

MedChi

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TO: The Honorable Brian E. Frosh, Chairman
Members, Senate Judicial Proceedings Committee
The Honorable David Brinkley

FROM: Joseph A. Schwartz, III
Pamela Metz Kasemeyer
J. Steven Wise

DATE: March 21, 2012

RE: **Letter of Information** – Senate Bill 995 – *Medical Marijuana Oversight Commission*

The Maryland State Medical Society (MedChi), which represents over 7,300 Maryland physicians and their patients, provides this letter of information on Senate Bill 995 – *Medical Marijuana Oversight Commission*.

In 2011, the Maryland General Assembly enacted legislation that directed the Department of Health and Mental Hygiene to convene a workgroup on the medical use of marijuana. The workgroup was chaired by Secretary Sharfstein and its membership included a wide representation of stakeholders and experts, including legislators, patients, scientists, health care providers, and law enforcement representatives. Over the course of its deliberations, it became clear that there were significant differences of opinion on a number of key issues including what framework the State should adopt for the next phase of its assessment of medical marijuana. As a result, the workgroup produced two different proposals for consideration by the General Assembly. One of these proposals is reflected in Senate Bill 995.

MedChi looked to the work that the American Medical Association (AMA) has done on this issue to formulate this letter of information of the issue. In 2009 the AMA's Council on Science and Public Health conducted an extensive study of medical

marijuana. The Summary of that study is attached to this letter for your review. Based on the findings and conclusions of that study, the AMA adopted the following Resolution which states the AMA's official position on Medical Marijuana:

“H-95.952 Medical Marijuana

(1) Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.

(2) Our AMA urges that marijuana's status as a federal Schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines and alternate delivery methods. 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.

(3) Our AMA urges the National Institutes of Health (NIH) to implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research into the medical utility of marijuana. This effort should include: a) disseminating specific information for researchers on the development of safeguards for marijuana clinical research protocols and the development of a model informed consent on marijuana for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of marijuana for clinical research purposes; c) confirming that marijuana of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the Drug Enforcement Agency who are conducting bona fide clinical research studies that receive Food and Drug Administration approval, regardless of whether or not the NIH is the primary source of grant support.

(4) Our AMA believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions. (CSA Rep. 10, I-97; Modified: CSA Rep. 6, A-01; Modified: CSAPH Rep. 3, I-09)”

While MedChi is not required to follow AMA policy, it finds the AMA's work on medical marijuana to be compelling. There has been much public controversy regarding the medical use of marijuana. Fourteen states have legalized access to marijuana so long as a physician either prescribes it or affirms that a patient has a condition that could be relieved by smoking marijuana. The federal government, however, has refused to recognize that marijuana has an accepted medical benefit and all efforts to remove marijuana from the list of Schedule I substances have failed.

Despite the interest in and controversy over the potential benefits and unintended consequences of the medical use of marijuana, there have been very few scientific studies of smoked marijuana (cannabis). Less than 20 small randomized controlled trials of short duration have been conducted over the last 35 or more years. The results of the short term controlled trials indicate that smoked cannabis has therapeutic potential such as the reduction of neuropathic pain, improvement of appetite and caloric intake in patients with reduced muscle mass, and relief of spasticity and pain in patients with multiple sclerosis. However, many more tests have been conducted on FDA-approved oral preparations of medications containing the chemicals found in marijuana. There is no evidence that herbal marijuana, that is smoked, is superior or even equivalent to these products.

Despite the positive indications that the medical use of marijuana may have potential benefits, there is much work to be done. The patchwork of state-based systems that have been established for "medical marijuana" does not reflect even the most basic safeguards that normally would be applied to appropriate clinical use of a psychoactive substance such as marijuana. The FDA medication approval process is the commonly accepted and appropriate mechanism for scientific review and approval of medical treatments. If marijuana is to be used as a medical treatment, then it and marijuana delivery devices should be subject to the same standards that are applicable to other prescription medications and medical devices. However, the FDA has never reviewed marijuana to assess its efficacy, its safety, or its side effect potential. If marijuana is effective in the management of certain medical conditions, it deserves to be studied and approved by the FDA in the same manner as would other potential legitimate treatments.

For more information call:

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Report 3 of the Council on Science and Public Health (I-09)
Use of Cannabis for Medicinal Purposes
(Resolutions 910, I-08; 921, I-08; and 229, A-09)

SUMMARY

Objective. This report: (1) provides a brief historical perspective on the use of cannabis as medicine; (2) examines the current federal and state-based legal envelope relevant to the medical use of cannabis; (3) provides a brief overview of our current understanding of the pharmacology and physiology of the endocannabinoid system; (4) reviews clinical trials on the relative safety and efficacy of smoked cannabis and botanical-based products; and (5) places this information in perspective with respect to the current drug regulatory framework.

Data Sources. English-language reports on studies using human subjects were selected from a PubMed search of the literature from 2000 to August 2009 using the MeSH terms “marijuana” “cannabis,” and tetrahydrocannabinol,” or “cannabinoids,” in combination with “drug effects,” “therapeutic use,” “administration & dosage,” “smoking,” “metabolism,” “physiology,” “adverse effects,” and “pharmacology.” Additionally the terms “abuse/epidemiology,” and “receptors, cannabinoid” in combination with “agonists,” or “antagonists & inhibitors” as well as “endocannabinoids,” in combination with “pharmacology,” “physiology,” or “metabolism” were used. Additional articles were identified by manual review of the references cited in these publications. Web sites of the Food and Drug Administration, Drug Enforcement Administration, National Institute on Drug Abuse, Marijuana Policy Project, ProCon.org, and the International Association for Cannabis as Medicine also were searched for relevant resources.

Results. The cannabis sativa plant contains more than 60 unique structurally related chemicals (phytocannabinoids). Thirteen states have enacted laws to remove state-level criminal penalties for possessing marijuana for qualifying patients, however the federal government refuses to recognize that the cannabis plant has an accepted medical benefit. Despite the public controversy, less than 20 small randomized controlled trials of short duration involving ~300 patients have been conducted over the last 35 years on smoked cannabis. Many others have been conducted on FDA-approved oral preparations of THC and synthetic analogues, and more recently on botanical extracts of cannabis. Federal court cases have upheld the privileges of doctor-patient discussions on the use of cannabis for medicinal purposes but also preserved the right of the federal government to prosecute patients using cannabis for medicinal purposes. Efforts to reschedule marijuana from Schedule I of the Controlled Substances Act have been unsuccessful to date. Disagreements persist about the long term consequences of marijuana use for medicinal purposes.

Conclusions. Results of short term controlled trials indicate that smoked cannabis reduces neuropathic pain, improves appetite and caloric intake especially in patients with reduced muscle mass, and may relieve spasticity and pain in patients with multiple sclerosis. However, the patchwork of state-based systems that have been established for “medical marijuana” is woefully inadequate in establishing even rudimentary safeguards that normally would be applied to the appropriate clinical use of psychoactive substances. The future of cannabinoid-based medicine lies in the rapidly evolving field of botanical drug substance development, as well as the design of molecules that target various aspects of the endocannabinoid system. To the extent that rescheduling marijuana out of Schedule I will benefit this effort, such a move can be supported.