

Testimony Submitted to the Massachusetts Medical Society

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Is marijuana medicine? Smoked marijuana is not; its isolated components and extracts can be.

Modern science has synthesized the marijuana plant's primary psychoactive ingredient – THC – into a pill form. This pill, dronabinol (or Marinol®, its trade name) is sometimes prescribed for nausea and appetite stimulation. Another drug, Cesamet, mimics chemical structures as that naturally occur in the plant.

But when most people think of medical marijuana these days, they don't think of a pill with an isolated component of marijuana, but rather the entire smoked, vaporized, or edible version of the *whole marijuana plant*. Rather than isolate active ingredients in the plant – like we do with the opium plant when we create morphine, for example – many legalization proponents advocate vehemently for smoked marijuana to be used as a medicine. But the science on smoking any drug is clear: smoking especially highly-potent whole marijuana, is not a proper delivery method, nor do other delivery methods ensure a reliable dose. And while parts of the marijuana plant have medical value, the Institute of Medicine said in its landmark 1999 report: “Scientific data indicate the potential therapeutic value of cannabinoid drugs...smoked marijuana, however, is a crude THC delivery system that also delivers harmful substances...and should not be generally recommended...”¹

It is not so unimaginable to think about other marijuana-based medications that might come to market very soon. Sativex ®, an oral mouth spray developed from a blend of two marijuana extracts (one strain is high in THC and the other in CBD, which counteracts THC's psychoactive effect), has already been approved in 10 countries and is in late stages of approval in the U.S. It is clear to anyone following this story that it is possible to develop marijuana-based medications in accordance with modern scientific standards, and many more such legitimate medications are just around the corner.

Recently, the federal government has expanded its enforcement actions against commercialized “medical marijuana” operations. They have closed down dispensaries in states like California (including the “Harvard” of medical marijuana learning – the now-defunct “Oaksterdam University”), Colorado, and Oregon.

¹ *Marijuana and Medicine: Assessing the Science Base*, Institute of Medicine 1999. http://books.nap.edu/catalog.php?record_id=6376

The Medical Community is Staunchly Against Smoked Marijuana as Medicine – And Rightly So

Marijuana itself is not an approved medicine under the Food and Drug Administration's (FDA) scientific review process. Yet 16 states and the District of Columbia have permitted marijuana to be sold as "medicine" for various conditions. Although, some of the individual, orally-administered components of the cannabis plant (*Marinol* and *Cesamet* are two such drugs available today) have medical value, smoking marijuana is an inefficient and harmful method for delivering the constituent elements that have or may have medicinal value. The FDA process for approving medicine remains the only scientific and legally recognized procedure for bringing safe and effective medications to the American public. To date, the FDA has not found smoked marijuana to be either safe or effective medicine for any condition.

In 1997, the White House Office of National Drug Control Policy (ONDCP) requested that the Institute of Medicine (IOM) conduct a review of the scientific evidence regarding the potential health benefits and risks of cannabis and its component cannabinoids. In 1999, the IOM issued the report *Cannabis and Medicine: Assessing the Science Base* that became the foundation of study into "medical marijuana." For a number of these conditions, the group concluded that there would only be limited value in pursuing further research into smoked cannabis, because effective treatments were already available. However, they did recommend new controlled studies on cannabis, since current research did not provide definitive answers on its risk/benefit profile. The consensus was that in these research studies, smoked cannabis must meet the same standards as other medications in terms of effectiveness and safety. IOM made a series of recommendations pertaining to the use of cannabis in medical treatment that revolve around the need for more research and evaluation. They concluded that: "The goal of clinical trials of smoked cannabis would not be to develop cannabis as a licensed drug but rather to serve as a first step toward the possible development of *nonsmoked rapid-onset cannabinoid delivery systems* (emphasis added)." And that: "there is little future in smoked marijuana."

No major medical association has come out in favor of smoked marijuana for widespread medical use. Further, public health organizations have weighed in:

American Society of Addiction Medicine: "ASAM asserts that cannabis, cannabis-based products, and cannabis delivery devices should be subject to the same standards that are applicable to other prescription medications and medical devices and that these products should not be distributed or otherwise provided to patients unless and until such products or devices have received marketing approval from the Food and Drug Administration. ASAM rejects smoking as a means of drug delivery since it is not safe. ASAM rejects a process whereby State and local ballot initiatives approve medicines because these initiatives are being decided by individuals not qualified to make such decisions."

American Cancer Society: "The ACS is supportive of more research into the benefits of cannabinoids. Better and more effective treatments are needed to overcome the side effects of cancer and its treatment. The ACS does not advocate the use of inhaled marijuana or the legalization of marijuana."

American Glaucoma Foundation: “Marijuana, or its components administered systemically, cannot be recommended without a long term trial which evaluates the health of the optic nerve,” said the editorial. “Although marijuana can lower IOP, its side effects and short duration of action, coupled with a lack of evidence that its use alters the course of glaucoma, preclude recommending this drug in any form for the treatment of glaucoma at the present time.”

National Multiple Sclerosis Society: “Although it is clear that cannabinoids have potential both for the management of MS symptoms such as pain and spasticity, as well as for neuroprotection, the Society cannot at this time recommend that medical marijuana be made widely available to people with MS for symptom management. This decision was not only based on existing legal barriers to its use but, even more importantly, because studies to date do not demonstrate a clear benefit compared to existing symptomatic therapies and because issues of side effects, systemic effects, and long-term effects are not yet clear.” -- Recommendations Regarding the Use of Cannabis in Multiple Sclerosis: Executive Summary. National Clinical Advisory Board of the National Multiple Sclerosis Society, Expert Opinion Paper, Treatment Recommendations for Physicians, April 2, 2008. <http://www.nationalmssociety.org>.

The American Academy of Pediatrics (AAP) believes that “[a]ny change in the legal status of marijuana, even if limited to adults, could affect the prevalence of use among adolescents.” While it supports scientific research on the possible medical use of cannabinoids as opposed to smoked marijuana, it opposes the legalization of marijuana. -Committee on Substance Abuse and Committee on Adolescence. “Legalization of Marijuana: Potential Impact on Youth.” *Pediatrics* Vol. 113, No. 6 (June 6, 2004): 1825-1826. See also, Joffe, Alain, MD, MPH, and Yancy, Samuel, MD. “Legalization of Marijuana: Potential Impact on Youth.” *Pediatrics* Vol. 113, No. 6 (June 6, 2004): e632-e638h.

The American Medical Association (AMA) has called for more research on the subject, with the caveat that this “should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.”

John Knight, director of the Center for Adolescent Substance Abuse Research at Children’s Hospital Boston, recently wrote: “Marijuana has gotten a free ride of sorts among the general public, who view it as non-addictive and less impairing than other drugs. However, medical science tells a different story.”

Similarly, Christian Thurstone, a board-certified Child and Adolescent Psychiatrist, an Addiction Psychiatrist, and also an Assistant Professor of Psychiatry at the University of Colorado, said:

“In the absence of credible data, this debate is being dominated by bad science and misinformation from people interested in using medical marijuana as a step to legalization for recreational use. Bypassing the FDA’s well-established approval process has created a mess that especially affects children and adolescents. Young people, who are clearly being targeted with medical marijuana advertising and diversion, are most vulnerable to developing marijuana addiction and suffering from its lasting effects.”

—Dr. Christian Thurstone, MD, Assistant Professor at Denver Health & Hospital Authority

What Would Massachusetts' Ballot Initiative Do?

Allows Virtually Anyone to Obtain Marijuana

- HR 3885 lists some conditions for which marijuana can be obtained, but then opens it up to “other conditions as determined in writing by a qualifying patient’s physician.”

Sets Up Illegal Medical Marijuana Bureaucracy Within Department of Health

- The bill would put Massachusetts in the compromising position of violating federal law by allowing the cultivation of a Schedule I controlled substance.
- In other states, like California, Washington, Arizona, and Colorado, U.S. Justice Department officials have raided such facilities, warned state officials of imminent arrest, and threatened states with significant criminal and civil action.

State Employees at Risk of Arrest

- U.S. Department of Justice officials have threatened to arrest state employees who facilitate marijuana use for purported “medical” purposes.²

Could Compromise Massachusetts' Ability to Obtain Federal Funds and Support

- By violating Federal law, Massachusetts threatens its ability to maintain federally-mandated drug-free workplaces. Additionally, the bill could compromise the State’s ability to obtain federal funds.

Allows 60-Day Supply of Marijuana Defined by the Department of Health

- This ensures that large amounts of marijuana could be used as a defense under the guise of “medicine.”

Marijuana Use Among Youth Would Increase

- Major studies by researchers at Columbia University and elsewhere have found that states with “medical” marijuana had marijuana abuse/dependence rates almost twice as high than states without such laws.^{3 4}

² See the Memo to the Washington Governor from US Attorneys Durkan and Ormsby:
<http://reason.com/assets/db/13050453232855.pdf>

- Since decriminalization passed in 2008, Massachusetts has already seen a rise in youth marijuana use and now has a 30% higher than that of the nation.⁵

Raids from Federal Government

- The Obama Administration has been unambiguous in their opposition to state-based medical marijuana programs and has been routinely raiding state-sanctioned marijuana dispensaries.
- The Department of Justice released two memoranda in 2009 and 2011 stating that that “prosecution of significant traffickers in illegal drugs, including marijuana, remains a core priority” of the Department, and that current policy “was never intended to shield such activities from federal enforcement action and prosecution, ***even where those activities purport to comply with state law***. Persons who are in the business of cultivating, selling, or distributing marijuana, and those who knowingly facilitate such activities, are in violation of the Controlled Substances Act, ***regardless of state law***.”⁶

Chronically Ill Are Not Using Existing State Programs

- Studies have shown that in California more than 95% of “medical marijuana” users were not suffering from life threatening illnesses and in one sample of over 4,000 users, 74% of people had used cocaine in their lifetime.^{7 8}

³ Cerda, M. et al. (in press). Medical marijuana laws in 50 states: investigating the relationship between state legalization of medical marijuana and marijuana use, abuse and dependence. *Drug and Alcohol Dependence*. Found at <http://www.columbia.edu/~dsh2/pdf/MedicalMarijuana.pdf>

⁴ Wall, M. et al (2011). Adolescent Marijuana Use from 2002 to 2008: Higher in States with Medical Marijuana Laws, Cause Still Unclear, *Annals of epidemiology*, Vol 21 issue 9 Pages 714-716.

⁵ CDC, Youth Online, High School YRBSS, <http://apps.nccd.cdc.gov/youthonline/App/Default.aspx>

⁶ Ogden, D. (Oct. 19, 2009). Memorandum to Selected United States Attorneys, *Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana*, **Department of Justice** and Cole, J. (Jun. 29, 2011). Memorandum to United States Attorneys, ***Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use***, **Department of Justice**.

⁷ O'Connell, T and Bou-Matar , C.B. (2007). Long term marijuana users seeking medical cannabis in California (2001–2007): demographics, social characteristics, patterns of cannabis and other drug use of 4117 applicants. *Harm Reduction Journal*, <http://www.harmreductionjournal.com/content/4/1/16>

⁸ Nunberg, Helen; Kilmer, Beau; Pacula, Rosalie Liccardo; and Burgdorf, James R. (2011) “An Analysis of Applicants Presenting to a Medical Marijuana Specialty Practice in California,” *Journal of Drug Policy Analysis*: Vol. 4: Iss. 1, Article 1. Available at: <http://www.bepress.com/jdpa/vol4/iss1/art1>

- The average user in California was a 32-year old white male with a history of alcohol and substance abuse and no history of life-threatening illness.
- In Colorado, according to the Department of Health, only 2% of users reported cancer, and less than 1% reported HIV/AIDS as their reason for marijuana. The vast majority (94%) reported “severe pain.”⁹
- In Oregon, there are reports that only 10 physicians made the majority all recommendations for “medical” marijuana¹⁰, and agitation, seizures, cancer, HIV/AIDS, cachexia, and glaucoma were the last six reasons people utilized marijuana for “medical” purposes.¹¹

How does medical marijuana currently work in the various states?

At present in California, and in several other states, it is widely recognized that the reality of the “medical use” of marijuana is highly questionable. For payment of a small cash sum, almost anyone can obtain a physician’s “recommendation” to purchase, possess, and use marijuana for alleged medical purposes. Indeed, numerous studies have shown that the most customers of these dispensaries do not suffer from chronic, debilitating conditions such as HIV/AIDS or cancer.^{12 13} Both sides of the argument agree that this system has essentially legalized marijuana for recreational use, at least amongst those individuals able and willing to buy a recommendation.¹⁴ To date many pot dispensaries are mom and pop operations, though some act as multimillion dollar, professional companies. A recent documentary on the Discovery Channel, which examined the practices of Harborside Health Center in Oakland, California—by its own admission, the largest marijuana dispensary “on the planet,” the buds (which are distributed directly to member-patients) are merely examined visually and with a microscope. The buds are also handled by employees who do not use gloves or face masks. Steve DeAngelo, Harborside’s co-founder, states that they must “take it as it comes.” The documentary noted that some plant material is tested by Steep Hill Laboratory, but there was no evidence that

⁹ See Colorado Department of Public Health, <http://www.cdphe.state.co.us/hs/medicalmarijuana/statistics.html>

¹⁰ See for example, Danko, D. (2005). Oregon Medical Marijuana Cards Abound, *The Oregonian*, January 23, 2005. Also see Oregon Medical Marijuana, Protect the Patients & Treat it Like Medicine, http://www.oregon.gov/Pharmacy/Imports/Marijuana/Public/ORStatePolice_OMMAMLegPP.pdf?ga=t

¹¹ Oregon Medical Marijuana Program Statistics, <http://public.health.oregon.gov/DISEASES/CONDITIONS/CHRONICDISEASE/MEDICALMARIJUANAPROGRAM/Pages/data.aspx>

¹² O’Connell, T and Bou-Matar, C.B. (2007). Long term marijuana users seeking medical cannabis in California (2001–2007): demographics, social characteristics, patterns of cannabis and other drug use of 4117 applicants. *Harm Reduction Journal*, <http://www.harmreductionjournal.com/content/4/1/1>

¹³ Nunberg, Helen; Kilmer, Beau; Pacula, Rosalie Liccardo; and Burgdorf, James R. (2011) “An Analysis of Applicants Presenting to a Medical Marijuana Specialty Practice in California,” *Journal of Drug Policy Analysis*: Vol. 4: Iss. 1, Article 1. Available at: <http://www.bepress.com/jdpa/vol4/iss1/art1>

¹⁴ According to Allen St. Pierre of NORML, “in California, marijuana has also been de facto legalized under the guise of medical marijuana.” See Transcript of Don Lemon CNN Television Show with Kevin Sabet and Allen St. Pierre: <http://transcripts.cnn.com/TRANSCRIPTS/0905/09/cnr.04.html>. Accessed January 22, 2012

Steep Hill’s instrumentation and techniques are “validated,” that its operators are properly trained and educated, that its reference standards are accurate, and that its results are replicable by other laboratories.

What if we rescheduled marijuana?

In the wake of recent enforcement efforts by the Obama Administration, the governors of Washington, Rhode Island, and Colorado have filed a petition with the Drug Enforcement Administration (DEA) to reschedule marijuana.¹⁵ Specifically, the petition asks the DEA to reclassify marijuana from Schedule I to Schedule II of the federal Controlled Substances Act (CSA). The governors contend that such rescheduling will eliminate the conflict between state and federal law and enable states to establish a “regulated and safe system to supply legitimate patients who may need medical cannabis.”

The current petition takes a unique approach. It seeks to move marijuana to Schedule II “for medicinal purposes only.” Marijuana advocacy organizations, such as the Marijuana Policy Project (MPP) and Americans for Safe Access (ASA) are urging other governors around the country to join onto the petition. The petition has garnered considerable publicity, but, as MPP acknowledges, “[r]escheduling is not a cure-all.”¹⁶ This is an understatement. Indeed, it is not even a significant step in the direction that the governors, MPP, and ASA hope to move.

Part of the confusion over the actual significance of Schedule II status stems from a misunderstanding of the interrelated, but distinct, functions of the CSA and the Food, Drug, and Cosmetic Act (FDCA). Under the FDCA, the FDA approves *specific medical products* produced by particular “innovator” (for branded products) or generic manufacturers. For example, oxycodone, an opioid, is in Schedule II. Specific products, such as OxyContin® (an extended release form), are also in Schedule II. Physicians prescribe a specific branded or generic product, in a particular dose and dosage form. So until the FDA approves a *smoked marijuana product*, it cannot be prescribed or sold in “dispensaries” for medical use. And the FDA has been clear that smoked marijuana does not pass its rigorous approval standards.

Imagine for a moment that the “medical marijuana” advocates were instead “medical opium” advocates and that various states passed laws decriminalizing (or affirmatively authorizing and regulating) the cultivation and distribution of opium plant material, i.e., opium latex or poppy straw. Even though opium latex and poppy straw **are each in Schedule II**, there would still be a conflict between such state laws and both the CSA and the FDCA. As a well-known drug reform advocacy website states: “If poppies are grown as sources for opiates, there is no question that it violates the CSA.”¹⁷ Furthermore, physicians would not be authorized to prescribe, nor pharmacists to dispense, dried opium latex or poppy straw.¹⁸ In order to be

¹⁵Ingold, J. (Dec. 29, 2011) “Colorado Asks DEA To Reschedule Marijuana.” *Denver Post* Accessed on January 20, 2012 at http://www.denverpost.com/news/marijuana/ci_19636149

¹⁶Marijuana Policy Project, Message to Governors, Letter. (2011). Accessed on Jan. 12, 2012: <https://secure2.convio.net/mpp/site/Advocacy?cmd=display&page=UserAction&id=1079>

¹⁷http://www.erowid.org/plants/poppy/poppy_law.shtml

¹⁸Both Laudanum and Paregoric (tinctures of opium) pre-existed the original Food and Drugs Act of 1906. Recently, the FDA has taken enforcement action against these products as “unapproved drugs” that have not undergone FDA trials to prove safety and efficacy, as well as for violations of Good Manufacturing Practices. See, e.g., FDA, Warning Letter, Hi-Tech Pharmacal Co., Inc (June 28, 2010),

prescribed, a specific product containing opiates would have to pass muster in the FDA approval process. Therefore, the mere act of placing herbal marijuana in Schedule II would not make it available to patients nor address the conflict between state and federal law.

But won't rescheduling allow for research to be done?

No. Rescheduling is not necessary to make marijuana products available for research. A committee of the California Medical Association recently called for the rescheduling of marijuana “so it can be tested and regulated.” However, it is not necessary for marijuana to be rescheduled in order for legitimate research to proceed. Schedule I status does not prevent a product from being tested and researched for potential medical use. Schedule I research certainly does go forward. In a recent pharmaceutical company-sponsored human clinical study investigating a product derived from marijuana extracts, the DEA registered approximately 30 research sites in the U.S. and also registered an importer to bring the product into the U.S. from the U.K., where it was manufactured.¹⁹ And a quick search of NIH-reporter reveals more than \$14 Million of current research going forward on marijuana and medicine. Research is happening.

What about obtaining marijuana for research?

Researchers wishing to conduct studies with herbal/whole plant marijuana may obtain it from the National Institutes of Health (or import formulated extracts).. Researchers who obtain grant funding from an institute of the National Institutes of Health (NIH), such as NIDA, can obtain marijuana for their study; researchers who are externally funded must undergo the equivalent of a grant review process (review of their study design by an expert committee of the Public Health Service) in order to obtain such marijuana at cost from NIDA. NIH (via the University of Mississippi's National Center for Natural Products Research) has the ability to produce standardized marijuana of varying THC potencies. Its cultivation area of five acres has been adequate to supply all marijuana-related studies to date.²⁰ In theory, NCNPR could also produce marijuana extracts, or such products could be imported from outside the US for research, as is currently the case with Sativex®.

What has been the result of medical marijuana in various states on drug use rates?

An in-depth examination of medical marijuana and its relationship to the explosion in use and users came in 2012 from five epidemiological researchers at Columbia University. Using results from several large national surveys, they concluded that: “residents of states with medical

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm219984.htm> (Paregoric). See also, FDA, Guidance for FDA Staff and Industry, “Marketed Unapproved Drugs—Compliance Policy Guide,” <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070290.pdf>.

¹⁹ GW Pharmaceuticals, “Sativex Commences US Phase II/III Clinical Trial in Cancer Pain,” <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070573.pdf> (press release); DOJ, DEA, “Importer of Controlled Substances; Notice of Registration,” 71 Fed. Reg. 64298 (Nov. 1, 2006).

²⁰ See DOJ, DEA, “Lyle E. Craker; Denial of Application,” 74 Fed. Reg. 2101, 2104 (Jan. 14, 2009).

marijuana laws had higher odds of marijuana use and marijuana abuse/dependence than residents of states without such laws.”²¹

States with medical marijuana laws also show much higher average marijuana use by adolescents, and lower perceptions of risk from use, than non-medical pot states. ¹¹This would seem to indicate that relaxed community norms about drug use contribute greatly to an increased prevalence of use and users, a situation resulting from the spread of an attitude that “if pot is medicine and is sanctioned by the state, then it must be safe to use by anyone.”

Medical marijuana should really only be about bringing relief to the sick and dying, and it should be done in a responsible manner that formulates the active components of the drug in a non-smoked form that delivers a defined dose. However, in most states with medical marijuana laws, it has primarily become a license for the state-sanctioned use of a drug by most anyone who desires it. Developing marijuana-based medications through the FDA process is more likely to ensure that seriously ill patients, who are being supervised by their actual treating physicians, have access to safe and reliable products.

²¹ Cerda, M. et al. (2011). Medical marijuana laws in 50 states: investigating the relationship between state legalization of medical marijuana and marijuana use, abuse and dependence. *Drug and Alcohol Dependence*. Found at <http://www.columbia.edu/~dsh2/pdf/MedicalMarijuana.pdf> ; Wall, M. et al (2011). Adolescent Marijuana Use from 2002 to 2008: Higher in States with Medical Marijuana Laws, Cause Still Unclear, *Annals of epidemiology*, Vol 21 issue 9 Pages 714-716.