

# The Ethics of Medical Marijuana: Government Restrictions vs. Medical Necessity (An Update)

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## Abstract

Cannabis, a genus of plant that includes several species, is more commonly referred to as marijuana. Cannabis has a long history of being used for recreational purposes, but in recent years there is growing support for its use in the medical arena. Because cannabis is considered an illegal substance on a federal level and has not been as extensively researched as other well established drugs, the implications of utilizing marijuana medicinally are complex not only from a clinical perspective but also from a legal and even ethical perspective as well. Marijuana has long been stigmatized due to its national prohibition, and this stigma remains even with changes in legislation across the country and advances in scientific research. However, despite any perceived immorality in using medical marijuana as a treatment modality, there are many proponents that argue that cannabis (and compounds derived from it) has the potential to become an important part of patient care across a variety of different medical specialties. In this paper we will discuss the established medical uses of marijuana and its derivatives (including pharmacological considerations) as well as current political and legal barriers to accessing medical marijuana. Finally, all of this information will be factored into the question of whether not it is ethical to use cannabis for medicinal purposes.

## 1. INTRODUCTION

Cannabis, a genus of plant that includes several species, is more commonly referred to as marijuana. Cannabis has a long history of being used for recreational purposes, but in recent years there is growing support for its use in the medical arena. Because cannabis is considered an illegal substance on a federal level and has not been as extensively researched as other well-established drugs, the implications of utilizing marijuana medicinally are complex not only from a clinical perspective but also from a legal and even ethical perspective as well. Marijuana has long been stigmatized due to its national prohibition, and this stigma remains even with changes in legislation across the country and advances in scientific research. However, despite any perceived immorality in using medical marijuana as a treatment modality, there are many proponents that argue that cannabis (and compounds derived from it) has the potential to become an important part of patient care across a variety of different medical specialties. In this paper we will discuss the established medical uses of marijuana and its derivatives (including pharmacological considerations) as well as current political and legal barriers to accessing medical marijuana. Finally, all of this information will be

factored into the question of whether not it is ethical to use cannabis for medicinal purposes.

## 2. MEDICAL USES OF MARIJUANA

Cannabis contains a number of separate chemical compounds known as cannabinoids. These cannabinoids exert a variety of different effects on the human body, including a degree of euphoria associated with recreational use of the drug. However, based on a number of other physiologic effects of the different components of the plant, there is potential for cannabis to be utilized as treatment for certain medical conditions. We will first explore some basic pharmacology of cannabinoids, including the effects of acute ingestion and chronic use. Current medical indications for medicinal marijuana will be discussed next, along with current literature and future research that may support the use of cannabis for further diseases and conditions.

### *Pharmacotherapy*

Cannabis primarily impacts humans through the endocannabinoid (eCB) system, which is a fundamental part of understanding the chemical basis behind medical marijuana. This system consists of many receptors, ligands,

and enzymes that have been identified throughout the human body, including in the nervous system, various internal organs, connective tissues, and many more. Of the many receptors involved in the system, the most abundant are G-protein receptors known as cannabinoid receptor 1 and 2 (CB1 & CB2). The eCB system plays a homeostatic role in hunger, energy, nociception, immune response, and neuroprotection.<sup>1</sup>

CB1 is primarily expressed in the central nervous system but can also be found in non-neuronal cells such as adipocyte and hepatocytes, as well as in connective and musculoskeletal tissue.<sup>1</sup> While CB2 receptors are also present on some neurons, they are more prominent on peripheral tissues of the immune system and the gastrointestinal system.<sup>1, 2</sup> The activation of these receptors causes an inhibitory effect on the release of neurotransmitters acetylcholine and glutamate while indirectly affecting  $\gamma$ -aminobutyric acid and N-methyl-D-aspartate.<sup>2</sup> When activated, these G-coupled protein receptors also noncompetitively inhibit mu and delta opioid receptors, as well as serotonin, norepinephrine, and dopamine receptors. Deficiencies found in the eCB system have been implicated in many medical conditions. Researchers have proposed that schizophrenia, multiple sclerosis, Parkinson's disease, anorexia, and chronic motion sickness may be related syndromes involving an eCB deficiency.<sup>3</sup>

Delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) are two of the most studied and well-known cannabinoids in marijuana. While THC is a partial agonist to both CB1 and CB2 receptors, it is sought out more for its major psychoactive effect mediated by activation of CB1 receptors in the central nervous system.<sup>3</sup> Aside from the psychoactive component of THC, it has also been shown to have anti-inflammatory, neuroprotective, anti-nausea, appetite enhancing, and analgesic effects. THC concentration has commonly been used as a measure of the potency of cannabis. CBD, on the other hand, is able to produce its pharmacological effects without eliciting substantial activity from CB1 and CB2 receptors. CBD has high potential for therapeutic use as it not only blocks the formation of 11-OH-THC (the most psychoactive metabolite of THC) but it also enhances THC's therapeutic effects.<sup>1</sup> Furthermore, CBD has also displayed antiepileptic, anxiolytic, anti-psychotic, and anti-inflammatory properties as well.<sup>3</sup>

THC is the component of marijuana that largely causes the intoxication sought after in recreational use. A high is

induced by THC (as little as 2.5 mg) which causes detachment, decreased anxiety, alertness, depression, and tension. These wide-ranging effects vary greatly depending on the amount and route of the drug. The two most common routes of marijuana are inhalation and ingestion. When inhaled, the drug has a clearer path to the blood stream and the peak effects are felt in 15 to 30 minutes. Bioavailability in the lung varies depending on the user. For example, chronic users are able to sustain the smoke in the lungs for a longer period of time compared to a naïve user. Ingested marijuana can take up to 3 hours to take effect due to chemical degradation from gastric acid and other digestive mechanisms. Once the chemical enters the bloodstream, the effects are similar.<sup>4</sup>

Acutely, marijuana has a number of metabolic effects on the body. Research has shown that cannabis has similar actions on the reward system of the brain as other addictive drugs including nicotine, opioids, and amphetamines. This is caused by the release of dopamine from the nucleus accumbens, as shown in studies done on rats.<sup>5</sup> THC is known to affect the sensory system as well. Visual and sound perception is greatly increased in acute exposure. Temporal and spatial perception is impaired as seen in a double blind study done on pilot's performances on flight stimulators.<sup>6</sup> Deficits included increased risk of errors, altitude deviations, and poor alignment on landing. In the acute phase it has shown to affect gait, speech, and cause generalized incoordination. There is an increased flight of ideas, speed of thought, and increased depth of thought with shortening of short-term memory and the inability to filter information in a cohesive manner. Anxiety and paranoia are among the most important acute adverse effects.<sup>4</sup> Short term use has also been linked to impaired short-term memory, motor coordination, and judgement. Many of these affects are short-lived, but chronic use creates dependence and other harmful adverse side effects. Long term use and heavy use has been associated with altered brain development, varying degrees of cognitive impairment, and increased risk of chronic psychosis. Other adverse effects noted include lethargy, vertigo, and hyperemesis syndrome.<sup>3</sup>

With chronic use, tolerance and dependence were the most common side effects. This was noted to affect: mood, memory, sleep, EEG, pulse, blood pressure, and antiemetic response. A daily dose of 180 mg of THC (two quality joints) for 20 days was found to be sufficient to cause withdrawal symptoms once discontinuing the drug. Compared to unexposed adults, people who smoked

regularly have impaired neural connective fibers. One study showed that CB-1 receptors in several regions of the brain were decreased in chronic users, which improved after 4 weeks of abstinence. Chronic users were found to be deficient in math skills, verbal retrieval, and memory retrieval. Lighter smokers (defined as using less than once per week) had no impairment.<sup>8</sup>

Chronic cannabis use is known to cause long term effects in other systems besides the nervous system—notably the immune system and respiratory system. The primary role of the immune system is to protect the body against infectious agents, whether it be bacterial, viral, or parasitic. The immune system has the brilliant ability to recognize foreign molecules as “non-self” and create an appropriate response. This is a collaboration between T cells and B cells. When the body is under an exaggerated or inappropriate response, it can lead to autoimmunity or allergy. Continued suppression of the immune system can lead to infection. Tobacco smoke lowers the humoral and cell-mediated response of the body. In vitro and animal studies have shown that marijuana lowers bactericidal activity in the lungs.<sup>9, 10</sup> One may believe this may affect humans as well, but studies have not shown evidence that this is statistically significant.

Two chronic infections are affected differently by chronic cannabis use. There was a large prospective study done on HIV positive men that showed cannabis use did not increase the progression of HIV.<sup>11</sup> Patients who have AIDS-associated anorexia and wasting syndrome have improved greatly with the use of marijuana. Although there is no statistical evidence that has shown a decreased morbidity or mortality, some patients who are on anti-retroviral therapy with symptoms of wasting syndrome may benefit from chronic cannabis therapy.<sup>12</sup> Unlike HIV, hepatitis C is significantly affected by chronic marijuana use. Chronic use of marijuana was shown to increase the fibrosis in people who have chronic hepatitis C.<sup>13</sup>

The respiratory system is also affected due to toxins that are introduced into the upper and lower airway. Many observational studies have shown that chronic smoking leads to airway inflammation. This ultimately leads to emphysema. Two studies done in the US have showed no significant increase in lung cancer due to marijuana use. There is however a concern for marijuana that is contaminated, especially when it is grown in indoor environments. *Aspergillus fumigatus* is typically found in these contaminated products. There have been several case reports and series on this phenomenon, but no dedicated

trials.<sup>8</sup>

There are both clear benefits and risks in using marijuana medically, as mentioned above. The question remains whether marijuana has a role as a gateway drug. Studies done on rodents have shown alterations of the mesolimbic system, which has affected dopamine reactivity. Ideally this could explain why there is an increased susceptibility of drug abuse later in life.<sup>12</sup> Still pending in our debate and studies of adverse effects are the unknown long-term impacts of chronic medicinal cannabis use. Further research will help evaluate the risk-benefit outcome of chronic medicinal use and its potential benefit or harm to the patient after prolonged use.

### *Approved Therapy*

Whole plant marijuana and isolated THC compounds are considered Schedule I controlled substances, with no FDA-approved uses.<sup>14</sup> This classification is relevant to the overall discussion regarding medical marijuana use, as the federal government defines a Schedule I controlled substance as “having a high potential for abuse, no currently accepted medicinal use in treatment in the United States, and a lack of accepted safety data for use of the treatment under medical supervision.”<sup>15</sup> CBD is now approved by the FDA and considered a Schedule V substance since it has indications for medical use validated by evidence-based medicine.<sup>14</sup> However, drugs that contain CBD may not contain more than 0.1% THC or else they fall under higher scheduling.<sup>7</sup> Synthetic cannabinoids have slightly different rules: only synthetic cannabinoids considered similar to THC (as decided by the FDA or DEA) are considered Schedule I substances, while other synthetic cannabinoids not naturally found in the marijuana plant do not fall under the same scrutiny.<sup>14</sup>

Currently, there are three cannabinoid drugs with FDA approval available on the market by prescription. Two of these are synthetic cannabinoids, dronabinol and nabilone, which are approved for treating anorexia in patients with AIDS or cancer patients undergoing chemotherapy who are experiencing nausea and vomiting refractory to conventional antiemetic medications. Dronabinol is a synthetic THC listed as a Schedule III substance.<sup>14</sup> Nabilone is a THC analogue listed as a Schedule II substance.<sup>14</sup> The third drug, cannabidiol (CBD), is a non-synthetic substance that is derived from the marijuana plant itself and is notably listed as a Schedule V controlled substance.<sup>14</sup>

CBD is FDA-approved for the treatment of seizures in patients older than age 2 who have epilepsy due to Lennox-Gastaut syndrome or Dravet syndrome.<sup>16</sup> This approval was granted as the result of three clinical trials which showed that the addition of cannabidiol (under the brand name Epidiolex, made by GW Research Ltd) to the subject's current medical therapy was effective in reducing frequency of seizures.<sup>16</sup> The investigation of CBD also included studies to ensure that it did not have a dangerously high abuse potential, which is a requirement due to the classification as a Schedule I substance. Official FDA approval for a cannabinoid that is found in the marijuana plant, even in the narrow use as discussed, is an exciting step forward. The path to FDA approval for CBD can be considered a blueprint strategy for other interested researchers to strategize how to investigate additional preparations of the marijuana plant for a variety of uses. However, it is important to note that CBD did receive special consideration from the FDA during its clinical trials including "Priority Review," which commits the FDA to a decision regarding the drug of investigation within 6 months. CBD also received "Fast Track" designation for filling an "unmet need" in regards to Dravet syndrome and fulfilled "Orphan Drug" requirements for both indications in Dravet syndrome and Lennox-Gastaut syndrome.<sup>16</sup>

Moving forward, there will be hurdles to overcome when attempting to conduct further research on cannabis at a treatment modality. Due to its classification as a federally scheduled controlled substance, there are expanded expectations and paperwork requirements for investigators who intend to study the marijuana plant and/or its components. In addition to receiving stepwise FDA approval, the research protocols must also be reviewed by the Drug Enforcement Administration (DEA). The DEA then provides approval for the researchers to obtain marijuana from either the National Institute on Drug Abuse (NIDA) at the University of Mississippi or other DEA-approved individual growers.<sup>17</sup> The DEA also ensures there is appropriate security for the storage of medical marijuana during the study. It is essential that research-grade marijuana is obtained from these sources, as inconsistency in variety, potency or composition of individual marijuana plants may inappropriately alter results.<sup>17</sup>

The next steps in research will be investigating whole plant marijuana (cannabis) and its components as treatment for a variety of illnesses. This research will be essential in light of the growing presence of marijuana dispensaries in many

states across America, fueled by patient demand for marijuana. Despite the limited number of FDA-approved indications for cannabis derivatives, many states have approved various medical conditions and/or symptoms for treatment with medical cannabis. Some of the most common conditions that qualify for medical cannabis as a treatment modality for symptomatic relief include multiple sclerosis, cancer, and glaucoma, among many others. However, it is important to note that there is only limited research to support many of these indications.<sup>18</sup>

While the current pool of evidence for further medicinal cannabis uses is small, it is also growing. There is optimistic support to expand the use of marijuana for various indications, including chronic pain. In a study from the British Journal of Clinical Pharmacology, a review was performed of 18 trials involving over 700 patients during the time period of 2003-2010.<sup>19</sup> It investigated the use and effectiveness of multiple marijuana products including cannabis, CBD, and the synthetic cannabinoids nabilone and dronabinol. They did not differentiate between the effects of the different products. This review supported a positive effect of cannabinoids on pain of various etiologies and improved sleep with no serious adverse events.<sup>19</sup> Generally, cannabinoids were found to be well tolerated by patients.

The potential for cannabis and its derivatives to be used as a means of pain relief are especially intriguing as it could apply to treatment for opioid use disorder (OUD), as many patients with OUD began taking opioid medications for chronic pain. The analgesic effects of cannabis, along with its favorable safety profile, could provide a means of safer pain relief as compared to opioids. In addition, some evidence exists that suggests that cannabis and its derivatives may help to alleviate the symptoms of opioid withdrawal and even decrease the likelihood of relapse. However, much of the current literature shows conflicting results, and further studies will be necessary.<sup>20</sup>

Regardless of whatever medicinal cannabis might be used for in the future, it is imperative that further clinical research be conducted on cannabis and its derivatives. If physicians are expected to be certifying patients to receive marijuana for medicinal use, then the requirements of modern medicine demand that a strong foundation of evidence-based medicine supports this application.

### **3. LEGAL AND POLITICAL BARRIERS**

The legalization of cannabis for medical usage has historically been a hot topic of political debate that is

difficult to navigate when considering potential clinical practice due to the many complexities of the issue. In this section, the nuances surrounding the legal and political landscape of medical cannabis in the United States will be discussed. The basis for differences in federal regulations as compared to state-level regulations represents another issue of debate regarding federal versus state power, but this will be briefly touched upon first. Secondly, the intricacies of laws regarding cannabis usage will be considered, as the laws (beyond federal policies) vary widely between states and even municipalities. These laws have been continuously changing in recent years, resulting in rules and regulations across the country that exist on a complex spectrum between completely prohibited to legal for recreational use. Next, the cultural impact of medical and recreational cannabis and public opinion on the subject - both of which are inherently tied to the legal and political considerations of the substance - will be analyzed. Lastly, it is important to realize that the rules and regulations in regards to any illicit and potentially addictive substance (not just cannabis) are especially important and under intense scrutiny today due to the nation's current struggle with opiate use disorder.

### *Legal Considerations*

The Controlled Substances Act, put into place in 1970, completely prohibited any use of marijuana on a medical or recreational level and established it as a Schedule I substance. Schedule I substances, such as marijuana and heroin, are defined by the Drug Enforcement Administration (DEA) and Food & Drug Administration (FDA) as substances without any accepted medical use that also have a high potential for abuse and/or dependence. Possession of a Schedule I substance is illegal and such drugs can only be used in research.<sup>21</sup> Despite this legislation, over the years many states have put into effect their own laws regarding the legality of cannabis, with some states lessening the punishment for possession and others actually allowing cannabis to be used in a medical or recreational capacity. Such states thus have laws in place that directly contradict the federal legislation that dictates the legality of cannabis, which then begs the question about which entity should (or even does) hold more power: the federal government or the state government? This subject has been an issue in United States legislation and government dating back to when the constitution was written.<sup>22</sup> Article VI paragraph 2 of the United States Constitution (also known as the Supremacy Clause) establishes that federal law "shall be the supreme Law of the Land," clearly above the laws of the states.<sup>23</sup>

This can be a very contentious subject in United States politics, and the implications of state laws defying federal law will be discussed in more detail later. While certain political parties sometimes claim to be for or against federal versus state rights, research shows that both major political parties in the United States (the Republican and Democratic parties) support preemption of state laws, depending on the exact circumstances.<sup>24</sup> We can thus conclude that viewing medical cannabis regulations through a lens of federal versus state rights is not necessarily dependent on political affiliation and, at its core, is a very different topic but still must be discussed due to the legal implications.

State laws on marijuana vary widely and range from completely prohibited to decriminalization to legal for medical use and finally, legal for recreational use. Three years after the Controlled Substances Act was put into place, Oregon became the first state to decriminalize possession of small amounts of marijuana, with many other states enacting similar legislation in the same decade.<sup>25</sup> Much later in 1996, California became the first state to legalize the use of cannabis for medicinal purposes.<sup>26</sup> At the time of writing this paper, medical marijuana is now legal in some capacity in more than 30 states, along with the District of Columbia, Guam, and Puerto Rico. Additionally, there are 15 states that allow the use of products with low THC and high cannabidiol (CBD) for medical reasons. Thus, there is not only a dichotomy between federal versus state law (at least in the states that have legalized cannabis use in some form), there is essentially a spectrum of cannabis legislation across the country that varies depending on the exact jurisdiction and circumstances of use. Marijuana was first made legal for adult recreational use in 2012 in the state of Colorado.<sup>27</sup>

Despite these differences in legislation from state to state, the fact remains that marijuana use is still prohibited by federal law. When factoring in the Supremacy Clause mentioned earlier, which makes it clear that federal law supersedes state law, one might assume that states are unable to make recreational or medicinal cannabis legal in direct contradiction of national law - but the reality is complicated. The federal government technically does have the jurisdiction to enforce its laws on cannabis use, and (for example) the federal government has the power to send in personnel to Washington state (where recreational marijuana use is legal) to charge people for violation of federal law. That being said, enforcing these laws in every single state that has some degree of legal cannabis usage would require a substantial amount of resources and could also be very

politically damaging considering public opinion on the subject.<sup>28</sup> Support of cannabis legalization (both for medicinal and, to a lesser extent, recreational use) or, at the very least, decriminalization and general minimization of stigmatization has been increasing over the past several decades.<sup>29</sup> The evolution of marijuana-related legislation reflects trends in public opinion in regards to the use of the substance. President Jimmy Carter was the first sitting president to endorse the decriminalization of cannabis in 1977, a position that was most recently supported by President Barack Obama in 2015.<sup>30, 31</sup>

The official stance of the federal government on medical marijuana has also been directly challenged beyond the states enacting their own laws. While serving in the US Air Force, Michael Krawitz suffered a car accident. His injuries left him with great pain and he was prescribed medical marijuana along with other medications while abroad. Eventually the Department of Veteran Affairs (VA) requested a drug test from Krawitz. Krawitz, who is the Executive Director of Veterans for Medical Cannabis Access, refused to provide a drug test, so the VA withdrew his pain treatment. On July 8, 2011, Krawitz joined forces with other advocates from the Americans for Safe Access (ASA) to file a lawsuit against the DEA to challenge the classification of marijuana under the federal government. They did so with the argument that the DEA's classification of marijuana as a Schedule I drug is responsible for VA policy not providing illegal substances under federal law and making patients sign a "Contract for Controlled Substance Prescription".<sup>32</sup> In court, there was controversy in determining whether or not the VA system's policy on medical marijuana is caused by the DEA's classification of marijuana as a Schedule I drug. This would mean that Krawitz suffered an injury directly from the DEA's classification. Since it was proven that the "VA has heeded the DEA's judgment regarding marijuana", the court concluded that the DEA's classification is the causation of the Veterans Affairs policies regarding illegal substances under federal law.<sup>32</sup>

Later, the ASA petitioners argued that there was sufficient scientific evidence that indicated the validity and effectiveness of medical marijuana as a Schedule III, IV, or V drug. However, this idea was rejected by the court because medical marijuana has not passed through the "five-part test", which requires the drug to have passed through regulated studies. The DEA requires quality studies accepted by the Food and Drug Administration (FDA) and

Department of Health and Human Services (DHHS), which have not yet been completed. Therefore, in January 22, 2013, the petition to review the DEA's scheduling of medical marijuana was refused by the Court of Appeals.<sup>32</sup>

After petitions calling for rescheduling marijuana from Schedule I, the DEA published filings describing their reasons to deny such petitions. The main cause for their rejection is due to the recommendations of the FDA and DHHS. These two organizations evaluated and conducted studies in which they concluded that marijuana should remain as a Schedule I drug. Marijuana fulfills their criteria on whether a drug should be classified as Schedule I under the Controlled Substances Act. According to the FDA, cannabis has "a high potential for abuse, has no currently accepted medical use in treatment, and there is a lack of accepted safety for use of marijuana under medical supervision." In the filings, the DEA indicates that the "FDA cannot conclude that marijuana has an acceptable level of safety relative to its effectiveness in treating a specific, recognized disorder without evidence that the substance is contamination free, and assurance of a consistent and predictable dose."<sup>33</sup> The fact that marijuana does not have a reproducible chemistry to provide "standardized doses" is mentioned greatly in the filings and used to support the argument that it has no accepted medical use. However, the need for research on the matter is touched upon: "Additionally, a procedure for delivering a consistent dose of marijuana should also be developed." This would also lead the way to an accepted and established manner of safe usage under medical supervision.<sup>33</sup> In addition, the DEA argues there are no studies that indicate that marijuana can treat a specific disorder. The filings state that "there are not adequate safety studies on marijuana in the medical literature in relation to a specific, recognized disorder" and that "there are no published adequate and well controlled studies proving efficacy of marijuana." Despite all the studies conducted indicating the beneficial effects of marijuana, the administration argues that there are no "qualified experts" in the scientific field that accept the use of medical marijuana.<sup>33</sup>

Despite all of this, in June 2018 the FDA approved its first drug containing an active ingredient from marijuana. The drug Epidiolex, containing CBD, is an oral treatment of seizures linked to two forms of epilepsy. FDA Commissioner M.D. Scott Gottlieb states that: "This approval serves as a reminder that advancing sound development programs that properly evaluate active

ingredients contained in marijuana can lead to important medical therapies. And, the FDA is committed to this kind of careful scientific research and drug development.”<sup>16</sup> CBD-based drugs that are approved by the FDA, such as Epidiolex, are now considered Schedule V substances as long as they contain less than 0.1% THC.<sup>7</sup>

Even with the drug schedules in place, there are actual concrete federal protections in place in regards to medical cannabis: the Rohrabacher-Farr amendment was passed in 2014 and prevents the Justice Department from using federal funds to interfere with medical marijuana laws that are passed by state legislatures.<sup>34</sup> Now renamed the Rohrabacher-Blumenauer amendment, this piece of legislation must be renewed every year.<sup>35</sup> This law has remained in place and at the time that this paper was written was most recently renewed in March 2018 with the updated federal budget.<sup>36</sup> But while the Rohrabacher-Blumenauer amendment grants some level of reassurance to practitioners and patients interested in medicinal marijuana options, there is nothing to guarantee that the amendment will continue to be renewed every year. Furthermore, under the Trump Administration, former Attorney General Jeff Sessions discouraged the renewal of the Rohrabacher-Blumenauer amendment, and had stated that the Justice Department would be enforcing federal cannabis laws to a much higher degree than previous administrations have.<sup>37</sup> Sessions also formally reversed a memo colloquially known as the Cole Memo, a policy memo put into place during the Obama administration that directed federal prosecutors to focus resources into other matters besides enforcement of federal marijuana laws (with some exceptions, including distribution to minors).<sup>38</sup> Despite the position of his former Attorney General, President Trump himself has stated support for legislation that would officially leave the matter of marijuana legalization and enforcement up to the states.<sup>37</sup> These positions are just the most recent developments at the time that this paper was written, and it is hard to predict where the next Attorney General or even the next presidential administration may stand in regards to medical marijuana. These conflicting stances within the federal government make the already complex balance between state and federal cannabis laws even more difficult to navigate when attempting to move forward with the utilization of medicinal cannabis in any capacity.

### *Political and Cultural Considerations*

Over the years public opinion has progressed to a majority of people supporting legalization of cannabis use, especially for

medical as opposed to recreational use.<sup>29</sup> However, support for recreational marijuana is also high, even though the public may not necessarily recognize the importance of distinguishing medical versus recreational cannabis use. These distinctions are important because the debate on recreational legalization is an entirely different one from the topic of medical legalization. Research conducted into possible therapeutic uses for cannabis has shown promise for a number of different medical conditions, as discussed earlier in this paper. The FDA itself supports “adequate and well-controlled clinical trials” investigating medicinal marijuana, and has to some degree worked with and supported research being conducted in several states.<sup>17</sup>

Despite all of this, the fact remains that cannabis usage is associated with the potential for some degree of abuse and addiction - a concern that resonates strongly with people across the country in the midst of our nation’s current struggle with the opiate epidemic. In many ways, the stories are similar: the recreational form of the drug was always available as opium and heroin (in the same way that recreational marijuana use is not a new phenomenon), but the true epidemic arguably began as a result of the approval and promotion of more medications that contained opiate derivatives (making it easy to imagine how something similar could occur if more medications containing marijuana derivatives were made legal). These concerns are very real and justified, but it is important to consider the many differences between cannabis derivatives versus opioids. Unlike the possibility of overdosing when abusing opioids, marijuana does not pose a “mortality risk.” There is a risk of developing a dependency on marijuana, but this risk is much lower in comparison to opioids.<sup>39</sup> All of that being said, there is still a possibility that the usage of cannabis derivatives could cause currently unrecognized medical problems and thus pose a significant threat to public health if made legal. However, it is that very possibility that makes it all the more important for quality clinical trials to be conducted into medical cannabis so as to avoid the mistakes that the healthcare industry made in the past with more widespread use of opioid medications. In addition, marijuana itself has shown some promise as a potential adjunct for patients undergoing treatment for opioid use disorder, as discussed earlier in this paper.<sup>20</sup>

If the trends of increasing political and cultural support continue for both medical and recreational marijuana usage, this may be an indication that widespread legalization is inevitable, which makes it imperative that responsible,

quality studies are conducted into the effects of cannabis and its derivatives on the human body - regardless of what the results may prove or disprove. Thus, removal of regulatory burdens on medical marijuana utilization can only benefit the future of our nation's health.

#### **4. ETHICAL ANALYSIS**

Society, in general, has always recognized that in our complex world there is the possibility that we may be faced with a situation that has two consequences--one good and the other evil. The time-honored ethical principle that has been applied to these situations is called the principle of double effect. As the name itself implies, the human action has two distinct effects. One effect is the intended good; the other is unintended evil. As an ethical principle, it was never intended to be an inflexible rule or a mathematical formula, but rather it is to be used as an efficient guide to prudent moral judgment in solving difficult moral dilemmas.<sup>40</sup> The principle of double effect specifies four conditions which must be fulfilled for an action with both a good and an evil effect to be ethically justified:

1. The action, considered by itself and independently of its effects, must not be morally evil. The object of the action must be good or indifferent.
2. The evil effect must not be the means of producing the good effect.
3. The evil effect is sincerely not intended, but merely tolerated.
4. There must be a proportionate reason for performing the action, in spite of the evil consequences.<sup>41</sup>

The principle of double effect is applicable to the issue of whether it is ethical for a physician to prescribe marijuana for medical reasons because it has two effects, one good and the other evil. The good effect is that marijuana may be more effective than conventional therapies in helping patients withstand the effects of accepted, traditional treatments which can bring about a cure or the amelioration of their condition. The evil effect is that marijuana and its derivatives have toxic effects and, as illegal drugs, could lead to more serious drug abuse and send a wrong message that illegal drug use is safe and even condoned. To determine if it is ethical for physicians to prescribe medical marijuana for patients as a medical therapy, this issue will be examined in light of the four conditions of the principle of double effect.

The first condition allows for the medical use of marijuana because the object of the action, in and of itself, is good. The moral object is the precise good that is freely willed in this action. The moral good of this action is to help

treat problems such as pain, nausea, severe weight loss associated with AIDS, and to combat muscle spasms associated with multiple sclerosis that cannot be treated adequately by traditional medicines. The immediate goal is not to endorse, encourage or promote illegal drug use. Rather, the direct goal is to relieve patients of their unnecessary pain and suffering.<sup>42</sup> The second condition permits the medical use of marijuana because the good effect of relieving pain and suffering is not produced by means of the evil effect. The two effects happen simultaneously and independently. The third condition is met because the direct intention of medical marijuana is to give patients suffering from certain illnesses relief. To deny a physician the right to discuss, recommend, and prescribe marijuana to patients is a direct violation of the physician-patient relationship. To make an informed decision about their treatment, patients have the right to expect full disclosure and discussion of all available treatment options from their physicians. Failure to do this violates the patient's right of informed consent.<sup>43</sup>

The hypothesized foreseen but unintended consequences of legalizing medical marijuana are two-fold. First, the smoke from marijuana is highly toxic and can cause lung damage. The intention of smoked marijuana is not to cause more health problems but to remedy the effects of existing treatments. Second, some members of the federal government believe that legalizing medical marijuana may lead to harder drug usage and may be seen as condoning and encouraging recreational drug use. Nevertheless, this has not been proven to be true. The March 17, 1999 report by the Institute of Medicine found no evidence that the medical use of marijuana would increase illicit use in the general population, nor was it a "gateway drug" that would lead to the use of harder drugs like cocaine or heroin.<sup>44</sup> In addition, a 1994 survey in *The New York Times* found that 17% of current marijuana users said they had tried cocaine, and only 0.2% of those who had not used marijuana had tried cocaine. Ethicist George Annas points out that there are two ways to interpret this study. One way is to conclude that those who smoke marijuana are 85 times as likely as others to try cocaine; another way is that 83% of pot smokers, or five out of six, never try cocaine.<sup>45</sup> A 2003 study by Jan van Ours of Tilburg University in the Netherlands, cannabis users typically start using the drug between the ages of 18 and 20, while cocaine use usually starts between 20 and 25. But it concludes that cannabis is not a stepping stone to using cocaine or heroin. Four surveys, covering nearly 17,000 people, were carried out in Amsterdam in 1987, 1990, 1994 and 1997. The study found that there was little difference in



the probability of an individual taking up cocaine as to whether or not he or she had used cannabis. Although significant numbers of people in the survey did use soft and hard drugs, this was linked with personal characteristics and a predilection to experimentation.<sup>46</sup> If officials in the federal government are worried that the legalization of medical marijuana will send the wrong message to our children about drugs, then Boston Globe columnist Ellen Goodman asks a good question: “What is the infamous signal being sent to [children] . . . if you hurry up and get cancer, you, too, can get high?”<sup>45</sup> Will some people view the legalization of medical marijuana as the condoning and encouraging of marijuana for recreational drug use? The answer is “yes.” But this is not the direct intention of legalizing medical marijuana. The direct intention is to relieve pain and suffering that cannot be relieved by presently approved medications. This misinterpretation of the legalization of medical marijuana can be corrected through public education. Finally, the argument for the ethical justification of marijuana for medical use by the principle of double effect focuses on whether there is a proportionately grave reason for allowing the foreseen but unintended possible consequences. Proportionate reason is the linchpin that holds this complex moral principle together.

Proportionate reason refers to a specific value and its relation to all elements (including premoral evils) in the action.<sup>47</sup> The specific value in legalizing medical marijuana is to relieve pain and suffering associated with treatment for certain illnesses. The premoral evil, which can come about by trying to achieve this value, is the foreseen but unintended possibility of the potential harmful effects of the smoke and the possibility that some may view this as condoning and even encouraging illegal drug use. The ethical question is: does the value of relieving pain and suffering outweigh the premoral evil of the potential harmful effects and the possibility of scandal? To determine if a proper relationship exists between the specific value and the other elements of the act, ethicist Richard McCormick proposes three criteria for the establishment of proportionate reason:

1. The means used will not cause more harm than necessary to achieve the value.
2. No less harmful way exists to protect the value.
3. The means used to achieve the value will not undermine it.<sup>48</sup>

The application of McCormick’s criteria to the legalization of medical marijuana supports the argument that there is a proportionate reason for allowing physicians to

prescribe marijuana. First, while there are adverse effects associated with cannabis use as discussed earlier in this paper, that does not mean that it could not be given on a short-term basis under close supervision to patients who do not respond to other therapies. The point would be that the benefit of the treatments outweighs the burdens, as is the case with any medication that has potential side effects. Second, at present, there does not seem to be an alternative medication that is as effective as smoked marijuana for a variety of ailments. Thousands of patients who have smoked marijuana illegally for medical purposes have attested to its effectiveness in ameliorating symptoms of various illnesses, more than any other medications available. Research has begun to show this definitively, as evidenced by studies on cannabinoid use for pain relief<sup>19</sup> and the FDA approval of a cannabis derivative for certain pediatric seizure disorders.<sup>16</sup> Third, using marijuana and its derivatives for medical reasons does not undermine the value, which is the relief of pain and suffering. Many of the patients who would use medical marijuana and/or its derivatives are suffering from intractable or even terminal conditions and may be undergoing therapies that have serious side-effects. Since this seems to be the only therapy to date for many patients that relieves pain and suffering, one can argue convincingly that it is a medical necessity. Therefore, it is ethically justified under the principle of double effect for the federal government to legalize marijuana for patients who do not respond to traditional therapies. Seriously ill patients have the right to effective therapies. To deny them access to such therapies is to deny them the dignity and respect all persons deserve. The greater good is promoted in spite of the potential evil consequences.

## **5. CONCLUSION**

Whole plant cannabis, as well as the cannabinoids that make up the plant and any compounds derived from them, have undeniable potential in the treatment of numerous medical diseases and conditions or, at the very least, in the relief of symptoms caused by these diseases and conditions. Federal and state legislation, in addition to public opinion, has been trending towards more freedom in the use of cannabis and its derivatives for medicinal purposes, but there are still numerous political and legal barriers in place that prevent cannabinoids from being researched and applied to clinical practice in the same manner that any other medication would be. Because it is clear that cannabis has safe clinical applications in modern medicine, to deny some degree of utilization or further research on the subject would be unethical and irresponsible. The United States federal

government needs to work with states where medical marijuana is already legal to coordinate efforts into further quality studies on efficacy, if not lower the schedule of whole plant cannabis and/or cannabinoid derivatives altogether so as to prevent anymore unnecessary hindrance of scientific progress.

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