Medical Marijuana: A Drug Without a Medical Model

Claire Frezza*

Table of Contents

Introduction ........................................... 1118

I. Overview of the Medical-Marijuana Problem ............. 1120
   A. Issues at the State Level ........................... 1121
      1. Varying Standards for Patient Qualification ........ 1121
      2. Differences in Practitioner Requirements .......... 1123
      3. Differing Possession Limits ...................... 1124
   B. Issues at the Federal Level ........................ 1125
      1. History of the Conflict Between Federal and State Medical-Marijuana Laws ...................... 1125
      2. Federal and State Tensions ....................... 1126

II. Medical-Marijuana Laws Fail to Operate as Intended ...... 1127
   A. The Scientific Issues of Smoked Marijuana as a Medicine . . . 1128
      1. The Medical Community Versus the Public .......... 1128
      2. The Issues of the Marijuana Plant as a Medicine ...... 1129
   B. Patient Population and the Issue of Ease of Access ...... 1130
   C. Dispensaries Do Not Properly Regulate Marijuana Distribution .................................. 1132

III. Proposals to Reform Medical-Marijuana Laws Are Insufficient ....................................... 1133
   A. Background on the Classification of Marijuana Under the CSA ........................................ 1134

* Georgetown University Law Center, J.D. expected 2014; Massachusetts College of Pharmacy & Health Sciences, Pharm.D. 2010. © 2013, Claire Frezza. I would like to thank my professors James Bulen, Sherman Cohn, and Patricia King for their invaluable guidance in the early stages of this Note and for encouraging me to publish. I would also like to thank my pharmacy coworkers for their support, and in particular, my colleague Nicole Dornbush for her assistance in the research process. Lastly, I would like to thank The Georgetown Law Journal for all of its editorial work.
INTRODUCTION

Although medical marijuana is legal in eighteen states and the District of Columbia,¹ it is challenging to recognize marijuana as a legitimate medicine in this country. The legalization of marijuana for medicinal purposes is a controversial topic, and the United States is far from reaching a consensus.² As more Americans continue to approve the use of marijuana as a medicine,³ government conflict with medical marijuana continues to progress, rooted in the conflict between state and federal law and stressed by the inadequacy of current state laws legalizing its use. Perhaps epitomizing the ongoing medical-marijuana problem is the federal crackdown on California dispensaries in late 2011,⁴ taking place in the state that was first to enact medical-marijuana laws just fifteen years prior on November 5, 1996.⁵

Viewing the legal context of medical marijuana from a pharmacist’s perspective, the solution to medical-marijuana laws is not a matter of supporting or prohibiting its use; medical marijuana is in need of a better refined medical model. A proper medical model is composed of the prescribing of medicine by a licensed prescriber and the dispensing of medicine by a separate licensed entity,
with attention to appropriate dosing and therapeutic use. The current method employed by medical-marijuana jurisdictions misses the mark. This Note will address the ever-growing complexities resulting from medical-marijuana laws, approaching the topic with an understanding that some form of medical marijuana will exist in the marketplace regardless of legal intervention. Without passing ethical or clinical judgments on the general acceptability of marijuana as a medicine, this Note will argue for reformation and uniformity of medical-marijuana laws on a national level.

Part I will provide an overview of the medical-marijuana problem on a state and federal level. Section I.A will focus on the issues at the state level, reviewing the current state medical-marijuana laws. This section will highlight the discrepancies that exist among the states, focusing on the leniencies that are present with regard to individuals’ access to marijuana and the lack of sufficient control in authorizing use. Section I.B will discuss the issues associated with the conflict of federal and state law regarding the legality of marijuana. This section will emphasize the overall instability of state medical-marijuana laws in the context of the federal standpoint and provide a brief overview of the developing tensions between the federal and state stances on marijuana. Part II will address various problems with the medical-marijuana laws currently in effect, providing support for the claims that medical-marijuana laws are in need of reformation and that important issues remain unresolved. Section II.A will address the scientific issues surrounding medical marijuana and the limitations on further research. Section II.B will focus on the access and control of medical marijuana as seen in practice, including an overview of the patients for whom marijuana is commonly prescribed. Section II.C will cover some of the issues concerning marijuana dispensaries in the states that permit them, emphasizing the need for a better system.

Part III will reject the prevalent proposal of reclassifying marijuana as a schedule II controlled substance, providing an overview of the Controlled Substances Act and explaining the impracticability of reclassification due to the nature of smoked marijuana as a medicine. Part IV will propose the reformation of medical-marijuana laws, arguing that the only operable manner by which to regulate medical marijuana is through federal action unifying state regulations, specifically the application of a medical model mirroring that of opioid-treatment programs. Section IV.A will provide an overview of opioid-treatment programs, and section IV.B will utilize this medical model to recommend an analogous federal medical-marijuana program. This section will outline how mirroring opioid-treatment programs will address the issues with current medical-marijuana laws, recommending better control over prescribers and patient access to medical marijuana. This proposal will argue that, as of this writing, marijuana should maintain its status as a schedule I controlled substance, yet it should legally be permitted to be used as a medicine in limited circumstances under the guidance and control of a federal agency.
I. OVERVIEW OF THE MEDICAL-MARIJUANA PROBLEM

Ballot Proposition 215, passed by 56% of California voters in November 1996 to legalize medicinal marijuana,6 changed the status of marijuana in the United States forever. The ballot proposition was introduced at the state level after a series of counties in California approved propositions supporting the use of marijuana for medicinal purposes.7 Since California’s revolutionary undertaking, eighteen states and the District of Columbia have followed suit, enacting medical-marijuana laws for a variety of indications via initiatives such as ballot or legislative action.8 However, state medical-marijuana laws vary greatly from state to state, and no two states’ regulations are identical.9 The jurisdictions legalizing medical marijuana10 present varying degrees of leniency of permitted use, some of which come across as surprising.11 The differences that exist among these nineteen jurisdictions bring light to the grayness of the laws of medical marijuana, making the need for reform and uniformity increasingly apparent.

The medical-marijuana laws passed since California’s have generally cited the same references in support for legalization. Many states referenced a 1999 Institute of Medicine report (“the 1999 IOM Report”),12 which found possible therapeutic benefits from the use of marijuana.13 Many states have framed their permitted therapeutic indications in accordance with the particular diseases mentioned in the 1999 IOM Report, though indications differ greatly from state to state, and states have perceived the weight of the study results differently.14 Other states have claimed that “[t]he legislature finds that modern medical

6. See id.
7. See Michael Berkey, Mary Jane’s New Dance: The Medical Marijuana Legal Tango, 9 CARDOZO PUB. L. POL’Y & ETHICS J. 417, 428 (2011). In 1991, San Francisco approved a proposition recommending “the Californian government and the California Medical Association include marijuana as an available medicine for physicians to prescribe . . . .” Id. In 1992, “the County of Santa Cruz passed Measure A, which called for the sheriff and district attorney to use discretion when pursuing those who violated [] drug laws . . . out of a medical necessity.” Id.
8. See ProCon, Medical Marijuana, supra note 1.
9. See id.; see also infra section I.A.1.
11. See id. For example, it may come as a surprise that Washington permits individuals to use medical marijuana with the mere written recommendation of a naturopath, an alternative-medicine practitioner, absent any proof of an actual office visit or registration with the state. See Wash. Rev. Code § 69.51A.010(2) (Supp. 2012).
research has discovered a beneficial use for marijuana\textsuperscript{15} without pointing to any actual clinical studies or data, whereas other state statutes do not refer to medical research at all.\textsuperscript{16} Many states also referenced the FBI’s Uniform Crime Reports and the Compendium of Federal Justice Statistics to support tackling the subject of marijuana at a state level, which identified that state rather than federal law accounted for approximately ninety-nine out of every one hundred marijuana arrests in the United States.\textsuperscript{17} Additionally, several of the state propositions listed the mere existence of other states’ medical-marijuana laws to support furthering legalization in their respective states.\textsuperscript{18} Eleven of nineteen medical-marijuana laws determined marijuana to be a proper medicine via ballot propositions with popular vote.\textsuperscript{19} Despite the similar fashion in which these medical-marijuana laws came to be enacted, the disparities present among the state laws are astounding.

A. ISSUES AT THE STATE LEVEL

1. Varying Standards for Patient Qualification

Registration requirements for patients to gain access to medical marijuana are not uniform across states.\textsuperscript{20} Most states require patients to complete an application and register with the state in order to acquire medical marijuana;\textsuperscript{21} however, some states, such as California, leave registration voluntary,\textsuperscript{22} and Washington does not have a registration program in effect at all.\textsuperscript{23} Many states with medical-marijuana laws require proof of residency in order to qualify as a patient for medical marijuana,\textsuperscript{24} with a handful permitting registration cards from out of state.\textsuperscript{25} Delaware and Rhode Island do not require any official proof for medical marijuana registration.
of identification, though other states require that a copy of a valid state identification card be attached to an application.

Every jurisdiction requires patients to be placed under one of the medical conditions specified by the respective jurisdiction’s law in order to qualify for medical marijuana—yet the approved indications determined by each jurisdiction vary considerably. The medical conditions that are approved by most or all jurisdictions permitting medical marijuana include: cachexia/wasting, cancer, chronic pain, glaucoma, HIV/AIDS, muscle spasms (often due to multiple sclerosis), nausea, and seizures. Jurisdictions vary as to whether conditions such as chronic pain or nausea need to be severe, and only some require that such conditions be in connection with a specified illness, such as cancer. Some states permit medical marijuana for ALS, Alzheimer’s disease, Crohn’s disease, hepatitis C, and other chronic conditions. In addition to these indications, various other indications are approved in only one, two, or three states, causing the definition of appropriate marijuana use to vary greatly among jurisdictions. Furthermore, additional discrepancies exist among the states’ efforts to obtain proof of diagnosis by an authorizing physician and to assess the medical necessity of marijuana use for qualifying patients.


28. See ProCon, Medical Marijuana, supra note 1. The state discrepancies on appropriate indications not only raise practical issues of access but also highlight the lack of consensus regarding the appropriate use of medical marijuana even among the states that approve its use.

29. See id.


31. See ProCon, Medical Marijuana, supra note 1. For example, Maine requires that symptoms of nausea and vomiting can be treated only if associated with treatments for AIDS or cancer, but the District of Columbia (more specifically) requires that such treatments be associated with chemotherapy treatments. See D.C. Code § 13-138(2) (Supp. 2012); Me. Rev. Stat. tit. 22, § 2383-B(5)(A)(1)(a)(i)-(ii) (2004); see also infra text accompanying notes 93–94 (explaining why this is a concern).

32. See ProCon, Medical Marijuana, supra note 1. Several states have also adopted unique indications of their own; for instance, California is the only state explicitly allowing medical-marijuana use for treatment of migraines and arthritis; Delaware is the only state specifically approving use for decompensated cirrhosis; and New Jersey is the only state specifically permitting use for muscular dystrophy. See id.; see also Cal. Health & Safety Code § 11362.7(h)(8) (West 2007); Del. Code Ann. tit. 16, § 4902A(3)(a) (Supp. 2011); N.J. Stat. Ann. § 24:6I-3(3) (West Supp. 2012).

33. See ProCon, Medical Marijuana, supra note 1. For example, anorexia, nail patella (a genetic disorder), and post-traumatic stress disorder are each approved by only a few states. See id. Several states have also adopted unique indications of their own; for instance, California is the only state explicitly allowing medical-marijuana use for treatment of migraines and arthritis; Delaware is the only state specifically approving use for decompensated cirrhosis; and New Jersey is the only state specifically permitting use for muscular dystrophy. See id.; see also Cal. Health & Safety Code § 11362.7(h)(8) (West 2007); Del. Code Ann. tit. 16, § 4902A(3)(a) (Supp. 2011); N.J. Stat. Ann. § 24:6I-3(3) (West Supp. 2012).

34. See ProCon, Medical Marijuana, supra note 1. Many states require the authorizing physician to have a bona fide patient–physician relationship, where the physician has seen the patient in person, reviewed the patient’s medical records, and conducted a physical to assess the medical condition(s). See, e.g., Or. Rev. Stat. § 475.326 (Supp. 2011).
2. Differences in Practitioner Requirements

Although every jurisdiction requires patients to receive a practitioner recommendation in order to gain access to marijuana, the laws differ greatly as to any practitioner requirements and are altogether insufficient to properly regulate marijuana as a medicine. Particularly, there are staggering variations among the states as to who may authorize medical marijuana for qualifying patients. Some jurisdictions, including Michigan, Nevada, and Oregon, require that the physician be licensed in the respective state as a medical doctor, surgeon, or doctor of osteopathy. States such as Arizona permit individuals to authorize medical-marijuana use for patients even if not licensed as doctors of medicine or osteopathic medicine, including those licensed as naturopaths and homeopaths. Few jurisdictions have placed any additional restrictions on the practitioners who may recommend marijuana, such as prohibiting practitioners with DEA flags on their medical licenses or those who have a financial relationship with a dispensary from prescribing marijuana. Consequently, the restrictions on practitioners who may recommend marijuana, a schedule I controlled substance under federal law, are more lenient than those in place

35. See generally ProCon, Medical Marijuana, supra note 1 (noting the state requirements for obtaining medical marijuana, including practitioner recommendation in states such as Arizona, New Jersey, and Oregon).


37. Controlled substances that may be legally prescribed are all regulated through a combination of law and prescribers; the laws restrict possession, and the prescribers are held accountable for appropriate prescribing and for guarding against abuse. The medical-marijuana laws tend to focus too much on outlining patient characteristics and too little on prescriber requirements and they ought to be reformed such that the emphasis is placed on prescriber requirements. In this case, prescribers would determine when a prescription is appropriate, as is standard for all other controlled substances. See infra section IV.B (proposing stricter regulations on prescribers, who will utilize guidelines to determine appropriate patients).


40. Compare D.C. CODE §§ 7-1671.01(15), 7-1671.04(d) (Supp. 2012) (excluding prescribers with dispensary relationships and those not in good standing with the District), with N.M. STAT. ANN. § 26-2B-3(E) (2007) (failing to include any safeguards to restrict practitioners who recommend marijuana).

for practitioners who may prescribe even the most loosely regulated controlled substances under federal law.42

3. Differing Possession Limits

Echoing the lack of standards on medical-marijuana distribution are the jurisdictional differences on appropriate possession limits.43 Although most jurisdictions have possession limits of eight ounces of marijuana or less,44 some states only permit a maximum of one ounce of usable marijuana,45 and some states, such as Washington, allow patients to possess up to twenty-four ounces.46 Most of the nineteen jurisdictions allow patients to privately cultivate marijuana, regulating primarily by limiting maximum quantities.47 Of these states, New Mexico is in the minority in requiring registration in order to obtain the legal right to grow marijuana.48 With patients growing their own marijuana freely, states appear to provide little guidance on how much marijuana may legally be consumed within a given time period.49 New Jersey is one of few states to specify consumption, highlighting the vast differences from state to state.50 As authors of a recent article have noted:

Under the New Jersey law, physicians must provide patients with written instructions specifying the amount of marijuana to be dispensed by legally sanctioned treatment centers, but the maximum amount for a 30-day period is
2 oz—making a “60-day supply” in New Jersey just 4 oz, one sixth of that in Washington, a disparity that underscores the absence of standards.51

B. ISSUES AT THE FEDERAL LEVEL

1. History of the Conflict Between Federal and State Medical-Marijuana Laws

The discrepancies among medical-marijuana laws are one matter, but the conflict of state and federal law better demonstrates the need for reform. Federal drug policy, detailed in the Controlled Substances Act (CSA), classifies marijuana as a schedule I substance.52 Schedule I substances are categorized as having a high potential for abuse, are not currently accepted for medical treatment in the United States, and are not sufficiently safe for use even while under medical supervision.53 Given that substances have been determined to lack any medical use under this schedule, practitioners cannot legally prescribe for the substance; therefore, any use of the substance, medicinal or not, is illegal under federal law.54

Although certain areas of the state–federal marijuana conflict have been clarified,55 the Supreme Court has yet to affirmatively speak on the issue of federal preemption of the CSA, and lower courts have disagreed on the issue.56 The CSA provides that the Act does not preempt state law “unless there is a positive conflict between that provision . . . and that State law so that the two

53. 21 U.S.C. § 812(b) (2006); see also infra text accompanying notes 119–20 (describing the DEA’s test for reclassifying to schedule II and reasons for not reclassifying marijuana).
54. See 21 U.S.C. § 812(b) (2006) (noting that schedule I substances have no medical use); id. § 844(a) (“It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice . . . .”); DRUG ENFORCEMENT ADMIN., PHARMACIST’S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT REVISED 29 (2010), available at http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_content.htm (detailing that valid prescriptions must be written for an acceptable medical use).
55. See Gonzales v. Raich, 545 U.S. 1, 9, 32–33 (2005) (holding that Congress could constitutionally apply the CSA to medical marijuana produced and consumed intrastate, even when cultivated in an individual’s home in the absence of commercial activity); United States v. Oakland Cannabis Buyers’ Coop., 532 U.S. 483, 491 (2001) (holding that given the express statutory language of the CSA, the medical necessity defense was not available); Conant v. Walters, 309 F.3d 629, 637 (9th Cir. 2002) (holding that although physicians may not prescribe medical marijuana, they may recommend it as required by medical-marijuana laws as a First Amendment right).
56. Compare Butler v. Douglas Cnty., No. 07-6241-HO, 2010 WL 3220199, at *3 (D. Or. 2010) (finding that the federal prohibition on the use of marijuana preempted the Oregon Medical Marijuana Act), with Cnty. of San Diego v. San Diego NORML, 81 Cal. Rptr. 3d 461, 481, 483 (Cal. Ct. App. 2008) (holding the California Medical Marijuana Program’s requirement that counties issue identification cards did not positively conflict with the Federal CSA and therefore was not preempted). See also Kevin D. Caton, Annotation, Preemption of State Regulation of Controlled Substances by Federal Controlled Substances Act, 60 A.L.R.6th 175, 185 (2010) (noting that some courts have found the CSA to preempt state law but others have expressly stated that it does not).
cannot consistently stand together.”57 In addition to the CSA explicitly stating that marijuana is a drug with no medicinal use, federal law also states that possessing any amount of marijuana is illegal.58 Considering that every state medical-marijuana law permits marijuana possession to some extent,59 it seems apparent that laws that permit some possession of marijuana cannot consistently stand with a law that prohibits any possession. As the conflict of law remains unaddressed, state and federal tensions continue to grow.

2. Federal and State Tensions

The federal government has been persistent in its opposition to state medical-marijuana laws throughout their existence. The Drug Enforcement Administration (DEA) has consistently reiterated marijuana’s proper classification as a schedule I substance, lacking any acceptable medicinal use.60 Likewise, the Food and Drug Administration (FDA) has stated that “no sound scientific studies support medical use of marijuana for treatment in the United States, and no animal or human data support the safety or efficacy of marijuana for general medical use.”61 Since California enacted the first medical-marijuana law, government agencies have voiced disapproval and demonstrated resistance to medical marijuana;62 however, state laws permitting medical-marijuana use have persisted.63 Furthermore, state and city efforts to relax marijuana enforcement have expanded at a growing rate.64

The recent initiation of the federal crackdown, announced in October 2011 to

58. See id. § 844(a).
59. See ProCon, Medical Marijuana, supra note 1.
63. In addition to new medical-marijuana laws being enacted, “no state has invalidated its medical marijuana laws in an effort to comply with Raich,” which held that the CSA applied to intrastate medical-marijuana activity. Berkey, supra note 7, at 435.
control dispensaries in California, illuminates the federal government’s mounting opposition to medical marijuana.65 Just two years prior, in 2009, Attorney General Eric Holder announced formal guidelines for federal prosecutors regarding medical marijuana, emphasizing that “the focus of federal resources should not be on individuals whose actions are in compliance with existing state laws.”66 This seeming change of heart was addressed in February 2011 when the Department of Justice (DOJ) issued a memorandum stating that “while the [DOJ] does not focus its limited resources on seriously ill individuals who use marijuana . . . [the DOJ still] . . . will enforce the CSA vigorously against individuals and organizations that participate in unlawful manufacturing and distribution activity involving marijuana, even if such activities are permitted under state law.”67

This action against marijuana dispensaries demonstrates the federal government’s attempt to regain power over a controlled substance—a power that has, until recently, been forfeited to the states.

II. MEDICAL-MARIJUANA LAWS FAIL TO OPERATE AS INTENDED

The stated purpose of most medical-marijuana laws is similar: as found in the California medical-marijuana law, a primary purpose is “[t]o ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate . . . .”68 Although it may appear that the mere passage of medical-marijuana laws would serve this purpose, there are many issues embedded within the medical-marijuana system that have not allowed this purpose to be adequately met. First, as of this writing, clinical trials, medical societies, and the medical community at large have not provided support or directly opposed many of the indications that state medical-marijuana laws have determined as an “appropriate use.” Second, access to medical marijuana is not adequately controlled, and the patient population receiving medical marijuana has differed significantly from what most states’ medical-marijuana laws initially intended, with question as to whether many of the ultimate users are in fact seriously ill. Last, rather than controlling access and providing medicine to those in need, issues with dispensaries are on the rise: dispensaries have not provided an acceptable and safe means for patients to obtain medical marijuana.

65. See Medina, supra note 4 (“Federal officials . . . warned dozens of marijuana dispensaries throughout California to shut down or face civil and criminal action as part of a major crackdown on the state’s growing medical marijuana industry.”).


68. CAL. HEALTH & SAFETY CODE § 11362.5(b)(1)(A) (West 2007).
A. THE SCIENTIFIC ISSUES OF SMOKED MARIJUANA AS A MEDICINE

1. The Medical Community Versus the Public

As succinctly stated by the DEA in January 2011 when expressing the agency’s stance on marijuana, “Science, not popular vote, should determine what medicine is.”69 Several medical organizations have stated outright that they do not support the current use of marijuana for medical purposes as provided under state medical-marijuana laws.70 The American Medical Association (AMA), the largest association of medical doctors in the United States, has reiterated that it does not endorse “state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for prescription drug product.”71 Likewise, many other organizations in the medical community have released statements recommending against a change at this time in the legal status of marijuana as a medicine.72

Despite the lack of support by medical organizations such as the American Glaucoma Society and National Multiple Sclerosis Society, most states permitting medical marijuana list glaucoma and multiple sclerosis as appropriate indications.73 The 1999 IOM Report noted that “[a]lthough glaucoma is one of the most frequently cited medical indications for marijuana, the data do not support this indication.”74 Furthermore, although many of the states’ medical-marijuana indications were intended to target cancer patients,75 the American Cancer Society (ACS) “does not advocate inhaling smoke, nor the legalization of marijuana, although the organization does support carefully controlled clini-

69. DEA ON MARIJUANA, supra note 60, at 6.
70. See id. at 3–4. The American Medical Association does, however, support furthering marijuana research. Id.
71. Id. at 4.
72. See id. at 3–5 (organizations include the American Glaucoma Society, American Academy of Pediatrics, and National Multiple Sclerosis Society).
74. See 1999 IOM REPORT, supra note 13, at 177.
75. See e.g., ME. REV. STAT. tit. 22 § 2383-B(5)(A)(1)(a)(i)–(ii) (2004) (specifying that symptoms of nausea and vomiting can be treated only if associated with treatments for AIDS or cancer); see also Craig Reinarman et al., Who Are Medical Marijuana Patients? Population Characteristics from Nine California Assessment Clinics, 43 J. PSYCHOACTIVE DRUGS 128, 131 (2011) (“Early studies showed most patients used MM to relieve symptoms of HIV/AIDS or cancer . . . [however, [this study] suggests that cancer and AIDS patients are now a significantly smaller proportion of the total . . .”).
cal studies for alternative delivery methods, specifically a tetrahydrocannabinol (THC) skin patch.”76 The 1999 IOM Report stated directly, “Although mari-
juana smoke delivers THC and other cannabinoids to the body, it also delivers
harmful substances, including most of those found in tobacco smoke.”77
Therefore, the study concluded that “there is little future in smoked marijuana
as a medically approved medication.”78

Despite a dearth of adequate studies, proponents of legalizing medical mari-
juana continue to argue that medical marijuana is an appropriate medicine,
citing various studies finding that marijuana use has therapeutic effects.79
Likewise, many medical-marijuana proponents have pointed to the 1999 IOM
Report to support medical-marijuana use, even though it is the same study cited
by the DEA to reject marijuana’s medicinal use.80 As the same clinical studies
appear to be providing support both for and against the use of marijuana as a
medicine, the need for further research and the need for evaluation by medical
professionals rather than by the public has been exemplified.

2. The Issues of the Marijuana Plant as a Medicine

When it comes down to it, a primary issue of marijuana is that, although
some studies have shown that marijuana exhibits some medicinal value, its
intake as a smoked plant is inadequate under United States standards to justify
its use as a medication.81 As the principal investigators in the 1999 IOM Report
stated, “[P]lants contain a variable mixture of biologically active compounds
and cannot be expected to provide a precisely defined drug effect.”82 The study
further stated that using smoked marijuana in clinical trials should “not be to
develop marijuana as a licensed drug but rather to serve as a first step toward

76. DEA ON MARIJUANA, supra note 60, at 4 (internal quotation marks omitted).
77. 1999 IOM REPORT, supra note 13, at 177. Studies have been inconsistent on the exact risk
smoked marijuana poses of lung diseases, but some preliminary research has suggested marijuana use
poses increased risk for damage to some lung functions, supporting the need for continuing studies.
Compare Mark J. Pletcher et al., Association Between Marijuana Exposure and Pulmonary Function
Over 20 Years, 307 JAMA 173, 173 (2012) (finding that occasional and low cumulative smoked
marijuana use did not produce adverse pulmonary effects), with S. Aldington et al., Cannabis Use and
eight-percent-increased likelihood of lung cancer in cannabis smokers), and Wan C. Tan et al.,
Marijuana and Chronic Obstructive Lung Disease: A Population-Based Study, 180 CANADIAN MED.
ASS’N J. 814, 814 (2009) (finding that smoked marijuana in addition to smoked tobacco increased the
risk of developing chronic obstructive lung disease).
78. 1999 IOM REPORT, supra note 13, at 178.
79. See, e.g., Peter J. Cohen, Medical Marijuana 2010: It’s Time To Fix the Regulatory Vacuum,
38 J.L. MED. & ETHICS 654, 661 (2010) [hereinafter Cohen, Regulatory Vacuum] (“There is now
sufficient evidence for the safety and efficacy of smoked marijuana administered for certain medical
purposes to justify its evaluation and, if the evidence continues to support its safety and efficacy for
these uses, its eventual approval by the FDA as a bona fide therapeutic agent.”).
80. See, e.g., Maia Szalavitz, U.S. Rules That Marijuana Has No Medical Use. What Does Science
no-medical-use-what-does-science-say.
81. See id.
82. 1999 IOM REPORT, supra note 13, at 177–78.
The possible development of nonsmoked rapid-onset cannabinoid delivery systems.\textsuperscript{83} The existence of cannabinoid-derived medications, purified to rid the harmful components of marijuana, stresses this point: smoked marijuana is not the only form of cannabinoids capable of providing patients with therapeutic relief.\textsuperscript{84}

The FDA currently recognizes the medication Marinol, which contains a synthetic form of THC (the cannabinoid present in marijuana believed to exert its therapeutic effects) and is indicated to treat nausea and vomiting for patients undergoing chemotherapy and to reduce loss of appetite for AIDS patients.\textsuperscript{85} With an FDA-approved medication on the market that lacks the potentially harmful components in the marijuana plant, the decision to use smoked marijuana instead of the prescription medication for these indications is arguably suspect. Despite this, a recent study of medical-marijuana patients at California clinics revealed that approximately 28\% of patients were using medical marijuana to relieve nausea or vomiting.\textsuperscript{86} Sativex, another emerging medication derived from marijuana as an oromucosal spray, is in Phase III clinical trials for cancer pain in the United States.\textsuperscript{87} As explained by the DEA, “unlike smoked marijuana, [Sativex] removes contaminants, reduces the intoxicating effects, is grown in a structured and scientific environment, administers a set dosage, and meets criteria for pharmaceutical products.”\textsuperscript{88} The existence of medications like these, coupled with the drawbacks of smoking marijuana in its plant form, does little to support medical-marijuana programs.

B. PATIENT POPULATION AND THE ISSUE OF EASE OF ACCESS

Since collecting data on the Arizona Medical Marijuana Program on April 14, 2011, the Arizona Department of Health Services reported that as of October 27, 2011, the state had denied only seven of the 14,925 applications for marijuana registration cards.\textsuperscript{89} Of those applicants, 86.4\% reported a medical diagnosis of chronic pain; a medical condition of cancer or HIV/AIDS accounted for less than 5\% of applicants.\textsuperscript{90} A recent survey conducted on 1,746 consecutive

\textsuperscript{83}. Id. at 7.  
\textsuperscript{84}. DEA ON MARIJUANA, supra note 60, at 5–6.  
\textsuperscript{85}. See id. at 6.  
\textsuperscript{86}. See Reinerman et al., supra note 75, at 131.  
\textsuperscript{88}. DEA ON MARIJUANA, supra note 60, at 6; accord Press Release, Bayer Schering Pharma, Sativex Launched in UK for the Treatment of Spasticity Due to Multiple Sclerosis (June 21, 2010), http://www.gwpharma.com/uploads/sativexconsrelease16.6.10.pdf.  
\textsuperscript{90}. See id.
admissions to nine California medical-marijuana clinics collected data on the characteristics of actual medical-marijuana patients, estimating that California has over 200,000 medical-marijuana patients.\textsuperscript{91} The self-reported results showed that 82.6\% of patients used marijuana to alleviate pain, unlike previous studies that showed the primary indication to be HIV/AIDS or cancer.\textsuperscript{92} It is noteworthy to point out that the most common indication qualifying patients for medical marijuana is diagnosed almost purely on a self-reported basis (the indication being pain, on a self-reported pain scale).\textsuperscript{93} Without requiring pain to be associated with medical conditions such as cancer or some other definable chronic condition, states run the risk of enabling individuals to gain access to a substance that is considered illegal under federal law.\textsuperscript{94} The self-reported answers further revealed that before turning to medical marijuana, less than half of patients tried physical therapy and over 20\% of patients did not try prescription medications.\textsuperscript{95} Although it is not necessary to attempt certain medical therapies prior to choosing a course of treatment for any diagnosis, given the nature of most medical-marijuana laws, which seek to provide relief for “seriously ill” patients,\textsuperscript{96} it is questionable whether these were the patients contemplated by the enactment of medical-marijuana laws.\textsuperscript{97}

A recent Oregon news article detailed the lack of control of the patient population and access to medical marijuana in that state, despite the existence of a registration system in Oregon.\textsuperscript{98} The article indicated a local sheriff’s concern over the diversified indications of use approved for medical marijuana, noting that “more than [ninety] percent of cardholders say they’re using pot to treat pain—not glaucoma or cancer—as the bill was initially marketed.”\textsuperscript{99} The article also explained that access to medical marijuana is less confined than was anticipated, remarking that “[t]he program, which was once billed as something that would apply to 500 people, has ballooned to more than 50,000.”\textsuperscript{100}

An undercover reporter demonstrated the incredible ease of access to medical marijuana while investigating the medical-marijuana domain in Oregon in

\textsuperscript{91} See Reinerman et al., \textit{supra} note 75, at 130.

\textsuperscript{92} See id. at 131.

\textsuperscript{93} See id.

\textsuperscript{94} Montana law now requires further proof for patients requesting medical marijuana for chronic pain. The law requires physicians to attest that the pain could be proven through a relevant MRI or X-ray, or a secondary physician must confirm the diagnosis of chronic pain. \textsc{Mont. Code Ann.} § 50-46-302(2)(c) (2011).

\textsuperscript{95} See Reinerman et al., \textit{supra} note 75, at 132.

\textsuperscript{96} See, e.g., \textsc{Cal. Health & Safety Code} § 11362.5(b)(1)(A) (West 2007).

\textsuperscript{97} Other interesting characteristics of the medical-marijuana patients surveyed included that the most prevalent age group of medical-marijuana patients was individuals aged twenty-five to thirty-four, and that 72.9\% of the patients were male. See Reinerman et al., \textit{supra} note 75, at 131.


\textsuperscript{99} See id.

\textsuperscript{100} Id.
Although the reporter’s medical records indicated her back pain had previously been treated with massage therapy, the doctor at the clinic she visited found she qualified and would benefit from medical marijuana. Perhaps more alarming than the ease of the reporter’s medical-marijuana approval, a marijuana grower provided her a sample and offered to provide up to three pounds of marijuana a year. As of July 2012, a statistical report on Oregon medical-marijuana-registered patients showed an astounding 95% of the 54,280 patients within the state are qualified to smoke marijuana for the indication of “severe pain,” the medical category in which the reporter would have been placed.

C. DISPENSARIES DO NOT PROPERLY REGULATE MARIJUANA DISTRIBUTION

The existence of dispensaries to distribute medical marijuana has created turmoil rather than structure with regard to providing a proper medical model. States are split on the issue of medical-marijuana-dispensary legality, with the District of Columbia being one of the few jurisdictions explicitly authorizing establishment. Although the existence of structured dispensaries may purport to better control the distribution of marijuana as compared to acquiring marijuana on the street, many issues have arisen with the existence and promotion of marijuana dispensaries.

The California Police Chiefs Association detailed in a recent report on marijuana dispensaries that crime surrounding the operations is prevalent. The report noted that in addition to twenty-four violent crimes reported from January 1, 2005, to June 23, 2006, the vast majority of crimes were going unreported due to dispensary owners’ fears of being shut down for possession of marijuana in excess of state regulations. In July 2006, officials issued eleven state and eleven federal search warrants to dispensaries in California; the records showed that none of the eleven owners were properly reporting income generated and several owners were involved in money laundering and tax evasion.

102. Id.
103. See id.
105. See D.C. CODE § 13-138(8) (LexisNexis 2010); see also PROCON, Medical Marijuana, supra note 1 (noting that although dispensaries exist in Colorado, “[t]he Colorado Medical Marijuana amendment, statutes and regulations are silent on the issue of dispensaries”).
106. See, e.g., Christopher Chung, County Looks To Overhaul Rules on Medical Marijuana, PRESS DEMOCRAT (Oct. 24, 2011), http://www.pressdemocrat.com/article/20111024/COMMUNITY/111029724/1010/sports?Title=County-looks-to-overhaul-rules-on-medical-marijuana. An officer commenting on the proposal for reform “cited a link to marijuana in two local homicides in the past 10 days, plus eight home invasion robberies over the past year as reason for his support of the rule changes.” Id.
108. Id. at 22.
evasion. Even more alarming is that the report specified that many of the owners had histories of drug- and violence-related arrests and that many of them had previously illegally sold marijuana on the street. As stated by the California Police Chiefs Association with regard to marijuana dispensaries, “Their presence poses a clear violation of federal and state law; they invite more crime; and they compromise the health and welfare of law-abiding citizens.”

A recently enacted medical-marijuana law, passed on May 31, 2012, in Connecticut, addressed the issue of dispensary corruption in a manner more amicable to forming a medical model, by requiring marijuana dispensaries to be owned or operated by a licensed pharmacist. The law also sets forth that dispensaries may dispense no more than a thirty-day supply of medication and that pharmacists must input the marijuana data into the state’s prescription monitoring program. Although this provision is a huge stride towards guarding against diversion compared to dispensaries currently in effect, there are still many issues that must be addressed in order to properly reform medical marijuana.

III. PROPOSALS TO REFORM MEDICAL-MARIJUANA LAWS ARE INSUFFICIENT

Proponents for the nationwide legalization of medical marijuana have urged the federal government to reclassify medical marijuana from a schedule I to a schedule II substance under the CSA. Schedule II substances differ from

109. Id. at 21, 23.
110. Id. at 23.
111. Id. at 40. A RAND study released in September 2011 found that closing medical-marijuana dispensaries actually increased crime; however, the study was subsequently redacted because the report failed to include crime data actually taken by the police. Press Release, RAND, RAND Retracts Report About Medical Marijuana Dispensaries and Crime (Oct. 24, 2011), http://www.rand.org/news/press/2011/10/24.html (stating that the study was a failure of the company’s peer review system).
114. As of this writing, the Connecticut medical-marijuana program has not taken effect, but there are many issues keeping it from being a true medical model. Although a thirty-day supply is to be determined, the lack of medical research on marijuana will make a determination of what constitutes a 30-day supply arbitrary. Although pharmacists are required to own or operate the dispensaries, the lack of guidelines on dosing for various indications will prevent pharmacists from being able to make educated verifications of appropriateness. Lastly, the program still has room for improvement on regulating the prescribers that may recommend marijuana; the program seems to put an appropriate amount of regulation on dispensing, but prescribing and clinical standards are subpar.
115. Ballot initiatives attempting to change the controlled-substance legend of marijuana have been continually introduced since the passing of the CSA in 1970. See, e.g., Berkey, supra note 7, at 428–29. Additionally, several organizations have been formed in an attempt to ease restrictions on marijuana, including the National Organization for Reform of Marijuana Laws (NORML), the Alliance for
schedule I substances in that, despite a high potential for abuse, drugs in this category have a currently accepted medical use for treatment in the United States, possibly with strict limitations.\(^\text{116}\) On its face, this would resolve the conflict of federal and state law, as the prescribing and medical use of marijuana would become legal upon the reclassification of marijuana under the CSA as a schedule II substance.\(^\text{117}\) However, this would be substantially easier to accomplish if the states currently allowing medical marijuana were treating the substance as a medicine classified as a schedule II controlled substance; they are not.\(^\text{118}\) Rescheduling marijuana as a schedule II controlled substance would do little to resolve the issues present with medical marijuana and, on its face, is not a practical solution to correct the abuse of medical marijuana.

A. BACKGROUND ON THE CLASSIFICATION OF MARIJUANA UNDER THE CSA

The classification of marijuana was addressed in *Alliance for Cannabis Therapeutics v. Drug Enforcement Administration* in 1994, where the D.C. Circuit blessed significant portions of the DEA’s test for classifying marijuana as a schedule I substance.\(^\text{119}\) The DEA’s test requires the following for a finding of a current medical use: “(1) [t]he drug’s chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available.”\(^\text{120}\)

An implicit consequence of the court upholding the DEA’s test is that medical marijuana fails to meet the conditions necessary for classification as a substance with medicinal use.\(^\text{121}\) The DEA has maintained its current stance against marijuana as a medicine since this hallmark decision nineteen years ago.\(^\text{122}\)

B. THE COMPLEXITIES OF COMPARING MARIJUANA TO TRADITIONAL MEDICATIONS APPROVED BY THE FDA

Traditionally, new drugs are introduced into the market after a pharmaceutical company has demonstrated that they meet the requirements of the FDA—with safety and efficacy shown through the exercise of clinical trials—

\(^\text{117}\) See id.
\(^\text{118}\) Compare supra section I.A, with infra section III.C.
\(^\text{119}\) 15 F.3d 1131 (D.C. Cir. 1994).
\(^\text{120}\) See id. at 1135 (citing 57 Fed. Reg. 10,506 (Mar. 26, 1992)).
\(^\text{121}\) See id. at 1132–33.
\(^\text{122}\) See DEA ON MARIJUANA, supra note 60, at 2 (reflecting the current stance of the DEA in opposition to medicinal marijuana use).
and then after classification by the DEA under the CSA. Conversely, marijuana is not a patentable product and is widely accessible across the country; thus the economic incentive for conducting clinical research is not present. Moreover, newly approved drugs consist of an identifiable chemical, with a scientific name given to the active ingredient itself; an identifiable chemical compound is physically quite different from a substance in its plant form. Indeed, “[v]ariations in soil, geographical region, water, light, harvesting, and storage conditions magnify the inconstant chemical makeup, making marijuana impossible of standardized reproduction.” In response to these barriers, some states have attempted to require that medical marijuana only be legally dispensed if it meets a specified pharmaceutical grade. Although if successful, these requirements would constitute a substantial improvement towards creating a pharmaceutical product, the marijuana plant still has its limitations in complying with FDA standards.

The reason marijuana is not a proper schedule II substance is not merely due to its properties relating to medicinal value, but it is also due to the nature of the substance in its original form. Though many plants offer therapeutic value, medicines for patients come only as purified forms, such as plant-derived tablets or capsules. Similarly, several medications are synthesized from plant products in order to decrease potential harmful effects from the original substance while maintaining therapeutic value. Although consumption of the plant itself would produce analgesic effects, using the plant directly is not practicable in medical practice due to the inability to properly control for dosing, therapeutic efficacy, and unnecessary side effects under United States standards.

There are, however, several benefits to listing marijuana as a schedule II substance rather than a schedule I substance. Because schedule I substances are deemed to have no medicinal value, physicians may not legally prescribe such substances, nor may pharmacies dispense them; rescheduling marijuana as a schedule II substance would give physicians the power to actually

123. See generally Cohen, supra note 87, at 42–43.
125. See Alliance for Cannabis Therapeutics v. Drug Enforcement Administration, 15 F.3d 1131, 1135 (D.C. Cir. 1994) (describing the first prong of the DEA’s test for new drugs as requiring that “[t]he drug’s chemistry must be known and reproducible”).
126. McGuire, supra note 115, at 77; see also id. (quoting Marijuana Scheduling Petition, 57 Fed. Reg. 10,499 (Mar. 26), which states that “marijuana’s chemistry is neither fully known, nor reproducible. Thus far, over 400 different chemicals have been identified in the plant. The proportions and concentrations differ from plant to plant . . . .”).
127. See H.B. 5681 2011–2012 Sess. art. 8 (Mich. 2012) (this bill was introduced to amend the state’s medical-marijuana law but has not been enacted as of this writing); see also 2012 Conn. Acts 12-55, § 10 (Reg. Sess.) (requiring that marijuana be of pharmaceutical grade, though the program has not been implemented as of this writing, and the requirements have not yet been specified).
129. See id. at 603, 606–07 (for example, the drugs atropine, digoxin, morphine, and taxol are all derived from plants).
130. See id. at 606–07.
prescribe the drug to patients.\footnote{131}{See Drug Enforcement Admin., supra note 54, at 29.} This would allow for protection against diversion, as patients wishing to gain access to marijuana not only would have to not first receive a prescription from a practitioner who holds a valid DEA license but also could receive marijuana from only a pharmacy that holds a valid DEA license through a pharmacist registered with the state.\footnote{132}{See 21 U.S.C. § 823(a), (b) (2006).} Furthermore, many states require patients to provide a valid state-issued identification card in order to fill a marijuana prescription,\footnote{133}{See Law: Requiring Patient Identification Before Dispensing, Ctrs. for Disease Control & Prevention, http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/laws/id_req.html (last visited Nov. 26, 2012).} and many states offer prescription-monitoring programs, which permit pharmacists to track the controlled substances a patient has filled at pharmacies within the state to assist in controlling fraud and abuse.\footnote{134}{See supra note 112 and accompanying text (Connecticut’s medical-marijuana law requires dispensaries to report to such a program).} Additionally, manufacturers and distributors who handle controlled substances must hold valid DEA licenses in order to supply the drugs.\footnote{135}{See 21 U.S.C. § 823(a)-(b) (2006).} Placing marijuana into this classification of substances would appear to resolve many of the issues with medical marijuana.

C. WHY RESCHEDULING MARIJUANA WOULD NOT RESOLVE ISSUES IN PRACTICE

Unfortunately, from a practical standpoint, rescheduling marijuana as a schedule II substance would not automatically allow for control over the substance given the way that schedule II substances are currently controlled. Without regard to the potential therapeutic benefits that medical marijuana may pose, from a pharmacist’s standpoint, the marijuana plant simply does not fit into the Western medicine model the United States has in place, and resolution of this problem will not occur merely by rescheduling marijuana as a schedule II substance. As the DEA described marijuana, “there is no standardized composition or dosage; no appropriate prescribing information; no quality control; no accountability for the product . . . .”\footnote{136}{DEA on Marijuana, supra note 60, at 6.} Logistically, reclassifying marijuana as a schedule II medication would raise a plethora of issues, and marijuana simply could not operate as other medications under this class are required to operate under the DEA’s regulations. In practice, the main barriers to marijuana reclassification are the lack of studies providing proper dosing and prescribing guidelines, the variation of marijuana potencies and insufficient removal of harmful substances present in the plant form,\footnote{137}{DrugFacts: Marijuana, Nat’l Inst. Drug Abuse, http://www.drugabuse.gov/publications/drugfacts/marijuana (last visited Sept. 14, 2012) (‘‘According to the National Survey on Drug Use and}
Imagine this hypothetical: a patient sees her DEA-licensed doctor, who writes her a prescription for medical marijuana. In addition to requiring the doctor’s signature and valid DEA registration number on a prescription written for the patient, to be valid for dispensing the prescription must contain the “(1) [d]rug name, (2) [s]trength, (3) [d]osage form, (4) [q]uantity prescribed, (5) [d]irections for use, and (6) [n]umber of refills authorized (if any).” Medical marijuana would have to be standardized in order to ensure that every given ounce of substance had a measurable dosage of therapeutic cannabinoid so that a doctor could properly prescribe for it and determine the amount of substance to be smoked on a daily basis. After verifying that the daily ingestion of marijuana is a proper dosage, presumably from dosing guidelines available to both the doctor and pharmacist, the pharmacist would then proceed to dispense the medication. In order to have the medication in stock, the pharmacist would have to order the marijuana from a DEA-registered supplier with use of a DEA Form 222, a special DEA-issued form required for the transfer of schedule II controlled substances, which requires the pharmacist to specify the National Drug Code of the medication and the exact amount of the product ordered.

Upon dispensing, the pharmacist would need to take the marijuana out of the C-II cabinet, a locked storage device within a pharmacy to maintain schedule II controlled substances, where presumably the substance would be maintained in order to ensure freshness of the plant and proper potency.

This scenario is further complicated by the availability of marijuana seeds for home cultivation, whether legal under current state marijuana laws or not. If marijuana were rescheduled as a schedule II substance and brought into the prescription world as all other schedule II medications are treated, what would happen to the thousands of individuals who are currently legally cultivating marijuana under state law? As previously mentioned, manufacturers and distributors must register with the DEA in order to legally make and transfer schedule II controlled substances. Therefore, each individual who cultivated marijuana would theoretically have to register with the DEA to receive a license for manufacturing. Moreover, the structure of a patient producing a schedule II controlled substance for his or her own use is baffling. Imagine if it were legally permissible for chronic pain patients to produce their own narcotics, such as oxycodone, and control the amount they ingested on any given day. On the contrary, a schedule II classification requires that only healthcare providers registered with the DEA may prescribe oxycodone, only DEA-registered manu-

139. See Drug Enforcement Admin., supra note 54, at 29 (format of numbering changed).
140. Cf. id. at 29–39.
141. See id. at 13.
142. See id. at 61.
143. See id. at 13.
144. Cf. id.
facturers may manufacturer the drug, and only DEA-registered pharmacies may dispense the product. The entire structure of the medical model, with separate parties in control of dispensing the medication and prescribing it, helps to control the potential fraud and abuse of controlled substances. Leaving the control entirely up to the ultimate user completely undermines the medical system in place; medical marijuana simply does not fit into this model.

IV. PROPOSAL FOR REFORMING MEDICAL MARIJUANA ACROSS THE COUNTRY

There are many issues present within current medical-marijuana laws—ranging from the conflict of federal and state law and among the states themselves, to state-level issues—including ease of access, corruption in dispensaries, and overbroad indications of use. A problem inherent in current medical-marijuana laws is that they do not abide by a properly designed medical model, especially considering that the laws concern a substance the federal government has determined to have a high potential for abuse. Exemplifying the lack of a sufficient medical model is the very process of bringing the medical-marijuana laws into effect: how can it be claimed that we are treating medical marijuana as a true medicine when we permit the public to vote on the appropriateness of indications for use? Notwithstanding the complexities and highly controversial permissibility of smoked marijuana as a medicine, the first passing of a medical-marijuana law in 1996 opened a Pandora’s box, and simply closing the “box” is not an option. At the same time, it appears highly unlikely that the DEA will capitulate and reschedule marijuana as a schedule II substance.

Despite its consistent opposition to medical marijuana, the federal government can no longer ignore the palpable role marijuana currently plays as a medicine for many patients across the country. The marijuana plant is not a suitable medicine under the United States medical model; it is, however, currently used medicinally and should therefore be treated as an alternative medicine. The FDA does not regulate alternative medicines and supplements currently available, such as herbal remedies and homeopathic products, in the same manner as traditional prescription and over-the-counter medications. Marijuana smoked as a medicine does not fit neatly into either category; it is certainly different from traditional Western medications, yet it is not simply an herbal product that ought to have loose regulations. Given the unique nature of marijuana as a medicine, the most proper means to regulate the substance is through the development of a new and separate federal agency. The most effective manner to regulate medical marijuana at the federal level is to structure a new program that would mimic the models used to provide opioid-addiction treatment in the United States.

145. See supra text accompanying note 5.
146. See supra section I.B.2 (detailing federal opposition to medical marijuana).
A. BACKGROUND ON OPIOID-TREATMENT PROGRAMS

There are two primary treatment protocols available for treating opioid addiction: treatment with methadone, implemented in 1972, and treatment with buprenorphine, implemented in 2002.\(^{148}\) Methadone is a schedule II substance that acts on opioid receptors in a manner similar to that of other narcotic medications.\(^{149}\) Methadone treatment requires patients to visit specially accredited clinics on a daily basis to receive doses of the medication, which is prescribed by specially registered physicians.\(^{150}\) Treatment with buprenorphine, a schedule III substance that acts on opioid receptors to a lesser extent than methadone,\(^{151}\) permits the use of outpatient access for opioid-addiction treatment but also may only be prescribed by specially registered physicians.\(^{152}\) Given the more tightly regulated nature of methadone, yet flexibility of buprenorphine with access at outpatient pharmacies,\(^{153}\) a combination program seems the most practicable medical model for medical marijuana to emulate.

Similar to the use of marijuana as a medicine, the use of narcotics to treat opioid addiction has been a debated topic.\(^{154}\) The controversial opioid-addiction-treatment program involves providing narcotics to patients who are known to be addicted to and have abused prescription drugs such as oxycodone or illegal drugs such as heroin.\(^{155}\) Despite widespread criticism of such a treatment protocol, the implementation of the opioid-treatment program is a hallmark example of the government accepting the real-life practicalities of drug use and taking measures to better control the use of addictive drugs.\(^{156}\) An essential aspect of methadone and buprenorphine treatment is that, due to the unique characteristics of treatment and strict indications for use, the federal government has treated the medications differently than other medications within the same controlled-substance schedule.\(^{157}\)

Though methadone was originally overseen by the FDA, as is typical of other prescription medications, in 2001 the oversight of methadone-treatment

\(^{148}\) See Steven L. Batki et al., Medication-Assisted Treatment For Opioid Addiction in Opioid Treatment Programs, Dep’t of Health & Human Servs. 22 (2005), http://www.ncbi.nlm.nih.gov/books/NBK64157/.

\(^{149}\) See id. at 26.

\(^{150}\) See 21 U.S.C. § 823(g)(2) (2006); Batki et al., supra note 148, at 63 (patients are required to take the medication on-site due to the risk of drug diversion).

\(^{151}\) See Batki et al., supra note 148, at 22, 26.


\(^{154}\) See generally Batki et al., supra note 148, at 11–16.


\(^{156}\) Id.; see also Batki et al., supra note 148, at 22.

\(^{157}\) See Batki et al., supra note 148, at 22.
programs shifted from the FDA to the Substance Abuse and Mental Health Services Administration’s (SAMHSA) Center for Substance Abuse Treatment.\textsuperscript{158} The FDA had previously been responsible for approving eligibility, dosages, and other related details of methadone-treatment programs.\textsuperscript{159} However, the 1995 IOM study found the FDA’s regulations were impeding physicians’ work and thereby depriving patients of quality care, leading the IOM to recommend a shift in oversight to end arbitrary restrictions on treatment practices.\textsuperscript{160} This administrative change allowed for a balance between the need to maintain tight regulations on methadone and the desire for physicians to focus on treatment without regulations hindering quality care.\textsuperscript{161}

Under the new regulatory scheme, SAMHSA-approved accreditation bodies must review opioid-treatment programs for accreditation, including site visits by specialists.\textsuperscript{162} Once accredited, programs are evaluated for certification using SAMHSA-established guidelines, developed by expert panels, to determine whether the program is qualified to meet SAMHSA’s standards.\textsuperscript{163} In addition to the SAMHSA requirements, the Narcotic Addict Treatment Act (NATA) of 1974 amended the CSA to establish additional procedures for the approval and licensing of prescribers involved in opioid-addiction treatment.\textsuperscript{164} Prescribers must complete an additional registration with the DEA specifically for narcotic treatment and the Department of Health and Human Services must approve prescribers as qualified according to treatment standards.\textsuperscript{165}

Though buprenorphine is regulated less stringently than methadone, its prescribers must also meet additional requirements. The Drug Addiction Treatment Act of 2000\textsuperscript{166} amended the CSA such that prescribers may waive the additional registration requirement of the NATA yet still prescribe buprenorphine under a special DEA registration number.\textsuperscript{167} In addition to being licensed and holding a

\begin{footnotes}
\item[158] See id.
\item[159] Id.
\item[163] See Batki et al., supra note 148, at 22–23.
\item[164] See Drug Enforcement Admin., supra note 54, at 52. Before this Act was passed, “any physician with a DEA registration could prescribe methadone for . . . addiction treatment.” Batki et al., supra note 148, at 21.
\item[165] See Batki et al., supra note 148, at 21.
\end{footnotes}
valid DEA registration number, to qualify for a waiver, physicians must also participate in additional trainings or certifications.\textsuperscript{168} Prescribers must also attest to provide specific referrals and treatment recommendations and are limited to a maximum of thirty patients during the first year of registration.\textsuperscript{169}

This medical model, structured with a focus on practitioner restrictions and made effective through best practice guidelines established by experts in the field,\textsuperscript{170} strikes the proper balance in regulating controlled substances effectively while permitting quality care for a unique area of medicine.

\textbf{B. APPLYING THE OPIOID-TREATMENT-PROGRAM MODEL TO MEDICAL MARIJUANA}

The handling of opioid-treatment programs is a hallmark example of the inability of certain medical protocols to fit neatly into traditional federal drug regulations. The approach to medical marijuana should be treated similarly. To best address the problems present in medical-marijuana laws, a federal agency separate from the FDA should structure a medical model for marijuana. First, the mere establishment of a federally driven program would allow for a resolution of the conflict of law and provide a uniform standard for the medical-marijuana program. Medical marijuana should be regulated through a tripartite system, as are opioid-treatment programs: by the federal agency, the DEA, and the states.\textsuperscript{171} With federal laws setting regulations specifically addressing medical marijuana, state laws would have to conform, allowing for better control against violations at the state level.\textsuperscript{172} Given the federal government’s resistance to incorporating marijuana into the traditional medical system, mirroring the treatment of opioid-treatment programs would permit the separate federal agency to greatly improve regulation and maintain control by the DEA, yet it would allow the FDA and DEA to maintain their stances against medical marijuana.\textsuperscript{173}

Like the opioid-treatment program, the medical-marijuana program ought to focus its restrictions on prescribers, who may then utilize guidelines to select appropriate patients.\textsuperscript{174} Similar to opioid-treatment programs, where physicians

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{168} See 21 U.S.C. § 823(g)(2)(B); see also \textsc{batki et al.}, \textit{supra} note 148, at 23.
\item \textsuperscript{169} 21 U.S.C. § 823(g)(2)(B).
\item \textsuperscript{170} \textsc{batki et al.}, \textit{supra} note 148, at 23.
\item \textsuperscript{171} Mimicking this three-party system would not only allow states to include stricter regulations as appropriate, but would also give states the freedom to decide whether to establish an intrastate medical-marijuana program.
\item \textsuperscript{172} Although marijuana violations at the state level may vary, setting stricter standards from the federal end that apply to the states would greatly increase control, considering ninety-nine out of every one hundred marijuana arrests occur at the state level. \textit{See, e.g., Mich. Comp. Laws} § 333.26422(b) (Supp. 2011).
\item \textsuperscript{173} Maintaining marijuana as a schedule I substance under the CSA yet permitting a separate agency to regulate marijuana use as a medicine would allow for this delicate balance by establishing appropriate regulation over a widely used controlled substance. At the same time, the proposal would not require the DEA to classify marijuana as a medicine and would thus allow for prevalent prescribing in the same manner in which other schedule II substances are handled.
\item \textsuperscript{174} The current medical-marijuana laws tend to focus too greatly on patient characteristics and far too little on the practitioners who are the ultimate safeguards to marijuana access.
\end{itemize}
\end{footnotesize}
must apply for a special DEA registration number to prescribe opioids for addiction, the medical-marijuana program ought to require that physicians specially register with the DEA, ideally for a unique DEA number that permits the prescribing of medical marijuana in limited circumstances despite its status as a schedule I controlled substance. In order to register, physicians likewise should be licensed with a DEA registration number in good standing and required to undergo additional certifications and trainings. As with buprenorphine prescribing, physicians should also be restricted in the number of patients they may maintain, and they should attest to provide specific referrals and treatment recommendations as specified by the federal agency. Prior to prescribing, physicians should also be approved by the federal agency as qualified according to treatment standards. Restricting and controlling the distribution of medical marijuana from the prescriber’s end rather than by patient eligibility is a more effective means to control ease of access, limit fraud, audit for appropriateness, and enhance medical care.

As pharmacies dispensing buprenorphine must register with the DEA and practitioners dispensing methadone must obtain a separate DEA registration as a Narcotic Treatment Program, dispensaries wishing to dispense marijuana should likewise be required to register specially with the DEA. Furthermore, as pharmacists are required to register with the respective state’s board of pharmacy, dispensers ought to be required to register through a parallel system specific to medical marijuana. Dispensers would be required to assess the appropriateness of the prescriber’s prescription and guard against abuse by maintaining patient profiles and entering information into a prescription-monitoring program as utilized for other controlled substances. Dispensaries should only be able to purchase marijuana from manufacturers or distributors who have also specially registered with the DEA.175 Patients ought to be dispensed medical marijuana only with a valid prescription from a specially registered physician, and the medical marijuana should be legally transferrable to the patient only through a specially registered dispensary. Quantities of dispensed medical marijuana ought to be limited to a thirty-day supply or less,176 as established by dosing guidelines. Limiting the day supply of marijuana will guard against diversion and apply an appropriate limit on legal possession. Heightened regulations on dispensaries will further provide a better means to prevent patient abuse and ease of access, enhance quality of care, and correct for the corruption present in many dispensaries.

175. If production of marijuana is permitted to occur on site, then the dispensary also should require a special DEA registration number for manufacturing.

176. A thirty-day supply limit is standard for highly regulated controlled substances. Opioid treatment programs often tend to allow varying daily supply limits based on factors such as the time period over which the patient has been treated. For example, some practices will limit a new patient to no more than a seven-day supply. See generally State-by-State Opioid Prescribing Policies, MEDSCAPE TODAY, http://www.medscape.com/resource/pain/opioid-policies (last visited Mar. 25, 2013).
C. NECESSARY STEPS TO IMPLEMENTATION

In addition to these regulatory changes, there are several areas of uncertainty that must be addressed in order to implement a federal medical-marijuana program as proposed in this Note. Most importantly, it is imperative that further research be conducted on medical marijuana for the purposes of assessing therapeutic appropriateness and to establish requirements on the cultivation of pharmaceutical-grade marijuana. As articulated by one commenter, “[g]iven the limited sources of support for research on marijuana (pharmaceutical companies, for example, are not interested in supporting such research), the U.S. government by now should have . . . sponsored its own clinical trials through the National Institutes of Health.”\textsuperscript{177} Although the federal stance on medical marijuana persists in urging that marijuana is not in fact appropriate for medicinal use, only with further studies will the government be able to appropriately narrow the indications for use of marijuana and better control access.\textsuperscript{178} Furthermore, additional studies are needed to determine appropriate dosing protocols, control against abuse, and limit unnecessary side effects.

Additional studies will assist with the creation of guidelines for specially registered physicians to determine which patients are eligible for medical marijuana and will further promote adequate healthcare in choosing better solutions for patients when medical marijuana is not a suitable option. This will not only correct for the overbroad indications for use, but will also provide for additional patient-specific criteria for determining whether marijuana is an appropriate option. Guidelines should specify appropriate indications for use, correlated with definable diseases, in order to ensure proper prescribing and prevention of abuse. Guidelines should further specify the point in treatment at which qualified physicians might nonnegligently consider medical marijuana as a therapeutic option. In addition, guidelines should specify the need for an established physician–patient relationship, the need for an adequate review of medical history, and a requirement that patients attempt and fail traditional therapies before permitting medical marijuana as a viable treatment option. Once a physician has determined that a patient is eligible for medical marijuana, the guidelines should also indicate appropriate doses, duration of therapy, follow-up protocols, and required monitoring in order to assess effectiveness and safeguard against potential adverse side effects, such as decreased lung function. Without further research limiting appropriate indications and establishing sound guidelines for registered physicians and dispensers, the practitioners


\textsuperscript{178} Many proponents have deemed the DEA resistant to provide support or pursue clinical studies, often suggesting that the lack of motivation is political in nature. See, e.g., id. at 655. However, in its January 2011 report, the DEA announced that as of December 2010, 111 researchers have registered with the DEA to perform studies on marijuana and its components, and the DEA has further approved fourteen researchers to conduct research of smoked marijuana on human subjects. DEA ON MARIJUANA, supra note 60, at 5.
held responsible for controlling medical-marijuana access will be uninformed of what patient access is in fact appropriate.

The second area of improvement relates to the regulation of cultivating medical marijuana. Some states have drafted guidelines on pharmaceutical grade requirements, but further research is needed to support manufacturing methods and to establish specific standards for medical marijuana. Given the existence of state laws that currently permit medical-marijuana patients to cultivate their own marijuana, the program would also have to in some way address controlling against private production. Regulations would likely have to categorize marijuana not of pharmaceutical grade as illegal marijuana, regardless of patient establishment, with regulations stressing enforcement at the state level. Alternatively, regulations could allow for an exception where prescribers authorized established patients to cultivate a limited amount of medical marijuana at home, with some method of consumption control in place, perhaps through mandatory drug testing to quantify the concentration of THC. Given the prevalence of marijuana use and its ease in production, regulations will have to be careful in balancing a prohibition on nonpharmaceutical-grade marijuana with acknowledgement that home cultivation will continue to persist. Without regulations that acknowledge the widespread presence of homegrown marijuana, it is likely that the federal medical-marijuana program would continue to drive individuals to the privatized marijuana trade, making the medical model futile.

CONCLUSION

The current state of medical-marijuana laws across the country is in critical need of reform—reform that will only take place if applied in a manner practicable with our medical system. The regulations currently in place do not adequately implement clinical research to frame its guidelines, nor do they control the distribution of marijuana in a manner that would ensure that the ultimate user is in fact a qualified patient. The regulations miss the mark in not restricting the practitioners or requiring training for those who may recommend marijuana, and they do little to control permissible doses of marijuana. Regulations over dispensaries are unsatisfactory, and allowing home cultivation for any qualifying patient sacrifices too much control over a substance currently classified as having a high risk of abuse. Given the unsatisfactory level of these regulations coupled with the direct contradiction they pose with federal law, it is time for the federal government to step in and regain its control over what it has determined to be an illegal substance.

An end must come to permitting the public to decide what “good medicine”

---

179. Michigan recently proposed a bill, subject to approval as of this writing, specifying that pharmaceutical-grade cannabis must be free of chemical residues, tested to verify cannabinoid levels, and in compliance with specified manufacturing practices. H.B. 5681, 2011-2012 Sess. art. 8 (Mich. 2012).
is and what indications marijuana ought to treat. The federal government and its agencies, along with many citizens, may not agree with the acceptability of smoking marijuana in its crude form for medicinal purposes. However, the federal government cannot simply turn a blind eye to the state legalization of medical marijuana; it must take affirmative action. To achieve proper regulation of medical marijuana, the federal government ought to structure a medical program tailored to the unique needs of marijuana, with opioid-treatment programs serving as a framework for medical-marijuana regulations to emulate. The program must better regulate the physicians, dispensaries, manufacturers, and consequently, the patients that are involved with medical marijuana, in order to better control access to the substance. With the federal government initiating the program, laws across the country will not only become uniform but also will put the control of a controlled substance where it rightly belongs and away from where it never should have been placed—the public. Paradoxically, federal support of medical marijuana through the implementation of a federal program is the only feasible means to effectively restrict marijuana use.