JUST THE FACTS: MARIJUANA AND MEDICINE

Is marijuana medicine? In short, smoked crude marijuana is not medicine. However, marijuana does have medicinal properties – found in its individual components. These components can be isolated and delivered in a safe and effective way. Many of these components are being researched; some have been approved as medicines in the U.S. and elsewhere. More research is needed.

Marijuana is not medicine. Marijuana is medicine. Marijuana might be medicine. These three seemingly contradictory statements *are actually all true in one way or another*. Over the past two decades, there have been major developments in the field of marijuana as medicine: 17 states and D.C. have approved legislation allowing the consumption of raw marijuana for medicinal purposes; the Food and Drug Administration (FDA) has determined that smoked marijuana is not medicine; and research has greatly advanced surrounding the individual components of the marijuana plant and how they might have therapeutic properties. The latter fact is by far the most exciting, even if the media rarely covers it.

What Does The Science Say?

An exhaustive review by the National Academy of Sciences, Institute of Medicine (IOM), has concluded that smoked marijuana should "generally not be recommended for medical use."¹ Additionally, smoked marijuana varies by dose, due to individual differences in absorption and metabolism in the liver, as well as puff frequency, depth of inhalation, and retention of inhaled smoke.² This makes it difficult to "standardize" a marijuana cigarette like a traditional medicine.

Additionally, the Food and Drug Administration ruled that smoked marijuana does not meet the modern standards of medicine in the United States. Here's what they said in 2006:

"No sound scientific studies supported medical use of marijuana for treatment in the United States, and no animal or human data supported the safety or efficacy of

¹ Joy, J. E., Waston, S. J., & Benson, J. A. (Eds.). (1999). *Marijuana and medicine: Assessing the science base*. Washington, DC: National Academy Press.

² Gorelick, DA & Heishman, SJ (2006). Methods for clinical research involving cannabis administration. In *Methods in Molecular Medicine: Marijuana and Cannabinoid Research: Methods and Protocols* (Ed. E. S. Onaivi). New Jersey: Humana.

marijuana for general medical use. There are alternative FDA-approved medications in existence for treatment of many of the proposed uses of smoked marijuana.³

Furthermore, the 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."

Non-Smoked Marijuana as Medicine

If smoked marijuana shows little promise, what might science focus on to develop a medicine from marijuana? First, it is important to distinguish between the *whole* cannabis plant material and *individual* components within the cannabis plant. Some constituents of cannabis, including THC, are indeed available today in pill form (dronabinol, or *Marinol*®); some synthetic versions of those constituents are also available (nabilone, or *Cesamet*®). These can be obtained at a pharmacy.

Though the whole cannabis plant is not medicine, several governments including Canada, the United States, the United Kingdom, the Czech Republic, Spain, and other European countries have robust research programs to determine the medical efficacy of some of the components of cannabis. In some of these countries, cannabis-based medicines have been approved to treat cancer pain and spasticity related to multiple sclerosis (MS). These products include nabiximols (Sativex®), which is an oral mouth spray comprised of THC and another cannabis component, which allows for precise dosing, eliminates the major health consequences of inhaling smoke and tends to lessen the intoxicating effects of THC.

Clearly, marijuana-related research is an exciting area of study, and more study will likely yield a greater benefit to the public health. We need to study what other components in marijuana may have medical value, and figure out how to best deliver those components to people.

³ Interagency memo regarding marijuana as medicine. Accessed Sept 3, 2012 at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108643.htm

Rescheduling Marijuana

Marijuana remains in the most restrictive schedule of the Controlled Substances Act – Schedule I. This means that it has no accepted medical use. Some have claimed that since marijuana is Schedule I, research is not possible on the drug. Additionally, a recent 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 today 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. ⁴ And a quick search of the "NIH-reporter" website reveals more than \$14 million of current research going forward on marijuana and medicine. Research is happening. But we could always use more.

Obtaining Marijuana for Research

Researchers wishing to conduct studies with marijuana may obtain it from the National Institutes of Health (or import formulated extracts like the U.K. company referenced above does). Researchers who obtain grant funding from an institute of the National Institutes of Health (NIH) can obtain marijuana for their study; researchers who are externally funded must undergo a review of their study design in order to obtain such marijuana at cost. NIH, through 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 marijuanarelated studies to date.⁵ In theory, University of Mississippi could also produce marijuana extracts, or

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). ⁵ See DOJ, DEA, "Lyle E. Craker; Denial of Application," 74 Fed. Reg. 2101, 2104 (Jan. 14, 2009).

⁴ GW Pharmaceuticals, "Sativex Commences US Phase II/III Clinical Trial in Cancer Pain,"

such products could be imported from outside the US for research, as is currently the case with Sativex®.

Non-FDA Approved "Medical" Marijuana

The American Medical Association, National Cancer Institute, American Cancer Society, National Multiple Sclerosis Society, American Society of Addiction Medicine, and most major medical associations oppose state-based, non-FDA approved whole marijuana as medicine.

It is important to distinguish between users of scientifically approved, legitimate marijuana based medications and those who seek to use "medical" marijuana as a shield for legitimizing general marijuana use. A 2007 study analyzing over 3,000 medical cannabis users in California, found that an overwhelming majority (87.9%) of those asked about the age they began using marijuana had tried it before the age of 19, and the average user was a 32-year-old white male. 74% of the Caucasians in the sample had used cocaine, and over 50% had used methamphetamine in their lifetime.⁶ According to a 2011 study in the *Journal of Drug Policy Analysis* that examined 1,655 applicants in California who sought a physician's recommendation for medical marijuana, very few of those who sought a recommendation had cancer, HIV/AIDS, glaucoma, or multiple sclerosis.⁷ Additionally, in the US state of Colorado, according to the state Department of Health, only 2% of users reported cancer, and less than 1% reported HIV/AIDS as their reason for cannabis. The vast majority (94%) reported "severe pain."⁸ Finally, in Oregon, there are reports that only 10 physicians made half of all recommendations for "medical" cannabis⁹, and agitation, seizures, cancer, HIV/AIDS, wasting

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 ⁶ O'Connell, T and Bou-Matar, C.B. (2007). Long term cannabis 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
⁷ Nunberg, Helen; Kilmer, Beau; Pacula, Rosalie Liccardo; and Burgdorf, James R. (2011) "An

⁷ Nunberg, Helen; Kilmer, Beau; Pacula, Rosalie Liccardo; and Burgdorf, James R. (2011) "An Analysis of Applicants Presenting to a Medical Cannabis Specialty Practice in California,"

⁸ See Colorado Department of Public Health, http://www.cdphe.state.co.us/hs/medicalcannabis/statistics.html

⁹ See for example, Danko, D. (2005). Oregon Medical Cannabis Cards Abound, *The Oregonian*, January 23, 2005. Also see Oregon Medical Cannabis, Protect the Patients & Treat it Like Medicine, http://www.oregon.gov/Pharmacy/Imports/Cannabis/Public/ORStatePolice_OMMALegPP.pdf?ga=t

syndrome (extreme weight loss), and glaucoma were the last six reasons people utilized cannabis for "medical" purposes.¹⁰

Marijuana as Medicine and Youth

The use of marijuana under the guise of medicine has also affected youth drug use patterns. A study by researchers at Columbia University looked at two separate datasets and found that residents of states with "medical" marijuana had marijuana abuse/dependence rates almost twice as high than states without such laws.¹¹ Another study in the *Annals of Epidemiology* found that, among youths age 12 to 17, cannabis usage rates were higher in states with medical cannabis laws (8.6%) compared with those without such laws (6.9%).¹² More research on this connection is needed.

These issues are not easy. No one wants to see their loved ones suffer, but that is a reason we should expedite research into FDA-approved medications containing components of marijuana, not increase the access and availability of marijuana.

http://public.health.oregon.gov/diseasesconditions/chronicdisease/medicalcannabisprogram/pages/data.aspx ¹¹ Cerda, M. et al. (2012). Medical cannabis laws in 50 states: investigating the relationship between state legalization of medical cannabis and cannabis use, abuse and dependence. *Drug and Alcohol Dependence*. Found at http://www.columbia.edu/~dsh2/pdf/MedicalCannabis.pdf;120(1-3):22-7.

¹⁰ Oregon Medical Cannabis Program Statistics,

¹² Wall, M. et al (2011). Adolescent Cannabis Use from 2002 to 2008: Higher in States with Medical Cannabis Laws, Cause Still Unclear, *Annals of Epidemiology, Vol* 21 issue 9 Pages 714-716.