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December 13, 2010

Mr. Arthur J. Parker
Chief, Rulemaking Section
Office of the Attorney General
Legal Counsel Division
1350 Pennsylvania Avenue, NW, Suite 409
Washington DC 20004

Dear Mr. Parker:

The Medical Society of the District of Columbia (MSDC), representing over 2000 licensed physicians who practice medicine in the District of Columbia, submits these comments on the draft regulations for the Legalization of Marijuana for Medical Treatment Amendment Act (Act). MSDC understands that the proposed rules do not address all aspects of the Act and that rule making will take place as implementation of the Act proceeds.

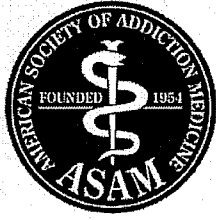
The Board of Directors of MSDC endorses the position statement on medical marijuana of the American Society of Addiction Medicine (ASAM) adopted in April 2010. A copy of the position statement is attached to this document and may be found at <http://www.asam.org/MedicalMarijuana.html>. Marijuana (cannabis) may have therapeutic potential in certain medical conditions. Accordingly the regulations specify that it is to be prescribed as part of physician supervised medical treatment. Implementation of the act thus requires physicians to serve as gatekeepers. In order to ensure a high standard of medical care, MSDC recommends consideration of the following points:

- 1) The use of medical marijuana in its inhaled form carries its own significant health risks. It also presents prescribing challenges since the dosing is difficult to regulate and medical marijuana is not subjected to the same stringent standards as FDA approved medications.
- 2) The District will face significant extrinsic challenges to enforcement of the regulations and the safe distribution of the medical marijuana. Administration of the program may be difficult to fund at a time of increasing budgetary constraints. Diversion to unintended use is a significant concern.
- 3) There are no adequate models to predict the full range of costs of medical marijuana in terms of increased need for addiction treatment and other medical morbidities associated with its use. These likely will add greatly to the health care cost.
- 4) Proper implementation of the Act will require good communication and coordination between the District government and physician groups to ensure that physicians receive the necessary information and means to deliver a high standard of care to District residents.

MSDC will be available to consult with appropriate DC agencies so that the Act may be implemented in a manner that best serves the medical needs of District residents.

Sincerely,

Frederick Finelli, MD, JD
President



ASAM

American Society of Addiction Medicine

Public Policy Statement on Medical Marijuana

Background

In the last twenty years, both the scientific community and the public have become interested in the therapeutic potential of cannabis and cannabinoids. Scientific interest has been based in large part on the discovery and elucidation of the endocannabinoid receptor system. Popular interest has focused on state initiatives and other legislation decriminalizing the use of smoked cannabis for personal medical use. Because of this legislation, herbal cannabis in various forms is now being distributed by dispensaries to large numbers of individuals with a wide variety of medical conditions. This cannabis is not, in most cases, standardized or quality-controlled; the dosage forms (smoked, vaporized, baked goods, teas, elixirs, etc.) do not provide a known and reproducible dose; and data on efficacy and adverse events are not being collected in a reliable manner.

Cannabinoids are insoluble in water and subject to degradation by temperature and light; thus, optimal delivery systems or dosage forms are difficult to design. As a result, research into their medical applications is technologically challenging and has lagged behind that of the opioids and other modern medications. With improvements in technology and the development of research tools, such as high affinity agonists and antagonists, preclinical research has flourished. At present, however, only a few properly controlled clinical studies, of adequate size and duration, have investigated the use of cannabis or cannabinoid products in specific therapeutic contexts.

The pace of such clinical research is increasing. As corporate sponsors successfully resolve the regulatory and technological challenges, new products will enter the market. These products will be accompanied by extensive quality, pharmacological, toxicity, safety/tolerability, and efficacy data that will allow physicians knowledgeably to prescribe them, thereby making them available to appropriate patients. Risk Evaluation and Mitigation Strategies (REMS) will reduce the likelihood of abuse and diversion by both patients and non-patients, including adolescents. The FDA approval process ensures that a robust body of data accompanies a product when it becomes available to patients. The FDA has invited industry to develop botanically based products and has set forth the regulatory path that must be followed to ensure that such products meet the standards of modern medicine. It is feasible for cannabis-derived products to proceed down that path. Doing so will enable them to be recognized by the medical community as legitimate treatment options.

Under the current state distribution systems, physicians serve as the gatekeepers of patients' access to cannabis, yet they lack both information on the quality/composition of the cannabis materials and data on their efficacy/safety. When specific cannabis-derived or cannabinoid medications have passed through conventional regulatory approval processes, and their

risk/benefit profile in a particular medical condition is known, physicians can be confident that they are meeting the standard of care when advising patients about potential treatment choices. "Cognitive dissonance" is a term that aptly describes the current approach to "medical marijuana." Scientists recognize the public health harms of tobacco smoking and urge our young people to refrain from the practice, yet most cannabis consumers use smoking as their preferred delivery mechanism. The practice of medicine is increasingly evidence-based, yet some physicians are willing to consider "recommending" cannabis to their patients, despite the fact that they lack even the most rudimentary information about the material (composition, quality, and dose, and no controlled studies provide information on its benefit and safety of its use in chronic medical conditions). Pharmaceutical companies are responsible for the harms caused by contaminated or otherwise dangerous products and tobacco companies can be held accountable for harms caused by cigarettes, yet, dispensaries distribute cannabis products about which very little are known, including their source. Efforts are being made to stem the epidemic of prescription drug abuse, including FDA-mandated risk management plans required for prescription medications, yet cannabis distribution sites proliferate in many states, virtually without regulation.

In order to think clearly about "medical marijuana," one must distinguish first between 1) the therapeutic potentials of specific chemicals found in marijuana that are delivered in controlled doses by nontoxic delivery systems, and 2) smoked marijuana.

Second, one must consider the drug approval process in the context of public health, not just for medical marijuana but also for all medicines and especially for controlled substances. Controlled substances are drugs that have recognized abuse potential. Marijuana is high on that list because it is widely abused and a major cause of drug dependence in the United States and around the world. When physicians recommend use of scheduled substances, they must exercise great care. The current pattern of "medical marijuana" use in the United States is far from that standard.

If any components of marijuana are ever shown to be beneficial to treat any illness then those components can and should be delivered by nontoxic routes of administration in controlled doses just all other medicines are in the U.S.

In order for physicians to fulfill their professional obligations to patients, and in order for patients to be offered the high standard of medical care that we have come to expect in the United States, cannabis-based products must meet the same exacting standards that we apply to other prescription medicines. Members of the American Society of Addiction Medicine (ASAM) are physicians first and experts in addiction medicine with knowledge specific to the risks associated with the use of substances with high abuse potential. ASAM must stand strongly behind the standard that any clinical use of a controlled substance must meet high standards to protect the patient and the public; the approval of "medical marijuana" does not meet this standard.

Recommendations

1. 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.
2. ASAM rejects smoking as a means of drug delivery since it is not safe.

3. ASAM recognizes the supremacy of federal regulatory standards for drug approval and distribution. ASAM recognizes that states can enact limitations that are more restrictive but rejects the concept that states could enact more permissive regulatory standards. ASAM discourages state interference in the federal medication approval process.
4. 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 (based upon a careful science-based review of safety and efficacy, standardization and formulation for dosing, or provide a means for a regulated, closed system of distribution for marijuana which is a CNS drug with abuse potential).
5. 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.
6. ASAM asserts that physician organizations operating in states where physicians are placed in the gate-keeping role have an obligation to help licensing authorities assure that physicians who choose to discuss the medical use of cannabis and cannabis-based products with patients:
 - Adhere to the established professional tenets of proper patient care, including
 - History and good faith examination of the patient;
 - Development of a treatment plan with objectives;
 - Provision of informed consent, including discussion of side effects;
 - Periodic review of the treatment's efficacy;
 - Consultation, as necessary; and
 - Proper record keeping that supports the decision to recommend the use of cannabis
 - Have a *bona fide* physician-patient relationship with the patient, i.e., should have a pre-existing and ongoing relationship with the patient as a treating physician;
 - Ensure that the issuance of "recommendations" is not a disproportionately large (or even exclusive) aspect of their practice;
 - Not issue a recommendation unless the physician has adequate information regarding the composition and dose of the cannabis product;
 - Have adequate training in identifying substance abuse and addiction¹.

¹ This is particularly germane to ASAM which consists of physicians knowledgeable in drug abuse and addiction and who advocate to ensure that all physicians have the knowledge to manage CNS medications responsibly in the general patient population and can identify and treat or refer for treatment cases of abuse and dependence to psychoactive substances.

Adopted by ASAM Board of Directors April 2010.

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American Society of Addiction Medicine

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