

## Commentary

November 15, 2011

### *California Medical Association is Misguided in its Support of Rescheduling and Legalizing Marijuana*

The California Medical Association (CMA) has released policy recommendations related to marijuana which would make this illegal drug widely available for “medical” and nonmedical use.<sup>1</sup> Because legalization of marijuana is not in the interest of the public’s health, the Institute for Behavior and Health, Inc. (IBH) encourages the CMA to reconsider its position on a number of important issues regarding marijuana.

#### **Should Marijuana be Rescheduled to More Easily Initiate Research?**

The CMA document says that in order to facilitate clinical research on marijuana the drug should be rescheduled at the federal level by the Drug Enforcement Administration (DEA). In June 2011, DEA Administrator Michele Leonhart explained why marijuana does not meet requirements for rescheduling under the Controlled Substances Act in response to a petition dating back to October 2002.<sup>2</sup> At that time DEA had requested that a scientific and medical evaluation and scheduling recommendation be conducted by the Department of Health and Human Services (HHS) and had subsequently concluded that “marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level for safety for use even under medical supervision.” Separately, in April 2006, the Food and Drug Administration (FDA) issued an interagency advisory which confirmed that a past evaluation by several HHS agencies had concluded that “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 marijuana for general medical use”.<sup>3</sup> Previously, in 2005 the US Supreme Court firmly established the federal preemption of state laws with a 7-2 vote against state-approved “medical marijuana” being exempt from the Controlled Substances Act due to “medical necessity.”<sup>4</sup>

While the CMA claims that the Schedule I status of marijuana inhibits the study of marijuana the reality is that Schedule I drugs are routinely studied. The Code of Federal Regulations provides direction for the development of research protocols using controlled Schedule I substances.<sup>5</sup> An applicant may submit a protocol to DEA and the FDA for approval prior to clinical testing of a proposed drug and, in fact, hundreds of protocols have been submitted and approved. Currently over 300 grants supporting research on marijuana and the cannabinoids (unique chemicals found in marijuana) are funded by the National Institutes of Health (NIH).

The American Society of Addiction Medicine (ASAM) notes in its recent White Paper on marijuana as medicine that the rescheduling of marijuana would not necessarily change the way

in which marijuana for research is cultivated and obtained.<sup>6</sup> The United States is a signatory of the Single Convention on Narcotic Drugs of 1961 which mandates that marijuana that is cultivated in the United States be delivered to a national agency.<sup>7</sup> The National Institute on Drug Abuse (NIDA) is the designated agency and contracts with the University of Mississippi to cultivate marijuana for research purposes. The treaty obligations related to cultivation of marijuana for research is unrelated to the Schedule I status of the drug.

### **Is Marijuana Useful as Medicine?**

For more than four decades the federal government has led the way for the world in studying marijuana and its cannabinoids. Most marijuana-based studies funded by NIH have been conducted on the cannabinoids, working on FDA-approved research protocols that investigate the safety, efficacy and dose of specific cannabinoids in the treatment of various diseases. For example, Marinol, synthetic THC (the primary active ingredient in marijuana), was approved by the FDA and has been available by prescription for medical use since 1985.

Millions of dollars have been directed towards investigating medical uses of smoked marijuana. In California the Center for Medicinal Cannabis Research (CMCR) is in its eleventh year of studying smoked marijuana and the cannabinoids for therapeutic effects. Marijuana has been available to CMCR for these studies through NIDA's contract with University of Mississippi. Approval for the use of marijuana that is cultivated at this university facility and harvested to provide uniform samples of the plant for research purposes is obtained from HHS. A significant number of CMCR studies have been discontinued due to the inability to recruit and retain participants for a variety of research protocols studying cancer pain relief, muscle spasticity, multiple sclerosis, severe nausea and vomiting and neuropathic pain. Of the few CMCR studies that have been completed most were limited to patients who were experienced marijuana users. While the CMA cites a report on CMCR studies as evidence to support the efficacy of marijuana to treat neuropathic pain,<sup>8</sup> the CMCR data do not provide evidence that smoked marijuana should be made available to patients.<sup>9</sup> Rather, these studies demonstrate that patients using marijuana "experience a range of significant CNS side effects, including cognitive impairment and intoxication. This further underlines the need for all cannabis-based products to develop a robust body of risk-benefit data in specific medical conditions and for patients using such products to be under the supervision of their personal physicians."<sup>10</sup> The CMCR program has had no difficulty obtaining marijuana for studies, despite its Schedule I status. The failure of this organization to conduct a wide range of studies of medical uses of smoked marijuana over more than a decade is powerful evidence that neither Schedule I status nor difficulty obtaining marijuana for studies is a significant barrier to research.

Many have argued that there is no point in conducting research on smoked marijuana because it is an unhealthy, unreliable route of administration. In its 1999 report, the Institute of Medicine (IOM) declared that there is no future for smoked cannabis as a medicine but there may be a future for individual cannabinoids if they are shown to be safe and effective for specific indications.<sup>11</sup> The development of specific cannabinoid-based medical products is the future role of marijuana in medicine. "Medical marijuana" advocates who oppose the use of purified cannabinoids do so to promote the virtual legalization of smoked marijuana.

## **Should Recreational Marijuana Use Be Legalized?**

In response to the query “what shifts in public policy could protect public health and benefit personal health?” the CMA recommends that “in order to fully evaluate and regulate cannabis, it should be legalized and decriminalized.”<sup>12</sup> Calling the criminalization of cannabis “a failed public health policy”, the CMA recommends that marijuana be legalized in a manner similar to alcohol and tobacco and be taxed. The CMA ignores the public health effects of legalization as well as the current heavy costs of both alcohol and tobacco. Setting aside the question of whether the CMA, an organization of medical doctors, is qualified to analyze and recommend this major change in public policy, the adverse medical, mental health and social consequences of legalization of marijuana to the public health are vast.

Marijuana use has serious short-term and long-term negative effects including impaired learning and memory and it puts users at increased risk for mental health disorders and addiction.<sup>13</sup> Marijuana is responsible for 60% of Americans who meet diagnostic criteria for substance abuse or dependence due to illicit drugs.<sup>14</sup>

The annual social cost in the US of alcohol is measured at \$235 billion<sup>15</sup> and of tobacco at \$193 billion.<sup>16</sup> Those costs vastly exceed the value of US tax revenue from the sale of these two substances (\$5.76 billion for alcohol<sup>17</sup> and \$16.57 billion for tobacco<sup>18</sup>). Keeping marijuana illegal has resulted in a significant decrease in marijuana use levels since the peak in 1979 (13%)<sup>19</sup> to 2010 (6.9%).<sup>20</sup> If marijuana were legalized, its social cost undoubtedly would increase with social costs comparable to alcohol and tobacco. Marijuana has the potential for being as widely used as alcohol and tobacco, which in 2010 were used in the past 30 days by 131.3 million Americans (51.8%) and 69.6 million Americans (27.4%), respectively, compared to 17.4 million (6.9%) current marijuana users.<sup>21</sup>

Potential tax revenue to the state of California from legalized marijuana is doubtful. In 2010 the RAND Drug Policy Research Center in California conducted an analysis of how marijuana legalization in California would affect marijuana consumption and budgets. RAND concluded that the price of marijuana would dramatically decrease after legalization but that the social cost of the drug and projected tax revenue are unknown given uncertainties of state taxes, tax evasion, and the shape of the demand curve.<sup>22</sup> It is likely that many individuals would continue to purchase lower-cost marijuana illegally, rather than the higher cost product subject to state taxes, thus maintaining the black market and reducing projected state tax revenues.<sup>23</sup> RAND also concluded that there would be significant reductions in drug revenues collected by Mexican drug trafficking organizations.<sup>24</sup>

## **Does the Current Policy that Places Physicians in the Gatekeeper Role Present Problems for the Profession?**

Physicians should not be placed in the role of gatekeepers to marijuana or any other illegal drug of abuse. The recommendations of the CMA to reschedule marijuana to facilitate research and regulate, legalize and tax marijuana for use by anyone for any purpose are not in the interest of public health or in the interest of physicians and their patients. It is perplexing that the CMA supports the use of smoked marijuana for any purpose when in 2009 the Carcinogen

Identification Committee of the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency added marijuana smoke to the list of known carcinogens.<sup>25</sup> Marijuana smoke is listed as one of the many chemicals known to cause cancer, as it shares many of the same properties of tobacco smoke.<sup>26</sup>

The CMA has brought national attention to the fact that physicians are in untenable positions as gatekeepers of an illegal drug in California and in other states where marijuana as medicine has been approved either by state legislatures or by ballot initiatives. ASAM “recommends its members and other physician organizations and their members reject responsibility for providing access to cannabis and cannabis-based products until such time that these materials receive marketing approval from the Food and Drug Administration.”<sup>27</sup>

Unlike marijuana-based medicines that are FDA has approved (e.g. Marinol), “medical marijuana” is not a product; it is relabeled street marijuana – a crude botanical substance that is grown and sold at different potencies and mixed with varying substances. Marijuana cannot and should not be rescheduled, nor should it be legalized for medical or any other use. Individual chemicals in marijuana can be isolated and studied to identify those with specific therapeutic potential. When they are shown to be safe and effective for individual illnesses, and judged to be pure, the FDA can approve them to be prescribed by physicians for distribution through the nation's pharmacies, in the same way all other medicines are handled in the US.

## **Conclusion**

IBH agrees with the CMA that “medical marijuana” places physicians in an untenable position as gatekeepers to the unmonitored use of a widely abused illegal drug. IBH disagrees with the CMA, and agrees with the Institute of Medicine, that there is no future for marijuana – smoked or otherwise consumed – as a medicine. IBH disagrees with the CMA that marijuana be rescheduled out of Schedule I precisely because it fits the definition of drugs that belong in Schedule I – drugs which are widely abused and lack FDA-approved medical uses. Marijuana should not be legalized for any use.

IBH strongly supports the continued study of the biology of the cannabinoids including their potential therapeutic uses. If such uses are identified, IBH encourages their submission to the FDA to be evaluated for safety, efficacy and purity. If these chemicals meet this well-established standard, IBH supports them being made available for physicians to prescribe through the nation’s professional pharmacies.

For more information on the Institute for Behavior and Health, Inc. and new ideas to reduce illegal drug use, visit [www.ibhinc.org](http://www.ibhinc.org). For more information about marijuana visit the NIDA webpage [www.nida.nih.gov/infofacts/marijuana.html](http://www.nida.nih.gov/infofacts/marijuana.html).

**Robert L. DuPont, M.D.**

**President, Institute for Behavior and Health, Inc.**

**First Director, National Institute on Drug Abuse (NIDA) 1973 to 1978**

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*Established in 1978, the Institute for Behavior and Health, Inc. (IBH) is a 501(c)3 non-profit organization working to reduce substance abuse through the power of good ideas. IBH websites include: [www.ibhinc.org](http://www.ibhinc.org), [www.StopDruggedDriving.org](http://www.StopDruggedDriving.org), and [www.PreventionNotPunishment.org](http://www.PreventionNotPunishment.org).*

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