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27 February 2013

Bureau of Medical Marihuana Regulatory Reform
Controlled Substances and Tobacco Directorate
Healthy Environments and Consumer Safety Branch
Health Canada
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RE: Submission of the British Columbia Civil Liberties Association (“BCCLA”) on the proposed *Marihuana for Medical Purposes Regulations* (“MMPR”) as published in the *Canada Gazette*, Part 1 on December 6, 2012

Introduction

1. The BCCLA is the oldest and most active civil liberties organization in Canada. We have spent fifty years working to preserve, defend, maintain and extend civil liberties and human rights in Canada. We have extensive experience in drug policy dating back to submissions before the LeDain Commission in the 1970’s and longstanding involvement in working to ensure the proper balance and respect for patient’s rights in the many difficult legal and ethical issues that arise in the provision of health care.
2. On July 30, 2011, the BCCLA made a submission to Health Canada as part of the consultation on proposed changes to the Medical Marihuana Access Program (“MMAP”). The changes proposed would result in a major redesign of the program. After many years of having Canadian courts repeatedly find the MMAP unconstitutional for failing to provide patients genuine access to medical marihuana, changes are long overdue.
3. The proposed changes would see individuals ceasing to apply to Health Canada for authorization to use medical marihuana and instead receiving an authorization directly from an authorized health care practitioner. After receiving authorization, an individual could

only access a legal supply of marihuana for medical purposes from licensed commercial distributors, as the proposed changes would eliminate personal and designated cultivation.

4. While the BCCLA welcomed some of the proposed changes on the grounds that they would genuinely improve the program, we urged against other aspects of the proposal which would make medical marihuana even less accessible to some patients than it is currently, thus prolonging and exacerbating the unconscionable discrimination against medical marihuana patients so long documented in a litany of court cases.
5. On December 6, 2012, notice was given that the Governor in Council proposed to amend the Medical Marihuana Access Program by bringing in the Marihuana for Medical Purposes Regulations (“MMPR”). As with our submission on Health Canada’s consultation documents, the BCCLA again recommends the adoption of some provisions of the proposed regulations and urges against the adoption of others. In our view, while the MMRP is likely to increase access for some Canadian patients, it will deny access to a substantial portion of patients who are the most ill, the most vulnerable and the most socially disadvantaged.

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Executive Summary of the BCCLA’s Recommendations

Patients should be directly authorized by health care providers to use medical marihuana.

Patients will not achieve “reasonable access” to medical marihuana with the current levels of physician participation, therefore education and other interventions must be targeted to assure significant health care provider participation that is reasonably

consistent in all geographical arenas of the country.

Patients must have appropriate patient identification, and Health Canada must consult more extensively to assure patients that the identity proposal will be acceptable to a wide-range of officials to ensure against wrongful arrests and medication seizures.

Patient and designate production licenses should be retained in order to provide low-income patients, including those on

disability benefits, some means of access to otherwise unaffordable medications. The possibility of some limitation on plant numbers could be explored to address purported safety concerns.

Patients' supply of legal medical marihuana cannot be dependent on the formation of an industry that does not currently exist. The proposal must have sufficient flexibility to ensure a legal supply to patients should industry not develop as anticipated.

Patients must not be relegated to substandard care by the proposed mail/delivery-only model. The new scheme should incorporate the proven model of community-based dispensaries.

Patients must not be restricted to dried medical marihuana; it is an obvious violation of patients' rights to be forced to smoke in order to take medication.

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The Applicable Legal and Ethical Framework

6. Section 7 of the *Canadian Charter of Rights and Freedoms* (the "Charter") provides that:

Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

7. In *R. v. Morgentaler*, [1988] 1 S.C.R. 30, Beetz J. (joined by Estey J.) expressly articulated a constitutional right to access to health care without fear of criminal sanction:

"Security of the person" within the meaning of s. 7 of the *Charter* must include the right of access to medical treatment for a condition representing a danger to life or health without fear of criminal sanction.

8. Section 7 of the *Charter* also pertains to certain delays in obtaining medical treatment. As Chief Justice McLachlin states in *Chaoulli v. Quebec (Attorney General)*, 2005 SCC 35 at para 118:

The jurisprudence of this Court holds that delays in obtaining medical treatment which affect patients physically and psychologically trigger the protection of s. 7 of the *Charter*.

9. In *R. v. Parker*, 146 C.C.C. (3d) 193, the Ontario Court of Appeal recognized that it is a violation of section 7 of the *Charter* to deprive a person with a serious illness for which marihuana provides relief of the right to use marihuana to treat her illness. The Marihuana Medical Access Regulations (“MMAR”), which are the current legislative framework allowing qualified patients to use marihuana for medical purposes, were created in response to the decision in *Parker*.
10. In *Hitzig v. Canada* (2003), 177 C.C.C. (3d) 449, the Ontario Court of Appeal did not fault the MMAP for establishing physicians as gatekeepers to determine eligibility for medical marihuana licenses, but did state that “if in future physician co-operation drops to the point that the medical exemption scheme becomes ineffective, this conclusion might have to be revisited” (*Hitzig* at para 139).
11. In *R. v. Mernagh*, 2011 ONSC 2121, the court found that the vast majority of physicians in Canada are refusing to participate in the MMAP and that the ordeal of medical marihuana patients forced to go to extraordinary lengths to access needed medications was “oppressive and unfair” (*Mernagh* at para 204).
12. In *R. v. Mernagh*, 2013 ONCA 67, the Ontario Court of Appeal found the evidentiary record was insufficient to support the trial court’s finding of a systemic failure of the MMAR, although it is clear on even the deficient record that some patients were experiencing difficulties in finding a physician to support their application. It remains to be seen if a more fulsome evidentiary record would support the de facto physician “boycott” that was found by the trial judge.
13. The concern about extremely limited access to physicians willing to authorize marihuana for medical purposes has been voiced from the outset of the program when leadership of the medical profession adamantly opposed the profession’s role as gatekeeper. Professional medical organizations such as the Canadian Society of Addiction Medicine and the Canadian Medical Association have been vocal critics of the MMAP, and have lobbied government to have the gatekeeper provisions removed.
14. The medical benefits of marihuana include relief of muscle spasticity, appetite stimulation for treating wasting syndrome, control of nausea and vomiting and analgesic effect (Joy 2003). Although these benefits are summarized in the Institute of Medicine, some medical

practitioners have argued that there is insufficient research to guide treatment decisions. Although important research has been done to establish the medical benefits of marihuana, this field of research is relatively new and currently under-resourced. More extensive investigations are needed to examine a range of issues, such as assessments of risk/benefits for specific populations.

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15. In *R. v. Smith*, 2012 BCSC 544, Mr. Justice Johnston found on the evidence before him that marihuana has medicinal benefits and noted that “the opening comments by the Ontario Court of Appeal in Parker should put the matter beyond question in any event” (*Smith* at para 81).
16. The issue in *Smith* was the constitutionality of s. 2 of the MMAR that limits those authorized to possess under the program to possession of marihuana in dried form only. The court found that the restriction to dried marihuana impermissibly impairs the security right of patients to choose how to ingest the medicinal ingredients in the safest and most effective manner (*Smith* at para 123).
17. Because marihuana is criminalized outside the narrow context of the MMAP, there are unique challenges in creating an effective health policy regarding medical marihuana use. Patients who use medical marihuana currently face profound risks and prejudice, including threats of criminal prosecution and eviction. As these patients already experience extensive discrimination and stigma, it is imperative that they not face any exacerbation of harms through attempts to remodel and improve the MMAP.
18. We submit that in keeping with the primary objective of the *Canada Health Act*, R.S.C. 1985, c. C-6, “to protect, promote and restore the physical and mental well-being of residents in Canada and to facilitate reasonable access to health services without financial or other barriers” (s. 3), that the MMAP must be amended to bring it into *Charter* compliance on the basis of demonstrable evidence and in ways that do not involve undue risk to patients. We do not believe that the newly proposed program meets this test.

The BCCLA Supports Removing Health Canada from the Authorization Process

19. Under the MMPPR, Health Canada would no longer be part of the authorization process for patients seeking to use medical marihuana.

Direct authorization would be available from physicians and some nurse practitioners (where supporting access to medical marihuana is included under their scope of practice or in legislation).

20. The BCCLA supports removing the needless burden on patients of seeking approval from Health Canada in order to access a therapy prescribed by an authorized health care practitioner. The Association also supports adding nurse practitioners to those who are able to provide direct authorization for patients to access medical marihuana.

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Insufficient Response to the Opposition of Medical Associations to the Program

21. While the BCCLA supports Health Canada's aim to provide comprehensive scientific information about the uses of marihuana to authorized health practitioners and streamline the practitioner's authorization process, it is our position that establishment of an expert advisory committee and elimination of the need for practitioners to make specific declarations is insufficient for the purposes of creating genuine access.
22. The dissemination of accurate medical information and research findings are obviously welcome, as is the simplification of the authorization process; however these measures are highly unlikely to have a transformative effect on the widespread reluctance of physicians to participate in the program. This is a program that has explicit non-endorsement from key stakeholders in the medical community. This opposition from important medical associations, doubtless fueled by the on-going stigma and lingering effects of decades of marihuana criminalization, requires a more extensive approach than is proposed under the new program, and even the limited benefits of the proposed approach would likely take many years to produce significant effects in patient access.
23. In our submission, the government should acknowledge that the Canadian Medical Association's own survey data from as recently as 2012 clearly shows that physicians are having difficulty acting as gatekeepers of the program for reasons that range from lack of clinical guidelines to concerns about liability.
24. Further, there appears to be very significant under-representation of participating physicians in certain geographical areas of Canada. It should not fall to individual patients like Mr. Mernagh to attempt to

conduct comprehensive, nation-wide, scientifically rigorous research on the extent of physician non-participation. In light of the well-documented opposition to the program by important medical bodies, it behooves Health Canada to acquire and act on a meaningful assessment of physician participation and to not only provide educational materials, but to actively target those jurisdictions where access is sparse or non-existent for more intensive intervention.

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25. Many patients have contacted the BCCLA over the years and related their inability to access a participating physician in their area or described the precariousness of their community's access to such a physician ; access that can effectively be lost with a single physician's relocation or retirement. Although the Court of Appeal in *Mernagh* noted that the numbers of physicians participating in the program has been steadily increasing, this neither indicates that the number is sufficient to meet the need nor does it speak to the question of geographical distribution.

Patients Must be Provided with Appropriate Identification

26. The BCCLA has received many reports from patients who use medical marihuana of incidents of harassment by authorities including law enforcement and airport security personnel. Given the on-going criminalization of non-medical marihuana, there must be some clear means for patients to identify themselves to authorities as medical marihuana patients in order to prevent their wrongful detention or arrest and the seizure of their medication.
27. The current proposal is that patients will identify themselves as legal possessors of marihuana by showing the product label from their packages of marihuana from licensed producers, as well as an appropriate piece of photo identification. The BCCLA questions whether this is adequate response to the need for patient identification.
28. Not only is the product label proposal cumbersome, it is not clear that the appropriate stakeholders (including law enforcement, Canadian and international customs and border security) have been consulted as to what means of identification would be most suitable. In our view, consultations must be undertaken to ensure that the proposed identification is appropriate and acceptable.

Patients Must Not be Denied Access because they Cannot Afford their Medication under the Privatized Business Model

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29. The heart of the new proposed program is the elimination of both patient and designate production licenses and the Health Canada medical marihuana supply program in favour of exclusive access through as-yet-to-be licensed producers. The BCCLA is gravely concerned that this proposed supply model will effectively deny access to many patients in need.
30. The remodeling of the program in terms of production and supply has seemingly been driven by concerns related to safety. The recent proposals have taken the implicit position that medical marihuana patients are currently a threat to their communities' safety and security, especially in regard to patient production.
31. Our information is that indoor marihuana cultivation is indistinguishable from any other indoor plant system, so that medical marihuana cultivation systems pose no more safety risk than indoor cucumber growing systems. Indeed, if hydroponic equipment is unregulated and unsafe, then this safety issue needs to be addressed for all indoor plant growers, with no need to target medical marihuana patients.
32. Further, we have been troubled by various officials' attempts to characterize medical marihuana patients as essentially 'criminogenic' – i.e.) if not a risk to community safety themselves, then attracting thieves by having marihuana in their homes. Such a stance is clearly based on stigma and prejudice, as we never see officials making the argument that wealthy people with valuable personal property are a "risk" to their communities by attracting home invasions.
33. In short, we believe that the stated rationale for depriving medical marihuana patients of personal and designated producer authorization does not withstand scrutiny. That said, the essence of our objection is that it is clear that personal production is for many their most cost-effective means of providing for their medical needs. We have been concerned since the outset of the private business model that there were no apparent plans for assuring that patients in need would be able to afford their medications under the supply system. We see from the latest iteration of the proposal that not only is there no plan to address the patients who will effectively be denied access, but that patients being denied access because of cost is an

entirely anticipated aspect of the program.

34. The Regulatory Impact Analysis Statement for the MMPR estimates that the average price of medical marijuana in 2014 will be \$8.80/g. Estimates as to what constitutes an average daily amount of medical marijuana appear to range widely, from 2 g/day to 10 g/day. This would mean that medical marijuana patients would be paying from \$17/day (2 g) to \$88/day (10 g). For those patients requiring daily medication, this amounts to approximately \$510/month (2 g/day) to \$2,640/month (10 g/day).

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35. For almost any Canadian, such costs would be a formidable barrier to access, but for people on fixed disability incomes, the cost is a complete bar to access. The current rate for a single person on provincial disability benefits in British Columbia at this time is \$906.42/month (BC Ministry of Social Development). There is *no possibility* that disabled persons receiving disability benefits could afford daily medication at even the low end of the average use estimates under the new system. While the new system is obviously not designed to prohibit access by people who are reliant on disability benefits, that is the inevitable result of withdrawing the current cost-effective production options (personal and designated production) and abandoning patients to market forces without cost coverage under provincial medical services plans.

36. Thus, denying patients the ability to produce or delegate production of medical marijuana constitutes a genuine threat to patient's ability to address their medical needs. This is a critically important matter, as has been highlighted in various statements of principle:

"No Canadian should suffer undue financial hardship for needed drug therapy"

-2003 First Ministers' Accord on Health Care Renewal

"Affordable access to drugs is fundamental to equitable health outcomes for all our citizens."

-10-Year Plan to Strengthen Health Care

37. The Regulatory Impact Analysis Statement is explicit that the program redesign will primarily benefit the government, in terms of anticipated cost reduction, and will have a negative impact on some

patients. Those patients, as we've pointed out, will be those with the greatest medical need and the least ability to pay for it. In other words, the burden will fall on the most vulnerable.

38. There is a great likelihood that the inability of patients to access their medication under the MMPR will trigger yet more legal challenges to the constitutionality of Canada's medical marijuana program. We urge the government to address this entirely anticipated problem at the outset and amend the proposed regulations.

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39. It is fair to note that at the outset of the MMPR the government may not have anticipated personal producers producing large numbers of plants and the concerns of fire safety and municipal authorities that have been voiced about larger production systems in residences. However, where demonstrable safety concerns can be documented, we urge the adoption of a compromise position that will address the needs of all stakeholders.

40. Personal production of medical marijuana is incorporated into some other jurisdictions' medical marijuana regimes with limitation on the number of plants (see, for example, the jurisdictions of Arizona, Hawaii, Michigan, Montana and New Mexico). Given the importance of personal production for low-income patients to access this medication, and the minimal safety risks presented by limited numbers of plants, there does not appear to be any compelling reason to deny patients the ability to personally produce within reasonable limits.

The Risks of Unproven Models – Supply

41. Under the MMPR, commercial licensed producers would be the only means of production for a legal supply of medical marijuana in Canada. While a regulated industry for the production of medical marijuana has long been called for among patient advocates, such an industry does not at this time exist in Canada. The current plan is to have patients solely reliant on this industry supply of medical marijuana by 2014, and yet, this industry does not yet exist. The proposal anticipates that not only will the industry be operating as per the rigorous safety and security standards stipulated in the regulations, but that it will be generating a supply sufficient to meet the need, including offering different strains of medical marijuana for different therapeutic purposes.

42. If the industry does not launch in the way that is anticipated, there will be a serious shortage of legally produced medical marijuana in Canada, which will force patients into the black market. The importance of ensuring a legal supply of medication cannot be overstated. Although we do not support industry as the sole means of legal medical marijuana production for the reasons that we have stated, we do appreciate that industry has a major role to play in the production of a regulated supply of medical marijuana. We urge that the time frames for the implementation of the new system be flexible enough to ensure that there is no shortage of legal medical supply.

Page 11/14 *The Risks of Unproven Model – Dispensing*

43. The BCCLA is disappointed, and frankly somewhat mystified, as to why Health Canada has gone so far out of its way to invent a new system that completely ignores the one proven model of access, which is the specialized pharmacy model of community-based dispensaries.

44. The MMPR does not appear to have a place for community-based dispensaries, but rather stipulates a scheme whereby patients in the main will be mailed or couriered their medication. As we have said before, the proposal to mandate delivery-only medication relegates many medical marijuana patients to a sub-standard level of care. The failure to provide for community-based dispensaries ignores the many patients who are completely uninformed about how to use medical marijuana and require compassionate expertise to manage the medication and social support to combat the on-going social stigma of marijuana use.

45. To repeat a point we've made in the past: no one at this juncture reasonably expects family doctors to be able to show patients how to prepare marijuana for smoking (or indeed how to smoke in the first place), so medical marijuana patients who do not have access to community-based dispensaries are often left without appropriate instruction and guidance. To suggest that such patients would be adequately provided for by accessing information on the Internet or by means of a brochure, is to deny these patients the standard of care (consultation with a knowledgeable professional to receive instruction and ask questions) that is afforded to patients of other prescribed medications.

46. We also note that extensive work has been done to develop a rigorous accreditation and certification program for community-based

dispensaries (Canadian Association of Medical Cannabis Dispensaries 2011).

47. We perceive many benefits that may be derived by building a regulated industry to contribute to the supply of medical marihuana, particularly if there were appropriate restraints on monetary returns of the producers, either through price regulation or non-profit models to ensure that the chronically and terminally ill are not deprived of needed medication. However, it is our submission that a non-discriminatory standard of care and a constitutionally-sufficient means of accessing medical marihuana is best provided by retaining at least some ability to produce personally and that distribution should include an option for delivery, but also build on and expand existing community-based dispensaries.

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Patients Must not be Restricted to Dried Marihuana

48. Finally, the absurdity of having to find someone to show you how to smoke in order to take medication is entirely of Health Canada's making, and must not continue into the remodeled program. We agree with the court in *Smith*, that forcing people to smoke to take their medication is an obvious violation of patients' rights. The new regulations must make provision for medication that can be administered by less harmful means, which means that this medication cannot be limited to its dried form. The stated rationale for the restriction to dried marihuana (to reduce risk of diversion) is insufficient to warrant the restriction on patients' rights and to force already ill people into a medication delivery mode that is widely held to be harmful to their health.
49. Thus, the BCCLA makes the following recommendations:

Patients should be directly authorized by health care providers to use medical marihuana.

Patients will not achieve "reasonable access" to medical marihuana with the current levels of physician participation, therefore education and other interventions must be targeted to assure significant health care provider participation that is reasonably consistent in all geographical arenas of the country.

Patients must have appropriate patient identification, and Health Canada must consult more extensively to assure patients that the

identity proposal will be acceptable to a wide-range of officials to ensure against wrongful arrests and medication seizures.

Patient and designate production licenses should be retained in order to provide low-income patients, including those on disability benefits, some means of access to otherwise unaffordable medications. The possibility of some limitation on plant numbers could be explored to address purported safety concerns.

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Patients' supply of legal medical marihuana cannot be dependent on the formation of an industry that does not currently exist. The proposal must have sufficient flexibility to assure a legal supply to patients.

Patients must not be relegated to substandard care by the proposed mail/delivery-only model. The new scheme should incorporate the proven model of community-based dispensaries.

Patients must not be restricted to dried medical marihuana; it is an obvious violation of patients' rights to be forced to smoke in order to take medication.

All of which is respectfully submitted,

A handwritten signature in black ink, appearing to read "M. Vonn", with a horizontal line extending to the right from the end of the signature.

Micheal Vonn
Barrister & Solicitor
Policy Director, BCCLA

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