decisions are considered. The burden of proof lies with the manufacturer of the drug to prove both acceptable levels of safety and efficacy in order to gain approval for manufacturing in order to protect the public from false or misleading claims. Cannabis is in a unique position as there is no single developer or manufacturer of the drug who stands to financially benefit from its

approval for use as medicine, so there is less incentive for private research to be conducted to establish levels of efficacy or safety. With an average cost of \$200 million to bring a drug to market, Grinspoon (1999) doubts that cannabis will ever gain approval for medical use in the usual manner, and will likely only be approved either through an executive order or through an act of Congress. The medicalization of cannabis lies in a political “Catch-22”, with the Drug Enforcement Agency refusing to consider rescheduling under the Controlled Substances Act due to a lack of evidence that cannabis has efficacy, while efficacy cannot be scientifically proven without additional medical research that is almost impossible to conduct while cannabis is classified as a Schedule I drug.

#### Implications for the Future Rescheduling

In conclusion, I have shown in this thesis that the federal organizations tasked with oversight of the Controlled Substances Act are at conflict due to their mission, goals and the ethical choices that underlie these missions and goals. The findings of this thesis support Grinspoon’s opinion that the status quo will not accept future attempts to reschedule. The DEA and NIDA would have to decide to ignore their ethical obligations to protect the public from a harmful, addictive drug that has no medical efficacy for cannabis to be successfully rescheduled. Considering their organizational motivations as determined by their mission and goals and their paternalistic worldview in protecting patients and third parties from harmful drugs, the DEA and NIDA have neither evidence nor motivation to reconsider the scheduling of cannabis under the CSA.

Other possibilities for rescheduling under the Controlled substances Act lie with Congress, the President, the Attorney General, or the Supreme Court. Under the CSA, the President has the right to cede authority to the Attorney General or to the DEA. Since the implementation of the CSA, every President has chosen to cede authority to the CSA. If the President should decide to grant authority to the Attorney General, this would remove the ability of the DEA to delay or deny the current petition to reschedule by the Coalition for Rescheduling Cannabis or future rescheduling attempts as it has done in the past. The President also has the power to reschedule cannabis through executive order. The Supreme Court has the ability to rule that the Schedule I status of cannabis is unconstitutional, but has refused to do so in previous cases. Congress has the ability to amend the Controlled Substances Act, as it has several times in the past. In 2011, Representatives Barney Frank and Ron Paul introduced H.R. 2306, the Ending Federal Marijuana Prohibition Act of 2011. This bill seeks to amend the CSA to not include cannabis, to repeal all federal penalties for the production, distribution, and possession of cannabis, and to grant states the authority to tax, regulate or criminalize cannabis (Wood, 2011). Congress could also amend the CSA to remove authority from the DEA and the Department of Justice and alternatively grant this authority to the Department of Health and Human Services, placing the power in the hands of medical authorities rather than law-enforcement authorities. Findings from this thesis indicate that medical authorities, such as HHS, may be more ethically appropriate than the DEA to make these decisions as their ethical obligation is to promote health rather than to enforce laws. Additionally, I

feel that any rescheduling attempt will require a public, scientific examination of the benefits and harms from medical use of cannabis in order to find agreement on these criteria. If clear scientific evidence demonstrating that cannabis has efficacy and an acceptable risk of harm and abuse, then the DEA, NIDA and other actors who are motivated to protect society from harmful drugs may change their stance that cannabis must be classified as a Schedule I drug.

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