

5-1-2014

# Weeding the Garden State: Remaining in Compliance With Federal Guidelines by Adopting a Proper Medical Model for Smoked Marijuana

Matthew M. Siti

Follow this and additional works at: [https://scholarship.shu.edu/student\\_scholarship](https://scholarship.shu.edu/student_scholarship)

---

## Recommended Citation

Siti, Matthew M., "Weeding the Garden State: Remaining in Compliance With Federal Guidelines by Adopting a Proper Medical Model for Smoked Marijuana" (2014). *Law School Student Scholarship*. 576.  
[https://scholarship.shu.edu/student\\_scholarship/576](https://scholarship.shu.edu/student_scholarship/576)

## Weeding the Garden State

*(Remaining in Compliance With Federal Guidelines by Adopting a Proper Medical Model for Smoked Marijuana)*

By Matthew Siti  
Seton Hall School of Law, Fall 2013

### **Introduction:**

If popular culture is indicative of public perception, the average person's concept of medical marijuana probably involves a good-natured, smiling pharmacist, wearing the traditional white coat but possibly sporting a grey ponytail, handing a trembling chemotherapy patient a prescription bottle containing a healthy-sized, shimmering nugget of government-grade marijuana. Perhaps they even picture a yellow smiley faced stamped neatly on the otherwise ordinary, orange prescription bottle, comforting the needy patient as he heads home to pack his pipe. Fortunately, or unfortunately, depending on how you view the issue, this is a fantasy. To begin, the fabled "government grade" cannabis isn't particularly good.<sup>1</sup> In addition, rather than a trusted, licensed pharmacist doling out medicine, often statutorily authorized dispensaries act in their place. Further, doctors are understandably hesitant to endorse a medicine whose most successful delivery method is via smoke.<sup>2</sup> To some, the idea stands in direct opposition to the Hippocratic oath they've sworn to uphold.<sup>3</sup> Though the limited body of credible research on cannabis has given the medical community pause, the majority is not convinced that the benefits outweigh the risks. Without consistent support from the medical profession, cannabis seems destined to be relegated into the somewhat ambiguous realm of "alternative medicine."

---

<sup>1</sup> Haney M, et al., *Dronabinol and Marijuana in HIV-Positive Marijuana Smokers: Caloric Intake, Mood, and Sleep*, 45(5) J. ACQUIR. IMMUNE DEFIC. SYNDR. 545 (2007) (reporting 3.8% THC content in NIDA-grown marijuana).

<sup>2</sup> William Vertes & Sarah Barbantini, *Caught in the Crossfire: The Dilemma of Marijuana "Medicalization" for Healthcare Providers*, 58 WAYNE L. REV. 103, 114 (2012).

<sup>3</sup> *The Role of the Physician in Medical Marijuana*, American Society of Addiction Medicine (April 10, 2010), [http://www.asam.org/docs/publicity-policy-statements/1role\\_of\\_phys\\_in\\_med\\_mj\\_9-10.pdf?sfvrsn=0](http://www.asam.org/docs/publicity-policy-statements/1role_of_phys_in_med_mj_9-10.pdf?sfvrsn=0) (medical marijuana violates the first principle, "do no harm").

Beyond this, prescription drugs are rarely, if ever, handed out in the form of raw plant matter.<sup>4</sup> For instance, though opioids are a derivative of the poppy plant, pharmacists do not distribute poppy seeds. Instead, the plant is processed and refined into pill form. Pharmacists are creatures of precision, at times relying on measurements down to a thousandth of gram in order to tailor medicine perfectly to individual patients in a celebrated process known as pharmacy compounding.<sup>5</sup> This presents an unusual obstacle for the pharmacist because raw marijuana plant matter is subject to significant fluctuations in effect and potency from plant to plant.<sup>6</sup> Ultimately, even if physicians and pharmacists were completely on board with medical cannabis, they would still lack a standardized treatment program, let alone the research to develop one. Section VII of this paper will explain how this problem could be temporarily addressed somewhat easily, allowing pharmacists to continue playing their essential role as pharmaceutical gatekeepers.

In 2010, New Jersey passed the Compassionate Use Medical Marijuana Act<sup>7</sup>, which until recently, stood in direct conflict with a federal law that outlaws marijuana for any purpose. In August 2013, the Department of Justice issued a memo<sup>8</sup> to prosecutors, which embodies a substantial departure from the previous federal stance on marijuana. In essence, the Department is willing to allow states to legalize marijuana in ways that comport with the federal government's goals.<sup>9</sup> With its medical marijuana law still in its infancy and the Department's blessing, New Jersey stands in prime position to define the national standard for an effective medical cannabis program. Through diligent formation of a comprehensive program, New Jersey

---

<sup>4</sup> Claire Frezza, *Medical Marijuana: A Drug Without A Medical Model*, 101 GEO. L.J. 1117, 1134 (2013).

<sup>5</sup> *Pharmacy Compounding*, U.S. Food & Drug Administration (last updated Dec. 2, 2013), [www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding](http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding). (Describing process of Pharmacy Compounding.)

<sup>6</sup> Frezza, *supra* note 4, at 1134.

<sup>7</sup> Compassionate Use Medical Marijuana Act, N.J. STAT. ANN. § 24:6I-1 (West 2011).

<sup>8</sup> James M. Cole, *Memorandum For All United States Attorneys*, U.S. Department of Justice (Aug. 29, 2013), <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>.

<sup>9</sup> *Id.* at 4.

can lead the country in a specialized area of treatment. This paper examines several factors New Jersey legislatures and the Department of Health would do well to consider in the development of its medical cannabis program.

To provide context, section I of the paper investigates the principal debates surrounding the use of smoked marijuana. Section II discusses the Controlled Substance Act,<sup>10</sup> which represents the Federal Government's position on marijuana and explores the conflict it has created with state laws legalizing medical marijuana. Section III considers the Department of Justice's dramatic new shift in its outlook on cannabis and explains the requirements it places on state marijuana programs.<sup>11</sup> Section IV examines New Jersey's new, untested medical marijuana statute<sup>12</sup> and notes specific points of federal compliance. Parts V, VI and VII then examine three things New Jersey should consider in the continued development of its program: a strong emphasis on sustained research, adherence to the principles of functional medical models and a regulatory scheme which considers the strengths of the Model Opioid Treatment Program.<sup>13</sup> All three components work in conjunction, ensuring New Jersey remains in strict compliance with Department guidelines, ultimately providing patients in genuine need with sustained access to effective relief.

## **I. Why Smoked Marijuana Needs to Remain an Option:**

### *A. Lung Cancer:*

When it comes to marijuana, perhaps the hardest issue for anyone to look past is the smoke inhalation that accompanies consumption. While it's often framed in black and white terms by detractors, the issue is as unclear as smoke itself. Perhaps the question to ask (and answer with

---

<sup>10</sup> Controlled Substances Act, 21 U.S.C. Ch. 13 (2012).

<sup>11</sup> Cole, *supra* note 8.

<sup>12</sup> Compassionate Use Medical Marijuana Act, N.J. STAT. ANN. § 24:6I-1 (West 2013).

<sup>13</sup> *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*, Federation of State Medical Boards (July 1, 2013), [http://www.fsmb.org/pdf/pain\\_policy\\_july2013.pdf](http://www.fsmb.org/pdf/pain_policy_july2013.pdf).

much-needed research) is not *whether* to standardize smoked marijuana as a medicine, rather, *who* should it be standardized for? Currently, the consensus amongst studies on whether smoked marijuana causes lung cancer remains undecided. Some declare marijuana smoke a likely contributor to pulmonary cancer,<sup>14</sup> while others determine there is no causal link.<sup>15</sup> Even if smoked marijuana was established as a cause of lung cancer, this would not disqualify it from medicinal use. Tobacco has been clearly connected to lung cancer,<sup>16</sup> yet remains legal to any adult for unlimited consumption. If this standard isn't applied to consumer products, it shouldn't be determinative in evaluating something as important as medicine. Taking this idea into a medical context, one need only recall the last time they watched television. When channel surfing, it seems impossible to avoid being bombarded with generic ad campaigns for the latest prescription drug. You're probably familiar with the type; a dissonant, emotional soundtrack coupled with sentimental imagery. The images are presented in soft-focus, lending a dream-like quality to the message. A gentle, non-judgmental voice sympathizes with the target audience, offering a new solution to their woes. "It's time for you to get back to living..." it says warmly. As the slow motion shot of the smiling old man hugging his granddaughter overlaps with a shot of him chipping on a sunny golf course, the voice reminds you that this drug "is not for everyone" and suddenly picks up the tempo, reeling off a horrifying list of potential side effects. The logical deduction made from years of watching these types of ads is simple: the potential to cause death or serious harm is not determinative in the evaluation.

Beyond this, there are two populations who remain candidates, despite the risk of lung cancer: those who are not responsive to traditional prescription drugs and those who are

---

<sup>14</sup> Sarah Aldington et al., *The Effects of Cannabis on Pulmonary Structure, Function and Symptoms*, 62 THORAX 1058, 1062 (2007).

<sup>15</sup> Marc Kaufman, *Study Finds no Cancer-Marijuana Connection*, WASH. POST, May 26, 2006, at A3.

<sup>16</sup> *Smoking*, National Cancer Institute, <http://www.cancer.gov/cancertopics/tobacco/smoking/> (last visited Nov. 28, 2013).

terminally ill. At an absolute minimum, members of both groups must be entitled to access. Principles of personal autonomy dictate, as with other prescription drugs, patients should be allowed to assess the risks with their doctor's blessing and decide for themselves.<sup>17</sup> The man who is finally getting relief from formally uncontrollable seizures should decide if the unsubstantiated risk is worth it. Somewhere along the line, politics, not science, made the decision for him. It is important to note this is most definitely an area research would address and supplement with additional knowledge, allowing more concrete resolution.

### B. *The Gateway Theory:*

One of the most commonly employed arguments against marijuana is the alleged function as a “gateway” which opens the door to harder drugs. This argument doesn't merit significant rebuttal for two reasons: first, there is zero scientific evidence supporting this theory.<sup>18</sup> Second, even if the gateway hypothesis were scientifically supported, we don't disqualify medicine based solely on its capacity for abuse. Acclaimed medical researcher and author Peter Cohen put it best when he said “It would be unfortunate, indeed, if opioid-induced pain relief were denied during or after surgery because of concern about its possible risks, while ignoring its known benefits.”<sup>19</sup>

In sum, while the theory's simple logic may appeal to some, it simply is not determinative in the medical context. In fact, the irony of the theory is it implies absent this gateway function, marijuana is not cause for concern on its own. It's only the drugs that come after (such as OxyContin®<sup>20</sup>) that society is worried about.

### C. *Why Current Alternatives Are Not Adequate:*

---

<sup>17</sup> Andrew J. Boyd, *Medical Marijuana and Personal Autonomy*, 37 J. MARSHALL L. REV. 1253, 1286 (2004).

<sup>18</sup> Peter J. Cohen, *Medical Marijuana: The Conflict Between Scientific Evidence and Political Ideology*, 70 UTAH L. REV. 35, 69 (2009).

<sup>19</sup> *Id.* at 69.

<sup>20</sup> Steven A. Tolman, *Opinion Addressing The State's OxyContin Epidemic*, Health Care News (Aug. 2005), <http://healthcarenews.com/opinion-addressing-the-states-oxycontin-epidemic/>.

Currently, synthetic THC exists. Nonetheless, its availability does not preclude the use of smoked cannabis. In 1986, Marinol®, a synthetic THC, was introduced. The drug's shortcomings became apparent quickly. Many patients weren't satisfied with its capacity to relieve symptoms as quickly or efficiently as smoked marijuana.<sup>21</sup> In addition, a primary use is treatment of nausea, thus, being a pill is an inherent design flaw. Further, it is significantly more expensive than traditional cannabis.<sup>22</sup> More recently, synthetic THC was developed into an oral spray, Sativex®. While this medication seems more promising than Marinol®, it is currently in Phase III clinical trials in the US,<sup>23</sup> and therefore, unavailable to US patients. Regardless of synthetic THC's status, smoked cannabis must remain a viable alternative to the non-responsive. Moreover, availability of a prescription drug is not determined solely by the existence of better alternatives. So long as it is effective, the drug doesn't need to be the best.<sup>24</sup>

## **II. The Controlled Substance Act and the State's Cannabis Conflict:**

In 1970, President Nixon signed Title II of the Drug Abuse Prevention and Control Act<sup>25</sup> into law. Known as the Controlled Substances Act (hereafter, CSA), it makes certain substances illegal and groups them into one of five schedules.<sup>26</sup> Each schedule has a set of unique qualifying criteria a drug must meet in order to be subject to a particular schedule's rules, regulations and exceptions. Marijuana is listed under schedule I of the CSA.<sup>27</sup> A schedule I substance is categorized by meeting the following three points of criteria: it has a high potential for abuse, a lack of accepted safety for use under medical supervision and no currently accepted medical use

---

<sup>21</sup> Cathryn L. Blaine, *Supreme Court "Just Says No" to Medical Marijuana: A Look at United States v. Oakland Cannabis Buyers' Cooperative*, 39 HOUS. L. REV. 1195, 1224 (2002).

<sup>22</sup> *Id.* at 1224.

<sup>23</sup> Frezza, *supra* note 4, at 1129.

<sup>24</sup> Cohen, *supra* note 18, at 45.

<sup>25</sup> Controlled Substances Act, 21 U.S.C. Ch. 13 (2012).

<sup>26</sup> *Id.* § 812.

<sup>27</sup> *Id.* § 812(a)(c)(1).

in the United States.<sup>28</sup> Whether marijuana has an “accepted medical use” is evaluated based on a 1999 report issued by the Institute of Medicine (hereafter, IOM), which was commissioned by the White House Office of Drug Control Policy.<sup>29</sup> Though the report indicated marijuana exhibited some degree of medical potential,<sup>30</sup> a great deal of concern was placed on the act of smoking and the associated health risks.<sup>31</sup> The CSA carries public safety and health implications, thus, oversight of the CSA is shared jointly between the Drug Enforcement Agency (hereafter, DEA) and the Food and Drug Administration (hereafter, FDA).<sup>32</sup> Regarding the public safety aspect of the Act, the DEA has been charged with determining the scheduling criteria, and has relied almost exclusively on the 1999 report in doing so. A 2005 release issued by the DEA stated: “the IOM...found that there was no scientific evidence that smoked marijuana had medical value, even for the chronically ill, and concluded that 'there is little future in smoked marijuana as a medically approved medication.’”<sup>33</sup> The DEA has held firm to its position, turning down multiple petitions to reschedule marijuana,<sup>34</sup> in addition to winning legal battles in the US Supreme Court.<sup>35</sup> Not surprisingly, in 1996, the enactment of California’s Proposition 219, the nation’s first medicinal cannabis law,<sup>36</sup> sparked fierce controversy about the nature of the dual sovereign, federal supremacy and fundamental rights. Since then, the CSA has withstood several constitutional challenges, including substantive due process,<sup>37</sup> fundamental

---

<sup>28</sup> *Id.* § 812(b)(1).

<sup>29</sup> JANET E. JOY, ET AL., *MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE* (1999).

<sup>30</sup> *Id.* at 101.

<sup>31</sup> *Id.* at 89.

<sup>32</sup> *Id.* § 811(d)(3).

<sup>33</sup> Karen P. Tandy, *Marijuana: The Myths Are Killing Us*, U.S. Department of Justice (Apr. 26, 2005), <http://www.justice.gov/dea/pubs/pressrel/pr042605.html>.

<sup>34</sup> *Americans for Safe Access v. Drug Enforcement Admin.*, 706 F.3d 438 (D.C. Cir. 2013), cert. denied, 134 S. Ct. 267 (U.S. 2013)

<sup>35</sup> *Gonzales v. Raich*, 545 U.S. 1 (2005).

<sup>36</sup> *Compassionate Use Act*, CAL. HEALTH & SAFETY CODE § 11362.5 (West 2013).

<sup>37</sup> *Gonzales v. Raich*, 545 U.S. 1, 20 (2005).

rights<sup>38</sup> and reliance on the commerce power.<sup>39</sup> Over the course of four decades, the CSA has been used to aggressively prosecuting millions of marijuana related offenses, generating life-altering consequences that are often hard to square against the crime.<sup>40</sup> In one state, possession of a gram of marijuana may lead to the equivalent of a parking ticket,<sup>41</sup> while in another, a person might be given a jail sentence along with thousands of dollars in fines.<sup>42</sup> Even though one might be less inclined to sympathize with those who meet this fate while using recreationally, it is a truly tragic situation for folks who genuinely rely on cannabis for relief from debilitating symptoms. Fortunately, on August 29, 2013, the Department of Justice issued a memorandum to prosecutors, which represents a tremendous shift in the federal outlook on cannabis-related CSA violations.

### **III. The Department of Justice's New Position on Cannabis:**

Recently, the Department of Justice (hereafter, DOJ) issued a restatement of its official position on the prosecution of marijuana related offenses.<sup>43</sup> The announcement was made on the heels of 2011 statement in which the DOJ vowed to continue rigorously prosecuting CSA violations.<sup>44</sup> While the second memo reiterated marijuana would remain an illegal Schedule I drug under the CSA, it instructs federal prosecutors to reprioritize their prosecution of marijuana related offenses.<sup>45</sup> As the memo notes, the primary goals of the CSA include preventing use by minors and preventing large-scale marijuana-related criminal activity, revenue, and related violence.<sup>46</sup> Unfortunately, the reality created by the Act does not comport with those goals. As it

---

<sup>38</sup> *Nat'l Org. for Reform of Marijuana Laws v. Bell*, 488 F. Supp. 123, 133 (D.D.C. 1980).

<sup>39</sup> *Gonzales v. Raich*, 125 S. Ct. 2195, 2196 (2005).

<sup>40</sup> GREG CABBELL, *POT INC.: INSIDE MEDICAL MARIJUANA, AMERICA'S MOST OUTLAW INDUSTRY* 42 (2012).

<sup>41</sup> Jessica Rao, *States Where Pot is a Slap on the Wrist*, CNBC (Apr. 20, 2010), <http://www.cnbc.com/id/36179381>.

<sup>42</sup> Compassionate Use Medical Marijuana Act, N.J. STAT. ANN. § 2C:43-6 (West 2013).

<sup>43</sup> Cole, *supra* note 8.

<sup>44</sup> *Id.* at 3.

<sup>45</sup> *Id.* at 2.

<sup>46</sup> *Id.* at 2.

stands, aggressive enforcement of the Act may have actually contributed to producing the opposite of what was intended. In reality, it is difficult to dispute the Department's former strategy failed to realize its express goals, especially when one considers the facts. As of 2013, the federal government has expended over 20 billion taxpayer dollars prosecuting marijuana related offenses that are often trivial in terms of quantity and motive.<sup>47</sup> In 2011, 750,000 Americans were arrested for marijuana related offenses, an average of one arrest every 42 seconds.<sup>48</sup> Police officers have been known to charge possession of paraphernalia *and* possession of a controlled dangerous substance based solely on the residual marijuana tar left inside of a pipe.<sup>49</sup> This relentless prosecution of small offenses has blemished many otherwise clean criminal records, haunting those charged for the rest of their lives. Despite these enormous fiscal, judicial and medical casualties of total prohibition, marijuana use remains as prevalent as ever.<sup>50</sup>

Moreover, the government's inability to regulate marijuana creates a perfect environment for criminal control of marijuana. In a technical sense, the very existence of the CSA is the reason drug-based criminal organizations have a black market in which to thrive. A drug dealer may argue if not for the CSA, he would be out of business.

However, few enjoy admitting defeat, and the DOJ is no exception. Rather than directly stating prohibition was a failure, its memo is couched in terms of a new understanding of prosecutorial priorities.<sup>51</sup> It indicates goals have not changed; rather, its interpretation of said

---

<sup>47</sup> CAMELL, *supra* note 40 at 42.

<sup>48</sup> Matthew Sledge, *Marijuana Prohibition Now Costs The Government \$20 Billion A Year: Economist*, The Huffington Post (Apr. 20, 2013), [http://www.huffingtonpost.com/2013/04/20/marijuana-prohibition-costs\\_n\\_3123397.html](http://www.huffingtonpost.com/2013/04/20/marijuana-prohibition-costs_n_3123397.html).

<sup>49</sup> *The People v. Michael Harold Pohle*, 20 Cal.App.3d 78 (1971).

<sup>50</sup> *Drug Facts: High School and Youth Trends*, National Institute on Drug Abuse (Dec. 1, 2012), <http://www.drugabuse.gov/publications/drugfacts/high-school-youth-trends>.

<sup>51</sup> Alex Kreit, *Federal Response to State Marijuana Legalization: Room for Compromise?*, 91 OR. L. REV. 1029, 1034 (2013).

goals has changed.<sup>52</sup> The memo also casually implies a lack of resources, not strategy, was the actual cause of the failure.<sup>53</sup> A failure the DOJ is not *necessarily* admitting occurred. Tricky, to be sure, but luckily, the bottom line of the memo is not as ambiguous, and it represents a stark contrast to past positions. For the first time ever, the DOJ is recognizing that allowing state governments to control and regulate marijuana may actually help accomplish CSA goals. Under the DOJ's new approach, state laws which legalize marijuana while simultaneously bolstering the CSA's goals won't incur the wrath of the federal government. However, the DOJ made clear that the memo does not represent a cannabis free-for-all. To gain this theoretical immunity, it expects states promulgating marijuana legislation to carefully develop marijuana laws with the goals of the CSA in mind.<sup>54</sup>

Though questions still remain for recreational marijuana, the memo undeniably gives medical use the green light. In addition, it allows for the redirection of millions of state taxpayer dollars previously expended prosecuting petty charges towards more pressing matters. While the memo makes no mention of public sentiment, it clearly reflects a changing tide in the popular perception of marijuana.<sup>55</sup>

#### **IV. A Proper Medical Model:**

In implementing medical cannabis regulation, the New Jersey legislature and courts could benefit from consideration of proper medical models. Doing this will accord validity to cannabis as a medicine, while simultaneously allowing New Jersey the opportunity to lead the nation in developing a standard model medical marijuana program. To begin, a proper medical model

---

<sup>52</sup> Cole, *supra* note 8 at 2.

<sup>53</sup> *Id.* at 2.

<sup>54</sup> *Id.* at 2.

<sup>55</sup> *A Bag of Weed*, Family Guy Wiki, [http://familyguy.wikia.com/wiki/A\\_Bag\\_of\\_Weed](http://familyguy.wikia.com/wiki/A_Bag_of_Weed) (last visited Dec. 1, 2013).

involves approval from the Food and Drug Administration (Hereafter FDA).<sup>56</sup> The difficulties associated with this component are discussed in section VI. Moreover, in a proper medical model, a licensed pharmacist distributes prescription drugs. Notice there are no raw opium dispensaries now, nor are they on the horizon. This topic will be covered in greater detail in section VII of the paper. However, awareness of the existence of the roles of pharmacists and the FDA aids in understanding the rest of the medical model. Parts A through G of this section analyze the fundamental components of a functional medical model.

*A. Additional Dispenser Assessment:*<sup>57</sup>

A proper medical model for a drug with significant potential for user dependence requires an additional opportunity for assessment on the part of the dispenser. Under the model proposed herein, this person would be the pharmacist. Placing this liability with the dispenser provides an additional patient safeguard, as the pharmacist is subject to oversight and licensure by state pharmacy boards as well as the DEA.<sup>58</sup>

*B. Doctor Patient Relationship:*<sup>59</sup>

An indispensable element of a functional medical model for a drug like marijuana is establishment of the doctor patient relationship. The prescribing doctor is tasked with a heightened responsibility for the care of the patient. Negligent observation of this duty has the potential to destroy both the doctor and patient's lives alike. Thus, doctors are quite motivated to remain vigilant for patient abuse and act once it's detected. The additional liability created by formation of this relationship will help reinforce state compliance with the DOJ's demand for tight regulation. This is especially true because physicians prescribing certain drugs scheduled

---

<sup>56</sup> Cohen, *supra* note 18, at 45.

<sup>57</sup> Frezza, *supra* note 4, at 1142.

<sup>58</sup> *Id.* at 1142.

<sup>59</sup> Peter J. Cohen, *Medical Marijuana 2010: It's Time to Fix the Regulatory Vacuum*, 38 J.L. MED. & ETHICS 654, 661 (2010).

under the CSA, such as opioids, are required to register with the DEA in order to prescribe said drugs.<sup>60</sup>

### *C. Practitioner Requirements:*<sup>61</sup>

A traditional medical model contemplates practitioner requirements promulgated by state medical boards.<sup>62</sup> As it should be, medical boards' decision making is rooted in science, not politics. As will be discussed in section V, New Jersey has delegated regulatory responsibility to the New Jersey Department of Health (hereafter, DOH). This raises the question of whether the DOH is truly in the most knowledgeable position to create practitioner requirements. After adequate research has been conducted, New Jersey might consider delegating decision-making authority to its state medical boards, which can then make applied, best practice decisions about practitioner requirements. In the meantime, the DOH should develop regulations with a similar mindset.

### *D. Patient Qualifications:*<sup>63</sup>

Like practitioner requirements, standard medical models for specific drugs also have uniform, albeit flexible, patient qualifications. New Jersey's statute provides a short list of qualifying conditions and vests discretion in the DOH to add additional ailments to the list.<sup>64</sup> While it probably isn't realistic to think the Legislature will re-delegate this authority to state medical boards anytime soon, courts and administrative agencies would be wise to interpret the statute with an eye toward a flexible patient standard which acknowledges the evolving medical context of the drug.

### *E. No Home Cultivation:*

---

<sup>60</sup> *Id.* at 660.

<sup>61</sup> Frezza, *supra* note 4, at 1123.

<sup>62</sup> Cohen, *supra* note 59, at 660.

<sup>63</sup> Frezza, *supra* note 4, at 1121.

<sup>64</sup> Compassionate Use Medical Marijuana Act, N.J. STAT. ANN. § 24:6I-1 (West 2013).

Just as society doesn't allow opioid patients to grow opium at home, nor should we allow marijuana patients to personally cultivate cannabis. While this concept may seem particularly harsh in the case of marijuana, the delicate nature of the current compromise between the state and federal governments necessitates it. Without regard for recreational users, ensuring the continuity of the program within NJ for patients in need is absolutely paramount. Along with personal cultivation comes a distinct lack of government oversight. Thus, prohibiting home growth embodies the type of substantive restriction the DOJ memo calls for.

#### *F. Distinguishing Between Minors and Adults:*

A medical model for a specific drug generally distinguishes between minors and adults. Given the psychoactive nature of THC, it is imperative to consider the effects usage might have on minors, whose brains are still developing, as opposed to adults, whose brains are fully formed. Due to lack of research, it is currently unknown what type of long-term cognitive effects marijuana has on a developing mind.<sup>65</sup> Until more information is available, access to minors in raw form should be strictly limited. This component is also critical in meeting one of the DOJ's express goals of keeping marijuana out of the hands of minors.<sup>66</sup> Without a like provision, New Jersey's program is open to attack from the DEA.

#### *G. Drugged Driving:*

Currently, it is unknown to what extent or in what way marijuana affects driving ability. While it is evidenced that marijuana does affect cognition, one study suggests these effects don't actually impair the ability to drive.<sup>67</sup> Regardless, it is safe to say for the time being, New Jersey

---

<sup>65</sup> Manzar Ashtari, et al., *Diffusion Abnormalities in Adolescents and Young Adults with a History of Heavy Cannabis Use*, 43(3) J PSYCHIATRIC RES.189, 200 (2009).

<sup>66</sup> Cole, *supra* note 8 at 2.

<sup>67</sup> G. CHESHER & M. LONGO, *Cannabis and Alcohol in Motor Vehicle Accidents* 313-323 in: F. GROTENHERMEN & E. RUSSO *CANNABIS AND CANNABINOIDS: PHARMACOLOGY, TOXICOLOGY, AND THERAPEUTIC POTENTIAL* 323 (2002).

would do well to err on the side of caution and develop a set of drugged driving laws aimed at sustaining its medical marijuana program.

## **V. New Jersey's Law:**

Before explaining how New Jersey's statute can be improved, it is necessary to evaluate the statute itself. For those hoping for easy access to medical marijuana, bad news: New Jersey's Compassionate Use Medical Marijuana Act (hereafter, CUMMA)<sup>68</sup> has been called "the most restrictive medical marijuana law in the nation."<sup>69</sup> For individuals who truly need medicinal marijuana, this is great news. Even as the law currently stands, it is not likely to conflict with the goals of the CSA. Patients can be reasonably certain they will have continued access to their medicine. Several provisions of the statute are clearly in line with DOJ objectives.

### *A. Strengths:*

The statute gives a short list of qualifying conditions, which doctors can use to generate a signed certification<sup>70</sup> (not a prescription) for marijuana. In addition, it appears the legislature took some of the concepts of the medical model into consideration when drafting CUMMA. For instance, CUMMA demands that a "bona fide physician patient relationship"<sup>71</sup> be firmly established. It defines this relationship as: "a relationship in which the physician has ongoing responsibility for the assessment, care and treatment of a patient's debilitating medical condition."<sup>72</sup> This is in line with the conception of the doctor patient relationship in standard medical models. The Act also charges the DOH with establishing and maintaining a registry of all patients and their primary caregiver.<sup>73</sup> Once qualified, the DOH issues an ID card to the

---

<sup>68</sup> *Id.* § 24:6I-1.

<sup>69</sup> Cohen, *supra* note 59, at 660.

<sup>70</sup> *Id.* § 24:6I-5.

<sup>71</sup> *Id.* § 24:6I-3.

<sup>72</sup> *Id.* § 24:6I-3.

<sup>73</sup> *Id.* § 24:6I-4.

patient, which expires after two years.<sup>74</sup> To qualify, the patient must have one of the predicate conditions in addition to signed certification from a registered physician.<sup>75</sup> While it would be nice if the physician were able to prescribe the medicine to be filled by a pharmacist who could provide additional oversight, the requirement of physician intervention in the process is a step in the right direction.

The statute's provisions relating to minors are also in line with DOJ goals. Specifically, CUMMA requires written consent to the medical use of marijuana from a parent or legal guardian and a commitment from the parent to "control the acquisition and possession of the medical marijuana and any related paraphernalia."<sup>76</sup> The DOJ maintains that one of its primary directives under the CSA is preventing usage by minors;<sup>77</sup> thus, this provision is absolutely necessary to the program's success.

#### B. *Weaknesses:*

Where CUMMA falls short is in its decision to make DOH-licensed "alternative treatment centers"<sup>78</sup> as the designated NJ marijuana dispensaries. While they are a popular choice in other states, this simply is not in line with proper medical practice. At the very least, the DOH regulations do prevent those with criminal backgrounds from working for the centers,<sup>79</sup> which is very important, as another express DOJ directive is preventing diversion to criminal activity.<sup>80</sup> However, this issue will be discussed in greater detail in section VII.

Another area CUMMA arguably fails is in its regulations. Unlike laws for other types of prescription narcotics, CUMMA delegates authority to regulate prescribing physicians and

---

<sup>74</sup> *Id.* § 24:6I-4.

<sup>75</sup> *Id.* § 24:6I-5.

<sup>76</sup> Melissa Brown, *The Garden State Just Got Greener: New Jersey Is the Fourteenth State in the Nation to Legalize Medical Marijuana*, 41 SETON HALL L. REV. 1519, 1549 (2011).

<sup>77</sup> Cole, *supra* note 8 at 2.

<sup>78</sup> *Id.* § 24:6I-7.

<sup>79</sup> *Id.* § 24:6I-7(a)(c).

<sup>80</sup> Cole, *supra* note 8 at 2.

dispensaries to the New Jersey DOH. With drugs like opioids, physician regulation is delegated to state medical boards, where science, not politics dictate decision making. While the DOH deserves credit for adopting some aspects of the Model Opioid Treatment Program, such as a duty of constant patient reassessment,<sup>81</sup> it would be wise to relinquish authority to the NJ State Medical Boards, who are in a better position to assess physician and pharmacist oversight. Currently, the Commissioner of the DOH is responsible for detailed annual reporting requirements which include: the number of registry applications, the number of registered patients and primary caregivers, the number of revoked cards, the nature of the reported conditions, the number of permits issued to and revoked from alternative treatment centers and the number of participating physicians.<sup>82</sup> This is all the type of information a medical board would want. However, a medical board is in a more informed position to create regulation based off such information. For instance, the DOH has decided that Alternative Treatment Centers (AKA “dispensaries”) are limited to distributing three strains each. Each strain may contain no more than 10% THC.<sup>83</sup> This 10% cap feels arbitrary and whether it is satisfactory to the patient who has built a month’s worth of tolerance<sup>84</sup> remains to be seen.

To recap, the non-permissive nature of CUMMA is an excellent first step in setting a national standard for medical marijuana programs. It demands strict oversight on multiple levels, consistent DOJ guidelines. Despite this, there are several things New Jersey Legislatures and Courts would benefit from taking into consideration when fashioning future laws.

## **VI. Research:**

### *A. Inadequacy of Existing Research:*

---

<sup>81</sup> Compassionate Use Medical Marijuana Act, N.J. ADMIN. CODE 13:35-7A.5(c) (2013).

<sup>82</sup> Compassionate Use Medical Marijuana Act, N.J. ADMIN. CODE 8:64-4.2(a)(2) (2013).

<sup>83</sup> *Id.* 8:64-10.7.

<sup>84</sup> JASON KING, *THE CANNABIBLE* 79 (2007). (“Supreme quality water hash...even at close to 50% THC, smoke it for awhile and the enemy-tolerance-sets in.”)

As one becomes familiar with issues faced by medical cannabis, something becomes clear immediately: there is a dire need for credible research within the United States. Specifically, this research needs to be conducted with a comparative outlook on other prescription drugs.<sup>85</sup> The borderline-insulting lack of research is the result of a vicious, self-feeding cycle. This requires some explanation. The normal avenue drugs take to prescription use is through the FDA. The standards governing this process are established under the Food, Drug and Cosmetic Act (hereafter, FDCA).<sup>86</sup> There is little doubt marijuana meets the FDCA's definition of a "drug". "The term 'drug' means . . . articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other than food) intended to affect the structure or any function of the body of man or any other animals."<sup>87</sup> Nevertheless, prior to entering the prescription market, provisions of the Act require new drugs to be rigorously evaluated in a comprehensive manner. This requires "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved."<sup>88</sup> The FDA shares authority under the CSA with the DEA.<sup>89</sup> Thus, once credible research on the benefits of a scheduled drug becomes available, the FDA may petition the DEA for medical use.<sup>90</sup> Normally, this arrangement works out fine. Perhaps predictably, in the case of marijuana, researchers have encountered great difficulty.<sup>91</sup> The United States is a signatory to the

---

<sup>85</sup> Cohen, *supra* note 18, at 69.

<sup>86</sup> Controlled Substances Act, 21 U.S.C. § 301 (2012).

<sup>87</sup> *Id.* § 321(g)(1).

<sup>88</sup> *Id.* § 355(d).

<sup>89</sup> *Memorandum of Understanding Between the National Institute on Drug Abuse and the Food and Drug Administration*, U.S. Food & Drug Administration (Mar. 10, 2009), <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucml16365.htm>.

<sup>90</sup> Cohen, *supra* note 18, at 50.

<sup>91</sup> Donald I. Abrams, *Letter to NIDA*, Multidisciplinary Association for Psychedelic Studies (Apr. 28, 1995), <http://www.maps.org/mmj/abrams.html>.

Single Convention on Narcotic Drug (hereafter, SCND) and as a result, foreign importation of marijuana is outlawed.<sup>92</sup> Complicating this is the CSA and the DEA's questionable reliance on the 1999 IOM report, which almost entirely precludes domestic cultivation. The only native entity authorized to grow marijuana for research is the National Institute on Drug Research (hereafter, NIDA). Right away, this means a ridiculously small supply available for research. To make matters worse, NIDA has been notoriously difficult in facilitating medical marijuana research with the tiny amounts it actually produces. In 2010, a NIDA spokesperson stated: "Our focus is primarily on the negative consequences of marijuana use. We generally do not fund research focused on the potential beneficial medical effects of marijuana."<sup>93</sup>

In sum, to become a standardized medicine, the FDA requires a drug to be supplemented with detailed research.<sup>94</sup> Until recently, through the combination of the CSA and SCND, marijuana available for research has been extremely limited. In turn, minimal US research has been conducted. Thus, under the FDCA, the FDA cannot approve it as a medicine. Luckily, the DOJ's 2013 memo most likely signals the end of this federal interference. It is highly unlikely controlled medical research will conflict with any CSA goals. In fact, more research should only help the DOJ develop more specialized policy regarding medical cannabis.

#### B. *Why We Need Research:*

There are many reasons why research is critical to the future of medical cannabis programs. From the outset, FDA approval (and the legitimacy it carries) requires a careful balancing of the risks and benefits of cannabis.<sup>95</sup> Without adequate information on either, this balancing simply cannot occur. However, the complexities of this situation have already been

---

<sup>92</sup> *Id.* § 952.

<sup>93</sup> Gardiner Harris, *Researchers Find Medical Study of Marijuana Discouraged*, N.Y. TIMES, Jan. 19, 2010, at A14.

<sup>94</sup> *Id.* § 355(d).

<sup>95</sup> Cohen, *supra* note 18, at 49.

addressed. Beyond accommodating the FDA's approval process, why is research essential to the future of medical cannabis? The medical answer is simple: there is an abundance of potential and a shortage of knowledge. Despite being used for thousands of years,<sup>96</sup> marijuana as a bona fide medical treatment is still in its infancy. Its greatest usage may not even be known yet. In a political context, the more we know, the more fine tuned regulations can become. Additional information about things like usage, dosage, addiction liability (specifically in the medical context) and side effects will allow development of best practice standards with the DOJ's goals in mind. These guidelines will allow New Jersey's medical marijuana program to continue to remain safe, productive and compliant.

### *C. Existing Research:*

Those unfamiliar with the topic of medical marijuana may get the impression no research exists at all. This is certainly not the case. If it were, it would be much more difficult to advocate its medicinal value. Unlike America, research in Europe has not been hindered by total prohibition. Scientists have increased access to raw material, which means relative ease in research. Legitimate, credible studies in countries like Spain and Switzerland are yielding exciting conclusions about the various medical applications of marijuana. One recent study conducted in Spain noted local treatment with a THC-based ointment on rodents produced a significant reduction in the size of skin cancer tumors.<sup>97</sup> One Swiss study concluded amongst all illicit drugs, cannabis is the only one capable of producing true antidepressant effects.<sup>98</sup>

---

<sup>96</sup> *Id.* at 35.

<sup>97</sup> Maria Salazar, et al., *Cannabinoid Action Induces Autophagy-Mediated Cell Death Through Stimulation of ER Stress in Human Glioma Cells*, 119(5) J CLIN INVEST. 1359, 1380 (2009).

<sup>98</sup> Xia Zhang et al., *Cannabinoids Promote Embryonic and Adult Hippocampus Neurogenesis and Produce Anxiolytic and Antidepressant-like Effects* 115(11) J CLIN INVEST. 3104, 3115 (2005).

Another study in Spain determined a possible correlation between Cannabis intake and a reduction in the degeneration of the brain tissue in those diagnosed with Alzheimer's disease.<sup>99</sup>

This is not to paint an inaccurate picture of the studies on medical cannabis. While it is true many present conclusions in support of marijuana, there are a fair number of studies reporting negative findings surrounding marijuana. Some of the more famous ones, such as the IOM's report,<sup>100</sup> have concluded there is little or no medical value to marijuana use. Others have gone further, reporting negative side effects from sustained use. Some report decrease in certain cognitive functions, such as memory.<sup>101</sup> Others bring up the risk of cancer that goes hand in hand with smoke inhalation.<sup>102</sup> Regardless, these studies aren't dispositive. Given the public concern with cancer, it is difficult to believe many Americans would maintain a neutral, let alone unsupportive stance on whether we should investigate new ways to shrink tumors. This year alone, cancer has claimed 580,350 lives throughout America, with 16,410 of those being from the Garden State.<sup>103</sup>

The bottom line is as it stands, we have a wealth of fascinating research upon which to expand. Unfortunately, very little of it originates in the United States. It is absolutely pivotal thorough research is both funded and prioritized in the US. The funding can be minimal, so long as it consistent. Doing this may quickly provide answers to some of medical marijuana's most challenging questions, while affording New Jersey a relatively low cost opportunity to pioneer

---

<sup>99</sup> Maria L. Ceballos, et al., *Prevention of Alzheimer's Disease Pathology by Cannabinoids: Neuroprotection Mediated by Blockage of Microglial Activation* 25(8) J NEUROSCIENCE 1904, 1913 (2005).

<sup>100</sup> JOY, *supra* note 29.

<sup>101</sup> Mark S. Gold, *The Pharmacology of Marijuana*, in *Principles of Addiction Medicine* 164-66 (2<sup>nd</sup> ed. 1998).

<sup>102</sup> Reena Mehra et al., *The Association Between Marijuana Smoking and Lung Cancer: A Systematic Review*, 166 ARCHIVES INTERNAL MED. 1359, 1359 (2006).

<sup>103</sup> *Estimated Number of Deaths for Selected Cancers by State*, American Cancer Society, <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-037128.pdf> (last visited Nov. 29, 2013).

the national field in research. Until then, existing information strongly suggests medical marijuana should continue to remain a viable, albeit regulated, option.<sup>104</sup>

## VII. Distribution From Licensed Pharmacies:

Once research has begun to yield reliable conclusions on things such as dosage, measurements and alternative delivery methods, researchers and pharmacists can begin working together to develop a uniform, scientifically accurate method of pharmacy compounding for refined THC. The FDA describes pharmacy compounding as “a practice in which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient.”<sup>105</sup> It goes on to say “pharmacy compounding, if done properly, can serve an important public health need if a patient cannot be treated with an FDA-approved medication.”<sup>106</sup> Unfortunately, without reliable research, accurate information remains unavailable to develop marijuana THC compounding methods. Until then, the practice of filling marijuana prescriptions remains much too speculative for most prudent pharmacists to **feel comfortable with**.<sup>107</sup> Once enough information exists to allow for proper prescribing and compounding, the final component of effective medical marijuana oversight can come into play: a comprehensive program for physicians to follow when evaluating potential patients and prescribing marijuana. For guidance, the Model Opioid Program<sup>108</sup> provides an excellent example which medical marijuana should seek to parallel.

### A. *In Lieu of the Ability to Compound:*

---

<sup>104</sup> Donald I. Abrams et al., *Cannabis in Painful HIV-Associated Sensory Neuropathy: A Randomized Placebo-Controlled Trial*, 68 NEUROLOGY 515, 520 (2007).

<sup>105</sup> *Pharmacy Compounding*, *supra* note 5.

<http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/>.

<sup>106</sup> *Id.*

<sup>107</sup> Moira Gibbons, *The Cannabis Conundrum: Medication v. Regulation*, 24 HEALTH LAW. 1, 7 (2011).

<sup>108</sup> *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*, *supra* note 13.

Short of an effective compounding technique, it is still possible for pharmacists to adequately control and dispense medicinal marijuana in a simple, effective way. This can be achieved through a process of plant reproduction commonly referred to as cloning. “In horticulture, a "cutting" is a branch that has been cut off from a mother plant...and then rooted, often with the help of a rooting liquid or powder containing hormones. When a full root has formed and leaves begin to sprout anew, the clone is a self-sufficient plant, genetically identical to the mother plant.”<sup>109</sup> In order to understand how pharmacists and doctors evaluating patient treatment could utilize this process, it is necessary to have a foundational knowledge of the nature of the marijuana plant.

*B. The Nature of the Cannabis Plant:*

To begin, marijuana is a plant that comes in thousands of varieties. While they often share common traits, no two strains are exactly alike.<sup>110</sup> In fact, certain varieties may possess qualities that will be extremely beneficial to some, while acting as a catalyst for anxiety in others. In lieu of experience, one might be inclined to draw parallels between marijuana and alcohol. Both come in different varieties. Both intoxicate the user. The difference is, unlike cannabis, the effect of alcohol is always the same, just varied in intensity.<sup>111</sup> A similar comparison can be demonstrated in a medical context. Where marijuana departs from a plant like opium is in its capability to deliver different therapeutic benefits to the user, regardless of the dosage level. While opium derivatives are strictly employed in pain treatment, the differing varieties of marijuana plants are thought to be capable of alleviating a wide variety of life-altering symptoms. With opioids, the effect on the user is the same every time. The only

---

<sup>109</sup> *Plant Reproduction*, Wikipedia the Free Encyclopedia (Nov. 20, 2013), [http://en.wikipedia.org/wiki/Plant\\_reproduction#cite\\_ref-rooting\\_cuttings\\_of\\_tropical\\_trees\\_4-1](http://en.wikipedia.org/wiki/Plant_reproduction#cite_ref-rooting_cuttings_of_tropical_trees_4-1).

<sup>110</sup> KING, *supra* note 84.

<sup>111</sup> *Id.* at 31.

variation would be the result of a fluctuation in the dosage (which, unlike marijuana, can prove fatal<sup>112</sup>), and regardless, it is the same effect, utilized for the same purpose, only intensified.

Due to the aforementioned lack of research, there is almost no comparative information available on how user effects differ from strain to strain. With this in mind, Jason King's "Cannabible"<sup>113</sup> provides excellent insight into the **blatant**, and occasionally subtle, differences amongst varieties. King spent more than a decade traveling the world, sampling hundreds of types of marijuana.<sup>114</sup> He neatly documented each of his experiences consuming different varieties and compiled them into a book, which serves as a source of review for self-proclaimed "cannabis connoisseurs."<sup>115</sup> While obviously, this is not the most scientific resource, King took great effort to ensure the book's reviews were as scientifically objective as his resources permitted. He did this by gathering controlled groups of experienced marijuana users and allowed them to sample particular varieties. He then conducted in-depth inquiry into the sensations each user experienced.<sup>116</sup> The only effects reported in the book's reviews are those that were common to multiple users consuming the same strain. The objective process was compounded by the fact that King gathered samples of the same strain from different growers, each of whom utilized different techniques and conditions during cultivation. Again, only user effects that were common to all samples of a particular variety, regardless of origin, were reported.<sup>117</sup> The end result is a compendium of reviews that detail significantly different experiences from strain to strain. Some failed to elicit any notable effect at all.<sup>118</sup> Others were

---

<sup>112</sup> *Prescription Painkiller Overdoses*, Center for Disease Control and Prevention (Jul. 3, 2013), <http://www.cdc.gov/vitalsigns/PrescriptionPainkillerOverdoses/>.

<sup>113</sup> KING, *supra* note 84.

<sup>114</sup> KING, *supra* note 84 at 34.

<sup>115</sup> JASON KING, *THE CANNABIBLE* 62 (3<sup>rd</sup> ed. 2007).

<sup>116</sup> KING, *supra* note 84 at 34.

<sup>117</sup> *Id.* at 34.

<sup>118</sup> JASON KING, *THE CANNABIBLE* 96 (1<sup>st</sup> ed. 2007). (The high generated from "Purple Star" is "nothing to write home about.")

very useful in stimulating appetite, mood, libido and sleep.<sup>119</sup> After all, it's called "The Cannabible." However, in lieu of adequate research, it serves as a great springboard for exploring marijuana's medicinal potential in a fun way.

### *C. The Solution:*

To quickly connect the dots, strains that are known to produce potent, consistent results, can be quickly standardized for treatment and prescription via cloning. With current technology, assessing the THC content of each strain will be very easy. In theory, the clones will have the same THC content and capabilities for symptom relief as the parent plant, provided they are grown in similar conditions, with similar techniques. Thus, different strains can be directed toward treating the type of symptom they are best suited for. In addition, dosages can be quickly assessed and distributed in terms of the weight of the raw plant matter. This method of distribution is similar to that currently utilized by many dispensaries, albeit with a distinct degree of standardization and third party oversight. In taking dispensaries out of the equation and placing responsibility in the hands of pharmacies, an extra layer of security is provided by state pharmacy boards, which heavily monitor generated pharmacist activity related to certain prescription drugs. This heightened scrutiny will ensure that New Jersey remains in strict compliance with the DOJ's terms,<sup>120</sup> ultimately ensuring needy patients remain consistently supplied.

## **VIII. The Opioid Program as a Model:**

When considering how to implement marijuana regulation in compliance with the DOJ guidelines, opioids are an excellent point of reference. Opioids have been called a "hallmark example of the inability of certain medical protocols to fit neatly into traditional federal drug

---

<sup>119</sup> *Id.* at 48. (The high generated from "Herojauna" is exceptionally strong and was noticeably stimulated libido, appetite, & sleep.)

<sup>120</sup> Cole, *supra* note 8 at 2.

regulations.”<sup>121</sup> It is not that opioids are comparable to marijuana in terms of medical use; rather they are similar in their nature. On the most basic level, like marijuana’s THC cannabinoids, opioids are a plant derivative. Both have the capacity to intoxicate the user, hence the attendant recreational black markets. Like marijuana, various opioids fund large-scale criminal enterprises, spurring violence in their wake. In addition, both marijuana and opioids carry proven risk (although different in degree) of dependency.<sup>122</sup> Conversely, both have been used all over the world for thousands of years medicinally.<sup>123</sup>

Both are delicate in the medical context but, unlike cannabis, opioids have been federally legalized for therapeutic use for quite some time. As such, they present a workable model that continues to evolve as new information is attained. Using this as a point of departure, cannabis regulation can mirror the model’s applicable components.

The Federation of State Medical Boards is a national non-profit organization representing the 70 medical and osteopathic boards in the United States. It is responsible for producing the “Model Policy on the Use of Opioid Analgesics in the Treatment of Common Pain,”<sup>124</sup> which state medical boards rely on in creating their regulations. As information and research on opioids continues to expand, the Federation revises and releases updated versions of the policy improving on the original. While it is not suggested that the cannabis model mirror the opioid model to a tee, there are a few staples of the model that are appropriately applied to marijuana. Parts A through H of this section detail these provisions.

*A. Understanding Symptom Treatment with Cannabis:*

---

<sup>121</sup> Frezza, *supra* note 4, at 1141.

<sup>122</sup> George F. Koob, *Neuroscience of Addiction*, 21(3) NEURON 467-476 (1998).

<sup>123</sup> Cohen, *supra* note 18, at 35.

<sup>124</sup> *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*, *supra* note 13.

The model opioid program provisions indicate that physicians prescribing painkillers are expected to possess a higher than average degree of knowledge in the treatment of pain.<sup>125</sup> This knowledge is considered fundamental to the program's success. Without it, the physician's ability to participate in other stages of the program is greatly compromised. Undoubtedly, a cannabis program demands a similar degree of knowledge. One might even posit that because cannabis is thought to be capable of treating a significantly wider variety of conditions than opioids, the physician's knowledge becomes all the more critical. Functionally speaking, this knowledge increases the effectiveness of cannabis as a medicine. Further, it helps prevent improper prescription, which can lead to serious, adverse consequences for the patient.

*B. Required Patient Screening:*

The opioid program demands the physician be trained to recognize individuals who are at a higher than average risk of abuse and dependency.<sup>126</sup> Unlike many other prescriptions, before prescribing an opioid, the physician is required to closely scrutinize the patient's medical history in order to determine whether they are predisposed to abuse. This determination is made from a list of factors that are considered reliable indicators of a significant potential for misuse. Examples of these include age, prior similar prescriptions, increasing dosages, depression, and being male.<sup>127</sup> Unquestionably, this aspect of the opioid program must be adopted by cannabis program. Not only will it add a distinct note of legitimacy to cannabis as a medicine, but it will likely filter out a good deal of the potential abusers who could compromise the program's future.

*C. Informed Consent/Treatment Agreement:*

---

<sup>125</sup> *Id.* at 8.

<sup>126</sup> *Id.* at 9.

<sup>127</sup> *Treatment Improvement Protocol (TIP) 54: Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders*, Substance Abuse and Mental Health Services Administration, <http://store.samhsa.gov/shin/content//SMA12-4671/TIP54.pdf> (last visited Nov. 20, 2013).

The physician is also expected to deliver an informed consent to the patient about opioid use. Specifically, the physician must address the risks, benefits and alternative treatment options.<sup>128</sup> New Jersey's regulations are wise in noting this aspect of the opioid program, requiring informed consent between doctor and patient.<sup>129</sup> Informed consent is designed to address the unusual risk of addiction which opioid use carries. However, it is not solely the responsibility of the doctor to mitigate these risks. The physician is only capable of investigating patient history to a certain extent before it becomes a full-time job. Thus, the responsibility to prevent abuse is one shared between the patient and doctor.<sup>130</sup> Informed consent is extremely important as it affords the patient an additional opportunity to make a knowledgeable decision with all risks in mind. Whether they choose to listen and make it a two-way conversation is ultimately up to them, but they can't say they weren't warned, thereby extinguishing practitioner liability. Further, additional, possibly sensitive information about personal and family history is always beneficial in forming the most complete treatment plan possible.

In conjunction with this informed consent, the physician may utilize a treatment agreement. Under such an agreement, a patient may be forced to submit to random drug testing to monitor for excessive usage.<sup>131</sup> In addition to being an effective deterrent, these agreements can yield early indication of abuse, allowing the doctor to intervene sooner rather than later. Treatment agreements are ideal for patients who are at risk of abuse, but could truly benefit from cannabis.

#### *D. Continued Monitoring During Patient Use:*<sup>132</sup>

---

<sup>128</sup> *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*, *supra* note 13 at 10.

<sup>129</sup> Compassionate Use Medical Marijuana Act, N.J. ADMIN. CODE 8:64-2.5(a)(9) (2013).

<sup>130</sup> *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*, *supra* note 13 at 5.

<sup>131</sup> *Id.* at 10.

<sup>132</sup> *Id.* at 11.

Though the idea is mostly self-explanatory, this aspect of the model opioid program is critical. This is because it is not just those with a history of addiction who are at risk. While the chances of becoming substance dependent are lower for some, addiction does not discriminate, and ultimately almost anyone is susceptible. Due to this possibility, continued patient monitoring provides a needed check. Opioids, like cannabis, benefit from a multi-step treatment program. Thus, staying updated allows the physician to effectively address other stages of the patient's treatment.<sup>133</sup> Thankfully, current DOH regulations require physician reassessment every three months.<sup>134</sup>

*E. Referral:*

Another important aspect of the program is embodied in the doctor's obligation to recognize situations beyond his control, such as a developing dependence. Once the doctor identifies active abuse, he is expected to refer the patient to a physician more qualified to deal with the situation.<sup>135</sup> This step in the program acts as damage control, recognizing the delicate and somewhat unpredictable course of opioid therapy. The referral process ensures the best interests of the patient, because it allows for more complete and effective treatment.

*F. Exploring Discontinuation of Usage:*

The model opioid program recommends physicians make a continuing effort to discontinue the patient's usage as soon as possible.<sup>136</sup> Once symptoms are alleviated, continued use only serves to increase the patient's risk of dependency. Thus, during patient monitoring, physicians should be required to discuss the possibility and consequences of discontinuing

---

<sup>133</sup> *Id.* at 12.

<sup>134</sup> Compassionate Use Medical Marijuana Act, N.J. ADMIN. CODE 13:35-7A.5(c) (2013).

<sup>135</sup> *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*, *supra* note 13 at 13.

<sup>136</sup> *Id.* at 13.

treatment. The logic of this theory translates well to medical marijuana, and should be considered by legislatures.

*G. Maintaining Complete and Accurate Records:*<sup>137</sup>

Though this duty always exists for physicians, in the context of opioids there is greater emphasis placed on the responsibility to do so. This relates back to the unpredictable course of treatment opioids can take in each individual. Keeping detailed, complete records functions as an additional precaution, allowing the treating physician to recognize any emergent problems and take the subsequent steps to resolution. Further, this ties in with the referral component of the program as it ensures the referred doctor has as much information as possible, which is invaluable to the treatment process.

*H. REMS:*

In 2012, the FDA announced it would be implementing a Risk Evaluation and Mitigation Strategy<sup>138</sup> (hereafter, REMS) for opioids. This is “a strategy to manage a known or potential serious risk associated with a drug or biological product. A REMS will be required if the Food and Drug Administration (FDA) determines that a REMS is necessary to ensure the benefits of the drug or biological product outweigh its risks.”<sup>139</sup> Essentially, a REMS functions as a policy revision devised to counteract known dangers associated with certain prescription drugs. In the case of opioids, the REMS places additional requirements on the prescriber to provide patients with highly detailed information regarding the danger of abuse.<sup>140</sup> This kind of additional safeguard is certain to please the DOJ in the context of marijuana.

---

<sup>137</sup> *Id.* at 14.

<sup>138</sup> *Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids*, U.S. Food & Drug Administration, <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>. (last updated Oct. 25, 2013).

<sup>139</sup> *REMS Resource Center*, American Society of Health-System Pharmacists, <http://www.ashp.org/REMS> (last visited Dec. 2, 2013).

<sup>140</sup> *FDA Required REMS Program for Serious Drug Risks*, The Extended-Release and Long-Acting Opioid

## Conclusion:

To conclude, if credible European studies are to be given any weight whatsoever, there is an ever-expanding wealth of evidence that cannabis serves as an effective treatment in alleviating some of the most uncomfortable symptoms known to man. There is substantiation cannabis is successful in remedying nausea,<sup>141</sup> lack of appetite,<sup>142</sup> inability to sleep<sup>143</sup> and chronic pain.<sup>144</sup> These are but a few examples, as the list is quite long. While the DOJ continues refusing to acknowledge the medical benefits of marijuana, it has begrudgingly agreed not to interfere with the state laws that do.<sup>145</sup> However, it has made clear in exchange for this concession, states are expected to maintain extremely strict oversight of cannabis laws.<sup>146</sup> State laws must continue to comply with the goals of the CSA, which include preventing violence, preventing illegal revenue from organized crime and preventing usage by minors.<sup>147</sup> Criminal charges that further these goals will continue to be prosecuted. To avoid any sort of conflict, New Jersey and other states with medical marijuana laws will find it extremely beneficial to consider continued research, mandatory pharmacy dispensing and the model opioid program when drafting laws and regulations. It is imperative that states consider not just one, but all three in conjunction with one another. Continuing research will allow the successful development and

---

Analgesics Risk Evaluation and Mitigation Strategy, [http://www.er-la-opioidrems.com/IwgUI/rems/pdf/dear\\_prescriber\\_letter.pdf](http://www.er-la-opioidrems.com/IwgUI/rems/pdf/dear_prescriber_letter.pdf) (last updated Nov. 20, 2013).

<sup>141</sup> JOY, *supra* note 29 at 43.

<sup>142</sup> Florian Strasser, et al., *Comparison of Orally Administered Cannabis Extract and Delta-9-Tetrahydrocannabinol in Treating Patients with Cancer-Related Anorexia-Cachexia Syndrome: A Multicenter, Phase III, Randomized, Double-Blind, Placebo-Controlled Clinical Trial From The Cannabis-in-Cachexia-Study-Group*, 24(21) J CLIN ONCOLOGY 3394, 3398 (2006).

<sup>143</sup> David J. Rog, et al., *Randomized, Controlled Trial of Cannabis-Based Medicine in Central Pain in Multiple Sclerosis*, 65(6) NEUROLOGY 812, 819 (2005).

<sup>144</sup> Jeremy R. Johnson, et al., *Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study of the Efficacy, Safety, and Tolerability of THC:CBD Extract and THC Extract in Patients With Intractable Cancer-Related Pain*, 39(2) J PAIN SYMPTOM MANAGEMENT 167, 171 (2009).

<sup>145</sup> Cole, *supra* note 8.

<sup>146</sup> Cole, *supra* note 8 at 2.

<sup>147</sup> *Id.* at 4.

modification of a model cannabis program, which pharmacists can then employ in their gatekeeper capacity.

So long as New Jersey considers these factors in its regulations, it is likely to meet the standards set forth by the DOJ, ensuring a low probability of conflict between state and federal law. And of course, it will afford millions reliable and predictable relief from their daily struggle with debilitating symptoms.