



Marijuana Dispensaries and the Federal Government: Recommendations to the Obama Administration 2009: Part 1

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Abstract

Cannabis dispensaries are proliferating at a rapid rate — a cause for concern, given the potential for such operations to take advantage of desperate patients and put seriously ill patients at affirmative risk. Local jurisdictions do not have sufficient resources to deal with these abuses. Requiring the DEA unequivocally to take a “hands-off” approach, no matter how egregious the dispensary’s practices, will not serve the best interests of patients.

Definitions

The terms “cannabis” and “marijuana” are used interchangeably in this paper to refer to the psychoactive material, in either herbal or resinous form, from the *Cannabis* genus of flowering plants.

The use of the terms “medical marijuana” and “medical marijuana dispensaries” in this paper should not be taken as conferring or acknowledging any validity to the use or distribution of cannabis for medical purposes.

I. Introduction

In the early weeks of his administration, President Barack Obama has voiced a number of laudable goals. He has stressed that “Science and the scientific process must inform and guide decisions of my Administration on a wide range of issues...”(1) He has expressed compassion for seriously ill patients and their families.(2) With regard to the use of marijuana for medical purposes, the president is said to believe that “federal resources should not be used to circumvent state laws.”(3) Prior to his election, then-Senator Obama noted that any use of marijuana for medical circumstances should take place “under strict guidelines... in the same way that other [pain relievers] or palliative drugs would be prescribed.”(4) These aspirations are not necessarily inconsistent. As this paper will show, each of these goals can be met without allowing marijuana dispensaries to multiply free of federal control and intervention.

The Administration need not fear that Drug Enforcement Agency (DEA) intervention into cannabis dispensaries will conflict with state law; indeed, dispensaries are, in almost all instances, not permitted by state medical marijuana laws. Nevertheless, cannabis dispensaries are proliferating at a rapid rate — a cause for concern, given the potential for such operations to take advantage of desperate patients and put seriously ill patients at affirmative risk. Local jurisdictions do not have sufficient resources to deal with these abuses. Requiring the DEA unequivocally to take a “hands-off” approach, no matter how egregious the dispensary’s practices, will not serve the best interests of patients.

Uncontrolled proliferation of these dispensaries will seriously undercut our Food and Drug Administration (FDA) drug approval system and deprive patients of important regulatory protections. Such a result will defeat the Administration’s avowed desire to support and follow the results of sound science. As President Obama has stressed, medical marijuana should be

controlled “the same ...as other drugs prescribed by doctors.” Other prescription medications, such as morphine, are subject to a host of quality, safety, and efficacy requirements. Without such requirements, vulnerable patients can be exposed to harmful or ineffective products.

The Food, Drug, and Cosmetic Act (FDCA) and the Controlled Substances Act (CSA) are carefully integrated to ensure that patients’ access to medications is determined by good medical science, not politics. The FDA approves specific medical products for marketing and, thereafter, for distribution to patients, based on a determination of those products’ safety and effectiveness. Through the scheduling process, the DEA -- after a scientific and medical evaluation by the Department of Health and Human Services (the FDA, in particular) -- determines whether and which restrictions should be placed on basic classes of substances that may have abuse liability. Under this coordinated system, only individual products that have undergone rigorous scientific testing can be made available for medical use; crude botanical substances, such as opium, coca, and cannabis, cannot be sold to patients. Cannabis dispensaries, by distributing herbal cannabis and unapproved cannabis preparations directly to patients, significantly undermine this system.

In addition to maintaining the integrity of our domestic drug approval system, the United States must uphold its international treaty obligations. Under the Single Convention on Narcotic Drugs, which governs the cultivation, distribution, and use of marijuana, the U.S. must prohibit or strictly regulate such activities. When Congress enacted the CSA -- which is enforced by the DEA -- it expressly recognized our obligation to adhere to this and other drug control treaties. Again, the scientific process should guide our path as we fulfill our global responsibilities. The Administration should therefore allow the DEA to determine when, and to what extent, federal intervention is required to meet our commitments in this area.

The legal status and common practices of cannabis dispensaries

Most Cannabis Dispensaries are Illegal Under State Medical Marijuana Laws.

The DEA’s intervention into the practices of marijuana dispensaries does not circumvent state law or violate the concept of “states’ rights.” First, state legislation relating to the use of cannabis for medical purposes is generally quite limited in scope. These laws merely qualify the reach of the state’s existing criminal legislation prohibiting the use, possession, cultivation, etc., of cannabis.⁽⁵⁾ California’s medical marijuana law -- the oldest in the nation -- clearly illustrates this fact. Proposition 215, the California Compassionate Use Act of 1996 (CCUA),⁽⁶⁾ was enacted by the voters in 1996. The Act renders possession and cultivation of cannabis noncriminal under specified conditions; that is, it creates a potential defense against criminal prosecution and conviction.⁽⁷⁾ The California Supreme Court has specifically ruled that the Act confers only a limited immunity which “operates by decriminalizing conduct that otherwise would be criminal.”⁽⁸⁾ Such enactments do not fall within the realm of classic “states’ rights.”⁽⁹⁾

Second, in most cases, cannabis dispensaries are not actually authorized under these state medical marijuana laws. In California, for example, the original CCUA decriminalized the cultivation and possession of cannabis by a patient, or by that patient’s “primary caregiver,” if the use of cannabis was recommended by the patient’s physician. A primary caregiver was defined as the individual designated by the patient who has consistently assumed responsibility for the patient’s housing, health, or safety. The California Supreme Court has ruled that a person whose responsibilities consist principally of supplying cannabis and instructing on its use, and who otherwise only sporadically takes a patient to medical appointments, cannot qualify as a primary caregiver under the CCUA.⁽¹⁰⁾ The Court concluded that a primary caregiver must prove at a minimum that he or she consistently provided caregiving, independent of any assistance in taking

medical marijuana, at or before the time he or she assumed responsibility for assisting with medical marijuana. A primary caregiver must be the principal, lead, or central person responsible for rendering assistance in the provision of daily life necessities.

In 2003, the California state legislature enacted the Medical Marijuana Program (MMP).(11) The MMP clarified, but did not modify or expand, the reach of the CCUA.(12) The MMP acknowledges that patients and their primary caregivers may “associate” in order to cultivate cannabis “cooperatively or collectively” for medical purposes, without becoming subject to criminal sanctions solely because of that fact.

This language does not establish a “green light” for cannabis dispensaries. The California Attorney General has recognized that this provision was intended to be quite narrow. In August 2008, the State Attorney General issued guidelines to identify legitimate cooperatives and collectives.(13) The guidelines stressed that neither cooperatives nor collectives should purchase cannabis from, or sell to, non-members; instead, “they should only provide a means for facilitating or coordinating transactions between members.” Both types of entities must carefully monitor their members, and both should document “each member’s contribution of labor, resources, or money,”(14) as well as tracking and recording the source of the cannabis. Neither type of entity should profit from the sale or distribution of cannabis.

These guidelines allow for small groups of patients and primary caregivers to share the labor, expenses, and other responsibilities of cultivation on a common piece of land or other facility. This description does not apply to the vast majority of cannabis dispensaries in California, which have hundreds or even thousands of members.

In California, dispensaries have had 13 years to flourish, and it is in California that their abuses have become evident. Most dispensaries are merely retail storefronts that distribute cannabis to customers. The California Attorney General has made clear that such dispensaries are operating outside the boundaries of state law: “dispensaries that merely require a patient to complete a form summarily designating the business owner as their primary caregiver -- and then offering cannabis in exchange for cash “donation” -- are likely unlawful.”(15) Nevertheless, dispensaries have proliferated across California.(16)

It is the current system and practices of medical marijuana dispensaries in California, and not the DEA’s disruption of their merchandising operations, that circumvent state law: both medical marijuana laws, and laws prohibiting the sale or possession of cannabis for non-medical purposes.

The Operation of Cannabis Dispensaries Will Not Generate Scientific Data Leading to a Meaningful Assessment of Cannabis-based Medications.

The practices of cannabis dispensaries will not enable this country to answer the pivotal question: what are the scientific data which demonstrate the risks and benefits of cannabis or cannabis-derived medications? Without such data, no new medical product can gain acceptance by the medical profession, policymakers, and an informed public. California’s cannabis dispensaries offer a broad menu of cannabis products to a wide and shifting range of customers. Different strains of herbal materials, as well as capsules, highly concentrated extracts, and edibles are available. Herbal material may be smoked or otherwise inhaled by means of a wide variety of devices. Patients may try one product (or one dispensary), then another. Some patients will have adverse reactions, or will obtain no benefit. Those individuals will simply not make further purchases; their experiences will not be recorded or otherwise captured for medical benefit/risk analysis.

Such practices cannot generate reliable, controlled data that could lead to a meaningful assessment of the future of cannabis or cannabis-based medical products—certainly not data on the myriad different cannabinoid preparations and dosage forms. Acceptable and usable scientific data can be generated only by transforming crude herbal material into standardized formulations of known and reproducible composition and dose, incorporating those into appropriate delivery forms, and testing such combinations through the modern regulatory system.

Cannabis Dispensaries May Put Seriously-Ill Patients at Risk.

State medical marijuana laws themselves recognize that cannabis is not a “harmless herb,” akin to a dietary supplement or a home remedy. These laws treat cannabis more like a prescription medication, making a licensed physician the gatekeeper to a patient’s access to cannabis⁽¹⁷⁾ (the physician, however, is not required to be federally registered, despite the fact that cannabis holds Schedule I status under the CSA). Despite this “quasi-prescription” status, there is little assurance of quality, consistency, safety, or efficacy. Cannabis in herbal form, or contained in crude preparations, is not a homogeneous substance.⁽¹⁸⁾ Depending on the concentration of various cannabinoids and other plant components, use of inert excipients, and delivery system or dosage form, patients may be exposed to a variety of active ingredients with quite different pharmacological effects. Increasingly, cannabis cultivated in North America and Europe is being bred to express very high concentrations of tetrahydrocannabinol (THC).⁽¹⁹⁾ By contrast, cannabidiol (CBD), a non-psychoactive cannabinoid that dampens down the effects (including the psychoactive effects) of THC, and which was present in significant amounts in cannabis used centuries ago, has been bred out of modern cannabis.⁽²⁰⁾

The delivery system also enormously affects the impact that a cannabinoid product has on a patient. If inhaled (as in smoking or vaporizing), THC blood levels rise rapidly and then fall dramatically, which is likely to cause undesirable psychoactive side effects. Indeed, when smoked cannabis is compared with standardized cannabis-derived product (containing equal amounts of THC and CBD and delivered by a sublingual method), the patients using smoked cannabis report more significant adverse events.⁽²¹⁾ In addition, in a recent small study examining the effects of cannabis delivered in a (non-FDA-approved) vaporizer,⁽²²⁾ the subjects experienced notable intoxication; they found the cannabis with an intermediate THC concentration (3.4%) more tolerable than the higher THC concentration (6.8%) material.⁽²³⁾ Oral consumption has delayed and unpredictable effects.⁽²⁴⁾ This variability and unreliability of effect may be particularly harmful to seriously ill patients, who are often debilitated and likely to be taking a range of other prescription medications.

Cannabis distributed by dispensaries also poses other, even more serious risks for patients. It may be contaminated by pesticides,⁽²⁵⁾ heavy metals, or fungus. For example, in the Netherlands, cannabis is grown for medical use by two cultivators who are licensed by the government’s Office of Medicinal Cannabis. The cannabis has such high microbial content that it must be irradiated before it can be distributed to patients.⁽²⁶⁾

In a U.S. cannabis dispensary, however, there is no such quality control. If seriously ill patients suffer harm from such contamination,⁽²⁷⁾ they will receive no compensation, there will be no product recall or governmental investigation, and there is no tool to deter future malfeasance. In short, none of the federal and state regulatory protections are in place, and the cannabis distributed by dispensaries is not subject to reliable oversight.⁽²⁸⁾

Cannabis Dispensaries May Take Advantage of Desperate Patients.

Reverend Scott Imler, one of the early California proponents of “medical marijuana,” co-author of Proposition 215 and a founder of one of the original dispensaries, has voiced concern that dispensaries can be predatory, taking economic advantage of desperate and vulnerable patients:

We created Prop. 215 so that patients would not have to deal with black market profiteers. But today it is all about the money. Most of the dispensaries operating in California are little more than dope dealers with store fronts.(29)

There is little doubt as to why cannabis dispensaries are multiplying at such a rate. The price of cannabis in dispensaries ranges from \$12.50 to \$25 per gram (28 grams per ounce).³⁰ The average “medical” user with a chronic medical condition may consume from 1.5 to 3.0 grams per day.³¹ Therefore, the monthly cost to patients ranges from \$562 (1.5 grams/day at \$12.50/gm) to \$2,250 (3 grams/day at \$25/gm). Since the herbal cannabis, which is of varying strains and quality, has not received FDA approval, none of this expense is covered by a patient’s health insurance,³² and there is no assurance of quality control or accurate dosage information.

This system actually impedes access by patients to cannabis-derived medications. If a medication has gone through the FDA process, there is at least an opportunity for it to be covered by public or private health insurance. Given its exclusion from health insurance plans, its cost exceeds that which most seriously ill patients, many of whom may not be working, can afford to purchase. This cost in turn implies that the majority of purchasers are not, in fact, patients who require cannabis for medical purposes. In the meantime, cannabis dispensaries are profiting; some dispensaries take in over \$20,000 per day.³³

The need for regulatory protections

Allowing a Proliferation of Cannabis Dispensaries Will Seriously Undercut the FDA Drug Approval System and Deprive Patients of Important Regulatory Protections.

President Obama has expressed his desire to ensure that the U.S. provides “continued global leadership in scientific discoveries and technological breakthroughs.” He has assured the public that modern scientific developments will “guide” the Administration’s policy decisions.³⁴ A proliferation of cannabis dispensaries in states across the country would have the opposite effect, seriously undermining the FDA approval system. The federal Food, Drug, and Cosmetic Act (FDCA)³⁵ and the federal Controlled Substances Act (CSA)³⁶ work in synergy to form this impressive regulatory fabric. The FDCA requires that rigorous scientific data determine which medications may enter the marketplace and, thereafter, be prescribed and distributed to patients. The CSA establishes a process (scheduling) through which those scientific data can be used to ensure that controlled substances are made available for -- and limited to -- appropriate medical and scientific use, through a closed system of distribution that includes proper registration, security, recordkeeping, reporting, quota, and other requirements.

The Requirements of the Food, Drug, and Cosmetic Act Reduce the Likelihood that Patients Will be Exposed to Harmful or Ineffective Products.

The FDCA has been developed over more than a century to protect the health and safety of vulnerable patients. It enforces rigorous standards at all stages in the development of a new medicine.³⁷

Before a medical product may be approved by the FDA and be released for marketing, it must be

assessed in various nonclinical and preclinical laboratory tests, including drug-drug and drug-food interaction tests. Its final formulation must be analyzed for batch consistency, stability, and absence of dangerous contaminants. Its manufacturing process must be validated and quality-controlled.

Even after extensive preclinical studies have demonstrated the likely safety of the product for human use, several phases of clinical (human) research must be conducted. If a product is intended to be used for a chronic condition, carcinogenicity and reproductive toxicity tests must be performed. Adverse events must be reported and described in the product label. The research is published in peer-reviewed journals, enabling physicians to judge the quality of the research, as well as the relative safety and efficacy of the product.

The FDA also inspects and supervises the pharmaceutical manufacturer's facility. If a flaw exists in the manufacturing process, the FDA can withhold marketing approval. Subsequent to approval, if the FDA receives reports of serious, unrecognized side effects, a product's label can be amended to include heightened warnings, or the product can be removed from the market entirely.

This thorough and dynamic process reduces the likelihood that patients will be exposed to dangerous or ineffective products, and provides important data to allow physicians to conduct meaningful dialogues with, and give informed advice to, patients regarding treatment options.

The Controlled Substances Act Plays a Critical Role in Ensuring that Properly-Tested Medications are Made Available for Appropriate Medical Use.

The CSA and the Drug Enforcement Administration (DEA) play important roles in this system of medication development. When medications contain controlled substances, and therefore pose a potential risk of abuse or addiction, the regulatory system is even more cautious. Mere FDA approval of such a medication is not sufficient; the product must also undergo review through an administrative process under the CSA (the scheduling process).

Cannabis proponents often contend that herbal cannabis should be moved from Schedule I to Schedule II in order to increase its availability to patients through cannabis dispensaries. This argument, however, reflects a misunderstanding of the scheduling process as it relates to the ultimate FDA approval and marketing of a medication. That process must be viewed in the context of the larger FDA/DEA regulatory scheme.

When Congress enacted the CSA, it established five categories, known as schedules, to which different levels of requirements, restrictions, and prohibitions are attached.⁽³⁸⁾ A drug's classification in a specific schedule is determined by its abuse and dependence potentials on the one hand, and by the evidence of its safety and therapeutic effectiveness on the other. The scheduling process involves independent but complementary roles for the DEA, Department of Health and Human Services, the FDA, and the National Institute on Drug Abuse (NIDA) in particular.

Substances in both Schedules I⁽³⁹⁾ and II are subject to the greatest restrictions because they have a "high potential for abuse."⁽⁴⁰⁾ For the most part, these restrictions are similar: for example, bulk manufacturers of Schedule I or II substances are subject to production quotas;⁽⁴¹⁾ manufacturers of finished dosage forms (products) containing Schedule I or II substances are subject to procurement quotas.⁽⁴²⁾ Because they have no "accepted medical use," Schedule I substances are subject to some additional restrictions and may only be used in FDA-approved

research programs.(43)

Under the CSA, Schedule II Placement Does Not Make a Substance Available for Direct Use By Patients.

The CSA schedules contain basic types or “classes” of substances (such as oxycodone), not specific products (such as OxyContin® or Fentora®), although each new “branded” medication undergoes a scheduling analysis as part of the FDA approval process. Placement of a substance in Schedule II is not sufficient to allow a specific product containing the substance to be marketed and distributed directly to patients. The latter requires FDA approval.

In order for a substance to move from Schedule I to Schedule II, the DEA must determine that it has an “accepted medical use.” In order for a substance to have an “accepted medical use,” the following criteria must be met:

1. Its 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. It must be accepted by qualified experts; and
5. The scientific evidence must be widely available.(44)

These criteria can only be met by data of very high scientific quality, essentially equivalent to the data that must be generated in order for a specific finished product to achieve FDA approval.(45) As a practical matter, therefore, the scheduling of new controlled substances generally occurs only after, or simultaneously with, FDA approval of products containing those substances.(46,47)

FDA Approval is Required in Order for a Specific, Finished Medication to be Marketed and Distributed to Patients.

By contrast to the CSA’s scheduling of substances rather than individual products, the FDA approves only specific products for marketing and distribution to patients. The FDA does not approve pure active pharmaceutical ingredients (APIs), nor crude herbal substances, such as narcotic raw materials (NRM). Only a finished dosage form containing a specific type of controlled substance can obtain FDA approval and become a prescription medication.

This applies to cannabis as well as to other controlled substance plant materials. In 1970, at the time it enacted the CSA, Congress placed opium and coca leaves in Schedule II of the CSA because modern, standardized, and refined medical products derived from these substances were already on the market. Such schedule II placement did not put crude opium or coca leaves on the pharmacy shelves. Opium and concentrate of poppy straw (CPS)(48) contain different concentrations of alkaloids, such as morphine, thebaine, and oripavine. These alkaloids are themselves considered Schedule II substances, from which final pharmaceutical products are developed.(49) If a dispensary were to attempt to cultivate and distribute crude opium or coca leaves, it is beyond doubt that the DEA would have both the authority and the obligation to take action against such conduct, whether or not that activity was decriminalized under state law.

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2. Montopoli, B., "Obama Announces Stem Cell Decision," CBS News Political Hotsheet (March 9, 2009) (President Obama remarks in full) at p. 2.
3. Egelko, B., "Feds Hint No More Raids on Pot Clubs in State," San Francisco Chronicle A1 (Feb. 27, 2009).
4. Town hall meeting in Audubon, Iowa, Nov. 24, 2007. "Medical Marijuana ProCon.org", <http://www.medicalmarijuana.org>

medicalmarijuana.procon.org/viewsource.asp?ID=002447.

5. See National Organization for the Reform of Marijuana Laws (NORML), “Active State Medical Marijuana Programs,” http://norml.com/index.cfm?Group_ID=3391. In 2004, Oregon voters rejected an initiative that would have authorized dispensaries in that state. At present, under SB 1085 (effective Jan. 1, 2006), Oregon permits a patient to register a “marijuana grow site,” which can cultivate cannabis for no more than four patients. In March 2009, New Mexico granted the first license for a cannabis dispensary, the name and location of which are undisclosed. See Major Holmes, S., “First medical marijuana producer in NM approved,” The Associated Press (March 19, 2009). In Michigan, dispensaries are springing up, even though the recently-enacted medical marijuana law does not authorize them. http://www.mlive.com/news/flint/index.ssf/2009/03/group_to_offer_marijuana_advic.html.

6. Calif. Health & Safety Code §11362.5.

7. *People v. Mower* 28 Cal.4th 457, 472; 122 Cal.Rptr.2d 326 (2002). It is not uncommon for a state to render certain conduct noncriminal that otherwise would be criminal under its laws. See, e.g., Calif. Penal Code sec. 602(n) (the crime of trespass on another’s property is not applicable to persons engaged in lawful labor union activities); Calif. Insurance Code sec. 12924(b) (“no individual shall be prosecuted or be subjected to punishment for any crime concerning which he/she is compelled by the Insurance Commissioner to testify or produce other evidence”).

8. *People v. Mower*, supra, at p. 473. This limited immunity entitles a defendant to raise a defense at trial and to bring a motion to set aside an indictment or information prior to trial. *Id.* at p. 470. It does not confer complete immunity from arrest and prosecution. *Id.* at p. 474.

9. Neither the CCUA nor, subsequently, its clarifying legislation, created other, affirmative “rights.” For example, there is no requirement for any accommodation of the use of cannabis on the property or premises of any place of employment or during the hours of employment. See Calif. Health & Safety Code §11362.785(a). Furthermore, nothing precludes an employer from discharging an employee who fails a drug test as a result of his/her use of cannabis for medical purposes (even outside of working hours or the workplace). See Calif. Health & Safety Code §11362.785(a); *Ross v. Ragingwire Telecommunications* (2008) 442 Cal.4th 920, 70 Cal.Rptr.3d 382 (pre-employment drug testing). These provisions demonstrate that no robust “rights” are created by the limited grant of immunity.

10. *People v. Mentch* (2008) 45 Cal.4th 274, 85 Cal.Rptr.3d 480.

11. Calif. Health & Safety Code §§11362.7-11362.83.

12. Under California law, the legislature cannot amend an initiative, such as the CCUA, unless the initiative grants the legislature authority to do so, Calif. Const., art. II, §10, subd.(c). The CCUA does not give the legislature authority to amend it without voter approval.

13. California Department of Justice, “Guidelines for the Security and Non-diversion of Marijuana Grown for Medical Use,” (Aug. 2008) (hereinafter Attorney General Guidelines). http://ag.ca.gov/cms_attachments/press/pdfs/n1601_medicalmarijuanaguidelines.pdf.

14. “Members also may reimburse the collective or cooperative for marijuana that has been allocated to them. Any monetary reimbursement that members provide to the collective or

cooperative should only be an amount necessary to cover overhead costs and operating expenses.” Id.

15. Attorney General Guidelines at p. 11.

16. See the partial listing of publicly-advertised dispensaries at <http://www.canorml.org/prop/cbclist.html>.

17. For example, patients cannot “self-diagnose,” as they do when purchasing dietary supplements, nor can patients seek a physician’s approval only after their use of cannabis, in an effort retroactively to “validate” such self-diagnosis. See, e.g., *People v. Rigo* (1999) 69 Cal. App.4th 409.

18. This is also true of opium. Different strains of the opium poppy may be rich in morphine, thebaine, or oripavine. These substances, in turn, are used to prepare very different medications. See DEA, “Authorized Sources of Narcotic Raw Materials,” 73 Fed. Reg. 6843 (Feb. 6, 2008).

19. Potter D.J., Clark P., Brown M.B., “Potency of Delta 9-THC and Other Cannabinoids in Cannabis in England in 2005: Implications for Psychoactivity and Pharmacology,” *Journal of Forensic Sciences* (2008 Jan) 53(1):90-4; Mehmedic Z., Martin J., Foster S., ElSohly M.A., editors, “Delta-9-THC and Other Cannabinoids Content of Confiscated Marijuana: Potency Trends, 1993-2003,” *International Association of Cannabis as Medicine* (2005 September 10) Leiden, Netherlands: International Association of Cannabis as Medicine; ElSohly M.A., Ross S. A., Mehmedic Z., Arafat R., Yi B., Banahan B.F., 3rd. Potency Trends of Delta9-THC and Other Cannabinoids in Confiscated Marijuana from 1980-1997,” *Journal of Forensic Sciences* (2000) 45 (1):24-30. A complete description of the adverse health effects of high-potency, inhaled herbal cannabis is beyond the scope of this document.

20. Russo E.B., “History of Cannabis and its Preparations in Saga, Science and Sobriquet,” *Chemistry & Biodiversity* (2007) 4(8):2624-48; Pertwee RG, “Cannabidiol as a Potential Medicine,” 47-65, in: Mechoulam R., ed. *Cannabinoids as Therapeutics*, (Basel, Switzerland ; Birkhauser Verlag) (2005).

21. Russo, E.B., “The Solution to the Medicinal Cannabis Problem,” in: Schatman, M.E. and Gant, B.L. eds, *Ethical Issues in Chronic Pain Management* 165, 176-181 (Boca Raton, FL; Taylor & Francis).

22. The Volcano® is produced by Storz & Bickel GmbH & Co. in Germany . A description and drawing can be found in Abrams, D., *infra*. It has limited portability. In use outside the clinical trial setting, the dose of cannabinoids, and the extent of pyrolytic products, will vary with the temperature setting and the patient’s inhalation practices.

23. Abrams, D., et al., “Vaporization as a Smokeless Cannabis Delivery System: A Pilot Study,” *Clinical Pharmacology & Therapeutics* (April 2007) at p. 4. <http://www.nature.com/cpt>.

24. Joy, J., Watson, S.J., Benson, J.A., Jr., *Marijuana and Medicine: Assessing the Science Base* (Washington DC; Institute of Medicine) (1999) at p. 203 (“Variation in individual responses is highest for oral THC and bioavailability is lowest.”).

25. There is no requirement in local legislation that cannabis sold in dispensaries must be

organic. Indeed, one dispensary in San Francisco advertises itself as the “only” dispensary offering organic cannabis in the City. <http://www.sanfranciscocannabisclubs.com/directory/san-francisco-alternative-patient-caregivers.htm>.

26. Scholten, W., “Therapeutic Cannabis in the Netherlands,” Drug Information Association Annual Meeting (June 17, 2004) (presentation); Hazekamp, A., “An Evaluation of the Quality of Medicinal Grade Cannabis in the Netherlands,” *Cannabinoids* 2006; 1(1):1-9. Canada also has a small government-sponsored and licensed cultivation program. There, too, the cannabis must be irradiated before it is distributed to patients. See Health Canada, “Product Information Sheet on Dried Marihuana.” <http://www.hc-sc.gc.ca/dhp-mps/marihuana/supply-approvis/dried-information-sechee-eng.php>. Certain high-technology cultivation practices, e.g., a computer-controlled greenhouse operated by a pharmaceutical company under strict standard operating procedures, can prevent such fungal growth. <http://www.gwpharm.com>.

27. One scientist has stressed that certain pathogens, such as aflatoxins, are not destroyed by heat (as in smoking or vaporizing) and are increasingly being recognized as an “underestimated source of neurological toxicity or infections such as aspergillosis.” Individuals who are using anti-inflammatory steroids or have compromised immune systems are especially vulnerable to such infections. See Hazekamp, *supra*, at p. 6.

28. Smoking also produces harmful pyrolytic products that can impair a patient’s pulmonary function and cause other harm. Tashkin DP, “Smoked Marijuana as a Cause of Lung Injury,” *Monaldi Arch Chest Dis.* (2005 June) 63(2):93-100. In addition, many dispensaries permit cannabis consumption on the premises. However, if cannabis joints or vaporizers are shared, dangerous pathogens can be spread amongst seriously ill patients. Zanicco V, “Meningococcal Cases Linked by Sharing Joints,” Vancouver, BC, Canada : Vancouver Coastal Health; 2005 [April 8]. http://www.vch.ca/news/docs/2005_04_07_mening_joints.pdf.

29. Office of National Drug Control Policy, “Medical Marijuana Reality Check.” http://www.whitehousedrugpolicy.gov/drugfact/factsht/medical_marijuana.html. Accessed Feb. 27, 2009. *Alternatives Magazine*, Fall 2006 Issue 39.

30. CNBC, “A Gallery of Medical Marijuana.” <http://www.cnbc.com/id/28561896>. Accessed March 1, 2009.

31. *People v. Mentch* (2008) 45 Cal.4th 274, 85 Cal.Rptr.3d 480 (patient using 3 grams per day).

32. In California, for example, state law does not require a government, private, or any other health insurance provider or health care service plan to be liable for any claim for reimbursement for the use of medicinal cannabis. Calif. Health & Safety Code §11362.785(d).

33. CNBC, “A Gallery of Medical Marijuana.” <http://www.cnbc.com/id/28561896>. Accessed March 1, 2009. CNBC, “Inside America’s Pot Industry,” (Jan. 22, 2009).

34. Montopoli, B., “Obama Announces Stem Cell Decision,” CBS News Political Hotsheet (March 9, 2009) (President Obama remarks in full) at p. 3.

35. 21 U.S.C. §§ 301-399a.

36. 21 U.S.C. §§ 801-971.

37. Even at the research stage, an investigational product may be tested in actual patients only if the physician-investigator has preliminary evidence of safety and a protocol approved by the FDA. The protocol must undergo careful scrutiny from an Institutional Review Board (IRB).

38. Congress placed most of these substances in their respective schedules as part of the CSA's enactment in 1970, but new substances are continually scheduled and existing substances are moved between schedules as new scientific data become available. DEA, "Controlled Substance Schedules," (Chronological Order). <http://www.deadiversion.usdoj.gov/schedules/schedules.htm>.

39. Examples of Schedule I botanical materials classified as "hallucinogens" are marijuana (cannabis), psilocybin, and ibogaine. Pure synthetic THC is also in Schedule I. 21 C.F.R. §1308.11.

40. A drug's potential for abuse is a threshold issue in determining the schedule into which the drug may be placed. The term is not defined in the CSA, but the legislative history demonstrates that the following factors are indicators that a drug or other substance has a potential for abuse:

- There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community;
- There is significant diversion of the drug or other substance from legitimate drugs channels;
- Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or
- The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

Of course, evidence of actual abuse of a substance is indicative that a drug has a potential for abuse.

H. R. Rep. No. 1444, 91st Cong., 2d Sess. (1970), reprinted in 1970 U.S. Code Cong. & Ad. News 4566, 4601.

41. 21 C.F.R. §1303.21; the registration application of a bulk manufacturer must pass through a notice (publication in the Federal Register) and comment procedure. 21 CF.R. §1301.33.

42. 21 C.F.R. §1303.12.

43. Substances in Schedule II-V have an accepted medical use. Substances in schedules III-V also have lower abuse potential and are subject to fewer restrictions. Interestingly, in California, cannabis remains in Schedule I of the state controlled substances law, despite the fact that it has been decriminalized for limited medical use. Calif. Health & Safety Code §11054(d)(13).

44. See 57 Fed.Reg. 10499, 10506 (March 26, 1992). See *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994). The DEA originally developed these criteria during the scheduling of MDMA. 53 Fed. Reg. 5156 (Feb. 22, 1988); *Grinspoon v. Drug Enforcement Administration*, 828 F.2d 881 (1st Cir. 1987).

45. Hence, FDA approval of a specific finished product is generally sufficient to establish an “accepted medical use” for the substance contained therein. There are rare exceptions. See, e.g., “dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product” is in Schedule III and has a Drug Code of 7369, 21 C.F.R. §1308.13(g), whereas pure synthetic THC remains in Schedule I, with a Drug Code of 7370. 21 C.F.R. §1308.11(d). See, 51 Fed. Reg. 1746 (May 13, 1986; 64 Fed. Reg. 35928 (July 2, 1999) (dronabinol product). FDA-approved products containing GHB are in Schedule III while “street” GHB is in Schedule I. 65 Fed. Reg. 13235 (March 13, 2000), Pub. L. 106-172 (GHB). Hence, a formulated cannabis-derived product could be placed in Schedule II or III after FDA approval, while crude herbal cannabis could remain in Schedule I.

46. FDA approval is not technically a legal precondition to rescheduling. *Grinspoon*, supra, at p. 8991.

47. See, e.g., tapentadol. The finished pharmaceutical product, manufactured by Johnson & Johnson, was approved by the FDA in November 2008. DEA has issued a proposed rule placing tapentadol into Schedule II. 74 Fed. Reg. 7386 (Feb. 17, 2009). The finished product does not yet have a trade, i.e., “branded,” name.

48. Under the CPS method (used by all cultivating countries except India), the plant is allowed to go to seed; portions of the plant are then processed into a concentrate. It is generally believed that CPS is less divertible than opium. CPS may be rich in morphine, thebaine, or oripavine. See DEA, “Authorized Sources of Narcotic Raw Materials,” 73 Fed. Reg. 6843 (Feb. 6, 2008).

49. Thebaine is used to manufacture oxycodone, which in turn can be used to manufacture hydromorphone; oripavine is used to make buprenorphine, as well as naloxone (an opioid antagonist). *Id.* See 72 Fed. Reg. 54208 (Sept. 24, 2007) (oripavine scheduled separately in Schedule II -- rather than as a derivative of thebaine -- to comply with the U.S. ’s obligations under the Single Convention).

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