MedChi

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TO: The Honorable Brian E. Frosh, Chairman
Members, Senate Judicial Proceedings Committee
The Honorable Thomas Mac Middleton, Chairman
Members, Senate Finance Committee
The Honorable Dan Morhaim

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

DATE: March 28, 2013

RE: **SUPPORT** – House Bill 1101 – *Medical Marijuana − Academic Medical Centers*

The Maryland State Medical Society (MedChi), which represents over 7,300 Maryland physicians and their patients, supports House Bill 1101. It is the first time MedChi has supported a bill relating to medical marijuana.

House Bill 1101 establishes a program for the investigational use of marijuana for medical purposes. The program is to be administered by a Commission established specifically for this purpose. The Commission is charged with the development, solicitation, approval and oversight of clinical programs to be operated by Academic Medical Centers.

An "academic medical center" is defined as a "hospital that operates a medical residency program for physicians and conducts research that is overseen by the U.S. Department of Health and Human Services and involves human subjects." An application submitted by an academic medical center must:

- specify the medical conditions to be treated, the criteria by which patients will be included in or excluded from participation, how patients will be assessed for addiction before and during treatment, and the length of treatment and dosage permitted;
- describe the source and type of the marijuana to be used, how health care providers will be eligible to participate and what training they will receive, and the plan for defining and monitoring the success or failure of treatment;

- demonstrate approval of the program by the center's institutional review board;

- include a description of whether and how caregivers will interact with participating patients, a plan for monitoring aggregate data and outcomes and publishing results, and a description of the sources of funding; and
- describe any required training for providers and patients on diversion-related issues, steps the center will take to prevent and monitor diversion, how the program will dispose of any unused marijuana, and how the center and the program will meet any other established criteria.

Further, the commission is required to establish an application review process that includes reviewers with expertise in scientific research and analysis, medical training, and law enforcement

MedChi has historically looked to the work that the American Medical Association (AMA) has done on the issue of medical marijuana to formulate its position on this 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. Several states have legalized access to marijuana under varying conditions. 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). MedChi feels that House Bill 1101 holds great promise to change that dynamic.

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. In contrast, House Bill 1101 provides the level of scientific integrity and accountability that enables MedChi to urge a favorable report on House.

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.