

# Some Straight Truth About

## Medical Marijuana Laws Provide State-sanctioned Use of a Drug by Most Anyone Who Desires it

BY KEVIN SABET, PHD

Is marijuana medicine? The answer is *yes, no, and maybe*.

Modern science has synthesized the marijuana plant's primary psychoactive ingredient — THC — into a pill form. This pill, dronabinol (or Marinol<sup>®</sup>, 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...<sup>1</sup>

It is not so unimaginable to think about other marijuana-based medications that might come to market very soon. Sativex<sup>®</sup>, 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 mari-

juana" 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. Here is some straight truth about marijuana for "medical" purposes."

### 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.<sup>2,3</sup> 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.<sup>4</sup> 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 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.<sup>5</sup> 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)



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# Marijuana for Medical Purposes

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.”<sup>6</sup> 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.”<sup>7</sup> Furthermore, physicians would not be authorized to prescribe, nor pharmacists to dispense, dried opium latex or poppy straw.<sup>8</sup> In order to be 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.<sup>9</sup> 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.<sup>10</sup> 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 marijuana laws had higher odds of marijuana use and marijuana abuse/dependence than residents of states without such laws.”<sup>11</sup>

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.<sup>11</sup> This 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.

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See references on page 27



For more on Medical Marijuana, check out the upcoming webinar on marijuana: September 10, 2013 @ 3-4pm EST with Allan Barger. Details at [www.naadac.org/education](http://www.naadac.org/education)