This is **Exhibit "RR"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Summary Report: Family Medicine Forum - November 3-5, 2011

Health Canada's Marihuana Medical Access Program

Note: Due to the small sample size, only counts are presented, not percentages and caution must be exercised when interpreting the results.

This report was prepared by the Strategic Advice and Coordination Unit, Consultation and Management Service Division, PACCB for the Office of Controlled Substances, HECSB.

What is your area of practice?

Response	Count	
General practice/family practice	58	
Specialist	2	
Other, please specify:	3	
	Total Responses	**63**

What is your area of practice? (Other, please specify:)

#	Response
1.	psychiatry
2.	addiction medicine
3.	both family MD & chronic pain specialist

What is/are your specialist certification(s)?

#	Response
1.	Public Health and Preventive Medicine
2.	public health

How many years have you been practicing?

Response	Count
0-5 years	32
6-10 years	7
11-15 years	11
16-20 years	5
Over 20 years	8
Total Responses	**63**

Have you ever been approached by a patient and/or his/her family to discuss the use of marihuana for medical purposes?

Response	Count
Yes	49
No	13
No response	1
Total Responses	**63**

Have you initiated a discussion with a patient and/or his/her family on the use of marihuana for medical purposes?

Response	Count
Yes	18
No	44
No response	1
Total Responses	**63**

Have you ever supported a patient's access to Health Canada's Marihuana Medical Access Program, that is, signed a Health Canada medical declaration in support of an application for an authorisation to possess marihuana for medical purposes?

Response	Count	
Yes	14	
No	48	
No response	1	
	Total Responses	**63**

What information source did you rely on to make your clinical decision? Please select all that apply.

Response	Count	
Health Canada's "Information for Health Care Professionals-Marihuana" document	9	
Symposia/conferences	5	
Peer-reviewed articles or literature reviews	4	
Patient suggestions/instructions	4	
On-line learning program as part of CME	2	
Compassion clubs	2	
Workshops/small-group learning sessions	1	
Other web-based information	1	
Other, please specify:	2	
	Total Responses	**14**

Which of the following routes of administration of dried marihuana have you indicated in the medical declaration? Please select all that apply.

Response	Count
Smoked	9
Oral (ie. edible)	9
Vaporized	4
Other, please specify:	0
Have not recommended a specific route of administration	1
Total Responses	**14**

Which of the following routes of administration of dried marihuana have you indicated in the medical declaration? Please select all that apply. (Other, please specify:)

#	Response

What are the ranges (grams/day) of dried marihuana you have indicated in the medical declaration? Please select all that apply.

Response	Count
Up to 1g/day	4
1g/day to less than 2g/day	1
2g/day to less than 3g/day	5
3g/day to less than 4g/day	2
4g/day to less than 5g/day	1
5g/day to less than 6g/day	0
6g/day or more	2
Don't recall	2
Total Responses	**14**

If you have not supported a patient's access to Health Canada's Marihuana Medical Access Program, what are your reasons? Please select all that apply.

Response	Count
Lack of personal knowledge/education or information regarding the appropriate use of marihuana for medical purposes	28
Lack of personal knowledge/education or information regarding the appropriate use of marihuana for medical purposes	28
Have never been asked by a patient to do so	23
Lack of clinical guidelines for the use of marihuana for medical purposes	22
Risks and benefits are not sufficiently clear for intended indication(s)	19
Potential liability concerns	12
Belief that marihuana is not an appropriate treatment in a specific case	9
Instruction from medical associations, licensing body, Royal College or College of Family Physicians	8
Requirement to sign a declaration indicating awareness that marihuana is not an approved therapeutic under the Food and Drug Regulations	6
Other, please specify:	4
Total Responses	**48**

If you have not supported a patient's access to Health Canada's Marihuana Medical Access Program, what are your reasons? Please select all that apply. (Other, please specify:)

#	Response
1.	refer to fp
2.	was inappropriate. 18 yo with depression and anxiety who was addicted to mj. did not meet criterea. I would support it for some of my MS patients who require it, but find presciption cannabiniods very effective without the need for risks of smoking.
3.	patient risk factors
4.	more research needed

Would additional education or information on the uses of marihuana for medical purposes be useful to you?

Response	Count
Yes	45
No	3
Total Responses	**48**

Which of the following topics would you like to have further information on? Please select all that apply.

Response	Count
Clinical guidelines (e.g. dosage, route of administration)	52
Potential therapeutic indications	49
Information on safety (potential toxicity and contraindications)	43
Evaluation of potential risks and benefits	42
Clinical studies	35
Information on the Marihuana Medical Access Program (forms, regulations, etc.)	34
Information on cannabis products or forms other than dried cannabis	27
Information only on dried cannabis	20
Pre-clinical studies	9
Other, please specify:	1
Total Responses	**59**

Which of the following topics would you like to have further information on? Please select all that apply. (Other, please specify:)

#	Response
1.	medicolegal implications

Please indicate your preferred format(s)/structure(s) for receiving further information. Please select all that apply.

Response	Count
On-line learning programs as part of CME	30
A monograph on Cannabis (similar to a drug product monograph)	26
Peer-reviewed literature reviews on specific topics	25
Topic-specific "one-pagers"	23
Updated information on the Health Canada website	23
Workshops/small-group learning sessions	23
Symposia, conferences	17
Expert speaker tour	12
Newsletter	5
On-line learning programs as part of CME	30
A monograph on Cannabis (similar to a drug product monograph)	26
Other, please specify:	1
Total Responses	**59**

Please indicate your preferred format(s)/structure(s) for receiving further information. Please select all that apply. (Other, please specify:)

#	Response
1.	training

Cross tabulation:

Please indicate your preferred format(s)/structure (s) for receiving further information. Please select all that apply.	Have you ever supported a patient's access to Health Canada's Marihuana Medical Access Program, that is, signed a Health Canada medical declaration in support of an application for an authorisation to possess marihuana for medical purposes?		
	Yes	No	Totals
On-line learning programs as part of CME	5	25	**30**
On-line learning programs as part of CME	5	25	**30**
A monograph on Cannabis (similar to a drug product monograph)	7	19	**26**
Peer-reviewed literature reviews on specific topics	4	21	**25**
Topic-specific "one-pagers"	6	17	**23**
Updated information on the Health Canada website	3	20	**23**
Workshops/small-group learning sessions	6	17	**23**
Symposia, conferences	4	13	**17**
Grand rounds	4	13	**17**
Expert speaker tour	4	8	**12**
Newsletter	2	3	**5**
Other, please specify:	0	1	**1**

Summary Report: Family Medicine Forum - November 3-5, 2011

Health Canada's Marihuana Medical Access Program (the "Program")

Note: Due to the small sample size, caution should be exercised when deriving percentages and interpreting the results.

At the Family Medicine Forum last week in Montréal we were able to have 63 doctors take part in the physician "needs assessment" which included questions on physicians' experiences with the Program and questions on their educational and information needs regarding marihuana for medical purposes.

Of the 63 doctors, the majority (92%) indicated they were General Practitioners/ Family Doctors, an excellent sample as this class of practitioners will be at the forefront of the 'gatekeeper' model under the reformed program. We noted that physicians came from all across Canada. During one-on-one discussions with physicians, some appeared to have experience with the program while others did not even know of the existence of such a program or had heard about it but did not know where to find more information about it.

- 77% (49/63) of respondents indicated they had been approached by a patient to discuss the use of marihuana for medical purposes; on the other hand only 28% (18/63) had initiated such discussions with patients.

- 76% (48/63) indicated that they had not supported a patient's access to the Program whereas 22% (14/63) had supported access.

Of those who had supported a patient's access to the Program:

- 64% (9/14) cited Health Canada's "Information for Health Care Professionals-Marihuana" document as one of the sources they relied on to make their clinical decision. Interestingly, 29% (4/14) cited patients' suggestions/instructions and 14% (2/14) cited compassion clubs as sources of information.

- 64% (9/14) had indicated "oral administration" in the medical declaration and 28% (4/14) indicated "vaporization" suggesting that physicians were open to alternative routes of administration (other than smoking).

- The majority (71%) of physicians supported less than 3g/day of dried marihuana. (Potential for a follow up question here to find out their rationale/what they based their decision on?)

Of those physicians who had not supported a patient's access to the Program:

- 94% (45/48) agreed that more education/ information on the uses of marihuana for medical purposes would be beneficial.

- The large majority indicated a lack of education on the uses of marihuana for medical purposes, the lack of clinical guidelines and the lack of clarity regarding the risks vs. benefits of marihuana as the principal reasons they do not support patient's access to the program. 48% (23/48) stated that they have never been asked by a patient for medical marihuana. Only 17% (8/48) indicated instructions from medical association, licensing body, Royal College or College of Family Physicians as a reason for not supporting access to the Program. One physician indicated that more research is needed.

Clinical guidelines on the use of marihuana for medical purposes, information on potential therapeutic indications, information on safety, and information on the evaluation of potential risks and benefits of marihuana for medical purposes were all identified as principal areas where physicians needed more information.

A majority of respondents also indicated that they wanted more information on the Medical Marihuana Access Program. Almost half of the respondents indicated wanting information on cannabis products or forms other than dried cannabis.

Physicians are open to learning more about the uses of marihuana for medical purposes, mainly through accredited on-line learning programs, a "monograph" on cannabis, peer-reviewed literature reviews on specific topics and topic-specific "one-page" documents. Updated information on the Health Canada website and workshops were also cited as important mediums for obtaining further information on the topic.

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Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Health Canada Santé Canada

Health Canada - Health Products and Food Branch (HPFB)
Bilateral Meeting Program

Record of Decisions
Canadian Pharmacists Association (CPhA)
1600 Scott Street, Holland Cross, Tower B, 2nd Floor, Boardroom 2048, Ottawa, Ontario
Wednesday September 28, 2011
(1:30 p.m. to 4:00 p.m.)

Canadian Pharmacists Association
Jeff Poston, Executive Director, Co-Chair
Janet Cooper, Senior Director, Professional and Membership Affairs
Philip Emberley, Director, Pharmacy Innovation
Jeff Morrison, Director, Government Relations and Public Affairs
Carol Repchinsky, Editor-in-Chief

Pharmacy Students
Niki Bajic, University of Waterloo
Vivian Lee, University of Waterloo
Rebecca Strong, University of Nebraska, United States of America

Health Canada Participants
Supriya Sharma, Director General, Therapeutic Products Directorate (TPD), Health Products and Food Branch (HPFB), Co-Chair
Jacques Bouchard, Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD), TPD
Mandy Collier, Bureau of Policy, Science and International Programs (BPSIP), TPD
Joanne Garrah, Office of Legislative and Regulatory Modernization (OLRM), Policy, Planning and International Affairs Directorate (PPIAD)
Gail Gervais, Liaison Unit, Office of Business Transformation (OBT), TPD
Frances Hall, Office of Pharmaceutical Management Strategies (OPMS), Strategic Policy Branch (SPB)
Paul Litowitz, Director General's Office (DGO), TPD
Genevieve Moore, Food and Drugs Act Liaison Office (FDALO), Public Affairs, Consultation and Communications Branch (PAACB)
Sharon Mullin, HPFB-Inspectorate
Denise Quesnel, Liaison Unit, OBT, TPD
Bruce Randall, OBT, TPD
Jeannine Ritchot, Controlled Substances and Tobacco Directorate (CSTD), Healthy Environments and Consumer Safety Branch (HECSB)
Christine Zaczynski, HPFB-Inspectorate
Hong Zhang, CSTD, HECSB

1. **Welcome and Introductions**
Dr. Supriya Sharma, Director General, Therapeutic Products Directorate (TPD), Health Products and Food Branch (HPFB), welcomed everyone and a roundtable of introductions followed.

Organizational Update
Dr. Sharma mentioned that there have been no major organizational changes at TPD, and Jeff Poston, Executive Director, Canadian Pharmacists Association (CPhA), mentioned the same situation for his organization.

2. **Review of Agenda**
Approved.

3. **Approval of the Meeting Notes of March 16, 2011**
Approved.

4. **Designation of Pharmacists as Practitioners under the *Controlled Drugs and Substances Act***
Hong Zhang, Senior Policy Analyst, Regulatory Policy Division, Office of Controlled Substances (OCS), Controlled Substances and Tobacco Directorate (CSTD), Healthy Environments and Consumer Safety (HECS), provided the update on this item.

On behalf of the Canadian Pharmacists Association (CPhA), Janet Cooper, Senior Director, Professional and Membership Affairs, mentioned that over the last four years, most provincial governments have made legislative and/or regulatory changes authorizing pharmacists with a range of prescriptive authority. In some provinces, this includes independent prescribing within a collaborative practice environment. Given this expanded scope of practice, CPhA feels that pharmacists should be included on the priority list for authorization under the proposed *New Classes of Practitioners Regulations* (NCPR) under the *Controlled Drugs and Substances Act* (CDSA).

Mr. Zhang mentioned the work that has been done on this project since 2007. In February and March 2011, the Office of Controlled Substances held information sessions with national health professional associations representing midwives, nurses and podiatrists to inform them of the key changes to be made to the proposed NCPR. All stakeholders were supportive of the proposed changes. It was noted that the NCPR are enabling in nature, and in the future, other professions including pharmacists could be designated as practitioners under the CDSA in order to be able to prescribe controlled substances if such authority is included in their scope of practice under provincial legislation.

Health Canada is presently preparing a revised regulatory proposal for NCPR, including a cost-benefit analysis that aims to assess the potential costs. For example (e.g.) potential increased diversion to the illicit market from an increased number of prescribers and benefits, e.g., increased patient safety, and improved efficiency in health care service delivery associated with this regulatory proposal to both governments as well as society at large.

Health Canada is currently aiming to submit this proposal to the Treasury Board Secretariat in the Fall 2011 for subsequent review and approval by the Treasury Board. Pre-publication of this regulatory proposal in *Canada Gazette* Part I, is anticipated in early 2012.

5. **Natural Health Products (NHP): Requesting Update from Health Canada on Status of Exemption Numbers and Enforcement Policy**

Christine Zaczynski, Compliance Coordinator, Drug Compliance Verification and Investigation Unit, HPFB-Inspectorate, provided the update on this item. She mentioned that the NHP Program has been focusing its efforts on a number of priorities, including the regulatory modernization initiative. The goal of this initiative is to modernize the current regulatory frameworks for food and health products to ensure an appropriate level of oversight based on the level of risk of the product.

The NHP Program continues to support the path forward for compliance and enforcement and is reviewing how it fits into this initiative. Under the new regulations, the NHP Program is doing well and showing great progress. It will communicate with stakeholders on moving forward when a decision is made. Until that time, industry should continue to take efforts to be in compliance with the new NHP Compliance and Enforcement Policy and the Regulations. The compliance promotion transition period will continue to apply with compliance and enforcement efforts focused on issues that pose a risk to health, or for which efforts have not been taken, to come into compliance. Quarterly reports can be found on the Health Canada website.

6. **Submission of Product Monographs (PM) to Health Canada**

Bruce Randall, Manager, Review Services Division, Office of Business Transformation (OBT), TPD, addressed this issue.

Health Canada is currently undertaking several initiatives in order to improve its capacity to operate in an electronic environment. This requires the analysis of current systems and processes and development of new tools to support e-business processes.

Currently the focus of this work is the expansion of the current electronic Common Technical Document (eCTD) to new submission types; the development of secure communication with external stakeholders; the development of smart electronic forms; digitization of legacy information; and infrastructure improvements to ensure stability of current systems.

Health Canada is aware of projects ongoing at the international level regarding structured product labelling, and recognizes the potential benefit to both industry and regulators. However, at this time no priority has been given to developing requirements for product monographs, nor has a timeline been established.

Carol Repchinsky, Editor-in-Chief, CPhA, indicated that CPhA is receiving electronic product monographs in Word format. She is willing to offer suggestions to Health Canada.

7. **Legislative Renewal**

Joanne Garrah, Associate Director, Office of Legislative and Regulatory Modernization (OLRM), Policy, Planning and International Affairs Directorate (PPIAD), provided the update.

OLRM was asked to put together a roadmap for the Branch in terms of modernization. OLRM is presently going through the internal consultations. Stakeholders should be hearing from Health Canada in the Fall, in terms of next steps.

Action: PPIAD to communicate next steps to stakeholders in the Fall.

8. **Drug Shortages Update**

Both the CPhA and Health Canada representative (Joanne Garrah, Associate Director, OLRM, PPIAD), provided an update on recent activities related to drug shortages, including the multi-stakeholder working group that was established with the goal of creating a national drug shortages monitoring system, and the recent Ministerial correspondence on this issue.

In August 2011, a Health Canada advisory regarding importation restrictions that may lead to drug shortages caused widespread media interest. CPhA has been heavily quoted in all these media stories. CPhA would like to receive a notification in advance of such communications. CPhA noted that due to the global challenges with drug shortages, the International Pharmaceutical Federation issued a statement in August.

The issue of risk communications was discussed and it was acknowledged that OLRM will be reviewing this issue in the context of establishing practices for identifying who may be impacted by risk communications, and who should receive advance notice to be able to respond to the issue.

Sharon Mullin, Health Products and Food Branch-Inspectorate, commented to the recent piece of communication that was sent to hospitals about potential drug shortages. The intent of the notice was to alert hospitals of a possible shortage, so that they could be ready, and not announcing an imminent shortage. When dealing with drug shortages, CPhA would like to receive early notification from Health Canada, with respect to any announcements or planned actions.

9. Medical Marijuana Regulatory Reform

Jeannine Ritchot, Office of Controlled Substances (OCS), Healthy Environments and Consumer Safety Branch (HECSB), presented Health Canada's proposal to change the Marijuana Medical Access Program. Ms. Ritchot is currently consulting with Canadians regarding the proposed changes, including holding a number of sessions with targeted stakeholders (provincial/territorial health and public security ministries, municipalities, law enforcement, fire chiefs, medical practitioners and cannabis dispensaries) to seek their views as the new regulations are being developed.

The proposed changes would reduce the risk of abuse and exploitation of the current program by criminal elements; keep children and communities safe; and significantly improve the way that program participants access marijuana for medical purposes.

The proposed changes reflect concerns raised by law enforcement, fire officials, municipalities, program participants and the medical profession.

Ms. Ritchot explained how the current program works. At the present time, individuals wishing to access marijuana for medical purposes must seek the support of a physician, and then submit a complete application to Health Canada. Once approved, applicants have three options for accessing legal marijuana (purchase it from Health Canada; produce for themselves by applying for a personal-use production license; or designate someone to produce for them under a designated-person production licence).

Ms. Ritchot mentioned that in Canada, approximately 11,800 persons are authorized to possess marijuana for medical purposes. 80% of them obtain their supply via a personal or designated-person production license. The program has grown rapidly in recent years, which in turn has led to a number of significant challenges, as well as a number of significant stakeholder concerns.

Participants have expressed concerns regarding the length and complexity of the application process; the need to renew authorizations and licences on a yearly basis; and the fact that only one strain of marijuana is legally available under the current program. Police, fire authorities and municipalities have expressed concerns with the public health and safety risks associated with the production of marijuana in private dwellings. Physicians and their associations have expressed mixed views about the program, but want more current information about the risks/benefits associated with the use of marijuana for medical purposes.

Under the proposed changes, marijuana would be treated as much as possible like any other medication. It would be sold by licensed commercial producers who would set their own prices. Health Canada's role in marijuana distribution and the issuance of Authorizations to Possess, and personal production licences, would end. The production of marijuana for medical purposes by individuals in their private dwellings would also be eliminated. Licensed commercial producers would be permitted to produce any strain of

dried marijuana, and would be regularly audited and inspected by Health Canada to ensure security of the location and safety of the product. Municipalities would be able to enforce their own zoning regulations for legitimate licensed commercial producers. Individuals would still be required to consult a physician to gain access to marijuana for medical purposes. Physicians would have access to up-to-date information on the risks/benefits of marijuana associated with the use of marijuana for medical purposes.

Ms. Ritchot added that all Canadians were provided with the opportunity to comment on Health Canada's proposed changes. As of July 31, 2011, over 2,600 comments were received. Health Canada is engaging key stakeholders in discussions relating to specific elements of the proposed changes. The Department will publish a summary of input received on its website.

Ms. Ritchot outlined the next steps. She is hopeful that the consultations will be completed by the end of November 2011, the development of the new regulations to begin in early 2012, and have full implementation in 2014.

Ms. Ritchot noted that through the course of consultations, certain stakeholders and partners, including provinces/territories and medical practitioners, had strongly recommended that pharmacists play a role in the new framework by dispensing marijuana for medical purposes. Provinces and territories in particular asked that Health Canada consult with pharmacists in order to determine their level of interest.

Janet Cooper, CPhA, mentioned that for mainly security reasons, she expects very few pharmacists would be interested in marijuana distribution, but are willing to explore discussions internally.

Dr. Poston noted that he would consult the CPhA's board to discuss this matter further and that he would let the Liaison Unit know CPhA's decision on whether or not pharmacists should play a role in this program by the end of December.

In response to questions regarding how other jurisdictions operate medical marijuana programs, Ms. Ritchot agreed to provide the Liaison Unit with such a list for distribution to CPhA members.

Actions:
Jeannine Ritchot agreed to provide the Liaison Unit with such a list for distribution to CPhA members.
Update: The list was sent to CPhA on September 30, 2011.

Dr. Poston to inform Health Canada of CPhA's decision on selling marijuana, by the end of December.

10. Round Table

Therapeutic Products Directorate Forward Planning Initiatives
Mandy Collier, Associate Director, Bureau of Policy, Science and International Programs (BPSIP), TPD, outlined the initiatives that are currently active and which will require industry input in the near future. Where possible, the anticipated timing of the projects was provided to facilitate the coordination of member input by CPhA.

11. Adjournment
Meeting adjourned at 4:00 p.m.

12. Next Meeting
Wednesday March 28, 2012, at 1:30 p.m.

Original signed by Barbara J. Sabourin for

Dr. Supriya Sharma
Director General
Therapeutic Products Directorate

Medical Marihuana Regulatory Reform – Meeting with the National Association of Pharmacy Regulatory Authorities (NAPRA)

June 12, 2012

Background
On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. Meetings with key stakeholders were held between August and November 2011. Many stakeholders groups, including P/T ministries of health, law enforcement and local governments requested that Health Canada consider distribution through pharmacies, as pharmacists have extensive knowledge and experience in dispensing therapeutic products.

Current Status
On June 12, 2012, representatives from Health Canada met with the Council of Pharmacy Registrars of Canada (an advisory committee to NAPRA) in Ottawa to discuss the potential role of pharmacists in a reformed MMAP.

Meeting Synopsis
Representatives from Health Canada outlined the key elements of the proposed changes to the Marihuana Medical Access Program and provided updates regarding the regulatory development process and timelines. Ensuing discussion centred on the supply, distribution and dispensing of marihuana for medical purposes and the role of pharmacies.

Key Discussion Points
- Participants were generally not opposed to continuing to offer flexibility for P/Ts to decide whether to enable pharmacists to dispense marihuana for medical purposes.
- It was noted that even if P/Ts authorized pharmacists to dispense marihuana for medical purposes, it would be the decision of the individual pharmacies whether they wish to offer the service.
- Participants questioned whether the new medical form could be defined as a prescription and therefore dispensed by pharmacists (P/T legislation authorizes dispensing pursuant to a prescription only);
- Education and information stemming from EAC recommendations would also need to be provided to pharmacists supporting access to marihuana for medical purposes.
    - Information regarding safety and efficacy would be needed for pharmacists to feel comfortable providing advice to patients, which is a key activity of dispensing.
    - Without appropriate research and evidence, concerns were raised regarding pharmacist liability for dispensing an unapproved therapeutic product.
    - Curricula of pharmacy schools do not cover plant pharmacology.

Other points of discussion
- In continuing consultations with the P/Ts, participants recommended that Health Canada include pharmacy regulatory authorities in those meetings.
- Participants requested that the EAC include members/experts from the pharmacy community.

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Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

MMAP Targeted Consultations – Federation of Canadian Municipalities

Background

On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and October, 2011.

Current Status

On September 29, 2011, representatives from Health Canada met with the Federation of Canadian Municipalities for a targeted consultation at the Capital Hill Hotel and Suites, Ottawa. The FCM organized a group of representatives from a number of municipalities that work in policy areas that have an interest/stake in the proposed reform of the Program. Representatives were from the following areas: by-law services, building and regulatory services, inspection services, law enforcement, and fire services.

Meeting Synopsis

Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on three themes:

1. Elements of the proposal that participants found to be positive.
2. Issues/concerns about the proposal.
3. Feedback on questions posed by Health Canada to meeting participants.

Overall, Health Canada's recommendation to create a regulated industry was well received. There were concerns related to the absence of interim measures to address municipalities' challenges regarding personal production in private dwellings. FCM representatives cautioned that Health Canada should consider the limited availability of inspection resources in some municipalities when designing the program, as there is the potential for increased pressure on municipal resources to monitor and inspect licensed commercial producers.

Positive Elements of the Proposal

- Overall agreement with the need for a regulated industry.
- Appreciation that Health Canada recognized that the current program is flawed.
- The elimination of personal and designated-person production in residential areas.
- Inspections ensuring quality of product and safety of growing procedures.
- The ability to regulate commercial entities through local by-law and zoning regulations.
- Mail-order delivery removes the centralization of crime and stigmatization of neighbourhoods that may result from dispensaries for the sole purpose of marihuana distribution.

Key Concerns

- The timelines for reform leave a significant period of time where municipal concerns and challenges with the current program will not be addressed.
- The elimination of PUPL and DPPL is welcomed, but questions were raised regarding remediation standards for those dwellings that are currently used as growing sites – the public health and public safety risks will continue after the program sunsets (ie mould spores, pesticide contamination, etc). Specifically, questions were raised regarding whether or not Health Canada has a responsibility to remediate, and what it plans to do in this regard.
    - Recommended that Health Canada send information packages to licence holders upon sunset of the program that highlights public health concerns and required steps of remediation.
- Compliance and enforcement framework may create a capacity issue for municipalities - will require clear distinction between federal and municipal jurisdictions. (ie. who inspects for what?)
    - Integrated service teams were highlighted as a model;
    - Communications protocol between municipal and federal inspectors would be imperative;
    - Review period would be required once the new regulations are in place (ie. how's it working? Do changes need to be made?)
    - If PUPL and DPPL are grandfathered, municipalities will not be able to maintain an inspection regime due to the volume of inspections that could be required.
- Questions were raised about how organized crime could be prevented from using the legal market to divert product to the illicit market.

Health Canada Questions

- Do you see a role for yourselves in determining/maintaining the eligibility of a licensed commercial producer? If so, what kind of role? (e.g. approving zoning)
    - Health Canada's licensing of commercial producers could be contingent on interested parties meeting municipal zoning regulations, obtaining municipal approval to operate, inspections, etc first. (eg. checklist to prove complete);
    - Municipalities will need to examine size and use of buildings and be able to assess the residual affects of commissioning old buildings;

- What are your thoughts on whether marihuana dispensaries have a role in the program? What threats/risks might be involved, and how could they be mitigated?
    - Municipalities were not comfortable with the addition of dispensaries to new framework for the program;
    - Recommended that Health Canada explore pharmacy models if seeking to expand beyond the mail delivery option;
    - Concerns with onsite consumption;

  - Patients could be at higher risk of robbery if leaving a dispensary with a large amount of dried marihuana;
  - Citizens may not welcome or support the addition of dispensaries in their neighbourhoods.

- If HC were to reconsider small-scale, personal production of marihuana in private dwellings, what program elements would increase your level of comfort?
  - Knowledge of location of medical grow operations;
  - Inspection and enforcement of regulations – a stronger accountability mechanism for patients;
  - Annual inspections (ie electrical, safety, etc);
  - Renewals (even in the interim) should be subject to similar regulations and transparency that will be required of commercial producers.

Other Points of Discussion

- The FCM requested that further consultation be undertaken with municipalities, especially if Health Canada's proposal changes;
- Health Canada officials committed to speak with the current program director to assess what can be done in the interim to address challenges of PUPL and DPPL.
- Health Canada committed to providing a breakdown on the number of authorizations to possess and personal and designated production licences by province.

Next Steps

Health Canada representatives will be meeting with members of the Canadian Association of Chiefs of Police and the RCMP on October 12. An analysis of these consultations will be written and incorporated in to the final reform package.

This is **Exhibit "UU"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

HEALTH CANADA

Marihuana Medical Access Program Reform

Law Enforcement Consultation
Meeting Report

October 12, 2011
Royal Canadian Mounted Police Headquarters
Barrhaven, Ottawa, Ontario

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1. Background and Introduction

On June 17, 2001, Health Canada (HC) announced improvements to the Marihuana Medical Access Program (the Program or MMAP) which provides access to marihuana for medical purposes for seriously ill Canadians. The impetus of these changes came from concerns about public safety and security and the potential for illicit use which were raised by police and law enforcement, fire officials, physicians, municipalities, and program participants. The proposed improvements would reduce the risk of abuse and exploitation by criminal elements and keep children and communities safe. To this end, Health Canada is launching public consultations on the proposed improvements. A number of stakeholder groups have been invited to these consultations, including Provinces and Territories, municipalities, compassion clubs and cannabis dispensaries, medical associations, law enforcement, fire officials, and other interested parties.

A consultation meeting with representatives of the Canadian Association of Chiefs of Police (CACP) and the Royal Canadian Mounted Police (RCMP) was held at the RCMP Headquarters, Ottawa, Ontario on October 12, 2011. In this morning meeting, there were 8 (eight) participants representing various police detachments from across the country.

Cathy Sabiston, Director General of the Controlled Substances and Tobacco Directorate of Health Canada welcomed participants and underscored the importance of hearing from law enforcement as they go forward with the proposed changes to the Program. In an effort to reform the Medical Marihuana Program, the government is consulting many stakeholders including the provinces and territories, the medical community, compassion clubs and cannabis dispensaries, and other key stakeholders. She noted there was an online consultation which generated over 2600 submissions.

She explained the objective of the meeting:

- to discuss elements of the proposed program changes and gather feedback from participants.

This report summarizes the discussion that took place at this consultation meeting.

2. Presentation of the key elements of the proposed improvements to the Program

Jeannine Ritchot, Director, Medical Marihuana Regulatory Reform (MMRR) began by thanking participants for attending and acknowledging that the contribution of ideas by law enforcement was critical to the success of improving the Program and to the reform of the regulations.

Jeannine proceeded to set the stage by giving participants a brief overview of the key elements of the proposed improvements to the MMAP. The office of the MMRR was tasked with reviewing and making proposed changes to the Program. The objective of the proposed improvements is to reduce risks to Canadians and keep communities safe, while improving access for Canadians to the use of marihuana for medical purposes. She noted that the legalization or decriminalization of marihuana is not part of the proposed changes.

Jeannine explained that under the current program individuals see their physician in order to have him/her sign a form supporting their use of marihuana for medical purposes. The patient must then apply to Health Canada for an authorization to possess marihuana for medical purposes. The medical practitioner's form and their choice of supply must accompany the application form. The package is reviewed by Health Canada and appropriate authorizations and licences are issued where approved. These authorizations and licences are reviewed on a yearly basis. The process of obtaining marihuana for medical purposes is cumbersome and complicated.

Jeannine stated that Health Canada is proposing that the first step remain the same, the requirement to consult with a physician, as this is the best place to make a decision about a patient's medical condition. The physician no longer needs to fill out the Health Canada declaration. Another document, yet to be created, would be supplied to the patient by the physician. The individual would submit this document to licensed commercial producers (LCPs) in order to obtain marihuana for medical purposes. Health Canada would no longer receive or process applications consequently, a government agency would no longer have access to the sensitive medical records of Canadians. They would no longer be responsible for producing and distributing medical marihuana. Licensed commercial producers would be charged with this responsibility, and Health Canada's role would be more of a more traditional regulatory role.

After the presentation of the principle elements of the MMAP proposed improvements, there were questions of clarification and comments. They are summarized below.

To the question about educating the medical practitioner in order to support their decision making around "prescribing" the use of medical marihuana, Health Canada stated they are creating an Expert Advisory Committee (EAC) and whose purpose is to ensure that physicians have the most up to date information on the uses of medical marihuana. This is a big concern for the College of Family Physicians of Canada (CFPC) in particular, and the medical community, in general. Health Canada is looking for ways in which to reach out to this community.

To the question about how the physicians will be organized, Health Canada said that other stakeholders suggested creating a registry model similar to that which services the Methadone Program, and Health Canada is currently analyzing this option. If the Personal-Use Production Licenses (PUPLs) are being eliminated, Health Canada needs to ensure a process that will provide adequate access to marihuana for medical purposes. To this end, there will need to be an effective and accessible training program in place, especially for family physicians.

3. Reactions to the proposal for improvements to the Program

Participants were asked to identify the impact of the changes to the Program would have on their policing role and law enforcement capability. They discussed their likes and dislikes about the proposal. A number of important topics were addressed in each discussion. The thoughts were summarized and are synthesized below.

> *Focus Question: What do you like about the proposed improvements to the Program?*

Participants liked some aspects contained in the proposal including the removal of personal production and the creation of LCPs. The discussions which took place in response to the question above are summarized. The responses have been themed for ease of comprehension.

✓ *Removal of personal production is progressive.*
- Having people growing marihuana for medical purposes in their residences is a serious health and safety risk both to the growers and to those living around them.

✓ *Creating licensed commercial producers (LCPs) is a step forward.*
- Having LCPs take responsibility for producing and distributing marihuana for medical purposes was seen as a positive step.
- It was suggested that local police could be designated inspectors for the LCPs.
- Caution: organized crime could infiltrate LCPs and use them as a legal way to sell illicit marihuana.

> *Focus Question: What are your concerns regarding the proposed change to the Program?*

A number of key issues were identified by the group. These included concerns about personal production/legalizing personal use of medical marihuana, grandfathering PUPLs, keeping organized crime out of LCPs, the continuance of illicit cannabis clubs and dispensaries, and fraud associated with falsifying documents for possession of marihuana for medical purposes. The discussion which took place in response to the question above is themed and summarized in the following bullets.

✓ *Concerns about personal production.*
- A document with a full statement of concerns was submitted to Health Canada; such concerns as, infiltration of organized crime, home invasion, etc.
- Public safety is an enormous concern. Lack of capacity for performing inspections and the inability to share information with the local jurisdictions is problematic.
  - There are an unknown number of grow-ops within the municipalities and communities; under the current structure, these cannot be checked to see if they are up to code and safe.
  - Example: sometimes firemen respond to grow-op where there are unknowns, including toxic chemicals, and this puts them at risk.

✓ *Possibility of grandfathering PUPLs was a serious concern.*
- Participants unequivocally agreed that grandfathering should not be in place; there is no need for people to grow marihuana for medical purposes in their residences. It was recommended that production be removed from residential neighborhoods.

- ✓ *Fear of legalizing the personal use of marihuana for medical purposes.*
  - Every user will have a "prescription" issued by a doctor and the police will not know the source of the prescription.
  - "Prescriptions" are too easy to get; participants suggested that some doctors charge a $100 processing fee in order to "prescribe" this medication.
  - The Quebec College of Physicians refuses to endorse the use of marihuana for medical purposes.

- ✓ *Keeping organized crime out of the LCPs.*
  - Organized crime is very adept at "hiding" in organizations and there was concern that they would infiltrate the LCPs. The group was interested in hearing the steps that would be taken to prevent this from happening.

- ✓ *The continuance of illicit cannabis clubs and dispensaries which are well organized and popular.*
  - They are growing an uncontrolled amount of marihuana and making large profits.
  - They are unwittingly creating health dangers such as moulds.
  - Health Canada noted that because the cannabis clubs are so well organized, they have a large membership that look to them for advice and education.

- ✓ *Vulnerability in the current proposal.*
  - There is concern that the illicit production of marihuana may continue to overshadow the medicinal side.

- ✓ *Fraud: falsifying documents for possession of marihuana for medical purposes is a major concern.*
  - The greatest concern for fraud is in the first contact between physician and patient. Most physicians employ due diligence to this process, but in the underground community, some physicians are known for "prescribing" easily.
  - Participants raised concern with the dosage/amount physicians are "prescribing". High doses are being diverted, therefore participants suggested that limiting the amount of marihuana that can be supported will help ensure that organized crime does not become involved.
  - Concerning the integrity of the identification document used to obtain medicinal marihuana:
    - The new proposal eliminates this step, and thus could facilitate an increase in the use of marihuana for medical purposes.
  - For law enforcement, there is no way to discern if a person's medical marihuana is from a legal source or if the authorization documents are from a doctor.
  - Organized crime will always be able to counterfeit identification documents, but may be slowed down with high integrity government issued identification.

- ✓ *Verifying identification of legitimate licensed holders for medicinal marihuana with Health Canada is problematic.*
  - Currently, communicating with Health Canada is difficult and time consuming.
  - There seems to be no standard answer to law enforcement queries, and an officer is often transferred many times.
  - It can take two (2) to 12 hours to get information.

4. Law enforcements considerations concerning Licensed Commercial Producers and their production operations.

In order to gain an understanding of law enforcement issues and the potential problems foreseen with the proposal for the new Program, the group were asked to give feedback and to share information on a number of key questions relating to the following focused themes.

- *Discussion themes:*
  - *a) Licensed Commercial Production Framework.*
  - *b) Safety and security.*
  - *c) Identification.*
  - *d) Compliance and enforcement.*
  - *e) Diversion.*

Based on their practical experience, participants shared their ideas and made recommendations on the discussion areas. A number of key themes emerged including recommended zoning requirements, minimum information required for law enforcement, methods of assessing threat levels, a potential role for dispensaries, seed sources, and the need for a focused regulatory framework for LCPs. Safety and security discussions included cost effective and reasonable security measures, disposal requirements, and secure delivery methods. Recommended identification requirements, law enforcement's role in inspection, and some thoughts on diversion rounded out discussions. This information was captured and is summarized below.

a. ***Licensed Commercial Production Framework..***

✓ *Recommended zoning requirements.*

- The group unanimously recommended against residential production for public safety reasons.
- The municipalities need to have input on where the LCPs are located.
- Commercial/non-residential locations were thought to be a better option. Some thought that even if it is properly zoned and inspected there would still be problems with invasion and break-ins that would put people around the location at risk.
- Others thought that if security requirements and zoning were properly authorized, a well thought out location with proper fencing, security and alarms could be acceptable.
- In all cases, law enforcement should be informed of the LCPs' locations.
- The idea of having a checklist for inspection by the municipality's fire and law enforcement, adapted to the specific environment and sensitivities of the different communities, was well received. Granting a license to a producer should be dependent on compliance with this check list. The checklist should include all the element of public safety and security, such as:
  - There should be a standard in place for electrical and HVAC.
  - Risk of fire and toxic environments should be on the list.

✓ *Minimum amount of information required by law enforcement.*

- The exact location of LCPs in each of the cities/ communities affected.
- An easily accessible floor plan and an indication of where the safest entrances are located.
- The kinds of chemicals being used in the production operation.
- A point of contact is needed.

- Some participants said the owners and employees names of the LCPs should be required for law enforcement, while others thought that only having the owners name would satisfy the security clearance required.
- It was suggested that the same security checks used by PPS should be employed by the LCPs, ex: criminal checks, etc.
- Maintaining a "hot line" and an updated list of authorized LCPs in order to share information and sustain the partnership with law enforcement would be useful.

✓ *Assessing threat levels to ensure effective security measures.*

- The threats need to be determined in each environment.
  - For example, smaller producers may present less of a risk whereas larger ones, a greater risk.
  - Location is an important variable.
- Consult with local, regional, and provincial law enforcement when an LCP wants to open in a community.
  - Seek out the authority in the communities in order to gather intelligence to perform threat assessments.
  - These authorities are able to determine the threat agents and can help build an appropriate risk assessment model that will help mitigate risks. Include stakeholders in the process.

✓ *Potential role for compassion clubs and dispensaries.*
Note: Participants had differing views on whether to allow compassion clubs and dispensaries to have a role.

- Some participants thought dispensaries should be eliminated.
  - There was concern that the compassion clubs and dispensaries are dispensing more than marihuana. Also, less than 1% of their clientele have valid Health Canada identification cards. These organization`s profiles are problematic and therefore should not be part of the supply system for medicinal marihuana.
  - Many patients who have access to marihuana for medical purposes do not have addresses and this is the argument for making medicinal marihuana accessible through compassion clubs or dispensaries.
  - Having LCPs is sufficient and will address the legal accessibility issue.
  - The recommendation was against a store front dispensary model, as it could provide an opportunity for organized crime to infiltrate. There was concern, however, that the community-based model offered by cannabis clubs and dispensaries would eventually allowed by the courts.
- If dispensaries are licensed, they need to be rigorously regulated and have stringent consequences for disregarding the rules.
  - As exemplar, the Dutch cannabis cafés who exceed their allowance of 30grams per café have had their licenses revoked as punishment.
- In conclusion, participants recommended against dispensaries, but if they do exist then they need to well-regulated.
- Health Canada noted that pharmacies have not indicated an interest in dispensing. Additionally, transforming medical marihuana into an authorized drug would involve clinical trials followed by a complicated process involving Provincial and Territorial legislation and regulation. Although this is not being contemplated at this time, it may be considered in future.

✓ *Seed Sources.*

- A few options for seed sourcing were suggested by Health Canada:
  - RCMP seizures;
  - Provide a number of illegal "seed dispensaries" with a Section 56 exemption to sell to LCPs for medical purposes.
  - Allow the LCPs to procure their own supply of seeds, independently.
- There needs to be a starting point for supplying seeds and participants agreed this could come from RCMP seizures where there are a number of strains available.

- Caution: there could be liability around seeds from seizures. From this perspective, it may be more prudent to buy the seeds from an established company.
- To the use of illegal "seed banks", participants were against using an illegal operation to source a legal one.
- Bedrocan BV Medicinale Cannabis and legal suppliers in the U.S. could be other sources for seeds.
- Health Canada noted that procuring from these international companies would involve the acquisition of complicated importation licenses for controlled substances and a time consuming process that may not be in place for the 2014 timeline.

✓ *Include a quality control requirement.*
- Regulate the THC content limit for medicinal marihuana.
    - The percentages of THC have increased over the years; the current average is about 15-17%. This makes the drug too potent. It is no different than any other pharmaceutical where the percentages would be regulated.
    - The Dutch have implemented a 15% THC content limit because they have acknowledged that higher content levels have health and safety risks.
- Physicians need to be educated on the effects of this medication in order to determine the dosage a person would need for therapeutic use. More research needs to be done.

✓ *Complaints about the quality of the current product.*
- Many patients complain about the quality of the medicinal marihuana which is produced and distributed by Prairie Plant System Inc. (PPS); this has driven patients to grow their own product.
- Another complaint is that patients need a variety of strains and contractually PPS is confined to producing one strain only.
- In the new Program, effective regulation of the product is important in order to address these two issues.

✓ *The regulatory framework for LCPs needs to be focused and rigorous.*
- The greatest risk for illicit activity lies with the producers.
- The LCPs should be strictly regulated to ensure the product is used for the medicinal purposes. The regulations should include:
    - A system to determine who is a legal supplier and to be able to trace the source of the product.
    - Regulate the amount of medicinal marihuana patients are allowed to possess.
- The "right regulations" will help eliminate some of the illegal productions.

✓ *Product packaging and warnings.*
- Participants recommended that packaging and warning labels on the product should be similar to those on cigarettes.
- Also they endorsed the idea that the liability for the product and its effects should be assumed by the LCPs.

✓ *Quotas for LCPs.*
- The number of LCPs will be driven by the number of people who demand the product.
- Health Canada stated they are not yet settled on a quota. It is imperative to provide access, and if Heath Canada caps the number of growers, it could be perceived as reducing access.

Question: Have there been any surveys on how many companies would want to become LCPs?
Response: Health Canada noted that there was little interest shown by large companies because of the liability issues. The current proposal is for dried marihuana, however options to allow for the distribution of other forms of medicinal marihuana are being analyzed. Step two (2) of the project will be to test interest in becoming LCPs. There is a list of 15 parties, in addition to PPS, interested in becoming LCPs provided they meet the regulations. There will be people who come forward who are not legal now and if they meet the requirements, they can be licenced and therefore subject to inspections. The existing monies in the program will be reinvested back into an inspection regime.

✓ *Costing and profitability.*
- Participants thought that with the new regulatory regime, it would be difficult for LCPs to be profitable. The market will not be very big. The real profit is in selling illegal marihuana, and therefore illicit grow-ops will not disappear.
- There was concern that the competition between legal and illegal growers could drive the price of the product down and there was a potential for monopolies to emerge.

b. *Safety and security.*

✓ *Cost-effective and reasonable security measures that will help keep the price of marihuana for medical use affordable.*
- Note: Regardless of the cost set for this product, the black market will always undercut legal market.
- There needs to be an absolute minimum standard set for security.
- The security measures should be similar to those employed by PPS. As noted by Health Canada, at PPS the staff have security clearances, there are storage vaults for the product and a separate storage for emergency stock, they use a bonded courier for transportation, and the location is kept secret.
- It was suggested that the security standards in place for pharmacies could be considered.
- Hire a security consultant to assess the risk assessment for indoor and outdoor production.
    - Regulations should stipulate that security is the responsibility of the LCPs, and they have to ensure appropriate security measures are in place. Obtaining a license should be contingent upon this proviso.
    - The penalty for non-compliance should be a loss of the LCP's license.

✓ *Disposal requirements:*
- Participants recommended a set of stringent guidelines for disposal of unused medical marihuana.
- Health Canada added that there is a regulated system in place for PPS and this could be the framework applied to LCPs.

✓ *Determining cash value of the product.*
- Law enforcement indicated that they could help Health Canada to determine cash value of medicinal marihuana in order to perform a proper cost benefit analysis.
- Caveat: It would be based on illicit values.
- Law enforcement can look at both large and small volumes and assess the market value by using intelligence and input from communities. This information can help Health Canada to build models that will help LCPs determine the appropriate security measures, and whether the business will be viable.

✓ *Security steps for ensuring safe delivery methods.*
- Currently, Health Canada receives a client order, authorizes it and sends it to PPS. PPS forwards the product to the patient by bonded Purolator courier (using vetted employees). The package is tracked through both PPS and the Purolator systems.
- It was noted that most of the courier problems occur when the DP growers send their product to a licensed holder.
- The use of a bonded courier system is the safest way of dispensing the product because it provides the straightest line between producer and patients; there is less opportunity for diversion.
- The risk associated with delivering through Canada Post small outlets is minimal; no more than any other relatively valuable merchandise.
- For those authorized individuals receiving marihuana for medical purposes with no mailing addresses, participants supported the option of their medication sent directly to their doctor's office.

✓ *Creating a working group to build the security regulations for LCPs.*
- Participants were receptive to the idea of establishing a working group who could support the drafting of the security regulations for LCPs.

c. ***Identification requirements.***

✓ *Identification recommended.*
- Participants recommended a card system which could be similar to that of the Firearms Registry.
- Regulating the "prescribed" amounts of marihuana for medical purposes is a key consideration.
    - Indicate the amounts that patients are allowed to possess.
    - Organized crime may not be interested if there are smaller amounts prescribed.

d. ***Compliance and enforcement.***

✓ *Concerning an interest and appetite for inspecting of the LCPs.*
- Law enforcement's resources are limited, so it would be difficult for them to participate in inspections.
- Participants thought that most businesses would comply with standards in place and have an interest in maintaining a clean work place.
- Inspections are not done by law enforcement with other restricted medications, e.g. oxycontin.

e. ***Diversion.***

✓ *Inadequate packaging of medicinal marihuana.*
- Improper packing of the product could lead to diversion.
- Participants agreed that diversion could be mitigated by regulating the LCPs packaging of medicinal marihuana.

After the discussions, there were some further questions and comments. These are summarized below.

To the question about providing law enforcement with the list of growers for the transition period, Health Canada responded by saying that currently, they cannot share lists with fire police and municipalities due to federal privacy legislation.

5. Closing Remarks and Next Steps

Jeannine Ritchot closed the meeting by thanking participants for taking time to share their perspectives and for the honesty in answers to the questions. She assured the group that the discussions and opinions shared in the meeting would help build the regulations. She noted that the regulatory process is a transparent one and encouraged participants to make submissions by email to the website or by fax, for an additional two (2) weeks. She outlined the next steps, as follows:

- ✓ The Regulatory process is in its beginning. The consultations will yield clearer recommendations that will be published in the *Canada Gazette* 1 in 2012;
- ✓ The goal is to have the new Program in place by 2014.
- ✓ In the meantime, the program will continue to operate in the way it has in the past.

Appendix A: Agenda

Health Canada
Marihuana Medical Access Program
Canadian Association of Chiefs of Police and RCMP
Date: October 12, 2010
Time: 9:00-12:30

Item	Time
Introduction	9:00-9:05
Presentation of key elements of the proposal	9:05-9:15
General Discussion 1. Which changes will affect you? Which changes will affect your clients/stakeholders? 2. What do you like about the new proposal? Why? 3. Do you have concerns regarding the proposed changes? What are your concerns? Why? What suggestions for improvement would you make?	9:15-10:15
Break	10:15-10:30
Discussion Themes a. Licensed commercial production framework b. Safety and security c. Identification d. Compliance and Enforcement e. Diversion	10:30-12:15
Next Steps, closing remarks	12:15-12:30

This is **Exhibit "VV"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

CACP Recommendations to Health Canada regarding the Marihuana Medical Access Program (MMAP)

Principal Recommendations

- The current regulations allowing for PPLs and DPPLs to grow marihuana themselves should be repealed
  - Addressed in the reform proposal
  - Personal and designated production to be eliminated

- PPLs and DPPLs should be given a reasonable time limit to cease their marihuana growing activities. This time limit should take into consideration the time it will take HC to have all its approved suppliers in place
  - Addressed in the reform proposal
  - Will require effective transition planning

- HC should contract reputable companies to produce a variety of medicinal marihuana throughout Canada to meet the needs and expectations of most medicinal marihuana users as well as the timely and reliable delivery of the product.
  - Addressed in the reform proposal
  - HC would *license* and not contract companies to undertake the supply and distribution role
  - These companies would be able to produce a variety of strains.

- Approved medicinal marihuana companies should be located in areas where they are easily accessible to the majority of MMAR licensed users.
  - Addressed in the reform proposal
  - Individuals would purchase marihuana from LCPs which would be shipped to them, regardless of geographic location

- The approved medical marihuana companies would be subject to HC regulations and inspections; have the necessary standardized security and safety measures in place; have regulated quality control and safety standards for the medicinal marihuana; and, have the ability to deliver the marihuana in a reliable and timely manner. This recommendation will allow HC to conduct regular inspections on and maintain oversight of the MMAR program, as the locations to visit will be reduced to a manageable size. This will also limit the criminal abuse of the MMAR and the public safety risks posed by some MMAR grow operations to their communities.
  - Addressed in the reform proposal
  - Regulations will include security standards and quality control standards to be met by companies applying for a license.

- HC returns to traditional role of regulating the industry, which will include conducting audits, verifications, and inspections.
- Regulations would include provisions to allow for revocation of licences when companies do not meet their requirements.

- The daily amount of marihuana recommended by a physician should be based on recognized training encompassing scientific findings and literature versus the demand of the patient.
  - Addressed in the reform proposal
  - HC is establishing an Expert Advisory Committee to ensure that medical practitioners have up-to-date information on the current uses of marihuana for medical purposes.
  - Have already begun conducting needs assessment to determine what educational needs are

- Physicians who recommend marihuana to their patients should receive an accreditation from their governing bodies who will in turn provide monitoring and compliance support on dispensation.
  - Not specifically addressed in the reform proposal
  - HC is currently consulting with physicians on the format that their support would take.

- The regulations should have meaningful penalties assess to MMAR violators which would include criminal prosecution and the immediate suspension and/or revocation of the licence of an individual and/or business believed to be committee abuses.
  - Will be addressed in the drafting of the regulations based on feedback and input from key stakeholders, including law enforcement.

- A regulation on the allowable methods of transport of medicinal marihuana should be incorporated in the MMAR to clearly dictate the rules for license holder to transport medicinal marihuana via all modes of transportation, whether it be from point A to point B, or for an extended absence from his/her residence.
  - Not specifically addressed in the reform proposal
  - Can be addressed in the drafting of the regulations based on feedback and input from key stakeholders, including law enforcement.

- HC and the CACP should improve cooperation, consultation and communication between agencies to better draft and apply any future regulations or other laws that may cause conflict with the CDSA. Initial consultation and cooperation is vital to prevent the problems experienced today with the current MMAR

- HC has consulted the CACP/RCMP on the content of the reform proposal and will continue to seek advice as it moves forward with the development of regulations

Provisional Recommendations for a Transition Period

NOTE: A number of the provisional recommendations could not be implemented without regulatory change. The process to change the regulations takes between 18 and 24 months. Immediate implementation of many of these recommendations is therefore not possible.

- HC inspectors should immediately begin to conduct MMAR grow inspections
  - OCS/NCED for input.

- HC inspectors should be trained to detect electrical, structural, chemical and mould hazards often associated to indoor marihuana grow operations.
  - OCS/NCED for input (should we say something regarding this being beyond the mandate of CDSA inspectors?)

- HC inspectors should have the authority to immediately contact police and/or municipal/provincial agencies to report any violations (suspected or actual) of the MMAR, Criminal Code, and provincial and municipal safety and building codes.
  - Requires regulatory change.

- HC should have the authority to inspect, within a period of one year, premises on which a MMAR licensed grower had a grow operation, but whose license has since expired. This would ensure that MMAR growers are not continuing to produce marihuana beyond the expiry of their license. A number of cases in this report found expired licenses at marihuana grow operations investigated by police. This recommendation would ensure that a residence used by a MMAR licensee has been remediated up to code of all potential hazards related to marihuana grow operations such as, but not limited to, mould contamination and structural modifications.
  - This issue will be addressed in the context of transition planning
  - Will require close collaboration with other partners, including law enforcement and municipal governments.

- HC should engage and consult with law enforcement officials to find ways to increase the number of HC inspectors. With only 14 multi-purpose HC inspectors across Canada, it is and will be extremely difficult for HC to conduct efficient and effective inspections of over 3,400 MMAR growers and counting.

- For OCS/NCED input.

- HC should not allow medicinal marihuana to be produced on properties accessible to children. Individuals with PPLs who have children should be given the option to purchase medicinal marihuana from an approved supplier; to have a DPPL produce their medicinal marihuana; or to produce their medical marihuana in a separate location not frequented by children. HC should have the authority to impose meaningful sanctions to MMAR license holders who expose children to the dangers of marihuana grow operations.
  - Requires regulatory change

- After consultations with marihuana production experts, HC should revise their guidelines determining the number of plants needed to produce X amount of dried marihuana (yield per plant). The current HC regulations indicate a yield of 30 grams of dried marihuana per plant to calculate the number of plants required to produce X amount of dried marihuana. This should be revised to a more accurate yield of 90 grams of dried marihuana per plant. As such, all MMAR production licenses should be amended accordingly to reduce the number of plants allowed to be grown.
  - Requires regulatory change
  - MMAP – Could we say that HC will consider more effective stakeholder information and education (e.g. that access marihuana must be destroyed and that these are means to destroy marihuana)

- HC should add to their regulations a maximum allowable size and height of the plants.
  - Requires regulatory change

- A subject accused of a designated drug offence involving the trafficking of controlled substances, still before the courts, should not be able to obtain a DPPL MMAR licence until all court proceedings have been dealt with and the accused did NOT receive a conviction for drug trafficking offence under the CDSA.
  - Requires regulatory change

- A DPPL MMAR licence holder charged with a designated drug offence involving marihuana trafficking should have his/her licence temporarily suspended until the conclusion of all court proceedings. In the case of an individual with a PPL charged with a marihuana trafficking offence, there should be measures in place to ensure that the user is still able to obtain medicinal marihuana through HC supplier(s) in a timely manner, should his/ her growing equipment and marihuana plants be seized by authorities. The same should apply to an individual with an ATP who can no

longer be supplied by his/her designated grower who was the subject of a police intervention.
  - Requires regulatory change

- HC should improve its communication strategy with all law enforcement agencies for educational and awareness purposes. Currently, some law enforcement agencies do not have any knowledge of HC's 24-hour pager system.
  - For MMAP input

This is **Exhibit "WW"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Health Canada's Marihuana Medical Access Regulations Consultations

Meeting with the Canadian Association of Fire Chiefs

September 27, 2011
Calgary, Alberta

Meeting Summary

The following meeting report summarizes the points raised during a meeting with the Canadian Association of Fire Chiefs (CAFC) on the proposed changes to the Marihuana Medical Access Regulations (MMAR) announced on June 17 2011. This 1.5 hour meeting was organized by Health Canada and took place on September 27th, 2011 at the Westin hotel in Calgary, Alberta.

1. Background

Jeannine Ritchot, Director of the Medical Marihuana Regulatory Reform Project, presented an overview of the proposed changes to the MMAR and provided an update on the consultation process to date. She noted that to date, consultations have been had with compassion clubs and cannabis dispensaries in Vancouver, Montreal and Toronto, and she indicated there are upcoming meetings with law enforcement, the medical profession and municipalities.

2. Participants

The CAFC's President, First Vice President, Second Vice President, and the President of the Fire Prevention Officers Association of British Columbia were present.

3. General Feedback

After a brief overview of the proposed changes to the regulations, participants were asked to identify aspects of the proposed changes that they liked and those they had concerns about. They were also invited to make suggestions for improvement.

All participants in the group were strong proponents of phasing out small-scale personal production of marihuana in private dwellings due to serious public safety and public health concerns. They noted a strong hope for an opportunity to accelerate the process and to advance the 2014 timeline.

The group was in agreement that the proposed changes alleviated many concerns related to in-home operations because a model involving larger commercial marihuana producers would eliminate the hazards and concerns associated with smaller home retrofits. In addition, participants appreciated the fact that the proposed model removes the cultivation of marihuana from residential areas, thus making those areas safer. They noted that the move to commercial operations allows for more regulation and control through zoning and by-laws.

Concerns

Participants noted the following concerns related to the proposed changes to the regulations:

- Participants were very concerned that Health Canada would not share information with Fire Chiefs on the location of private dwellings where the personal production of marihuana has or is taking place. They strongly emphasized the serious public safety risks, related to electrical and fire hazards, as well as public health risks, related to excess mould and poor air quality, that are created by the cultivation of marihuana by individuals in homes. Participants highlighted the fact that certain factors such as the heavy use of electricity, poor electrical wiring, as well as products used to grow marihuana, such as fertilizing agents or boosters, often represent serious safety hazards for occupants of the home, neighbours and fire fighting personnel. Advance knowledge of where these homes are located and what the size and scope of the hazards are is critical, at least during the transition period, to help properly prepare first responders teams and ensure the safety of fire fighting personnel. It was noted that because of the close integration of police and fire departments on local issues, Fire Chiefs are currently relying on relationship-building with police at the local level to have access to that information when required and where appropriate.
- Participants expressed very strong concerns regarding the absence of a remediation mechanism for homes where marihuana has been grown. They emphasized that it is critical for structures that may have been contaminated (e.g. with excess mould) be identified so that remedial action can be taken to ensure the safety of the building for its present and future occupants.
- Concerns were expressed over the fact that there is poor recognition of the legal documentation/authorization required by individuals to grow marihuana for medical purposes in their own home.
- Given these safety and health concerns, there was some concern that the proposed timelines would be delayed and that the transition period would be extended beyond 2014.

Suggestions and Recommendations

The group made the following suggestions and recommendations to address the above-listed concerns:

- Until personal production is phased out, make the renewal or issuing of a new personal production license conditional upon demonstration of evidence of compliance with local government zoning and by-laws.
- Provide guidelines and best practices on how to safely grow marihuana to individuals who are granted a license for personal and/or designated production during the transition period.

- Establish timelines for the transition period in consultation with stakeholders to ensure feasibility and buy-in.
- Ensure that wording in the regulations provide enough flexibility for local police agencies to share confidential information provided by Health Canada on the location of private dwellings where marihuana is grown with fire officials, EMS officials, etc., as required and as permitted, in order to protect public safety and ensure that first responders teams are adequately prepared.
- Disseminate information on the legal documentation/authorization for the possession of marihuana for medical purposes to Fire Chiefs during the transition period to ensure they are familiar with it.
- Establish a remediation program to assess all homes where marihuana has been produced and ensure remedial action steps are taken to properly address safety concerns regarding the integrity of the building (e.g. provide access to information on the location of specified homes to Fire Chiefs after a marihuana production license has lapsed so that they may inspect it).
- Ensure individuals who grow marihuana in their own homes are aware of the responsibilities and financial implications associated with remediating the home (spore and mould issues, electrical hazards) for the next owners.
- Invest more resources into undertaking "checks and balances" with commercial marihuana producers.

4. Targeted Discussion Themes

Licensed Commercial Production Framework

- A fire inspection should be mandatory for all premises where marihuana will be produced to mitigate fire threats and risks.
- In principle, the onus should be on the licensed commercial producer to demonstrate compliance with local municipal by-laws and zoning.
- Participants noted that Fire Chiefs may have a role to play in terms of the regular inspection of licensed commercial producers within municipalities.
- The Fire Marshall's office and Commissioner are critical stakeholders that could be engaged to address issues that arise with licensed commercial producers that are located outside of municipal jurisdictions.
- The regulations should reference a minimum standard (e.g. a fire inspection) that must be met before a license will be issued by Health Canada to a commercial producer. This standard could be superseded by municipal standards.

By-laws, Zoning and Codes

- Building and/or fire codes to be considered will depend on the nature of the commercial growing operation (green house/indoor/outdoor).
- Commercial marihuana producers should demonstrate compliance with local zoning, electrical safety and fire codes as a condition for licensing
- Participants strongly felt that commercial marihuana producers should be decentralized in the community and adopt a no store-front model.

5. Conclusion

In conclusion, participants noted they appreciated the opportunity for consultation and indicated their interest in remaining engaged throughout the development of the new regulations. To this end, the idea of establishing a Working Group was proposed by participants as they noted it would provide a place where Fire Chiefs could bring their ideas, suggestions and concerns.

This is **Exhibit "XX"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

CMA Response: Health Canada's Medical Marihuana Regulatory Proposal

Submitted to the Office of Controlled Substances
Health Canada

February 28, 2013

ASSOCIATION MÉDICALE CANADIENNE
CANADIAN MEDICAL ASSOCIATION

A healthy population and a vibrant medical profession
Une population en santé et une profession médicale dynamique

The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, CMA's mission is to serve and unite the physicians of Canada and be the national advocate, in partnership with the people of Canada, for the highest standards of health and health care.

On behalf of its more than 77,000 members and the Canadian public, CMA performs a wide variety of functions. Key functions include advocating for health promotion and disease/injury prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and 51 national medical organizations.

ASSOCIATION MÉDICALE CANADIENNE

CANADIAN MEDICAL ASSOCIATION

The Canadian Medical Association welcomes the opportunity to comment on proposed changes to Health Canada's *Marihuana for Medical Purposes Regulations*, published in the *Canada Gazette, Part I* on December 15, 2012.

CMA provided comments on the proposed changes when Health Canada first announced them in June 2011. Our position on these changes, and indeed on the entire *Medical Marihuana Access Program* (MMAP), has been consistent since the program was initiated. We remain deeply concerned that, though the program has made a physician's authorization the key to a patient's access to medical marijuana, physicians and other health professionals have little to no evidence-based information about its use as medical therapy. As our President, Dr. Anna Reid, noted in December, the regulatory proposals are "equivalent to asking doctors to prescribe while blindfolded."

Health Canada gives two reasons for its regulatory proposal: first, to address concerns about the safety of home grow-ops; and secondly, to reduce the cost of administering a program that has proven more popular than anticipated. Neither of these reasons is related to improving patient care or advancing our clinical knowledge of marijuana as a medical treatment.

CMA understands that many Canadians suffer constant pain from chronic or terminal illnesses and are searching for anything that will provide relief. We know that some patients find that use of marijuana relieves their symptoms and that some health professionals also believe it has therapeutic value. However, we are concerned that these claims remain inadequately supported by scientific research. Controlled studies of medical marijuana have been published recently and some have shown benefits. However, these studies are few in number, of short duration and with small samples, and knowledgeable clinicians say that more research is required. In addition, some say that marijuana has become more potent since it became a popular recreational drug in the 1960s, though others disagree,[1] and growers say they can develop strains tailored to the needs of individual medical users.[2] Though these claims are part of the popular understanding of medical marijuana, there is no scientifically valid evidence that supports them.

What Physicians Have Told Us

In May 2012, CMA surveyed members of its "e-panel" of physicians to obtain more information about their attitudes and needs regarding medical marijuana. The survey received just over 600 responses out of more than 2,200, for a 27 per cent response rate. Among the findings:

- About 70 per cent of respondents had been asked by patients to approve medical marijuana, though only four per cent said they were asked to do so "often." Of those

[1] Bonsor K: "How marijuana works". Accessed at http://science.howstuffworks.com/marijuana5.htm
[2] http://medicalmarijuana.ca/learning-center/marijuana-strains

who were asked, one-third reported that they "never" supported such requests, while 18 per cent "usually" did so.

- 64 per cent of respondents were concerned that patients who request medical marijuana may actually be using it for recreational purposes;
- A large majority of respondents said they would find more information on the appropriate use of marijuana for medicinal purposes, and on its therapeutic benefits and risks, useful or very useful.
- About two-thirds agreed or strongly agreed that they would feel more comfortable if:
    - Physicians wishing to use medical marijuana in their practices were required to undergo special training and licensing; and,
    - Health Canada offered them protection from liability.
- In open-ended questions, some respondents expressed favourable views on marijuana's medical benefits. However, a larger number expressed concern over its harmful effects, such as: psychotic symptoms, especially in younger people; potential for addiction and dependency; and the risks to lung health from smoking it or any other substance.

Marijuana is Not Like Other Therapeutic Products

Theoretically, marijuana, when used for medicinal purposes, is regulated under the *Food and Drugs Act*. However, because of its unique legal position, Health Canada has exempted it from the applications of the *Act* and its regulations, and it has not undergone the scrutiny of benefits and risks required of other therapeutic products approved for use in Canada, be they prescription-only or over-the-counter.

According to the *Food and Drugs Act (FDA)*, all drugs requiring a health professional's authorization must be approved for use by Health Canada, based on evidence of effectiveness obtained from controlled clinical trials, which remain the best currently available means of validating knowledge. In addition, Health Canada has a system of post-market surveillance to keep track of problems that arise with prescription drugs in real-world use. Though the CMA has been critical of some aspects of this system,[3] we acknowledge that it has added to our body of knowledge on drug safety risks. If marijuana were not an illegal product, it might have been assessed through some form of pre-approval and post-approval surveillance. By exempting marijuana from the *FDA*'s pre-approval and post-approval requirements, Health Canada has lost an opportunity to improve our knowledge of the drug's therapeutic uses.

[3] CMA Submission to the House of Commons Standing Committee on Health: Post-Market Surveillance of Prescription Drugs (February 28, 2008). Accessed at http://www.cma.ca/multimedia/CMA/Content_Images/Inside_cma/Submissions/2008/brief-drug-en-08.pdf

The Views of Canadians

A recent online survey conducted by Ipsos-Reid on behalf of the CMA provides insight into the views of Canadians on Health Canada's regulatory proposal.[4] The survey found:

- 92 per cent of Canadians think it is very or somewhat important that Health Canada not remove itself from its oversight role until guidelines are put in place for physicians;
- 90 per cent believe that research on the effectiveness, safety and risks of medical marijuana is needed before Health Canada removes itself from the authorization process;
- 85 per cent of Canadians believe medical marijuana should be subject to the same rigorous testing and approval standards as other medicines;
- 79 per cent agree that Health Canada has a responsibility to maintain its role in the authorization process.;

The Role of the Physician

The CMA cannot with certainty predict the consequences of these regulatory changes for the practising physician (and, if the regulations are approved, for the nurse practitioner as well). However, we have several causes for concern:

- *The gatekeeper role of health professionals:* The most significant change, from our point of view, is that Health Canada is removing itself from the approval process, making it a transaction between the patient, the practitioner and the licensed producer. In addition, Section 125 of the regulatory proposal would reduce the content of the authorization form, from its current two-page format to a brief document requiring little more information than is required for a standard medical prescription.

  We are concerned that these changes will put an even greater onus on physicians than do the current regulations. The CMA agrees with the Federation of Medical Regulatory Authorities that the lack of evidence to support the use of marijuana for medicinal purposes signifies that it is not a medical intervention. In our opinion, putting physicians in the role of gatekeeper for access to marijuana is inappropriate and may be an abdication of responsibility on Health Canada's part.[5] Such a move could increase physicians' liability risk and put them at odds with their medical regulatory authorities, which have no choice but to continue to advise physicians to exercise extreme caution.

  The CMA believes, as does the Canadian Medical Protective Association, that a drug's approval under the *Food and Drugs Act* does not impose a legal obligation on physicians or nurse practitioners to authorize its use if, in their judgment, it is clinically inappropriate.

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[4] Online survey of 1,000 Canadians the week of Feb. 24, 2013 conducted by Ipsos-Reid. Summary report of the poll can be accessed at www.cma.ca/advocacy/cma-media-centre.

[5] Letter to Health Canada from Yves Robert, MD, President of the Federation of Medical Regulatory Authorities of Canada, November 4, 2011.

The Ontario Court of Appeal reached a similar decision recently in the case of *R. v. Mernagh*.

- *Protection of Physician Privacy.* Under the proposed regulations, health information and physician data – such as the patient's name and date of birth, or the provider's licence number – will be collected by licensed producers who may not be subject to the same regulatory and privacy constraints as the health care sector. The draft regulations also indicate that the licensed producer is expected to confirm that the data on the "medical document" is correct and complete – in other words, health providers who authorize medical marijuana use will receive correspondence from the producer. We are very concerned about the risks this would pose to the privacy of patient and health care provider information. We believe Health Canada should conduct a privacy impact assessment of its proposed regulations or, if it has done so, to share the results.

- *Physicians as Dispensers.* Section 124 of the proposed regulations would allow authorized health care practitioners to "sell, provide or administer dried marijuana." This is contrary to Article 46 of the CMA Code of Ethics, which states that "Physicians should not dispense pharmaceuticals or other products unless they can demonstrate that these cannot be provided by an appropriate other party."

- *Other possible consequences.* We are also concerned about other potential consequences of the regulatory changes. Will more people go to health professionals requesting an authorization, on the assumption that the new regulations will make it easier to get? Will entrepreneurs seize the opportunity to establish "dispensaries" whose intended clientele are not those in legitimate medical need, as recent news stories have suggested?[6] Will medical marijuana advocates put increased pressure on physicians to authorize its use?

Meeting the Information Needs of Physicians

In one respect, Health Canada has listened to physicians' concerns regarding the lack of evidence about medical marijuana, and acknowledged the need to remedy this problem. Though it is not addressed in the draft regulations, Health Canada has established an Expert Advisory Committee (EAC) to help provide comprehensive information to health professionals. The CMA has attended meetings of this committee in an observer capacity, suggested the names of practising physicians to serve as members, and made a presentation to the committee at its meeting in November 2012.

If the EAC follows the CMA's suggestions, it will consider actively supporting the following activities:

- Funding of scientific research on the clinical risks and benefits of marijuana;

[6] Lee J. "Ross Rebagliati to Open medical marijuana franchise." *Vancouver Sun.* January 23, 2013. Accessed at http://www.vancouversun.com/health/Ross+Rebagliati+open+medical+marijuana+franchise/7860946/story.html

- Knowledge translation activities to convert this research into accessible, user-friendly tools for education and practice;

- Development of best practice guidelines in the therapeutic use of marijuana. Though this guideline would of necessity be based on "C" level evidence, it would be an improvement on what now exists; and

- Support for a compulsory training and licensing program for physicians wanting to authorize marijuana for medicinal purposes.

The CMA believes that the EAC should be given the mandate and resources to undertake these activities.

Conclusion

Health Canada's stated mission is to help the people of Canada maintain and improve their health. The CMA believes that if Health Canada wants its Medical Marihuana Access Program to serve this mission, it should not withdraw from administering the program, leaving it to health professionals working within a large knowledge gap. Rather, it should support solid research into the use of marijuana as medication and make a commitment to share this knowledge with the health professional community and to support best clinical practices.

This is **Exhibit "YY"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Summary Report:
Physician Needs Assessment – 2012

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1. Introduction

1.1 Background on Health Canada's Marihuana Medical Access Program (MMAP)

On June 17, 2011 the Government of Canada announced that it is considering improvements to Health Canada's Marihuana Medical Access Program (MMAP). The proposed improvements are intended, among other things, to reduce the risk of abuse and keep children and communities safe, while continuing to ensure that program participants have reasonable access to marihuana for medical purposes.

The core of the redesigned Program would be a new, simplified process in which Health Canada no longer receives applications from program participants. A new supply and distribution system for dried marihuana that relies on licensed commercial producers would be established. These licensed commercial producers, who would be inspected and audited by Health Canada so as to ensure that they comply with all applicable regulatory requirements, would be able to cultivate any strain(s) of marihuana they choose. Finally, the production of marihuana for medical purposes by individuals in homes and communities would be phased out.

Individuals wishing to use marihuana for medical purposes would still be required to consult a physician who is licensed to practice medicine in Canada.

1.2 Purpose of the survey

In an effort to reach out to the medical community and to better understand its needs, Health Canada consulted with Canadian physicians regarding their views on the proposed improvements to the Marihuana Medical Access Program via an online consultation to gather physicians' feedback on the proposed improvements as well as an online needs assessment survey. This report contains the results from the online survey portion of the consultation process. The results of this consultation will be shared with the Expert Advisory Committee on Information for Physicians on Marihuana for Medical Purposes. This committee provides Health Canada with advice on the scientific and medical information on the use of marihuana for medical purposes with the goal of improving the quality of the information that is provided to physicians by Health Canada regarding the use of marihuana for medical purposes. A report summarizing physician's feedback on the proposed program improvements will be released separately.

2. Methods

2.1 Survey content

The survey was designed to collect demographic information about the responding physicians including their area of practice (family practice or other specialist), location (rural or urban), and the number of years practicing.

Information was also collected about whether the physician had ever supported an application to the MMAP. If the physician had supported a patient's access to the MMAP, they were asked about the information they used to make their decision to support access, as well as which route of administration (e.g. smoked cannabis) and how many grams of dried marihuana per day they indicated on the medical declaration. Physicians who had not supported a patient's access to the program were asked about the reasons behind their decision.

In regards to information needs, all physicians who indicated that additional information would be useful to them were asked to select which topics they would like additional information on and in which format they would like to receive the information.

2.2 Procedures and participants

Invitations to participate in the survey were sent electronically and by Canada Post. Emails containing a link to the online survey were sent out to physicians through the Canadian Health Network and the College of Family Physicians. A total of 12 271 e-mails were sent out to members of the Canadian Health Network. Of these, 4 379 were opened and 323 recipients clicked the link to the survey that was embedded in the email. The College of Family Physicians sent emails with a link to the survey to 3 000 of its members. In addition, 4 000 letters of invitation containing the web address of the survey were mailed to physicians who had supported an application to Health Canada's MMAP. Of the 4 000 sent, 447 were returned to sender unopened.

The survey was available in English and French on the Health Canada website between May 24th and July 3rd. A total of 213 responses were received.

3. Results

3.1 Participant demographics

3.1.1 Area of practice

Two thirds of physicians surveyed identified themselves as general or family practitioners. Twenty one percent identified themselves as family practitioners with an area of enhanced skills, which included addiction medicine, chronic pain, emergency medicine, oncology and palliative care. The remaining 34% of physicians identified themselves as other specialists; their certifications included anesthesia, internal medicine, neurology and psychiatry. Additional areas of practice that specialists identified were addiction medicine and palliative care.

Table 1. Area of practice, n=213

Response	%	n
General practice/family practice	45	95
General practice/family practice with an area of enhanced skills	21	45
Other specialist	25	54
Other, please specify:	9	19
Total	**100**	**213**

Survey question: What is your area of practice?

3.1.2 Years in practice

The majority of physicians surveyed have been practicing for more than 20 years (55%).

Table 2. Years practicing, n=213

Response	%	n
0-5 years	12	26
6-10 years	10	22
11-15 years	9	20
16-20 years	13	28
Over 20 years	55	117
Total	**100**	**213**

Survey question: How many years have you been practicing?

** Numbers may not total 100 due to rounding*

3.1.3 Rural/Urban

The majority of responding physicians indicated that they practice in an urban area (62%) while the remaining physicians practice in a rural area (21%) or practice in both urban and rural areas (17%).

Table 3. Rural or urban location of practice, n=213

Response	%	n
Rural only	21	45
Urban only	62	131
Rural and urban	17	37
Total	**100**	**213**

Survey question: Do you practice in a rural or urban area?

3.2 Marihuana for medical purposes and cannabinoids in practice

3.2.1 Approached to discuss marihuana for medical purposes

Most physicians surveyed had been approached by a patient and/or his/her family to discuss the use of marihuana for medical purposes (93%). This proportion was similar for both family practitioners and other specialists and among those who practice in rural and urban areas. Physicians who had been practicing for 5 years or less were the least likely to have been approached by a patient and/or his/her family to discuss marihuana for medical purposes (85%), while physicians who had been practicing for 11-15 years were most likely (95%).

Table 4. Area of practice by ever approached to discuss the use of marihuana for medical purposes

		Have you ever been approached by a patient and/or his/her family to discuss the use of marihuana for medical purposes?		
		Yes	No	Total
What is your area of practice?	General practice/family practice	130 93%	10 7%	140 100%
	Other specialist	67 92%	6 8%	73 100%
	Total	**197** **93%**	**16** **8%**	**213** **100%**

Survey question: Have you ever been approached by a patient and/or his/her family to discuss the use of marihuana for medical purposes?

** Numbers may not total 100 due to rounding*

3.2.2 Initiated a discussion on marihuana for medical purposes

Half of the physicians surveyed had initiated a discussion with a patient and/or his/her family about marihuana for medical purposes. When examined by area of practice, 56% of specialists and 46% of family practitioners had initiated such discussions. Among physicians who practiced in both rural and urban areas, 65% reported initiating a discussion about marihuana for medical purposes with a patient compared to 49% of those working in urban areas only and 40% of those practicing in rural areas only. The proportion of physicians who had initiated a discussion about marihuana for medical purposes was lowest among physicians who had been practicing for five or fewer years (23%) and highest among those who had been practicing for 16-20 years (57%).

Table 5. Area of practice by ever initiated a discussion on the use of marihuana for medical purposes

		Have you ever initiated a discussion with a patient and/or his/her family on the use of marihuana for medical purposes?		
		Yes	No	Total
What is your area of practice?	General practice/family practice	65 46%	75 54%	140 100%
	Other specialist	41 56%	32 44%	73 100%
	Total	**106** **50%**	**107** **50%**	**213** **100%**

Survey question: Have you ever initiated a discussion with a patient and/or his/her family on the use of marihuana for medical purposes?

Table 6. Years of practice by ever initiated discussion on the use of marihuana for medical purposes

		Have you ever initiated a discussion with a patient and/or his/her family on the use of marihuana for medical purposes?		
		Yes	No	Total
How many years have you been practicing?	0-5 years	6 23%	20 77%	26 100%
	6-10 years	12 55%	10 46%	22 100%
	11-15 years	10 50%	10 50%	20 100%
	16-20 years	16 57%	12 43%	28 100%
	Over 20 years	62 53%	55 47%	117 100%
	Total	**106** **50%**	**107** **50%**	**213** **100%**

** Numbers may not total 100 due to rounding*

3.2.3 Cannabinoid drug products

Seventy percent of all physicians surveyed reported ever prescribing a cannabinoid drug such as Sativex®, Marinol® or Cesamet®. A higher proportion of other specialists (75%) had prescribed a cannabinoid drug compared to family practitioners (68%). The proportion of physicians who reported prescribing a cannabinoid drug product was highest among those with 11 to 20 years of experience.

Table 7. Area of practice by ever prescribed a cannabinoid drug product

		Have you ever prescribed a cannabinoid drug product such as Sativex, Marinol or Cesamet?		
		Yes	No	Total
What is your area of practice?	General practice/family practice	95 68%	45 32%	140 100%
	Other specialist	55 75%	18 25%	73 100%
	Total	150 **70%**	63 **30%**	213 **100%**

Survey question: Have you ever prescribed a cannabinoid drug product such as Sativex®, Marinol® or Cesamet®?

Table 8. Years of practice by ever prescribed a cannabinoid drug product

		Have you ever prescribed a cannabinoid drug product such as Sativex, Marinol or Cesamet?		
		Yes	No	Total
How many years have you been practicing?	0-5 years	18 69%	8 31%	26 100%
	6-10 years	15 68%	7 32%	22 100%
	11-15 years	17 85%	3 15%	20 100%
	16-20 years	23 82%	5 18%	28 100%
	Over 20 years	77 66%	40 34%	117 100%
	Total	150 **70%**	63 **30%**	213 **100%**

3.3 *Physicians who have supported an application to the MMAP*

3.3.1 Demographics

More than half (58%) of physicians surveyed had supported a patient's access to Health Canada's Marihuana Medical Access Program (MMAP). The proportion was similar among both family practitioners and other specialists (58% and 59% respectively). Seventy one percent of physicians who practice in rural areas had supported a patient's access to the program, while 54% of urban physicians and 57% of those who practice in both an urban and a rural area did. Half of the physicians who had been practicing for five years or less had supported a patient's access to the program, compared to 64% of those who had been practicing 6-10 years.

Table 9. Area of practice by ever supported a patient's access to Health Canada's MMAP

		Have you ever supported a patient's access to Health Canada's Marihuana Medical Access Program, that is, signed a medical declaration in support of an application for an authorization to possess marihuana for medical purposes?		
		Yes	**No**	**Total**
What is your area of practice?	General practice/family practice	81 58%	59 42%	140 100%
	Other specialist	43 59%	30 41%	73 100%
	Total	**124** **58%**	**89** **42%**	**213** **100%**

Survey question: Have you ever supported a patient's access to Health Canada's Marihuana Medical Access Program, that is, signed a medical declaration in support of an application for an authorization to possess marihuana for medical purposes?

Table 11. Years practicing by ever supported a patient's access to the MMAP

		Have you ever supported a patient's access to Health Canada's Marihuana Medical Access Program, that is, signed a medical declaration in support of an application for an authorization to possess marihuana for medical purposes?		
		Yes	No	Total
How many years have you been practicing?	0-5 years	13 50%	13 50%	26 100%
	6-10 years	14 64%	8 36%	22 100%
	11-15 years	11 55%	9 45%	20 100%
	16-20 years	17 61%	11 39%	28 100%
	Over 20 years	69 59%	48 41%	117 100%
	Total	124 **58%**	89 **42%**	213 **100%**

3.3.2 Discussions on marihuana for medical purposes

Sixty three percent of physicians who had been approached by a patient and/or his/her family to discuss the use of marihuana for medical purposes had supported access to the program. None of the physicians who had not been approached by a patient to discuss marihuana for medical purposes had supported access to the MMAP.

Among physicians who had initiated a discussion about marihuana for medical purposes with a patient and/or his/her family, 77% had supported access to the program. In contrast, 39% of physicians who had not initiated this type of discussion had supported access to the program.

Seventy percent of physicians who had ever prescribed a cannabinoid drug supported a patient's access to the program, while 30% of those who had not prescribed a cannabinoid drug supported a patient's access.

Table 12. Ever approached to discuss the use of marihuana for medical purposes by ever supported a patient's access to the MMAP

		Have you ever supported a patient's access to Health Canada's Marihuana Medical Access Program, that is, signed a medical declaration in support of an application for an authorization to possess marihuana for medical purposes?		
		Yes	No	Total
Have you ever been approached by a patient and/or his/her family to discuss the use of marihuana for medical purposes?	Yes	124 63%	73 37%	197 100%
	No	0 0%	16 100%	16 100%
	Total	124 **58%**	89 **42%**	213 **100%**

Table 13. Ever initiated a discussion about marihuana for medical purposes by ever supported a patient's access to the MMAP

		Have you ever supported a patient's access to Health Canada's Marihuana Medical Access Program, that is, signed a medical declaration in support of an application for an authorization to possess marihuana for medical purposes?		
		Yes	No	Total
Have you ever initiated a discussion with a patient and/or his/her family on the use of marihuana for medical purposes?	Yes	82 77%	24 23%	106 100%
	No	42 39%	65 61%	107 100%
	Total	124 **58%**	89 **42%**	213 **100%**

Table 14. Ever prescribed a cannabinoid drug product by ever supported a patient's access to the MMAP

		Have you ever supported a patient's access to Health Canada's Marihuana Medical Access Program, that is, signed a medical declaration in support of an application for an authorization to possess marihuana for medical purposes?		
		Yes	No	Total
Have you ever prescribed a cannabinoid drug product such as Sativex, Marinol or Cesamet?	Yes	105 70%	45 30%	150 100%
	No	19 30%	44 70%	63 100%
	Total	124 **58%**	89 **42%**	213 **100%**

3.3.3 Information sources used in decision to support access to the MMAP

The physicians who had supported access to the MMAP consulted a variety of sources to decide whether to support access to marihuana for medical purposes. The sources of information most frequently selected were:

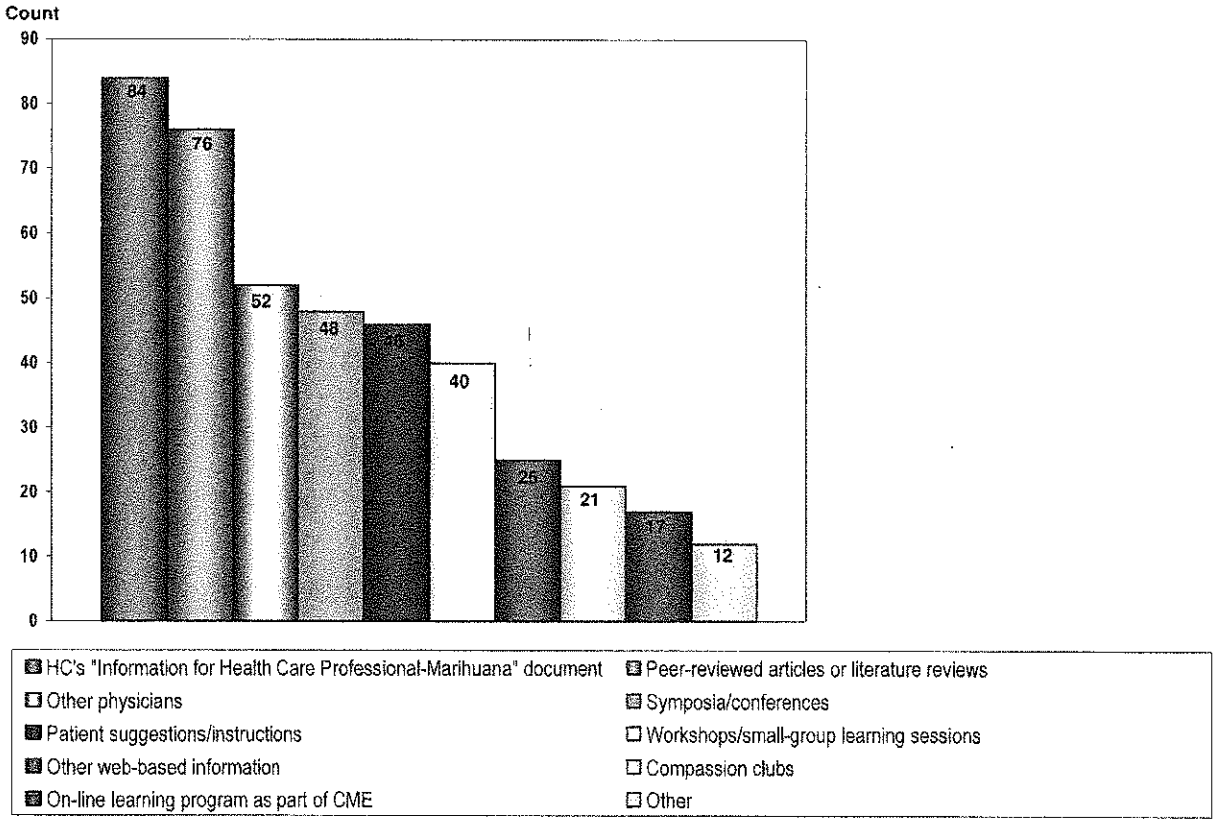
- Health Canada's "Information for Health Care Professionals – Marihuana" document,
- peer-reviewed articles or literature reviews,
- other physicians,
- symposia/conferences and
- patient suggestions/instructions.

Health Canada's "Information for Health Care Professionals – Marihuana" document and peer reviewed articles or literature reviews were the two sources of information most frequently consulted by family practitioners and by other specialists who have supported access to the MMAP. This also did not vary by how long the physician had been practicing (20 years or less or over 20 years).

Figure 1. Information sources used to decide whether to support access to marihuana for medical purposes, n=124**

Question: What information source (s) did you rely on to make your decision? Please select all that apply.

**Respondents were able to select more than one response; therefore the results presented are counts and not percentages. **124 physicians were asked this question*



3.3.4 *Route of administration and quantity indicated in a MMAP declaration*

The most common route of administration indicated by the physician in a declaration was smoked cannabis (90) followed closely by oral (i.e. edible) cannabis (82). Vaporized cannabis was less commonly indicated (40). This ranking remained the same when comparing family practitioners and other specialists, as well as physicians who had been practicing 20 years or less and more than 20 years. Other routes indicated by physicians were juiced raw cannabis, tea, cooked, topical creams, tinctures and lotions.

The most common range (grams/day) of dried marihuana indicated by physicians on a declaration was 1 gram to less than 3 grams per day. Family practitioners and other specialists most frequently indicated 1 gram to less than 3 grams per day of dried marihuana. Those who had been practicing for longer than 20 years indicated 2 to less than 4 grams or over 6 grams most frequently, while physicians who had been practicing 20 years or less indicated less than 1 gram to less than 3 grams most frequently.

Figure 2. Routes of administration of dried marihuana indicated by physician in medical declaration, n=124**

Question: Which of the following routes of administration of dried marihuana have you indicated in the medical declaration? Please select all that apply.

**Respondents were able to select more than one response; therefore the results presented are counts and not percentages. ** 124 physicians were asked this question*

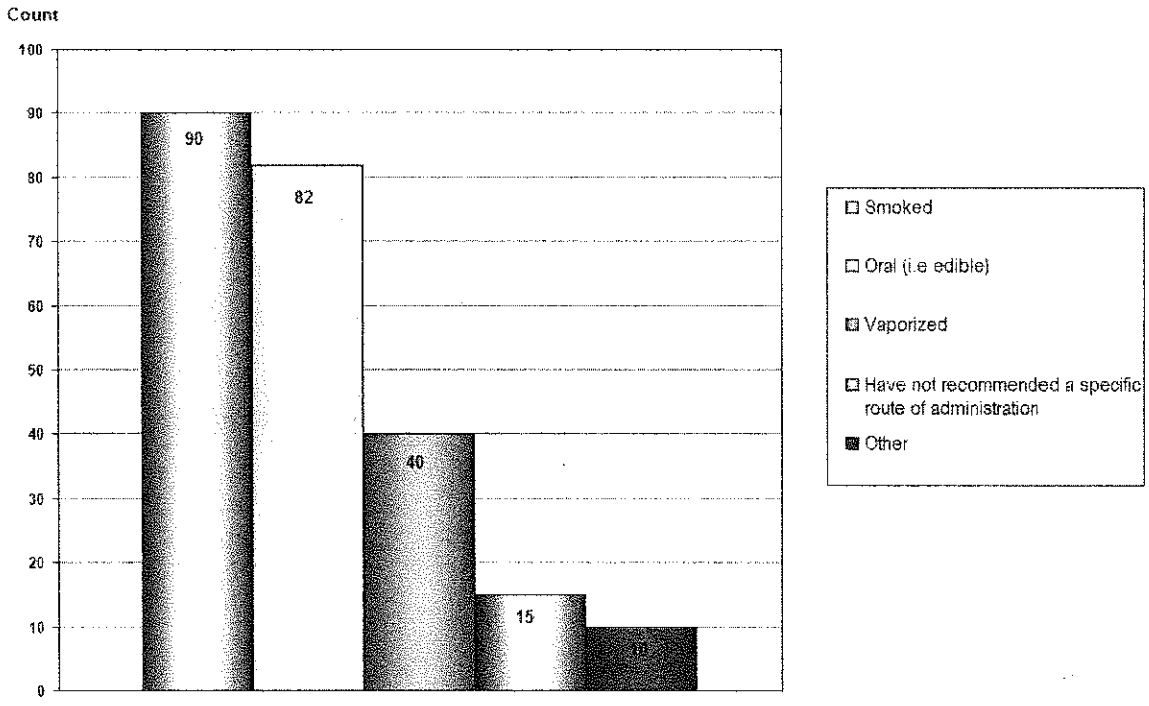
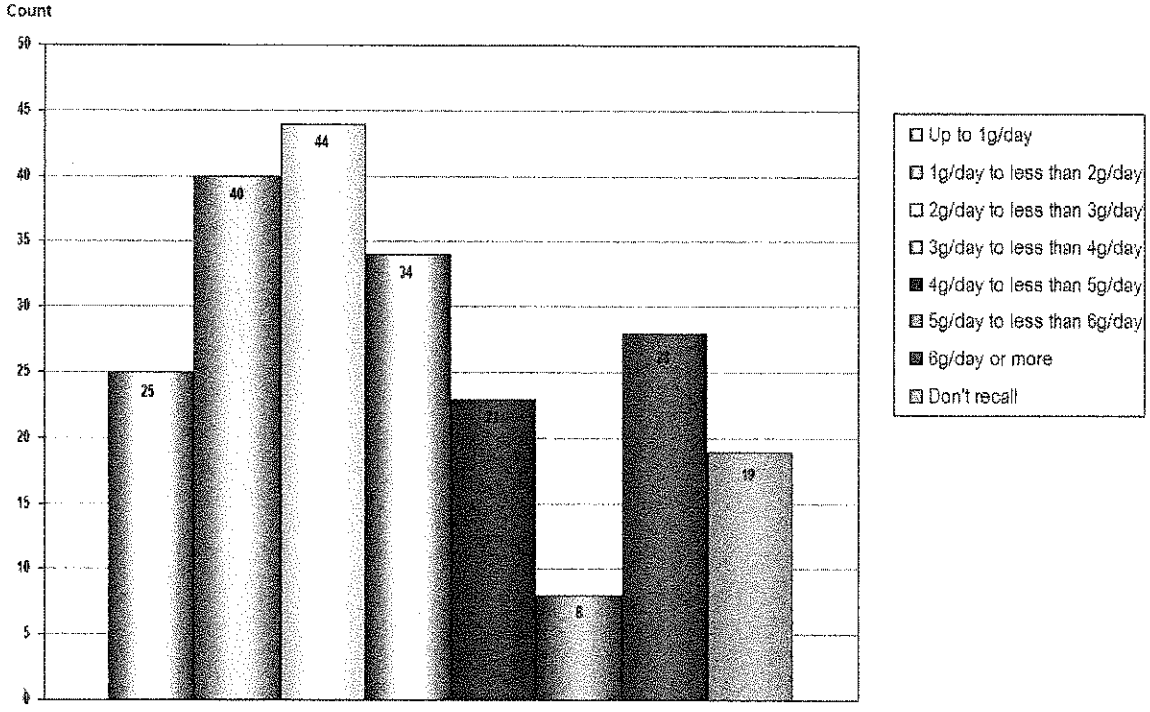


Figure 3. Quantities of dried marihuana indicated in the medical declaration, n=124**

Question: What are the ranges (grams/day) of dried marihuana you have indicated in the medical declaration (s)? Please select all that apply.

** Respondents were able to select more than one response; therefore the results presented are counts and not percentages. ** 124 physicians were asked this question*



3.4 Physicians who have not supported an application to the MMAP

Among the 89 physicians who had not supported access to Health Canada's MMAP, 40 were family practitioners, 19 were family practitioners with an area of enhanced skills, and 30 were other specialists.

3.4.1 Reasons for not supporting access to the MMAP

The physicians who had not supported access to the program cited many reasons for their decision. The reasons most frequently selected from the list provided were:

- risks and benefits not sufficiently clear for potential therapeutic uses,
- lack of clinical guidelines for the use of marihuana for medical purposes,
- belief that marihuana is not an appropriate treatment in a specific case and
- lack of personal knowledge/education or information regarding the appropriate use of marihuana for medical purposes.

When examined by area of practice, family practitioners and other specialists selected the same top three reasons for not supporting access to the MMAP, and the selections did not vary by length of time practicing (20 years or less or over 20 years).

Physicians who had not supported access to the MMAP were also able to provide their own reasons for not supporting access. Among the responses given, 12 "themes" were identified:

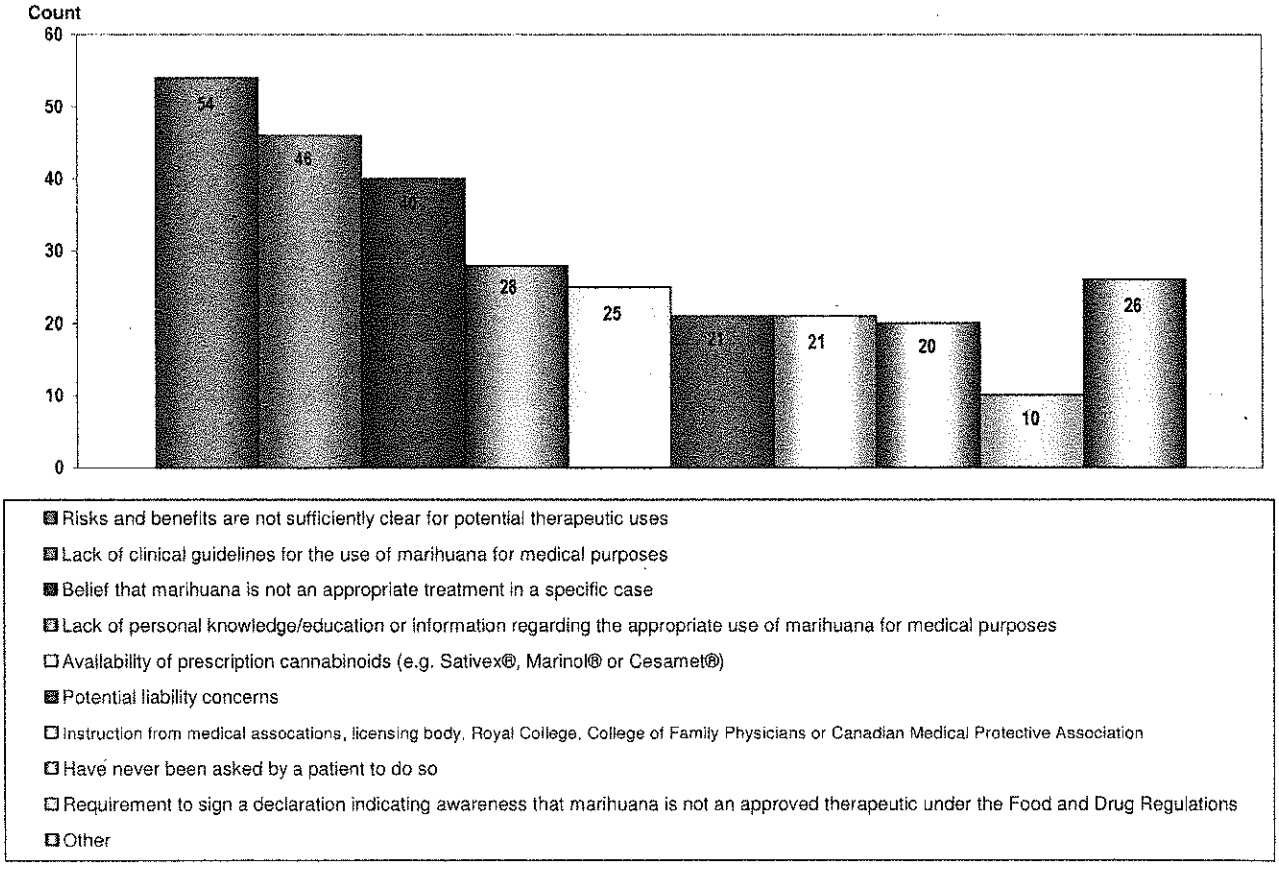
- Administrative barriers,
- Harms outweigh benefits,
- Additional research is required,
- Fear of being labeled or seen as a "prescriber",
- Undesirable patient population,
- Requests from social users not for medicinal use,
- Lack of provider knowledge about marihuana for medical purposes,
- Would not be responsible medical practice,
- Patient did not present with condition that warranted treatment with marihuana for medical purposes,
- Alternative treatment found,

- Patient was not interested in trying alternatives for therapy,
- Marihuana medical access program is not required.

Figure 4. Reasons for not supporting access to Marihuana Medical Access Program, n=89**

Question: If you have not supported a patient's access to Health Canada's Marihuana Medical Access Program, what are your reasons? Please select all that apply.

**Respondents were able to select more than one response; therefore the results presented are counts and not percentages. ** 89 physicians were asked this question*



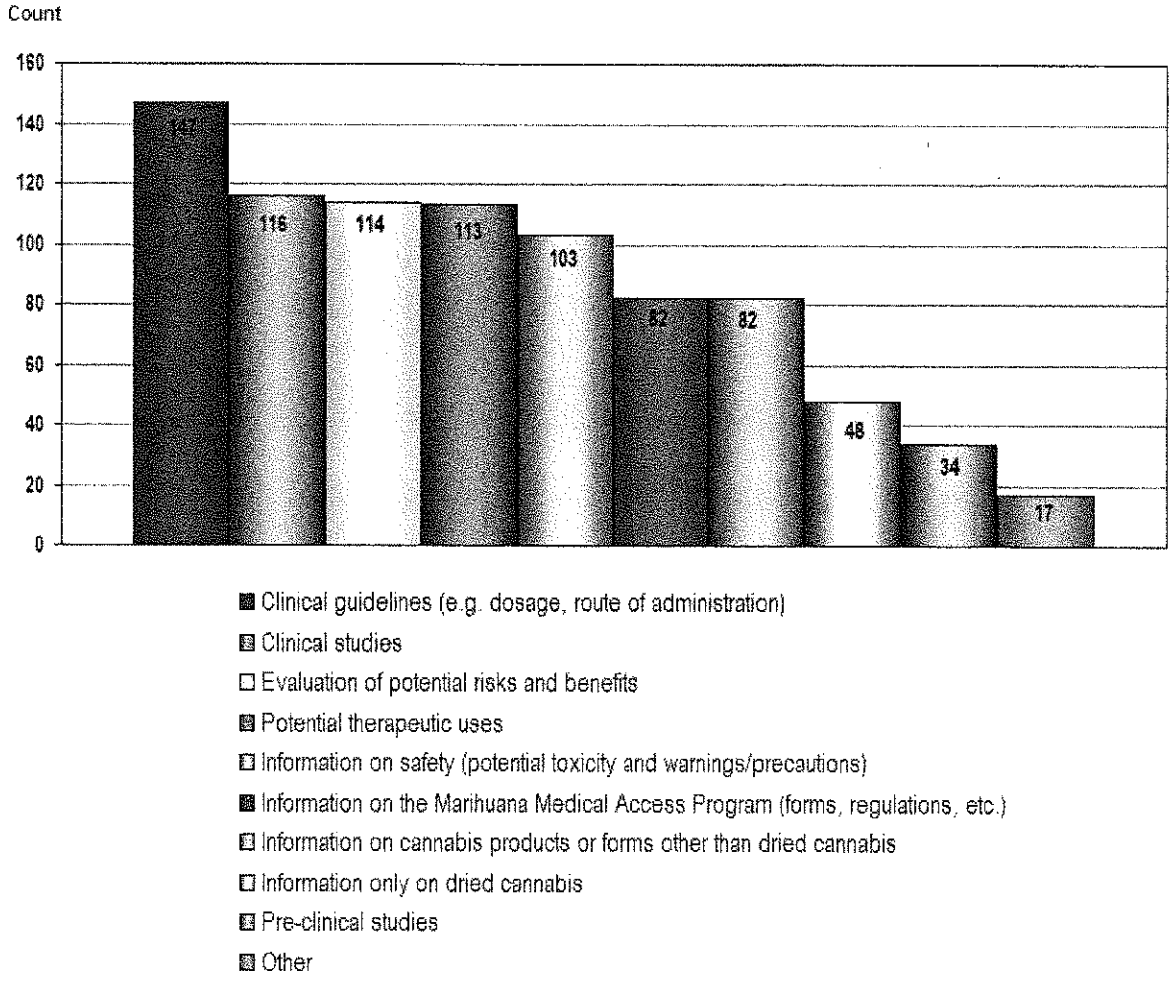
3.5 Information needs of physicians

Physicians who indicated that additional information about marihuana for medical purposes would be useful to them (n=176) were asked about their information needs. They were provided a list of topics (they could pick more than one topic), and were also able add their own suggestions. Additional information on clinical guidelines was the topic most selected by these physicians.

Figure 5. Topics of interest for further information

Question: Which of the following topics would you like to have further information on? Please select all that apply. n=176**

**Respondents were able to select more than one response, therefore counts are presented below and not percentages. ** 176 physicians were asked this question*



3.5.1 *Topics of interest by area of practice*

General practitioners and other specialists chose the same topics for their top five; however they ranked in a slightly different order:

Table 15. Topics of interest by area of practice, n=176

General practitioners	Other specialists
1. Clinical guidelines	1. Clinical guidelines
2. Potential therapeutic uses	2. Evaluation risks/benefits
3. Clinical studies	3. Clinical studies
4. Evaluation risks/benefits	4. Potential therapeutic uses
5. Information on safety	5. Information on safety

3.5.2 *Support for the MMAP and topics of interest*

Physicians who said that additional information would be useful to them chose the same top five topics of interest, regardless of whether they had or had not supported a patient's access to the MMAP.

The only difference in their top five topics of interest was that physicians who had not supported access to the MMAP requested additional information on the MMAP.

3.5.3 *Suggestions for other topics*

Respondents were also able to suggest their own topics of interest. They indicated that additional information would be useful on:

- A trial access program,
- Assessment tools (i.e. monitoring),
- Canadian Medical Association consensus statement,
- The difference between dried products and prescription cannabinoids,
- A double blind randomized control trial,
- Evidence based guidelines,
- The selection process and selection criteria for designated growers,
- The health experiences of patients using marihuana for medical purposes,
- Registry of users,

- Therapeutic uses of cannabinoids for post traumatic stress disorder,
- Peer reviewed articles,
- Potential uses for those under 18 years of age,
- Security issues,
- Cannabis use in elderly people with severe pain

3.5.4 Preferred format(s) for additional information

Physicians who said that additional information would be useful to them (n=176) were asked to select from a list which format(s) they preferred to receive this information in (they were able to select more than one type). The most common selections from the list were:

- peer-reviewed literature reviews on specific topics,
- online learning as part of continuing medical education,
- a monograph on cannabis,
- topic specific one pagers and
- updated information on the Health Canada website.

Family practitioners and other specialists selected the same top 4 formats for additional information, though ranking them in a different order. The same top 4 formats were selected by physicians who had and who had not supported access to the MMAP.

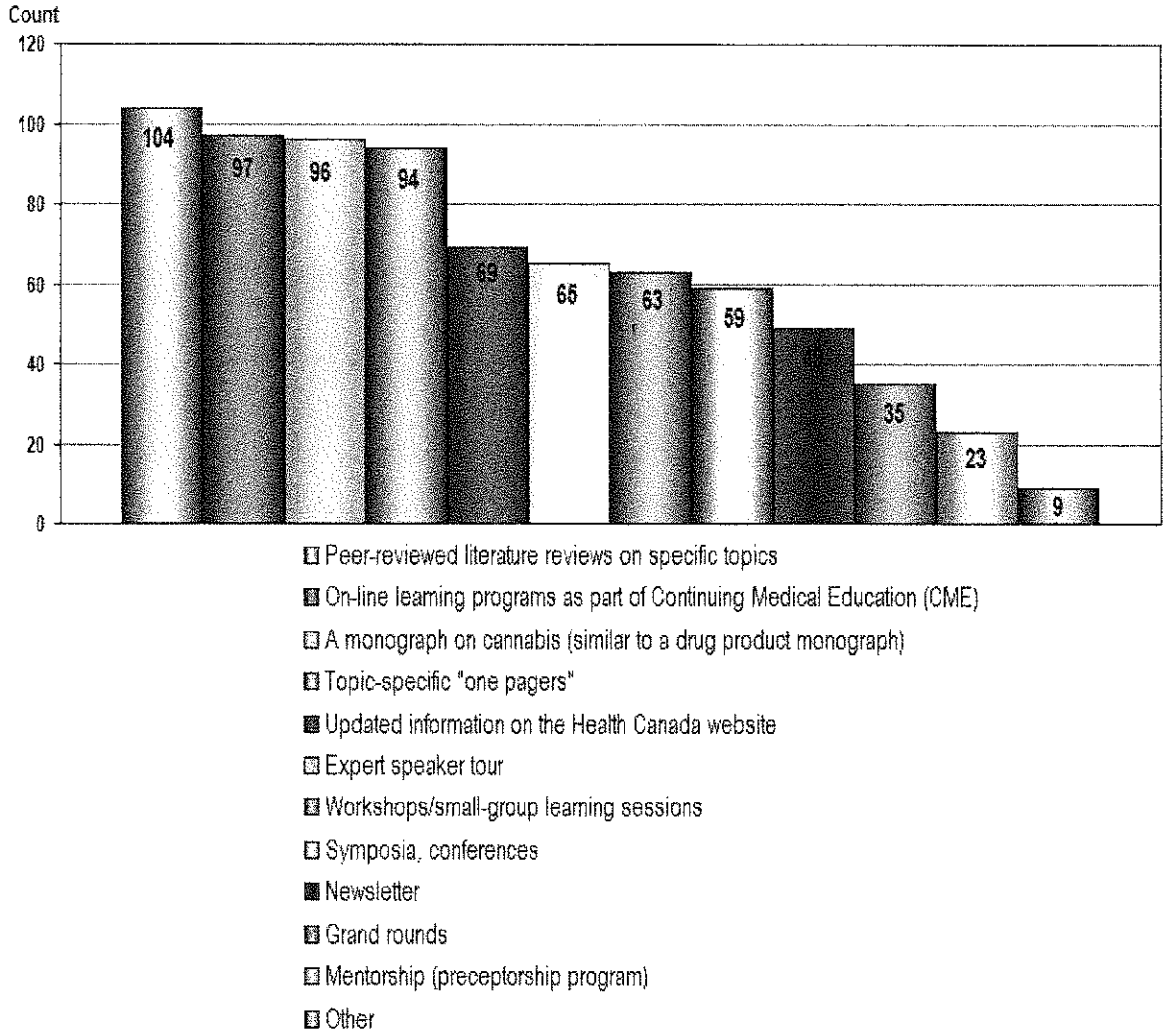
Table 16. Formats for further information by area of practice, n=176

General practitioners	Other specialists
1. Monograph	1. Peer reviewed literature reviews
2. Online learning program	2. Online learning programs
3. Peer reviewed literature reviews	3. Topic specific one pagers
4. Topic specific one pagers	4. Monograph on cannabis

Figure 6. Formats for further information

Question: Please indicate the format(s)/structure(s) you would prefer for receiving further information. Please select all that apply, n=176**

**Respondents were able to select more than one response; therefore the results presented are counts and not percentages. **176 physicians were asked this question*



3.5.5 *Suggestions for additional formats*

Physicians were also able to suggest additional formats in which they would prefer for receiving further information. Their suggestions included:

- In service training
- Information physically attached to the Health Canada MMAP application form
- Information on colleges and medical association websites
- Clinical experience outcomes

4. *Limitations*

There are several limitations to this study. The physicians surveyed were not a random sample; respondents were solicited via emails and letters from several databases but not all physicians in Canada received an invitation to participate. Family physicians were overrepresented due to the assistance of the College of Family Physicians in distributing the link to the online survey. The sample size was small, in total 213 physicians completed the online survey.

It is likely that those practitioners with strong opinions on the topic, both positive and negative, would be more likely to respond to the survey. Multiple responses from the same computer were not allowed, but there was no other way to control the possibility that respondents filled out the survey multiple times. There was also no verification process to ensure that respondents were physicians, and a link to the survey was available publicly on the Health Canada website. A very small number of responses (2) to the question *other, please specify* under *what is your area of practice* were ambiguous, however they did appear to come from individuals registered in a health profession.

5. *Conclusion*

Two hundred and thirteen physicians completed this needs assessment survey. Two thirds of respondents (66%) identified themselves as family practitioners and 34% as other specialists. More than half the sample (55%) had been practicing longer than 20 years, and the majority of physicians (62%) worked solely in an urban area. Overall, 58% of the responding physicians had supported access to Health Canada's MMAP.

The information on marihuana for medical purposes that physicians deemed most useful included: clinical guidelines, clinical studies, evaluation of potential risks and benefits, potential therapeutic uses and information on safety. The most commonly requested formats were: peer-reviewed literature reviews on specific topics, online learning as part of continuing medical education, a monograph on cannabis, topic specific one pagers, and updated information on the Health Canada website. Family practitioners and other specialists identified similar information topics of interest and formats for further information. Similarly, physicians who had supported a patient's access to the MMAP and those who had not but who indicated that additional information and/or education would be useful to them reported similar information needs and preferred formats for receiving further information. The general consensus in terms of information needs and preferred formats among physicians will result in a more streamlined approach to developing information tools for physicians.

The results of this consultation will be shared with the Expert Advisory Committee on Information for Physicians on Marihuana for Medical Purposes. This committee provides Health Canada with advice on the scientific and medical information on the use of marihuana for medical purposes with the goal of improving the quality of the information that is provided to physicians by Health Canada regarding the use of marihuana for medical purposes.

Appendix A: Survey Questions

Health Canada's Marihuana Medical Access Program

Q1. What is your area of practice?

- ○ General practice/family practice
- ○ General practice/ family practice with an area of enhanced skills (go to Q1a)
- ○ Other specialist (go to Q1b)
- ○ Other, please specify: _____

Q1a. What is/are your area of enhanced skill(s)?_____

Q1b. What is/are your specialist certification(s)?_____

Q2. How many years have you been practicing?

- ○ 0-5 years
- ○ 6-10 years
- ○ 11-15 years
- ○ 16-20 years
- ○ Over 20 years

Q3. Do you practice in a rural or urban area?

- ○ Rural only
- ○ Urban only
- ○ Rural and urban

Q4. Have you ever been approached by a patient and/or his/her family to discuss the use of marihuana for medical purposes?

- ○ Yes
- ○ No

Q5. Have you ever initiated a discussion with a patient and/or his/her family on the use of marihuana for medical purposes?

- ○ Yes
- ○ No

Q6. Have you ever prescribed a cannabinoid drug product such as Sativex®, Marinol® or Cesamet®?

- ○ Yes
- ○ No

Q7. Have you ever supported a patient's access to Health Canada's Marihuana Medical Access Program, that is, signed a medical declaration in support of an application for an authorization to possess marihuana for medical purposes?

- ○ Yes (go to Q8)
- ○ No (go to Q13)

Q8. What information source(s) did you rely on to make your decision? Please select all that apply.

- ☐ Health Canada's "Information for Health Care Professionals-Marihuana" document
- ☐ Peer-reviewed articles or literature reviews
- ☐ Workshops/small-group learning sessions
- ☐ Symposia/conferences
- ☐ On-line learning program as part of Continuing Medical Education (CME)
- ☐ Compassion clubs
- ☐ Other web-based information
- ☐ Patient suggestions/instructions

☐Other physicians

☐ Other, please specify: _____

Q9. Which of the following routes of administration of dried marihuana have you indicated in the medical declaration? Please select all that apply.

☐ Smoked

☐ Oral (ie. edible)

☐ Vaporized

☐ Other, please specify: _____

☐ Have not recommended a specific route of administration

Q10. What are the ranges (grams/day) of dried marihuana you have indicated in the medical declaration? Please select all that apply.

☐ Up to 1g/day

☐ 1g/day to less than 2g/day

☐ 2g/day to less than 3g/day

☐ 3g/day to less than 4g/day

☐ 4g/day to less than 5g/day

☐ 5g/day to less than 6g/day

☐ 6g/day or more

☐ Don't recall

Q11. Which of the following topics would you like to have further information on? Please select all that apply.

☐ Information only on dried cannabis

☐ Information on cannabis products or forms other than dried cannabis

☐ Potential therapeutic uses

☐ Clinical guidelines (e.g. dosage, route of administration)

☐ Information on safety (potential toxicity and warnings/precautions)

☐ Evaluation of potential risks and benefits

☐ Clinical studies

- ☐ Pre-clinical studies
- ☐ Information on the Marihuana Medical Access Program (forms, regulations, etc.)
- ☐ Other, please specify: _____

Q12. Please indicate the format(s)/structure(s) you would prefer for receiving further information. Please select all that apply.

- ☐ A monograph on cannabis (similar to a drug product monograph)
- ☐ Topic-specific "one-pagers"
- ☐ Newsletter
- ☐ Peer-reviewed literature reviews on specific topics
- ☐ Updated information on the Health Canada website
- ☐ On-line learning programs as part of Continuing Medical Education (CME)
- ☐ Workshops/small-group learning sessions
- ☐ Symposia, conferences
- ☐ Expert speaker tour
- ☐ Grand rounds
- ☐ Mentorship (preceptorship program)
- ☐ Other, please specify: _____

(End of survey for physicians who have supported a patient's access to Health Canada's Marihuana Medical Access Program)

Q13. If you have not supported a patient's access to Health Canada's Marihuana Medical Access Program, what are your reasons? Please select all that apply.

- ☐ Have never been asked by a patient to do so
- ☐ Risks and benefits are not sufficiently clear for potential therapeutic uses
- ☐ Potential liability concerns
- ☐ Lack of personal knowledge/education or information regarding the use of marihuana for medical purposes
- ☐ Instruction from medical associations, licensing body, Royal College, College of Family Physicians or Canadian Medical Protective Association
- ☐ Requirement to sign a declaration indicating awareness that marihuana is not an approved therapeutic under the Food and Drug Regulations

- ☐ Belief that marihuana is not an appropriate treatment in a specific case
- ☐ Lack of clinical guidelines for the use of marihuana for medical purposes
- ☐ Availability of prescription cannabinoids (e.g. Sativex®, Marinol® or Cesamet®)
- ☐ Other, please specify: _____

Q14. Would additional education or information on the uses of marihuana for medical purposes be useful to you?

- ○ Yes (go to Q15)
- ○ No (go to end of survey – thank you)

Q15. Which of the following topics would you like to have further information on? Please select all that apply.

- ☐ Information only on dried cannabis
- ☐ Information on cannabis products or forms other than dried cannabis
- ☐ Potential therapeutic uses
- ☐ Clinical guidelines (e.g. dosage, route of administration)
- ☐ Information on safety (potential toxicity and warnings/precautions)
- ☐ Evaluation of potential risks and benefits
- ☐ Clinical studies
- ☐ Pre-clinical studies
- ☐ Information on the Marihuana Medical Access Program (forms, regulations, etc.)
- ☐ Other, please specify: _____

Q16. Please indicate the format(s)/structure(s) you would prefer for receiving further information. Please select all that apply.

- ☐ A monograph on cannabis (similar to a drug product monograph)
- ☐ Topic-specific "one-pagers"
- ☐ Newsletter
- ☐ Peer-reviewed literature reviews on specific topics
- ☐ Updated information on the Health Canada website
- ☐ On-line learning programs as part of continuing medical education (CME)

- ☐ Workshops/small-group learning sessions
- ☐ Symposia, conferences
- ☐ Expert speaker tour
- ☐ Grand rounds
- ☐ Mentorship (preceptorship program)
- ☐ Other, please specify: _____

Thank you

This is **Exhibit "ZZ"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

DISTRICT OF
Mission
ON THE FRASER

OFFICE OF THE MAYOR

File: GOV.FED.VAG
Ministry of Health

3RD INCOMING
ECD Health Canada
DCHG Santé Canada
Rec'd Reçu FEB 13 2013
13-000181689

February 5, 2013

The Honourable Leona Aglukkaq, P.C., MP
Health Canada
Brooke Claxton Building, Tunney's Pasture
Postal Locator: 0906C
Ottawa, Ontario K1A 0K9

Dear Minister Aglukkaq:

Re: Proposed Marihuana for Medical Purposes Regulations

The District of Mission has reviewed the proposed Marihuana for Medical Purposes Regulations and requests that the following comments be considered prior to finalizing the regulations:

- The District is in general support of the proposed approach. In particular, the abandonment of individual and designated producer licenses and the need to notify local police and fire forces and the local government of the location of licensed producer operations is a positive change.
- The District believes that no new individual or designated producer licenses should be given out prior to the new regulations being enacted. The significant investment required by license holders for a short time until their license expires will likely result in many of these operations remaining active after the new regulations are enacted leading to public safety and enforcement issues for our community for years to come.
- There is a need for inspections of all expiring existing licenses to ensure the production of marihuana has ceased. This should include provision of existing personal and designated license holder information (name and address) to the local detachment of the RCMP as well as additional time-durated resources for the RCMP to perform follow-up inspections once the new regulations are enacted.
- There is a need to ensure potential licensed producers are aware that they will also be subject to provincial regulations (e.g., Building Code, Fire Services Act, Electrical Safety Act) and local government regulations (e.g., Zoning Bylaw, Business Licensing Bylaw, Building Bylaw, Water and Sewer Bylaws). At the very least, the federal government's cover letter for future licenses needs to include a statement that license holders must check with their provincial and local governments to ensure compliance with all applicable legislation. It would be preferred if the local government was involved in a formal referral process for new licenses (see next bullet).

- A referral process from the federal government to the local government in advance of issuing new licenses should be instituted to ensure the licensed producer is aware of all local government requirements.
- The new regulations must be accompanied by adequate resources to support a comprehensive compliance and enforcement inspection program that includes notification of the local and provincial government officials of suspected non-compliance with any applicable regulations.
- New licensed producers must be able to demonstrate that an adequate electrical supply is available without the risk of affecting electrical supply to nearby residences and businesses.
- The new regulations must include good production practices to ensure nuisance factors such as odours, noise and light from their operations does not affect neighbouring residences and businesses.

I would like to congratulate your government on making the changes necessary to ensure that the production of marihuana can be carried out in a way that protects communities and treats marihuana like any other pharmaceutical product. I trust that you will consider the comments supplied here and adjust the regulations as necessary to ensure that the current issues associated with the production of marihuana in our community are prevented from occurring under the new regulations. Thank you for considering our comments, please contact the undersigned with any questions.

Yours truly,

Ted Adlem
MAYOR

cc: Randy Kamp, M.P.
Randy Hawes, M.L.A
Marc Dalton, M.L.A

This is **Exhibit "AAA"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

CITY OF SURREY

the future lives here.

January 30, 2013

File: 0430-01
0360-20

Bureau of Medical Marihuana Regulatory Reform
Controlled Substances and Tobacco Directorate
Healthy Environments and Consumer Safety Branch
Health Canada
Address Locator: AL3503D
Ottawa, Ontario K1A 0K9
consultations-marihuana@hc-sc.gc.ca

Re: Canada Gazette, Part I, Vol. 146, No. 50 – December 15, 2012: Marihuana for Medical Purposes Regulations

On behalf of the City of Surrey, BC, the Surrey Fire Service has reviewed the gazetted Marihuana for Medical Purposes Regulations (MMPR), proposed by Health Canada as an alternative to the existing Marihuana Medical Access Regulations (MMAR). Overall, the City is fully supportive of Health Canada's intent to create a legislated process to safely regulate the production and distribution of marihuana for medical purposes. Having said this, however, the proposed alternative MMPR fail to address the need to repair buildings that will almost certainly have been damaged as a result of inappropriate, agricultural use under the MMAR.

Attached is a document entitled, *What the Marihuana for Medical Purposes Regulations Overlook: Disclosure and Remediation of Inappropriately Used Dwellings*, which is available for download via the Centre for Public Safety and Criminal Justice Research, the University of the Fraser Valley (http://www.ufv.ca/CPSCJR/Reports_and_Publications.htm). This paper explains why a comprehensive process for disclosing and remediating the structures that have been utilized by MMAR-licence holders to produce medical marihuana is required in addition to moving away from a process of licencing individuals to produce marihuana in homes.

The attached report explains why, in addition to the gazetted MMPR reforms, three additional recommended steps should be undertaken in parallel:

1. Develop a centralised, consistent process for disclosure of property history information for those buildings previously used as sites for the production of marihuana under the MMAR.
2. Develop a centralised, consistent process for remediation of inappropriately used buildings previously used as sites for the production of marihuana under the MMAR.
3. Implement these disclosure and remediation processes in a top-down manner, with each provincial government and/or the federal government playing a controlling role, and exploring the potential to use existing legislation as the foundation for this approach.

Implementation of these recommendations would simultaneously reduce health and safety risks to building occupants and increase the ability of property purchasers/lessees/tenants to make informed decisions. A comprehensive process is required for disclosing and remediating the residential properties that have already been utilized to produce medical marihuana under the MMAR, thus ensuring future health and safety issues do not arise.

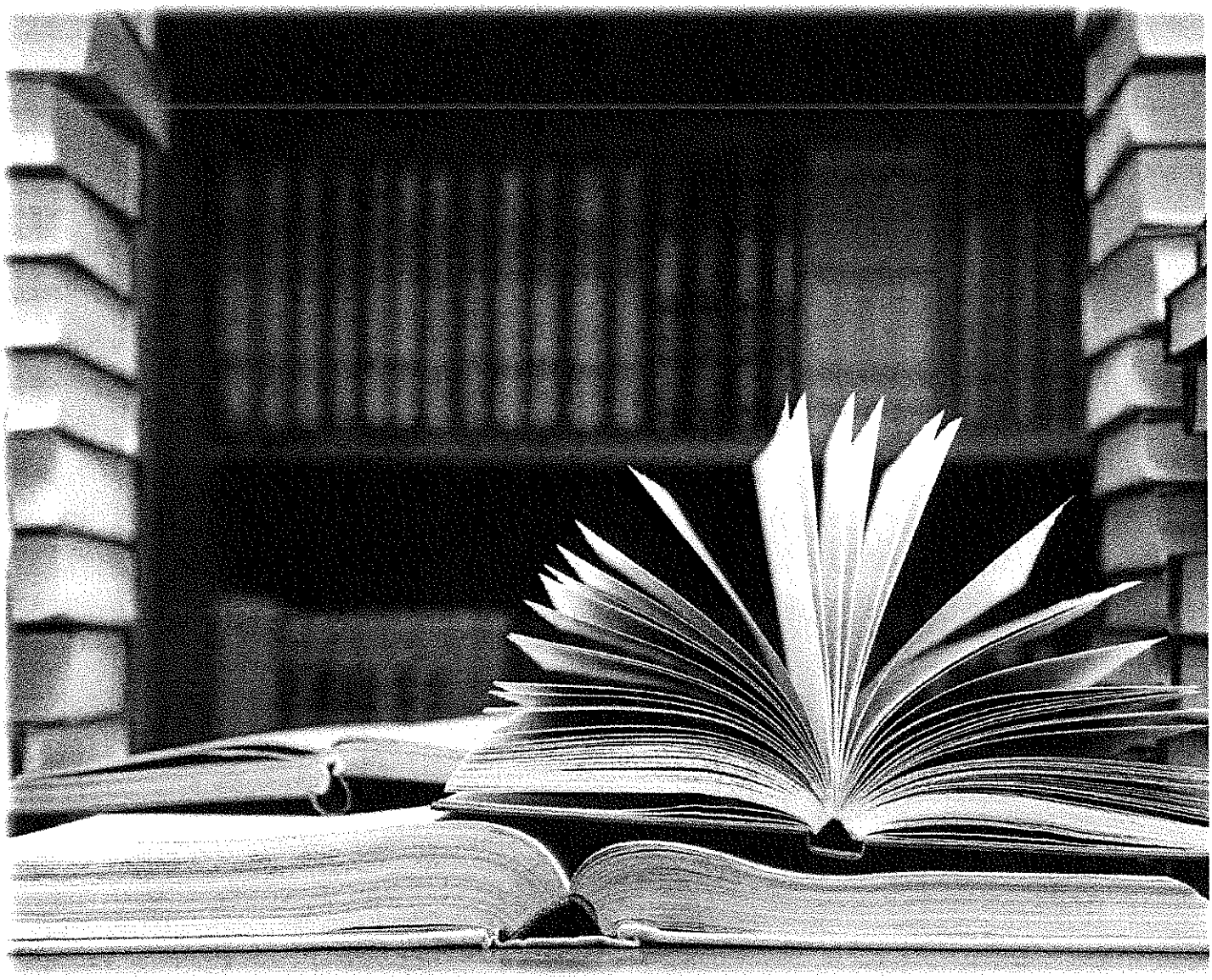
Len Garis
Fire Chief, Surrey Fire Services, City of Surrey, BC
Adjunct Professor in the School of Criminology and Criminal Justice
University of the Fraser Valley

Cc: Mayor & Council
SMT

1 Attachment

What the Marihuana for Medical Purposes Regulations Overlook

Disclosure and Remediation of Inappropriately Used Dwellings



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Executive Summary

1. The Marihuana Medical Access Regulations (MMAR), which are currently administered by Health Canada, permit Canadians access to marihuana for medical use provided they have been deemed to require this medical treatment by a physician. The MMAR enable individuals to grow marihuana for themselves, empower a third-party to grow marihuana on their behalf, or purchase marihuana directly from Health Canada.

2. In response to a broad range of concerns that have been identified with the MMAR, in late 2012 Health Canada gazetted an alternative framework, termed the Marihuana for Medical Purposes Regulations (MMPR)[1], under which the "production of marihuana for medical purposes by individuals in homes and communities would be phased out" [1] with a view to moving towards a system of licenced commercial producers.

3. While supportive of the MMPR, this document details why the revised regulations fail to address the need to repair buildings that will almost certainly have been damaged as a result of inappropriate, agricultural use under the MMAR. To this end, an argument is developed as to why a comprehensive process for disclosing and remediating the structures that have been utilized by licence holders to produce medical marihuana is also required in addition to moving away from a process of licencing individuals to produce marihuana in homes.

4. Currently in BC, it is not possible for any prospective property purchaser or tenant to be certain if a building they are interested in has: (a) been identified as having been used in an inappropriate, potentially unhealthy/unsafe manner, or (b) been remediated through a process that would ensure health and safety risks have been eradicated. This term, "inappropriate use", incorporates a range of activities, including, but not restricted to, agricultural activity (e.g., grow-ops, regardless of the legality) and the production of synthetic drugs, which can result in significant damage to the properties. If inadequately remediated, this type of damage can have serious health and safety implications for occupants.

5. Without a consistent, reliable process for disclosing property histories for inappropriate use and for ensuring remediation addresses existing health and safety issues, it is not possible to make an informed decision about the potential risk posed by any property of interest as a result of previous inappropriate, damaging use of the structure.

6. To alleviate these concerns, in addition to the gazetted MMPR reforms, three additional recommended steps should be undertaken in parallel:
    1. Develop a centralised, consistent process for disclosure of property history information for those buildings previously used as sites for the production of marihuana under the MMAR.
    2. Develop a centralised, consistent process for remediation of inappropriately used buildings previously used as sites for the production of marihuana under the MMAR.
    3. Implement these disclosure and remediation processes in a top-down manner, with each provincial government and/or the federal government playing a controlling role, and exploring the potential to use existing legislation as the foundation for this approach.

7. Implementation of these recommendations would simultaneously reduce health and safety risks to building occupants and increase the ability of property purchasers/lessees/tenants to make informed decisions. The authors are fully supportive of the planned moved towards licenced commercial production of medical marihuana and a phasing out of existing licences for individuals to produce marihuana in homes and communities. In addition to this, however, the authors believe a comprehensive process is required for disclosing and remediating the residential properties that have already been utilized to produce medical marihuana under the MMAR, thus ensuring future health and safety issues do not arise.

[1] Canada Gazette, Part I, Vol. 146, No. 50 – December 15, 2012: Marihuana for Medical Purposes Regulations.

The Purpose of this Research Note

The Marihuana Medical Access Regulations (MMAR), which are administered by Health Canada, permit Canadians access to marihuana for medical use provided they have been deemed to require this medical treatment by a physician. These regulations enable individuals to (a) grow marihuana, (b) empower a third-party to grow marihuana on their behalf, or (c) purchase marihuana from Health Canada. To address a range of key stakeholders concerns identified with the MMAR, Health Canada has gazetted a proposed revised framework entitled the Marihuana for Medical Purposes Regulations (MMPR)[2], the main objectives of which would be to phase out individual licences to grow and focus the scheme on licenced commercial producers.

This paper outlines the motivation underlying the proposed changes and then explains why the revisions fail to address the need to repair buildings that will almost certainly have been damaged as a result of inappropriate, agricultural use permitted by the MMAR. The paper concludes by arguing that in order to completely address the health and safety issues that will have arisen through the MMAR, a comprehensive process is also required for the disclosure and remediation of the structures that have been utilized by licence holders to produce medical marihuana under the existing regulations.

Overview of the Marihuana Medical Access Regulations

A Brief Background to the Marihuana Medical Access Program and Regulations

Health Canada outline the history to the Marihuana Medical Access Program and the establishment of the MMAR [1], the main component of which are as follows:

- In 1999 the Program was established to provide a legal source of dried marihuana for medical purposes to seriously ill Canadians. This program operated under exemptions to *Section 56* of the *Controlled Drugs and Substances Act* (CDS) [2].
- In 2000, following an Ontario Court of Appeal ruling, the MMAR were established. These regulations enabled any seriously ill Canadian who wanted access to marihuana and who had an appropriate declaration from a physician to "obtain an authorization to possess and/or a licence to produce dried marihuana for their own personal medical use" [1]. The MMAR also enabled those with authorization to designate a third party to produce marihuana on their behalf.
- In 2003, the MMAR was further amended, with Health Canada also supplying dried marihuana and/or marihuana seeds for medical purposes to authorized persons.

As a result, authorized persons have had three avenues through which they could obtain dried marihuana for medical purposes: (a) a Personal-Use Production Licence, (b) a Designated Person Production Licence, or (c) by purchasing dried marihuana from Health Canada. Production licences have clearly specified terms and conditions, including maximum quantities of marihuana that can be possessed and the maximum number of plants that can be cultivated at any one time [1].

The Scope of the Program in British Columbia (BC)

As of October 12, 2012, across Canada there were:

- 26,222 persons who held an Authorization to Possess marihuana for medical purposes;

[2] Canada Gazette, Part I, Vol. 146, No. 50 – December 15, 2012: Marihuana for Medical Purposes Regulations.

- 16,549 persons who held a Personal-Use Production Licence [3];
- 3,199 persons who held a Designated Person Production Licence [3]; and
- A total of 19,748 persons who held a licence to produce marihuana for medical purposes [3].

In comparison, an equivalent snapshot from June 4, 2010, revealed that, less than three years earlier, there had been:

- 4,654 persons who held an Authorization to Possess marihuana for medical purposes;
- 2,680 persons who held a Personal Use Production Licence [3];
- 760 persons who held a Designated Person Production Licence [3]; and
- A total of 3,440 persons who held a licence to produce marihuana for medical purposes [3].

Nation-wide, this translates to a 474% increase in licences to produce marihuana for medical purposes in approximately 28 months.

The demand for MMAR licences has been very uneven across Canada. BC has approximately 4.62 million people (13.3% of the estimated 2012 national total) [4]. Assuming the proportion of MMAR licences in BC was consistent with the relative contribution the province makes to the national population, it would be expected there would be 3,488 Authorizations to Possess marihuana for medical purposes, 2,201 Personal-Use Production Licences, and 425 Designated Person Production Licences. Instead, however, as of October 12, 2012, there were:

- 11,486 persons who held an Authorization to Possess marihuana for medical purposes (43.8% of the national figure) [3];
- 7,799 persons who held a Personal Use Production Licence (47.1% of the national figure) [3];
- 2,075 persons who held a Designated Person Production Licence (64.9% of the national figure) [3]; and
- A total of 9, 874 persons who held a licence to produce marihuana for medical purposes (50.0% of the national figure) [3].

Concerns with the Program and Proposed Improvements and Reforms

Health Canada explains that a, "wide range of stakeholders including police and law enforcement, fire officials, physicians, municipalities, and program participants and groups representing their interests, have identified concerns with the current" MMAR [1]. Some of the major public safety concerns identified include [1]:

- The potential for diversion of marihuana produced for medical purposes to the illicit market;
- The risk of home invasion due to the presence of large quantities of dried marihuana or marihuana plants;
- Public safety risks, including electrical fire hazards, stemming from the unpermitted building alternations required to enable cultivation of marihuana in homes;
- Public health risks due to the presence of excess mould and poor air quality associated with the cultivation of marihuana plants in homes.

In response to the range of concerns raised with the MMAR, Health Canada has proposed the MMPR as an alternative [5], motivated by the desire to reduce the risk of abuse and potential for exploitation by organized crime [1]. The MMPR have nothing to do with legalization of marihuana, with the core of the redesigned program representing [1]:

"...a new, simplified process in which Health Canada no longer receives applications from program participants. A new supply and distribution system for dried marihuana that relies on licensed commercial producers would be established. These licensed commercial producers, who would be inspected and audited by Health Canada so as to ensure that they comply with all applicable regulatory requirements, would be able to cultivate any strain(s) of marihuana they choose. Finally, the production of marihuana for medical purposes by individuals in homes and communities would be phased out."

What the MMPR Overlooks: Consistent Disclosure and Remediation Processes

While the MMPR definitely would represent a positive step towards addressing concerns raised by key stakeholders, what is currently lacking in these proposed new regulations is any plan to deal with remediation of premises where MMAR-licenced marihuana growing operations were located, or the fire, health, and safety issues associated with occupying a residence that once was an active, federally-licenced marihuana growing operation [6]. This issue is exacerbated by the fact that, as it stands, the physical location of the grow operations associated with the MMAR licences are unknown, with municipalities and police/fire services only becoming aware of them as a by-product of their daily public safety duties.

To give some sense of the scope of this issue, a recent request made by the City of Surrey under the *Access to Information Act*, revealed that as of October 1, 2012, there were a total of:

- 753 licences to produce marihuana for medical purposes (includes Personal Use Production licences and Designated person Production licences) issued to individuals who indicated a physical address in the City of Surrey, BC [7]; and
- 510 production sites in Surrey, BC [7].

Since March, 2005, the City of Surrey has become aware of 97 MMAR-licenced grow operations (approximately 1% of these locations in BC) in residential properties, meaning that as it currently stands, the location of 81% of the licenced grow production sites in Surrey remains unknown to the municipal government. Furthermore, from a provincial level, only 7.6% of the total production licences that have been allocated to BC can be traced to Surrey.

There has not been any indication from Health Canada of any intent to fully disclose the addresses of production sites to the Local Government Authorities, which would assist in the enforcement of remediation of premises damaged as a result of licenced production of marihuana [6]. While it is the case that by eliminating licensed marihuana production in homes the proposed MMPR would eliminate additional public health, safety and security concerns developing as a consequence of licensed activities, it is not the case that the existing health and safety issues will be "eliminated" as proposed by the Government of Canada [5]. As has been previously discussed in a paper produced for the Fraser Valley Real Estate Board [8], the absence of any such process from Health Canada with respect to existing, damaged properties will exacerbate the current situation in BC, which already renders potential property purchasers, lessees, and renters unable to make informed decisions about the likelihood that prospective properties pose health and safety risks as a result of previous inappropriate use. There are two causal, related factors that have produced this concern. On the one hand, the current process for disclosure of information about properties that have been identified as having been used inappropriately is flawed. There is no centralised, consistent process in place to ensure this information is recorded and disseminated in a standardised, timely, meaningful manner. This first issue is exacerbated by the unreliable, inconsistent processes for remediating buildings that have been identified as having been used inappropriately. As a consequence of these two issues, it is not possible to know unequivocally whether: (a) a building in BC has been identified as having previously been used for

inappropriate, potentially unhealthy/unsafe purposes, or (b) how the remediation process was executed (if at all) when the building was identified as having experienced inappropriate use.

The Sources of Risk Posed by Inappropriate Use of Properties

Damage to Properties

There is a range of ways in which inappropriate use of a building can result in significant physical damage. The most obvious of these involves unauthorised alteration to the building's support structures; for example, cutting into foundations for ventilation and power access. These renovations can extend as far as manipulating chimneys and roofs. The combined effect of these alterations is to severely degrade the structural integrity and fire rating of the building. Following from this, wiring defects are another issue that frequently require remediation. These alterations are often completed to a poor quality standard by unqualified individuals who are aiming to achieve one or more of the following: (a) illegally bypass electrical metres with a view to stealing power, (b) enable power to be provided to the structure by additional means, such as generators, and (c) internal rewiring to support a large number of industrial strength grow-lamps. The substandard workmanship and the absence of standardised safety processes mean that these properties pose a highly elevated risk for electrocution and fire after these electrical renovations. When buildings are used for these inappropriate purposes, there can also be a large amount of moisture damage that can significantly deteriorate the building's structural materials. Finally, there is the potential that inappropriate disposal of dangerous goods through the drainage system can degrade the plumbing infrastructure to the extent that it may need to be replaced. For a recent review of some of these issues, see the work by Plecas and colleagues [9].

Environmental and Public Health Concerns

In contrast to these overt signs of physical damage, the environmental and public health concerns that emerge from inappropriate use of properties can also produce an alternative class of hazards, typically more difficult to detect and harder to address [as discussed by 10]. The first of these, mould and fungi, typically grow in conditions of high humidity, poor ventilation, and heat. These do not always grow in obvious places (e.g., they can prosper inside wall cavities) and are highly resilient, so without proper remediation they are very likely to return. Given that mould has the potential to be allergenic, pathogenic, or toxigenic, its presence within commercial or residential buildings creates a significant health concern for future building occupants [10]. In combination with chemicals such as pesticides and fertilizers, these microscopic organic particles can linger for lengthy periods of time after the source of the contaminant has been removed, significantly impacting on the safety and quality of the air inside the property. Inappropriate use of commercial or residential buildings for agricultural purposes can also result in toxic residue contaminating the building materials and the soil in the building's surrounds. This issue can persist even after the source of the contaminants has been removed, as a result of spills, over-spraying, and the absorbent properties of building materials [10]. Finally, following from the potential damage to the plumbing infrastructure of these buildings discussed previously, inappropriately disposing of chemicals through the drains or onto the ground can also cause contamination to the surrounding ground water supplies to the extent that the content of these areas could need to be reclaimed.

Insurability

Section 11, Permitted Exclusions - Defects (1) and (2) of the *Home Warranty Insurance and Statutory Protection* clause of the *Homeowner Protection Act* permits warranty providers to exclude a range of items from home warranty insurance, including:

> *"(c) any loss or damage which arises while a new home is being used primarily or substantially for non-residential purposes;*
>
> *(e) any damage to the extent that it is caused or made worse by an owner or third party, including:*
>
> *(i) negligent or improper maintenance or improper operation by anyone other than the residential builder or its employees, agents or subcontractors [which includes bodily injury, or damage to personal property, caused by mould],*
>
> *(ii) failure of anyone, other than the residential builder or its employees, agents or subcontractors, to comply with the warranty requirements of the manufacturers of appliances, equipment or fixtures,*
>
> *(iii) alterations to the new home, including the conversion of non-living space into living space or the conversion of a dwelling unit into 2 or more units, by anyone other than the residential builder or its employees, agents or subcontractors while undertaking their obligations under the sales contract, and*
>
> *(k) changes, alterations or additions made to a new home by anyone after initial occupancy, except those performed by the residential builder or its employees, agents or subcontractors as required by the home warranty insurance or under the construction contract or sales agreement;*
>
> *(l) contaminated soil;*
>
> *(n) diminution in the value of the new home."*

The implication of this legislation for prospective home purchasers is that, in addition to the health and safety issues that arise from the inappropriate use of dwellings, unknowingly purchasing properties that are potentially uninsurable (under the *Homeowner Protection Act*) also poses serious financial risks.

These Concerns are Not Specific to Illegal Inappropriate Use

Although these health and safety concerns do encompass the issues associated with using dwellings for the production of marihuana and methamphetamine, the problem is not illegal activity in the building, per se. Instead, it is the potential of injury/disease for interested buyers if they purchase properties that are unsafe/unhealthy without being able to make an informed decision about the risk. This risk is paralleled by prospective tenants when making a choice about potential rental properties. Legality of activity aside, therefore, the issue is the health and safety issues associated with improper use of buildings. Taking the case of indoor marihuana grow operations, for example, regardless as to whether the business owner has been granted a licence to produce under the MMAR, if the building is not zoned or constructed to be used for agricultural purposes, safety inspections have not been passed, and agricultural grade fertilizers/pesticides have been used, then the health and safety issues that result are equivalent to an illegal indoor marihuana grow operation. By extension, even if information is made available about the relevant history of a property, if there is an inconsistent, unreliable remediation process, then being informed a property has been remediated does not provide the necessary basis for an informed decision.

Disclosure

Across BC's Fraser Valley region[3], despite the implementation of a range of municipality-specific *Controlled Substance Property Bylaws*, there is a clear lack of desire to record any permanent information identifying properties as having been used inappropriately.[4] The one exception to this approach is the City of Surrey, BC, which requires the owners of formerly remediated properties in perpetuity to provide written notification to any future occupants advising them that the building was formerly identified as needing rehabilitation and that the requirements of this rehabilitation process were met. Furthermore, a notice is included on the City of Surrey property tax certificate advising that the property is/was subject to a bylaw infraction (with the number of the bylaw cited).

In contrast, the City of Abbotsford, BC, ensures that all references to inappropriate use are removed from the property land title when the structure is deemed to have been successfully remediated. However, the records relating to the inappropriate use of the property are kept by the city for seven years, in accordance with the city's record management system. This means that some documents associated with inappropriate use of buildings in Abbotsford can be accessed via a Freedom of Information request. In addition to this, the city also keeps searchable binders at their front counter which contain dates when notices were filed and removed.

These approaches both contrast the positions currently adopted by the City and the Township of Langley, BC, neither of which rely on their own employees to make judgements about the success of remediation and the corresponding inhabitability of the property. This simultaneously reduces each municipality's liability in any post-rehabilitation health and safety complications, and also means that neither municipality possess complete information about the outcome of any rehabilitation process. Once again, no permanent record is made to the property title or tax certificate in either Langley municipality that would indicate a remediation process had taken place.

Caution with Disclosure: The Freedom of Information and Privacy Act

As it stands, the default strategy from institutions in possession of this information about known history of improper use of buildings is non-disclosure. The end result is that it is not currently possible to say definitively whether any given property in BC is currently or was previously used inappropriately. There are at least two reasons for this. First is the inconsistent sharing of information between agencies (e.g., police, bylaw inspectors, and others). Second is the lack of a centralized, searchable record of identified and/or remediated unhealthy dwellings. The major impediment to this information flow seems to be public officials' interpretation and understanding of the *Freedom of Information and Protection of Privacy Act* RSBC 1996 (*FIPPA*). Given the penalties for non-compliance with the *FIPPA* include fines of up to $25,000 for a service provider and up to $500,000 for a corporation, non-disclosure has been adopted as the default stance by the majority of municipalities in BC with a view to limiting their liability exposure. The source of complication posed by *FIPPA* with respect to prospective buyers determining the safety of a potential purchase emerges as a consequence of the following steps:

1. *FIPPA* makes public bodies more accountable to the public and to protect personal privacy;
2. *FIPPA* gives the public the right of access to records with specified limitations (*accountability*);

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[3] For the purposes of this paper, "Fraser Valley" refers to the communities of Abbotsford, Mission, Langley City and Township, Surrey, White Rock and Delta – the communities in which members of the Fraser Valley Real Estate Board live and work.

[4] These issues are discussed fully within a White Paper Discussion entitled, "Standards of Reporting and Remediation: The Impact of Illegal Drug Operations on Housing", prepared for the Fraser Valley Real Estate Board in September 2008. Copies of this paper can be accessed by contacting the Fraser Valley Real Estate Board at mls@fvreb.bc.ca.

3. One specified limitation to *FIPPA* is the disclosure of personal information (defined as "information about an identifiable individual") by public bodies (*privacy*);
4. Information about any known history of improper use of a property is of immediate importance to potential buyers/lessees/tenants;
5. Information about any known history of improper use of a property has been determined by public officials to be personal information (with one concern to do with record linkage that potentially could result in the disclosure of personal information that causes harm to individuals);
6. Information about any known history of improper use of a property is not being disclosed, with *FIPPA* cited as the reason: privacy trumps accountability.

The reoccurring message here is that, for the most part, these municipalities are concerned about record keeping and disseminating information in cases where they have acted on evidence that buildings have been used inappropriately. The default strategy is to ensure that these records are non-permanent (when they are retained at all) and that they are not maintained in an easy-to-search format (such as a database). This protects the governments in these areas from being able to disseminate information that could later be perceived to have contravened FIPPA. However, it has not been determined by the Courts whether such disclosure actually does constitute a breach of this Act.

In the absence of a definitive Court ruling with respect to the legality of disclosing this type of information, an alternative, valuable perspective on this issue has been provided by the former BC Information and Privacy Commissioner, David Loukidelis, in a letter to Fire Chief Garis, City of Surrey Fire Services [11]. It must be noted that Loukidelis' perspective was qualified by stating that, "Because of my role investigating and enforcing privacy issues under the [FIPPA], I cannot give a formal much less binding opinion on any specific issue." This caveat noted, however, Loukidelis continued to explain:

> *"...it can be argued that information about the physical condition of a particular property, or about any building bylaw or other bylaw infractions, notices or actions respecting a piece of property is not personal information of anyone, including the registered owner. FIPPA offers protections for personal information, which it defines as 'information about an identifiable individual', while information of the kind just mentioned is information about a piece of real estate, not about an identifiable individual. Of course, personal information may be found in or associated with this type of information, so a local government would have to ensure that it discloses only information about building bylaw or other bylaw infractions, notices or actions respecting the property and not personal information of individuals."*

This perspective was supported by subsequent correspondence from the Executive Director of the Office of the Information and Privacy Commissioner of BC to the Fraser Valley Real Estate Board [12], which indicated that, "[t]here is a positive duty in law to disclose information about a significant risk to someone's health or safety."

Inconsistencies with Respect to Disclosure

In addition to disregarding these opinions that disclosure of health and safety information about properties should be occurring, the current practices with respect to disclosure about inappropriate use of buildings are also arguably inconsistent, being treated differently from other property information that is recorded and disclosed. The first major example of this involves the release of excessively-high power consumption data from BC Hydro to local municipalities. This information is released under the *Safety Standards Amendment Act* and gives an indication of inappropriate use of residential dwellings, in a manner that is highly likely to result

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in a fire-related health and safety risk. As it stands, approximately twelve municipalities in BC regularly access this information without any legal backlash with respect to breaches of *FIPPA*.[5] Given BC Hydro collects this information about consumption as a key aspect of their business, there are no municipal boundaries at play here. The dissemination of this information actually represents a current, working example of a centralised process where information about potential inappropriate use of dwellings is disclosed.

A second, similarly centralised process is demonstrated by the BC Provincial Contaminated Site Registry, which is a registry of (a) confirmed contaminated sites, (b) sites under investigation for contamination, and (c) formerly contaminated sites that have been remediated. A contaminated site in this context is defined as "an area of land in which the soil or underlying groundwater or sediment contains a hazardous waste or substance in an amount or concentration that exceeds provincial environmental quality standards," resulting in a site being unsuitable for specific land, water, and sediment uses [14]. All information gathered since 1988 about contaminated sites is completely accessible to the public and site-specific information can be attained via an online search at www.bconline.gov.bc.ca.

On a municipal level, it is also routine procedure to record permanent information about other building-specific information, such as renovations, building permits, and structural damage. Although there is no centralised process capturing this information, it is possible to visit municipal offices and learn about these aspects of a building's history. These amendments to the building records are not temporary, removed from the record following remediation, in the same way that some municipalities currently deal with information about inappropriate use of dwellings.

Potential Novel Approach to Addressing the Disclosure Issue

Despite these inconsistencies, and working within the current concerns about privacy and disclosure, some alternatives for achieving the necessary dissemination of information have been proposed. Given the former Information and Privacy Commissioner's perspective on the non-personal nature of information about (a) the physical condition of a particular property, (b) any building bylaw or other bylaw infractions of a particular property, or (c) any notices or actions respecting a piece of property, the Fraser Valley Real Estate Board has proposed a protocol which would enable members of the public and real estate professionals representing them to access information necessary to make an informed decision about a property without contravening *FIPPA*. Potential wordings that have been trialed [15] include:

- According to City records, has the property ever been investigated for the cultivation of marihuana or as a clandestine drug lab?
- Was the property ever invoiced by the City on the basis that it had been used for cultivation of marihuana or as a clandestine drug lab enforced at this property?
- Was a City action taken as a result of findings in a residential building on the property?
- Was a City action taken as a result of findings in a non-residential outbuilding, barn, shed or other shelter situated away from the residence?
- Has the City's Controlled *Substance Property Bylaw* been enforced at this property?

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[5] This is not to say that this process has not been scrutinised with respect to *FIPPA*, and the status quo has emerged as the outcome of extensive lobbying of the provincial government that led to the introduction of *Bill 25* (the *Safety Standards Amendment Act*) in 2006. Subsequent to this, the legitimacy of this process has been tested in the BC Supreme Court (2008) and the BC Court of Appeal (2010). In both instances the rulings have been upheld. For a comprehensive summary of these cases see [13] L. Garis, et al., *Community Response to Marijuana Grow Operations: A Guide Towards Promising Practices*, 2009, City of Surrey: Surrey BC. p. 32. http://www.surrey.ca/files/DCT - Community Response to MGOs Guide Sept 2009.pdf

- Have the requirements of the action been undertaken such that the requirements of the Bylaw or other City order been satisfied?
- If the answer to any of the above questions is "yes," and the potential purchaser/lessee/tenant of the property are still interested in the property, they may wish to ask, "What was the date of the occurrence?"

The assumption underlying the proposal of these questions is that they could be answered by officials with a yes/no response without contravening the scope of *FIPPA*. Garis and Bond [15][6] then discuss that if this argument is incorrect, and that personal information was being disclosed when a property was listed for sale, this issue may be resolved by the property owner giving their consent to disclose, as explained by Loukidelis [11]:

> *"Even if this argument were wrong, such that personal information were being disclosed, when a property is listed for sale, the seller could consent in writing at the time of listing to disclosure by the relevant local government of information about the condition of the property and whether it has been used for grow-ops or other illegal drug operations. This would avoid any issue under FIPPA altogether, since s.33.1(b) authorizes a local government to disclose personal information 'if the individual the information is about has identified the information and consented, in the prescribed manner, to its disclosure'."*

In addition to this, Loukidelis [11] also outlined that the BC Real Estate Association property disclosure statement (Part 2, clause P) requires a yes/no response to the following: "Are you aware if the premises or property have been used as a marihuana grow operation or to manufacture illegal drugs?" Given that the answer to this question is a representation and warranty under any subsequent sale agreement, it is plausible that a failure to provide this information to a potential buyer would be good grounds for suspicion.[7]

Remediation

Moving on from the discussion of disclosure of information about improper use of dwellings, the next section of this report discusses the issues around the process for remediating unhealthy/unsafe buildings. In their discussion paper that focused on marihuana grow operations, Garis, Plecas, Cohen, and McCormick [13] explain that it is essential that the damage done to properties that have been used inappropriately are completely remediated before they are reoccupied. The primary purpose for this remediation is to ensure these buildings do not become abandoned. This issue can be (and, in a range of BC municipalities, is being) addressed through the use of bylaws that place the remediation costs back onto the property owner. However the issue that remains is that the current process allows inconsistent, highly variable standards to influence the remediation of these structures.

The General Prototype Approach to Remediation in BC

As with the approaches to disclosure already discussed, across BC there is a wide range of approaches to remediation of properties that have been identified as having experienced inappropriate use. Grounded in

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[6] The full paper is available at http://www.surrey.ca/city-services/7388.aspx

[7] The BC Real Estate Association's property disclosure statement is not currently mandatory, and even if it were to become mandatory, this would not address the problems associated with property sales (a) conducted by real estate agents who do not belong to a real estate board/association, (b) conducted privately by property owners, and (c) for commercial properties. This would also not addresses issues arising for tenants and lessees as landlords are not required to complete this disclosure statement.

municipal bylaws, the general approach to remediation that has been adopted contains some/all of the following components:

- A site visit is conducted by an inspection team under a locally developed Controlled Substance Property Bylaw;
- If inappropriate use is detected, further occupation is prohibited and a notice is served that commences the remediation process;
- Within a certain period of time the remediation requirements must be addressed;
- If these requirements are satisfactorily addressed, then the occupation prohibition is lifted.

This process occurs at the property owner's expense, and the final source of approval for the remediation process is a non-government, designated expert. In some cases the records of this process are kept in such a way that they can only be accessed by municipal staff and there is generally little to indicate in the permanent record that the property had been used in this inappropriate, potentially unhealthy/unsafe manner.

Issues with the Various Existing Approaches to Remediation

Although on first inspection these steps appear comprehensive and thorough, closer examination exposes a range of issues associated with these various approaches to remediation of inappropriately used buildings. To highlight this issue, Garis [16] produced a summary paper entitled *Improving the Remediation Process for Marihuana Grow Operations* that succinctly summarises the outcomes of a workshop involving remediation experts that focused on addressing concerns with the status quo. These issues are expanded in length within Garis's paper,[8] but for the purposes of this paper they are summarized as follows:

- Due to a range of different qualifications that are available, different requirements for maintaining qualifications, rules about the number of qualified individuals required for a company to hold a licence, and necessary insurance standards, it is very difficult for laypeople to determine which service providers are appropriately qualified/certified to undertake remediation work.
- Uncertainty exists regarding the process and roles of environmental consultants and restoration companies in the remediation process.
- There are inconsistencies and inefficiencies in how these remediation processes are executed across-municipalities, with no guarantee that remediation is being undertaken consistently and effectively to ensure that the work is completed correctly.
- The recommendations for the scope of remediation work required are often insufficient to complete the remediation task. This is often the consequence of the environmental consultants making recommendations following a superficial inspection, which tends to miss more covert damage (e.g., under carpets and within wall cavities). A detailed scope of work is essential to (a) ensure the property is completely and effectively remediated, and (b) enable the prospective buyers/lessees/tenants to know exactly what work was completed. In addition to the lack of clear scope of work for remediation, there are also additional logistical constraints with respect to the quantity of suitable remediation companies, hygienists, and Hazmat staff that are available to remediate inappropriately used dwellings [e.g., 10, 17].
- Inconsistencies are also an issue with respect to the quality of remediation work that is done. There is generally no obligation on the behalf of the property owner to procure the services of certified restoration companies. Consequently, property owners can cut corners to save money by doing

[8] The full paper is available for download at http://www.surrey.ca/city-services/7388.aspx

remediation work themselves or hiring uncertified contractors. This generally has a detrimental impact on the quality of the workmanship, which directly impacts on the success of the remediation process and the subsequent amelioration of the health and safety risks created by the inappropriate use.

- Although remediation cannot generally be concluded without the authorisation of a certified industrial hygienist or registered occupational hygienist, it is rarely the case that these individuals are providing consistent project oversight for the duration of the remediation process. Furthermore, there are concerns about a lack of independence between the environmental consultants who originally scope the size of the damage, the cleaning companies responsible for the remediation, and the hygienists who sign-off on the process as being complete.
- Concerns about premature removal of the occupancy ban were also identified, stemming from the fact that the hygienist conducts their final site visit and inspection while the building's walls are still open for building/electrical inspection (and hence, not yet in a liveable state).

Addressing these Limitations by Standardizing the Process

In order to address these issues, a coherent, clearly defined process needs to be developed and applied consistently. Following this, sufficient numbers of appropriately trained staff need to be deployed to ensure this remediation process is being adhered to. The fundamentally important issue here is that each instance of inappropriate use of a building needs to be assessed in its own rights, based on the context. This means that the process is the key and the issue as it stands is the inconsistency of the process. Garis's [16] paper identified a set of detailed roles and recommendations that property owners, environmental consultants, restoration contractors, and governments must play in this process. Furthermore, Garis provided a concise process overview for remediation that included the following steps:

- Issuing and posting a "Do Not Occupy" order on the inappropriately used building;
- The government involved providing the property owner with the necessary information about the remediation process;
- The property owner hiring appropriate environmental consultants and restoration contractors;
- The environmental consultant investigating/assessing the site, preparing the scope of work for the restoration contractor, coordinating hiring registered professionals (as required), and monitoring remediation;
- The restoration contractor obtaining permits (by submission of documents prepared by registered professionals, as required), hiring trades, ensuring all work is completed and signing-off;
- The environmental consultant signing-off on the project and issuing a "Certificate of Entry";
- The property owner completing the finishing work on the property;
- The government involved receiving the final approvals from the environmental consultant of a successful final inspection, and subsequently removing the "Do Not Occupy" order; and
- Inclusion of a permanent record of remediation in the building records for the property.

A Top-Down, Centralized Process for Disclosure and Remediation

The question remains then as to what the best method is for achieving these revisions to the process for disclosure and remediation. In addressing these issues it is important to heed the position outlined in Loukidelis' [18] report into local governments and the growth of surveillance, which discusses the scope for the provincial *Safety Standards Amendment Act*, 2006 to be used to its full effect, rather than developing piecemeal municipal bylaws that attempt to combat criminal activity. Loukidelis [18] cautions against the

development of municipal bylaws that would "compel businesses to collect, compile, or disclose customers' personal information" suggesting that:

> *"Such [bylaws] should only be adopted as a last resort. Other measures ought to be considered before a bylaw is entertained as a solution. A bylaw should be adopted only where conventional means for achieving the same law enforcement objectives are substantially less effective than the bylaw promises, on clear evidence, to be and the benefits of surveillance substantially outweigh any diminution of privacy inherent in the bylaw's operation."*

The BC provincial *Safety Standards Amendment Act*, 2006, is the legislation that has enabled BC Hydro to provide power consumption information to municipal governments under the grounds of potentially elevated health and safety risks. This has been achieved without contravening *FIPPA*. Consequently, the authors feel it is worth exploring other existing provincial legislation, such as the *BC Building Code*, the *BC Residential Tenancy Act*, and the *BC Homeowner Protection Act*, which all also dictate aspects of safety that apply across the province.

This move towards lobbying for taking provincial responsibility for these issues has already begun in other areas within Canada. In 2007 there were discussions in Toronto regarding the development of a provincial, centralized registry of indoor marihuana grow operations to help inform and protect consumers in the same sense as information regarding other hazards (e.g., flooding risks, and Urea Formaldehyde Foam Insulation). Indeed, it would make sense for such a registry, motivated by maximising public safety, to incorporate information about factors such as vermiculite, which are neither banned substances nor latent defects, but do pose potential liability risks at a later date if not disclosed when selling a property [as dicussed by 19]. Furthermore, Garis [16] discusses how "The Alberta Real Estate Association (AREA) is actively lobbying the provincial government for consistent standards for assessing and remediating drug houses to protect future property owners from structural and health problems." As Lee and Rollins [10] explain:

> *Inconsistent interpretation of remediation procedures and techniques can lead to inadequate remediation resulting in a continued health and safety risk for occupants, or a costly and unnecessary sterilisation of a property. Recommendations adopted by the Province would remove inconsistencies and facilitate a more cohesive remediation process. They would also assure prospective property buyers in Alberta that all properties identified as illegal drug operations have been restored to a provincial standard [10]*

Recommendations

In conclusion, in addition to supporting the proposed MMPR, there are three recommendations from this research note. In combination, these amendments to current processes would simultaneously address the damage done to existing residential properties as a result of MMAR-licenced indoor marihuana production and better enable Canadian residents to make informed decisions about the potential health and safety risks posed by residential buildings they are looking to purchase, lease or rent. As suggested from the outset, these recommendations make no comment about the legality of inappropriate activity in properties. The three recommendations are as follows:

1. *Develop a centralised, consistent process for disclosure of property history information for those buildings previously used as sites for the production of marihuana under the MMAR*

A consistent process needs to be developed, which does not breach *FIPPA*, for ensuring that information about inappropriate use and remediation of properties used as sites for the licenced production of marihuana under the MMAR. This information needs to be made available in a timely, straightforward manner. This process

would need to enable prospective property purchasers/lessees/tenants to learn about the relevant history of the property to ensure they could make an informed decision about the potential health and safety risks.

2. *Develop a centralised, consistent process for remediation of inappropriately used buildings previously used as sites for the production of marihuana under the MMAR*

As the situation currently stands, even if potential purchasers/tenants are able to learn about the history of inappropriate use and/or remediation at a specific property, they are unable to be certain that the property has been safely and completely remediated. In order to address this issue, it is recommended that a consistent process for remediation is developed that enables each remediation situation to be addressed in its own right, whilst providing a framework for determining:

- What is required to be tested and remediated?
- Who is responsible for completing the remediation process?
- What is the time frame within which remediation must take place?
- Who is responsible for assessing the completeness of the remediation process and guaranteeing it has been undertaken?
- Who is responsible for determining when buildings are safe to be occupied following remediation?
- What are the impacts, if any, for the insurability of the building?
- How and where is this documented?

3. *Implement these disclosure and remediation processes in a top-town manner, founded in existing provincial and/or federal legislation*

To address municipal boundary issues about information sharing and to avoid unnecessary legislation being developed, it is recommended that the disclosure process and remediation process for dwellings used as licenced production sites under the MMAR both be implemented in a top-down manner, directed by provincial and/or the federal governments, and founded on the existing legislative framework.

As stated previously, the proposed MMPR program does not go far enough to ensure the damage done to existing building stock under the MMAR will be redressed. The authors are fully supportive of the MMPR's planned moved towards licenced commercial production of medical marihuana and a phasing out of existing licences for individuals to produce marihuana in homes and communities. However, for the reasons outlined above, the authors believe the Government of Canada also needs a comprehensive process for disclosing and remediating the residential properties that have already been utilized to produce medical marihuana under the MMAR, thus ensuring future health and safety issues do not arise as a result of this Federal programs implementation to date.

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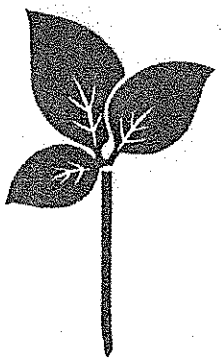
This is **Exhibit "BBB"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

2013

Comment to Health Canada on the Proposed MMPR



Prairie Plant Systems Inc.

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February 20, 2013

Jeannine Ritchot, Director
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Controlled Substances and Tobacco Directorate
Healthy Environments and Consumer Safety Branch
Health Canada
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Dear Ms. Ritchot,

Thank you for the opportunity to respond to the proposed regulation changes outlined by CG1 Vol. 146, No. 50. The management team of Prairie Plant Systems has reviewed the proposed regulations and developed 10 recommendations; 3 overarching recommendations and 7 specific program recommendations.

As you are aware, Prairie Plant Systems Inc. (PPS) has been involved with the file since the first contract was established December 23, 2000. The Company has been involved with the evolution of this project with the department at many levels and through many transitions, trials and regulatory challenges in an ever growing patient need for safe and reliable medical cannabis. As a whole the Company has devoted over 1.2 million person hours to producing and delivering medical cannabis to licensed patients. Personally, I have held the responsibility of managing this file since that time and have spent in excess of 20,000 hours working through the program evolutions and improvements. All of the ten recommendations stem from the many lessons learned through the extensive involvement over that time.

First, allow me to commend you and your department for attempting regulatory changes which anticipate a "pharmaceutical styled" patient access program provided by the private sector which would be appropriately regulated by Health Canada (HC). That said, regulatory changes, as with any significant change, represent both opportunities to "make it right", as well as threats which could do just the opposite. As such, we view the new proposed amendments or changes to make the program a prudent first step in providing a safe yet functional system for Canadian patients accessing medical cannabis.

It appears some of the new proposed regulations appear to retreat from the safety aspects, both patient and public safety, and focus more on patient access. The "softening" of the regulations such as exemplified

by shifting the production regulations from Good Manufacturing Practices standards to Good Production Practices standards would seriously undermine patient safety. This is discussed in greater detail further in this document.

General Recommendations

Our over-arching three general recommendations for the proposed regulatory changes in creating the new MMPR are:

1. **Maintain the GMP quality standards for testing, production, labeling and packaging as already established given their rigor and evidence for functional patient safety and reliability of product;**
2. **Enforce those regulations with greater effort and efficiency for improved public safety and effective reduction of diversion and;**
3. **Regulate that all medical cannabis be only produced in Canada for cost effective, patient/public safe enforcement of the regulations and establish a moratorium on any new foreign supplies of this controlled substance.**

It is our position that the Canadian industry can uphold those quality standards already established under the MMAR. Businesses can operate effectively within those sets of existing regulations while still availing patient appropriate access and without compromising their safety.

Clearly these new proposed regulations are designed to entice new business (including foreign companies) to increase supplies of medical marihuana (MM) to provide broader "access" as perhaps propelled by recent court rulings in Canada. This could almost be considered a cleverly designed effort by the illicit drug trade to create legal "fears" within the department in order to undermine the regulatory safety and security standards. Such relaxing of the quality and security requirements in supplying medical cannabis for immunocompromised individuals will undoubtedly undermine their safety and leave ample room for diversion. These new regulations essentially **undo** much of the lessons learned and safety testing established over the last 12 years which endeavoured to make the product **safe** and **reliable** for Canadians.

The three pillars required to make this program effective yet regulatory manageable are:

1. Patient safety and reliability through the regulated production and manufacturing as any other drug in Canada;
2. Public safety and diversion prevention through the exacting security measures for inventory controls; and
3. Patient access for the total volumes required and the chemical (cannabinoid) profiles needed for various symptom management.

The management team at PPS has prepared a brief response to some specifics to the proposed regulations (attached). The backdrop for those specific recommendations is as follows:

Patient safety has evolved with the program generating Good Manufacturing Practices (GMP) styled production systems as governed by all pharmaceutical drug manufacturing not just by Good Production Practices (GPP). Testing requirements were established over the years as issues from the general public

were raised. Such issues involved mold testing and with subsequent potential mycotoxin testing, metals and heavy metal testing, concentration of cannabinoids and moisture content generating the most attention.

As you are aware, safety standards were set by HC which followed both the recommendation of immunologists and toxicologists (see attached CANTOX report) for individuals who are immunocompromised. They also cited the Natural Health Products Directorate (NHPD) to establish safe daily consumption limits for metals and heavy metals. Since patients "self titrate", each dosage form is appropriately labeled and released in lots for potential recall, just like any other pharmaceutical drug.

The current MMAR system works well in terms of patient acceptance and reliability as exampled by Health Canada's 2012 shipments to patients. There were 11,315 patient shipments in 2012 and only 95 shipments were returned - this represents 0.83% of all shipments in 2012. Those returns were segmented between individuals who moved without notice, deceased, those who indicated it didn't work for them, and product that was damaged in shipping. This translates into more than 99% acceptance and usability of the medical marihuana received under the MMAR. Based on our data, the current system for patient acceptance and reliability appears to be functioning well.

The proposed regulations largely discount such safety aspects for patients aside from the GPP which ultimately do not guarantee safe finished product for patients. The finer details for appropriate testing are obtrusively void in the CG1. We highly recommend that HC re-think and reconsider this GPP position to instead enforce GMP thereby maintaining its standard of safety already established through the rigors of historical public/patient demands (as demonstrated through traditional pharmaceutical manufacturing). Simply testing for cannabinoids in no way ensures safe product for patients for things such as molds or foreign chemicals.

Second, public safety is best served through appropriate diversion prevention and inventory management reporting to HC. It would appear that the softening of the security components will in fact increase the diversion events. Now it may have been assumed that such security measures are too expensive for the average business but in fact that is **not** the case. For example, the capital cost differential at PPS between concrete walls for growth chambers compared to mesh and fibre glass (polyurethane) greenhouse walls translates into a difference of $0.14 to $0.05 per gram respectively and an immaterial price differential to the patient. Upholding the security measures currently observed by PPS for both physical and IT security is simply a cost of doing business and represents a relatively minor expense to ensure protection against diversion and protection of private/confidential information. The specific comments in the attached responses speak to this subject as well.

The Company therefore recommends upholding the security requirements for both physical security and inventory control as already functioning with the MMAR Program. It is important to note that in the almost 13 year history with this medical marihuana program, there has **not been a single event of diversion from PPS facilities**. The current system **works**. It is in fact affordable for any company planning to operate in this controlled substance business. Systems technology today is surprisingly manageable and cost effective for businesses.

Thirdly, patient access for appropriate MM clinical grade material is crucial to maintaining growing patient demands. We understand the potential legal challenges surrounding "sluggish" or "restricted" patient access however "lowering the bar" too far would often result in potentially creating more threatening issues. Specifically, this is related to enforcement of foreign suppliers. It is widely viewed that many individuals within Canada have taken liberties beyond their license for trafficking; one of the impetuses of the current regulatory reform. For this reason, the Company also believes that any "dispensary" model would continue to operate as a significant source of diversion and illicit drug trafficking.

It appears that HC assumes that Canadian businesses won't move fast enough to meet the patient demand and that Canada may need to rely on imports to meet patient access. We do not believe this to be true or factual. It would seem much more prudent to allow Canadian businesses to establish themselves within a firm regulatory environment to maintain patient safety and public safety aspects. Legitimate businesses can and will make those required investments. Adhering to such safety, security, and GMP standards would require significant investment. However, enforcement would first need to be well established in Canada in order to truly manage the industry. The problem with foreign suppliers is that their form of GPP would most likely be significantly different, especially coming from places such as Mexico or Bangladesh. Such foreign suppliers would simply drive the price so low that the Canadian businesses would not be able to compete while trying to maintain safety/regulatory standards within Canada. Moreover, HC inspections of those foreign suppliers would be expensive and questionable from an enforcement authority basis.

A good parallel example is the Nutraceutical industry. That industry really began to "blossom" in the early 1990's with producers and processors developing new products. Eventually the NHPD was established to set standards for efficacy, active principle content, metals, etc. However, all of the production shifted to China and other Asian countries. Today, the industry in Canada is largely only importing companies such that over 90% of the supply is imported from Asian countries. There is no enforcement of GPP for those nutraceuticals but rather it relies on the importation companies to be responsible largely allowing them to set their own standards for safety testing. Moreover this has also decimated the Canadian businesses (and their respective jobs) that once flourished in the nutraceutical business.

The true economic realities are that "capital" is mobile. Should a foreign company desire to have itself in this business, it could make these investments in Canada creating the "value-added" economic activity in the country while at the same time enabling greater profitability (and lower expense) for regulatory enforcement. That said, enforcement by HC would still be crucial for the industry to function properly providing appropriate patient access to safe and consistent medical marihuana with a "level" regulatory playing field and level competitive environment for Canadian businesses.

As medical cannabis is both a controlled substance and a natural product, it is imperative that HC maintain regulatory control over the process from production to the finished product to ensure product safety. That said, legitimate businesses could begin to function in this industry in Canada and would be willing to comply with the new rules but they need a fair and equitable "playing field" or competitive landscape. It is highly unlikely that foreign suppliers would abide by similar regulatory rigor and therefore undercut those Canadian firms trying to legitimately comply and operate within the regulations.

It is in this light that PPS **highly** recommends a moratorium on any foreign supplies of medical cannabis (or their version of it) being allowed into Canada. MM product for Canadians should be made in Canada. We are the world leader in this aspect. Canada has the best system in the world according to the Milan Conference *"Cannabinoids and Pain"* held on August 25, 2012. If foreign companies desire to participate in this Canadian market, they can establish operations in Canada and abide by the same rules as any of the Canadian businesses. Fledgling Canadian companies need time to adapt to such new regulations and opening the industry up to foreign markets would simply hinder and undermine those opportunities for Canadian companies.

I trust you will seriously consider these recommendations. We believe patient access will be appropriately addressed from Canadian business operations. We also believe that the legitimate economic activities would be best realized through (GMP) production within the country creating new employment opportunities as this industry grows. Moreover, we recommend Health Canada regulates this controlled substance more in line with the current MMAR regulatory frame which already provides "tried and true" patient and public safe medical cannabis. Health Canada does not have to "soften" the regulations, undermining patient safety in order to increase industry uptake for this medical marihuana production process. Health Canada can in fact provide the appropriate regulatory framework which accomplishes all three aspects of product safety, patient access and public safety.

Should you require any further clarifications, please do not hesitate to contact me directly at my office.

Sincerely,

Brent H. Zettl
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Addendum A

Additional Recommendations to Health Canada on the Proposed MMPR

In addition to the initial three aforementioned recommendations, PPS has reviewed and commented on specific aspects of the proposed MMPR.

Prairie Plant Systems Inc. (PPS) concurs with Health Canada's proposed changes to the Medical Marihuana (MM) Program as a necessity to better facilitate Public Safety through more strict controls.

As Canada's only current Medical Marihuana (MM) Licensed dealer, Prairie Plant Systems believes it has a unique industry viewpoint. With change comes an opportunity for awareness and improvement; while the proposed MMPR would result in many benefits for the Government, society, and ultimately Licensed Producers (LP), there are still some issues that could be considered for the proposed MMPR.

To this end, we have thought through some of the components of the proposed new program and have the following suggestions:

Security Clearance

In the proposed MMPR it states: *"Key personnel, along with directors and officers in the case of a corporation, would have to hold a valid security clearance, issued by the Minister of Health"*. Also in section 82 it states that only the persons in charge and officers of a corporation must be security cleared. It is the opinion of PPS that **all staff** working for the Licensed Producer should be required to be security cleared. There should be a reliability status or at least a clean criminal record check for everyone. If a Licensed Producer goes through the steps of ensuring that the officers and senior staff are security cleared and does not clear the rest of the workers it defeats the purpose. Organized criminals may use surrogates, which have no overt connection to crime, to work behind the scenes. In order to make sure that the designation of "Licensed Producer" ensures safety and prevents diversion, all staff should hold a security clearance.

Section 84 (1),(2) also makes mention of the type of clearance required. If, in fact, the check incorporates intelligence gathered by separate law enforcement units and intelligence databases, this may include unconfirmed or sensitive information that will allow for scrutiny and court challenges. PPS suggests that all staff require a security clearance, as stated above, that would be provided through the LP. This provides no access to the intelligence databases, and also alleviates extra work through the Minister for enhanced clearance.

4. **RECOMMENDATION: All staff employed by a Licensed Producer in Canada as proposed in the MMPR should be required to be security cleared for the safety of staff, the public, and to prevent diversion.**

Security Measures

General security measures suggested in the MMPR provide a good outline. PPS would suggest additional wording in Section 43(2) and 46 (2) to include activity that is monitored by an U.L.C. approved monitoring company, rather than leaving it up to the Person in Charge, or other personnel.

In addition to this, Section 44 mentions that "*Restricted areas must be equipped with a system that filters exhaust air to prevent the escape of pollen and odours*". This should be provided in an outlined security plan by the LP, as differences exist for very rural locations versus industrial areas versus high-traffic/ urban areas, as well as function and design of the facility.

5. **RECOMMENDATION: There should be more detail with regards to the level of security required, such as requiring facilities to have an approved security monitoring company. As well, there should be a formally designated Security Officer on staff to monitor the operations and process security checks for employees.**

Good Production Practices

It is the opinion of PPS that patient safety and product quality are paramount and that requirements should be strictly defined and enforced, rather than reduced regulation simply to allow or entice more businesses to enter the market.

The proposed MMPR mentions only the need for Good Production Practices. While it is essential to include a section on cultivation and production practices, there should also be regulations which include details on manufacturing practices such as drying, further processing, packaging, testing and storage. Currently, PPS operates as a licensed dealer and follows GMP guidelines subject to inspections, which encompasses every aspect of production, packaging and distribution including testing as a core aspect. This same requirement should be applied to all production and distribution facilities so patient safety is paramount and that standards are consistent throughout the entire country. It is important to note that the rules surrounding this GMP production are already established within Health Canada. Consistent enforcement will become the issue to maintain patient safety.

Specific sections for suggested review:

- Section 1(3) states that "*For the purpose of these Regulations, the production of marihuana includes the drying of it*". This should be expanded to include: "the drying, and any further

processing, packaging, and storage of it". All processes necessary to be performed in order for a patient to receive supply should include practices to allow safe, consistent supply.

- Section 65(1),(2) references that an expiration date is not included unless a stability study is completed. Stability study and expiration dates should be made mandatory for producers, having 3, 6, and12-month studies (minimally) performed during the first 12 months of production in order to produce an expiration/stability date when acquired. This should also be identified in Section 49 (2), as "*Dried marihuana must be stored under conditions that will maintain its quality*". This storage condition should be defined along with stability requirements, aiding in the provision of an expiration date.
- Section 48(1),(2),(3) should include that all testing is performed using verified and validated analytical methods; including mycotoxin content as per current requirements. Section 48(3) should also include any chemicals or cannabinoids that are claimed on label, and should be measurable against verified standards. Without validated methodology, there is no allowable consistency amongst batches. This also gives a 'gold standard' to aid patients in determining comparison material if required to obtain from a different producer, as all safety characterization and chemical identification will be equivalent.

These individual items are all identified within GMP regulations and should continue to be identified as requirements in MMPR production schema. If the proposed regulations do not clearly identify requirements for personnel, procedure, equipment and services, and suitable stability requirements, it allows for the possibility of poor manufacturing practices and safety issues to occur, perhaps without even being identified. If, in fact, the proposed regulations are to provide an appropriate regulated environment, the production should occur in a "pharmaceutical-like" manner therefore requiring adequate testing via validated methods. This can be captured with reference to the NHPD, as similar requirements for testing are already identified for similar material (nutraceutical plant materials).

6. **RECOMMENDATION: Licensed Producers under the MMPR should be held to GMP standards for the entire manufacturing system for production, processing, packaging, and storage confirmed by validated test methods and subjected to GMP audits by the department.**

Professional Regulatory Staff Requirements

The MMPR states in 54 (1)(a)(ii): *"A licensed producer must have a quality assurance person who has the training, experience and technical knowledge relating to the activity conducted and the requirements of this Division..."*. To ensure MM production continues to be held to a high standard, there should be more clarification on qualification requirements. Ideally, requirements for Responsible Person in Charge (RPIC), and Senior Person in Charge (SPIC) will be clearly defined to ensure that they are relatively the same as QPIC requirements as currently used. Section 22 (3) of the MMPR mentions only that the SPIC needs to be familiar with the Food and Drugs Act, but makes no mention of experience or education. This should be expanded to ensure manufacturing, growing, inventory, or quality experience, along with in

depth knowledge of the Narcotic Control Regulations, Controlled Drugs and Substances Act and the Food and Drugs Act. Without experience in regulated environments, and the markets to which they belong, persons in charge may not have the adequate training or experience to deal with customer safety issues or the quality control demands of the industry.

As well, while the MMPR mentions the need for senior person in charge and responsible person in charge, it makes no mention of the need for a Qualified Person in Charge (QPIC). As more companies join the industry there will be more publicity, hence an increased need for ensuring quality. A QPIC with experience in regulatory enforcement and quality control activities should be made a requirement to ensure that **all** production issues are dealt with appropriately. Producers need these identified personnel to respond to deficiencies, deviations and unexpected changes in the production system, particularly as this biology of this plant is less predictable under varying conditions. Without being required to identify a QPIC, it is possible that Licensed Producers may be in danger of contamination such as mold, staff cover-ups and other manufacturing aspects that put patients at risk.

7. **RECOMMENDATION: Require Licensed Producers to have a Qualified Person in Charge on staff in order to ensure manufacturing safety and testing compliance.**

Import and Export

It is suggested that import of dry marihuana material be limited to standards and analytical requirements or to legitimate starting materials such as seeds or cuttings. Having a proven, regulated and controlled Canadian market is imperative prior to allowing importation of material to provide for patient use. Allowing importation of bulk material may open up safety issues due to poor manufacturing practices and limited oversight on the quality and regulatory requirements, putting patients at risk. In order to assess and impose proper regulations, it is important to have tight control on the domestic industry as a starting point. Opening the market to foreign producers opens Canadians up to unregulated production practices, no quality control, and an increased cost burden on Health Canada to complete inspections.

8. **RECOMMENDATION: Production of Medical Marihuana for Canadians should be completed within Canada to ensure conformity to all requirements of production and manufacturing under the regulations.**

Inventory

Section 142 makes mention only of quarterly inventory requirements, and no mention of tracking plants in growth stages prior to harvest. With the intended record keeping requirements for patient tracking, the additional inventory requirements for material should be easily possible and made mandatory. All inventory control and security requirements should be maintained for all production and processing facilities. Minimally, quarterly inventory reports should be provided to Health Canada which can be

audited periodically or as deemed necessary by the Crown. This high level of inventory control best facilitates prevention of diversion from both potential external threats and internal (staff) removals. The current policies and regulations within Health Canada's office of Controlled Substance are sufficient. However, those rules would need to be applied consistently to all operations in Canada. Monthly reporting of physical inventory, including all products mentioned in Section 142 (" *marihuana seeds, harvested marihuana, marihuana that is destined for destruction, packaged marihuana, cannabis other than marihuana"*)and, in addition, all plants in growth phases (anything between and including seed/cutting and harvest), should be included for inventory purposes to ensure tracking and reconciliation for diversion investigations.

9. **RECOMMENDATION: There should be a high level of inventory control and security requirements for all production and processing facilities. This inventory control should include all stages of development and should be contained in quarterly reports that can be audited by the Crown.**

Packaging and Labeling of the Medical Marihuana

It is mentioned in the proposed MMPR that *"dried marihuana would have to be packaged in a tamper-evident and child-resistant container."* It is the opinion of PPS that child-resistant containers may impede the exact patients the MM is supposed to be helping (e.g. patients with arthritis, joint pain, fibromyalgia, etc.). The company would push for consideration of tamper-evident packaging that is re-closeable for shipment to patients, and no further restriction. It should be noted that herbal cannabis in its natural form is not psychoactive or toxic to humans. There is no child safety reason that would warrant child proof containers. The Company has not been able to find any reports of toxicity in children being attributed to herbal cannabis that had been dried and stored properly to maintain it in its non-psychoactive state. All incidents reported in the literature (MacNab *et alii*, 1989; Appelboam & Oades, 2006; Spadari *et alii*, 2009) involve cannabis that had been processed to make it psychoactive (*e. g.* hash, remnants of cigarettes, tea). Moreover, child-resistant containers may cause undue hardship on the patients requiring relief especially those suffering from acute arthritis.

10. **RECOMMENDATION: It is recommended that the packaging be defined as re-closable and tamper-evident with no further restriction.**

The ten aforementioned recommendations are presented to Health Canada from the collective core competencies of 12 years in this medical cannabis industry. Clearly, the MMPR set out to enhance patient access, but in that effort undermine many of the patient safety and public safety aspects of the current MMAR which have evolved, developed and have proven effective to those means. Enhancing patient access can be concurrent to maintaining those regulations appropriately established in the MMAR. Consistent enforcement across the country could be improved. There is sufficient market and margin for Canadian businesses to operate within a properly managed regulatory environment granting patient safety and access while guaranteeing public safety.