May 7, 2001

The Honourable Allan Rock, PC, MP
Minister of Health
16th Floor, Brooke Claxton Building
Headquarters Tunney's Pasture
Postal Locator: 0916-B
Ottawa, ON KlA 0K9

Dear Minister Rock:

Subject: Draft *Marijuana Medical Access Regulations*

I am writing to bring to your attention the serious concerns the Canadian Medical Association (CMA) has with the draft *Marijuana Medical Access Regulations* as found in the *Canada Gazette,* Part 1, of April 7, 2001. As the national voice of Canadian physicians, the CMA's mission is to provide leadership for physicians and to promote the highest standard of health and health care for Canadians. After consultation with our members, we welcome the opportunity to provide the following comments.

The CMA recognizes and acknowledges the unique requirements of those individuals suffering from a terminal illness or chronic disease for which conventional therapies have not been effective. We also recognize, and are sympathetic to, the needs of those individuals who may have gained, or hope to gain, benefit from the use of marijuana in relieving their symptoms. The CMA supports the use of any therapy proven safe, effective and manufactured with appropriate diligence, and has long advocated for equitable access to all such therapies. However, we have fundamental concerns about the use of marijuana for medicinal purposes at this time.

Marijuana is an herb, and as such can be considered a natural health product. Unlike many natural health products, however, marijuana is an addictive substance, is known to have psychoactive effects and, in its smoked form, is harmful to health. We are concerned, as well, about the broader social implications of marijuana as a medicine and its potential impact on one's ability to function at home or at work. The CMA holds that natural health products should be held to the same evidence-based regulatory standards as all pharmaceutical health products.

The CMA supports Health Canada in its efforts to establish research into the safety and efficacy of marijuana and its active components, and to establish a safe and licit source of marijuana from which to

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conduct this research.

We are hopeful that, through sound research, the active ingredients of marijuana will be found to be safe and beneficial for those patients who continue to suffer from conditions for which current therapies have not proven effective.

In the interim, however, we are concerned that the use of marijuana for medicinal purposes without adequate scientific support and regulatory controls may create risks to both patients and physicians that might not be justified by possible short-term benefits. **Physicians must not be expected to act as "gatekeeper" to this therapy given these risks and concerns**.

The CMA holds that the following four fundamental principles are paramount in designing regulations for medicinal marijuana:

A. The regulations should be based on safety, quality and efficacy.

B. The same evidence-based regulatory standards that apply to pharmaceuticals should apply to marijuana as a medicine.

C. The regulations should incorporate the need for clinical research to provide information that will enable patients and physicians to make informed choices and decisions.

D. The regulations must not undermine the patient-physician relationship by imposing upon physicians the role of gatekeeper to a still unproven therapy.

The CMA recognizes the particular challenges facing the Federal Government in designing regulations for this issue. However, the current draft regulations do not adequately reflect these fundamental principles. We have serious concerns in the following areas:

1) Lack of patient and provider information on the risks and benefits of medical marijuana

2) The breadth of Categories 2 and 3

3) Role of the physician

4) The Minister's reporting powers

We offer the following comments and recommendations:

1) Lack of patient and provider information on the risks and benefits of medical marijuana

There is a lack of comprehensive and credible scientific evidence on the risks and benefits of medical marijuana. Given this lack of evidence, physicians are not in a position to counsel patients regarding the use of marijuana, and are unable to provide thorough and necessary information regarding such issues as marijuana's interaction with other drugs, its impact on other pre-existing medical conditions and the impact of its effect on one's ability to drive. Furthermore, the CMA is concerned about the harmful effects of smoking marijuana, especially in light of the fact that smoking is an inefficient means by which to deliver the active ingredients, carries similar health risks to tobacco smoking, and is exceptionally difficult to monitor, especially given the variability in potency.

There needs to be a wider recognition in the draft regulations about the lack of scientific evidence. In Section 4 (9)(b), the patient has to make a statement as part of the application that he or she is "aware that no notice of compliance has been issued under the *Food and Drug Regulations* concerning the safety and effectiveness of marijuana as a drug, and understands the significance of this fact". However, it is arguable that this statement lacks the explicitness needed to be enforceable. As well, as part of the application process, the physician has to make the same statement (see 4(3)(e), 4(4)(f), 4(5)(b)(iv)). Arguably, this could be used against the physician in subsequent litigation.

In a similar vein, the CMA also has concerns about the recommended daily dosage, especially given that the daily dosage recommended by the individual physician is the base factor for the formulae used to determine how much marijuana an individual may possess. Section 4(2)(f) reads that the physician must provide the daily dosage in grams, and specify the form and route of administration. However, there is no scientific evidence to substantiate a claim that, for example, one patient should have 4 grams as opposed to 6 grams. Section 4(6) (a)-(b) does build in extra safeguards and scrutiny in cases where the recommended daily dosage is more than 5 grams. But one might ponder where the evidence exists to determine the risks associated with higher dosages. Unlike scientifically tested therapeutic agents, there is insufficient evidence from clinical trials to underpin the physician's individual dosage recommendation.

2) The breadth of Categories 2 and 3

Category 2 symptoms are associated with the following medical conditions: cancer, HIV/AIDS, multiple sclerosis, epilepsy, spinal cord disorders and severe arthritis, where the medical condition is not terminal. As a requirement for exemption under Category 2, there is a reference in Section 4 (4) (e) to a physician having weighed the long-term risks.

This last statement is troublesome since it appears from the scientific evidence that a physician could not state credibly that he or she knows the risks associated with the long-term use of marijuana.

The definition of category 3 symptoms reads: " a symptom, other than a category 1 or 2 symptom, that is associated with a medical condition or its medical treatment." In other words, it is not one of the following symptoms: "severe nausea, cachexia, anorexia, weight loss, persistent muscle spasms, seizures, severe pain," and is not associated with the following diseases, "cancer, AIDS, HIV infection, multiple sclerosis, spinal cord injury or disease, epilepsy, severe form of arthritis".

Category 3, therefore, represents a catch-all category for everything that is not included in category 1 or 2. The CMA is concerned that physicians may come under pressure from patients, particularly those in category 3, and also, possibly those in category 2, who are seeking psychoactive drugs for predominantly recreational purposes. This pressure could undermine the trust necessary for the optimal patient-physician relationship. Consideration of dose is also more problematic within categories 2 and 3 because patients who fall within these categories will presumably be using the marijuana for a longer period of time. They are therefore more susceptible to the long-term negative effects, particularly since marijuana will be used in the smokeable form.

3) Role of the physician

The CMA is concerned that the draft regulations appear to have blurred the line between physician and patient. Section 4(1) indicates that the application "shall be made to the Minister by a medical practitioner on behalf of a patient." We are concerned that the physician could be named a third party in any attempt to judicially review the decision of the Minister to reject an application (see Section 6(2)). Moreover, Section 4 (9) states that the patient has to make certain statements as part of the application process. There is no definition of "applicant" in the definition section of the draft regulations, and we are opposed to the physician being named as proxy applicant.

It appears that the physician is implicated in the whole supply chain since Section 4 (2)(h)(i) states that the physician shall indicate who is to produce the marijuana. As well, it appears that the physician could furnish or supply the marijuana (see Section 60) if the physician has obtained the marijuana from a dealer licensed under the *Narcotic Control Regulations*. Given the concerns raised in this letter, the CMA recommends that physicians must not be involved in the direct supply of marijuana.

4) The Minister's reporting powers

The CMA is concerned about the vagueness of Section 58 (a)(ii) in which the Minister may report physician behaviour where the Minister believes "on reasonable grounds", for instance, that a physician has contravened a rule of conduct or made a false statement under the regulations. The Minister has given himself the role of overseer of physician conduct in this process and the self-initiated power to report physicians to the medical licensing authorities. The CMA submits that this is not acceptable in the absence of clear guidelines as to what might constitute "reasonable grounds".

CMA Recommendations

Based on the concerns described above, the Canadian Medical Association finds the current draft regulations inadequate. Consideration must be given to the following nine recommendations:

- As a therapeutic product, marijuana must be subject to the same regulations as other drugs under the *Food and Drugs Act*, ensuring good manufacturing practices, controlled sale and distribution to ultimately ensure the quality, safety and effectiveness of the product and its delivery mechanism. In addition, research is required to assess the broader social implications of marijuana as a medicine and its impact on one's ability to drive and function at home or at work.

- Given the lack of scientific evidence, physicians must be free to choose whether or not they recommend the use of marijuana and provide assistance in the application process.

- As the benefit of using marijuana is unproven, and smoking marijuana has known harmful effects, physicians should be treated as they are in clinical trials of pharmaceuticals. In addition, Health Canada should conduct ongoing post-market surveillance of the short and long-term effects of marijuana in patients.

- An expert committee, convened by Health Canada, should develop evidence-based guidelines and parameters for the use of marijuana and set recommended daily dosage ranges for certain medical conditions.

- Supporting information on benefits and risks should be furnished to both patient and provider.

- The criteria for eligibility under category 3 should be rigorous, particularly since these individuals are likely to be harmed by long-term exposure.

- There should be an explicit definition of “applicant” in the draft regulations with the patient explicitly named as such.

- Physicians must not be involved in the supply of marijuana.

- The Minister’s power to report physicians should be narrow in scope and clearly defined.

For the reasons listed above, the CMA is unable to support the regulations in their present form. We look forward to working with you and your department to develop suitable regulations.

Sincerely,

Peter H. Barrett, MD, FRCSC
President

c. c. Bruce Erickson, Policy and Regulatory Affairs Division, Health Canada
CMA Divisional CEOs
Affiliate CEOs
Registrars - Provincial/Territorial Colleges of Physicians and Surgeons