This is **Exhibit "M"** 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

Potential Reforms to the Marihuana Medical Access Program

Healthy Environments and Consumer Safety Branch
Controlled Substances and Tobacco Directorate

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Potential Reforms to the Marihuana Medical Access Program

Introduction:

In the fall of 2009, the Minister of Health outlined to Cabinet the challenges, both legal and operational, faced by the Marihuana Medical Access Program (MMAP) and committed to reform the program. The reform would include:

- preserving public safety and security;
- ensuring reasonable access; and
- reducing overall costs.

The *Marihuana Medical Access Regulations* (MMAR) were initially designed in response to a July 2000 decision of the Court of Appeal for Ontario (*R. v. Parker*), where the court declared the prohibition against possession was constitutional only if a clear legal standard was established to provide access to marihuana for those who require it for medical purposes. Further court decisions at the provincial level have ruled the Government of Canada must provide reasonable access to marihuana for medical purposes.

The MMAR were originally intended for what was believed would be a small number of authorized persons seeking to grow a small number of plants for their personal use.

However, with growth to almost 5,000 authorized persons, 80% of whom grow their product in residential settings, and some individuals seeking approval for upwards of 70 grams per day (approximately 140 marihuana cigarettes), the program has outgrown its regulatory framework of providing to individuals, on compassionate grounds, an unproven medical product to those in end-of-life situations. Additionally, due to the unique nature of the MMAP, the role of physicians and their responsibilities requires further clarification and education.

In addition, there are serious public health and safety concerns as well as financial pressures faced by the program as a consequence. For example, the MMAR do not specify where marihuana for medical purposes can or cannot be smoked. Existing laws and regulations governing the use of tobacco products do not generally apply to the smoking of marihuana for medical purposes. The scope of the federal *Non-Smoker's Health Act* which prohibits smoking in federally-regulated buildings and workplaces is limited to tobacco.

For a complete description of the evidence gathered to-date regarding the problems and issues associated with the MMAP, please see Appendix A for further information.

What follows are a series of reforms and options that could be implemented and for ease of consideration, are divided into two sections, A and B. Section A provides short term solutions and Section B provides long term solutions. In deciding which options to choose, both A and B can be analysed separately or as part of an entire reform package.

Section A Options – Short Term:

Options 1, 2, and 4 identified in Section A can be implemented through changes to the MMAR following the regulatory process. This process could take upwards of 12 to 18 months. The period could be shortened if these regulatory changes are only gazetted once in Part II of the *Canada Gazette*. Options 2, 3 and 6 do not require a regulatory change but will likely require increased funds.

These options are not meant to be considered in isolation, but should be viewed as a suite of short term actions the Government of Canada can undertake to address the most pressing problems associated with the MMAP.

1. Limit the Number of Plants Grown in Any Setting to 15.

Description
Limit all licensed producers (personal/designated) to a uniform and maximum number of marihuana plants set at 15. The dosage/plant number formula in the MMAR will be removed irrespective of the daily amount they have discussed with their physician.

Include a uniform maximum possession (150 grams) and storage amount (450 grams) irrespective of daily amount indicated on authorization. Removal of possession and storage formula in the MMAR.

Background
The majority, roughly 80%, of authorized persons in the MMAP currently produce their own dried marihuana (either under a personal or designated production licence).

The number of marihuana plants is determined by the use of a formula embedded in the MMAR which takes the daily amount ("dosage") and production area (i.e. growing location of indoor and/or outdoor but only one crop at any one time) and converts it into a number of plants (and possession and storage amounts). The higher the daily amount, the higher the plant, possession and storage amounts.

Production has become a serious concern for the government given the scale of this activity leading to unacceptable risks regarding public safety and security including the risk of fire, diversion to the illicit market and environmental health concerns.

This includes health risks to the authorized persons, co-occupants and neighbours due to the formation of mould, other potential pathogens and toxins resulting from high humidity and chemicals (e.g. fertilizers, pesticides, fungicides) and gases (e.g. carbon dioxide) used to foster plant growth. The integrity of the building infrastructure is often compromised leading to lost property value and/or costly remediation.

Considerations
Advances in marihuana cultivation render the old formula currently in the regulations obsolete. Fifteen plants will satisfy the supply of the majority of Authorized Persons (~ 80-85%) and is consistent with those American states that have similar programs.

Insufficient supply may be augmented by ordering from Health Canada in order to ensure reasonable access (which would affect approximately 25% of MMAP participants). This will also address the most urgent risks concerning: environmental health and safety (which suggests the maximum number of marihuana plants should not exceed 20 plants), diversion and fire.

Placing restrictions on possession and storage amounts to what is a reasonable holding for an individual, helps to disconnect the production from the authorization process. Higher daily dosage amounts (as agreed to by a physician and patient) do not translate into a proportionate increase in personal production and storage.

Should a personal use production licensee require more product, they would have access to the Prairie Plant Systems (PPS) product or those organizations who are in the Health Canada pilot program. This would also allow the government to monitor and control ordering limits.

However, with possession and storage amounts as well as a plant cap, there is still the possibility for diversion; therefore an inspection regime would be paramount to ensure compliance.

Legal Considerations
To be provided.

2. Change the Medical Categories to Limit the Number of Indications.

Description
Change Category 2 so that only those indications with any medical or scientific evidence, as determined by Health Canada (with the support of a scientific review panel), are allowed.

Background
The permitted indications under the MMAR are: Category 1 – end of life use and Category 2 – which allows almost any other indication supported by a physician. It is this second category which is problematic as there is little to no medical or scientific research for a number of these indications (e.g. marihuana as a specific treatment for an "ear ache").

Considerations
Health Canada would need to have an appropriate mechanism (such as a annual scientific review panel) to determine what conditions/diseases should be considered for Category 2 authorization.

Such a panel could be tasked with a mandate that would provide Health Canada with timely expert medical and scientific advice on questions and issues related to the MMAR and MMAP, in particular the content of the schedules to the MMAR, and those indications that are suitable for Category 2.

In the past, when the MMAR had 3 categories (Category 1 was for end-of-life, Category 2 was for conditions supported by scientific/medical evidence, and Category 3 was for any other conditions), such a panel was created but it was quickly disbanded after it became clear that, except for those conditions that had already been identified in 1999 (i.e. Category 2), there was little to no evidence for the committee to review for their consideration of scheduling review (i.e. moving a symptom/disease from Category 3 to Category 2).

Recent rulings on *Beren* and *Supervised Injection Sites* have indicated that judges question whether Parliament has a "right" to determine the "medical" treatment that a person may require. Although these discussions have not been heard, upheld or dispelled by the Supreme Court, health care policy design could take this into consideration.

Legal Considerations
To be provided.

3. Education of Physicians.

Description
Work with the Canadian Medical Association and the Colleges of Physicians and Surgeons to design an awareness program that informs doctors of the benefits and harms associated with marihuana use. As new scientific and medical evidence is developed, the Health Canada research monograph on marihuana for medical usage will be updated and posted on the Health Canada web site.

Similar to the current situation for methadone, any doctor wanting to support a marihuana application must take such a course and apply for a section 56 application under the *Controlled Drugs and Substances Act* (CDSA) to be

allowed to support applications for their patient to use marihuana for medical purposes.

Background
Physicians are the gatekeepers to the MMAP, but no Health Canada supported education program exists to advise them of the current research into the medical usage of marihuana, nor its possible harms. There is however, an accredited education program on cannabinoids provided by the Canadian Consortium for the Investigation of Cannabinoids (CCIC). Over 600 physicians have attended that program in Canada last year.

There is a trend of increasing amounts of marihuana being prescribed by physicians. Recently, Health Canada received a request (supported by a physician) to authorize the use of 70 grams per day for an individual with spinal cord disease. While this is an anomaly versus current practices, it would be prudent to provide information to doctors so they can better assess the implications of such use (e.g. translating this to the number of marihuana cigarettes per day, and the number of plants being grown in a home).

Considerations
For this awareness/education program to be successful, Health Canada would need support for its development from both the Canadian Medical Association and the College of Physicians and Surgeons.

Instituting a path for a section 56 exemption would allow Health Canada to increase its monitoring capability and to foster increased information exchanges with the Canadian Medical Association and the College of Physicians and Surgeons.

Legal Considerations
To be provided.

4. Ban Smoking of Marihuana for Medical Purposes in Public.

Description
Develop a list of public settings and situations (similar to the restrictions imposed on the use of marihuana for medical purposes in the United States) where marihuana for medical purposes cannot be smoked, by amending the current MMAR, developing stand alone regulations, or amending the CDSA.

Background
While the MMAR do not indicate where marihuana can be consumed, Health Canada holds the position that individuals authorized under the MMAR are expected to abide by all other applicable federal, provincial and municipal legislation, including legislation restricting smoking in public places.

Authorized individuals are advised of this through a letter upon approval of their application and issuance of an Authorization to Possess. They are also advised not to consume marihuana in a public place and not to expose others to any effects related to the inhalation of secondary smoke while using this controlled substance.

Considerations
Undertaking such a reform avoids any confusion about where authorized persons should smoke marihuana for medical purposes given that for all other purposes marihuana is a controlled substance and possession is illegal and subject to penalties such as a fine or imprisonment or both.

This path could also align with federal, provincial, territorial and municipal non-smoking legislation/regulation, where appropriate. Marihuana for medical purposes is primarily used as a smoked product. The potential risks to health from second-hand marihuana smoke need to be considered in developing appropriate restrictions regarding the place of use for marihuana for medical purposes.

However, Health Canada does not restrict the use of any other medicine (e.g. a diabetic can inject insulin at any place during a time of medical need).

Health Canada will also have to be careful as to when such an option will be consulted upon. Timing will be crucial if it goes before the larger regulatory reform.

Legal Considerations
To be provided.

5. Raise the Price of Marihuana Provided by Health Canada.

Description
Increase the fees for dried marihuana and seeds from the current amounts. Fully recover the purchase price of products and delivery charges to $10 per gram of product and $35 per seed packet (including all applicable distribution charges, i.e. shipping and handling).

Background
The MMAR currently allow applicants in the program to choose among 3 sources of marihuana. Among those, Health Canada provides access to a legal and a quality-controlled supply of marihuana seeds and dried marihuana for medical purposes, via a contractual agreement with PPS.

Currently, the cost of marihuana seeds is $20 per 30-seed package while the cost of dried marihuana is $5 per gram, plus applicable taxes. These fees were determined by assessing the street value of marihuana at the time (2001) with

the goal of ensuring that the price of Health Canada's marihuana products would be lower in order to encourage individuals to purchase legal quality-controlled dried marihuana. As such, the fees represent just a portion of the overall costs for the production and distribution of marihuana products.

The cost to supply the contract to the 20% who accesses Health Canada's supply is approximately $5M per year with an average collection of $1.3M in accounts receivable of purchased product.

The entire program, both Health Canada administration as well as the PPS contract, is now operating at an approximate $4M deficit, with a projected deficit of $6M in 2010/2011. With projections that more persons will be seeking entry into the program (likely 19,000 by 2013/2014), this deficit will grow and become unsustainable for the Government of Canada.

Considerations
Increasing the fee charged by Health Canada can be done without a regulatory change; however, any additional funds would still be allocated to the Government Consolidated Revenue Fund and would not be allocated to Health Canada. If Health Canada wanted to change this authority, Treasury Board Secretariat would have to agree to such a change. Initial discussions with Treasury Board Secretariat have indicated that given the size of the program deficit when compared to Health Canada's overall budget, it would be unlikely the Board would support a change in authority. Even before this avenue could be pursued, Treasury Board Secretariat has made it clear that policy cover would have to be first granted by Cabinet regarding the larger reform.

Increasing any of the fees associated with the program could be problematic because only 20% of current authorized users are accessing their product through the PPS supply. An unintended consequence of a fee structure increase could see these clients moving to other options for marihuana, such as growing their own, designating a producer or buying on the illegal street market.

If individuals do change their source for marihuana from the Government supply to private, there is a further need for an inspection regime to determine whether those growing marihuana for personal or designated use are meeting regulatory requirements.

Legal Considerations
To be provided.

6. Undertake Inspections.

Description
Create a team of inspectors that can inspect personal and designated production. These inspectors would work in conjunction with local by-law, public

safety, and law enforcement services. The goal would be to determine if inspections could take place given the limited powers of the MMAR and gather additional information.

Background

The MMAR have limited powers of inspection. Abuse of the production licence has been a serious concern for many and the ability to inspect production sites unannounced to verify appropriate security, production amounts and storage of inventories of a controlled substance, is a crucial cornerstone to a meaningful and comprehensive monitoring and compliance strategy.

All individuals who are authorized or become authorized under the MMAR are reminded and informed that they must abide by all other applicable federal, provincial, territorial or municipal legislation and regulations. This is clearly stated in the information material provided to persons authorized to possess and/or produce marihuana for medical purposes when they receive their authorization and licence from Health Canada.

However, Health Canada has no authority under the current MMAR to revoke licences should a licensee breach any of the above rules or even share any information with those responsible with the administration of these applicable rules.

It is not known by Health Canada whether a few, some or all of the licensees are in compliance with the terms of the MMAP regulations and authorizations. Without fully understanding this issue through inspections and compliance activities, it is difficult for a coordinated Government of Canada approach to address illegal grow operations vs. designated producers.

Health Canada has no authority under the current MMAR to revoke licences should any of these breaches occur, or to share any information with law enforcement in situations where there is contravention of the MMAR. Health Canada does compliance inspection while law enforcement does investigation; however, only limited information can be shared with law enforcement.

Considerations

The powers of inspection are the basis for ensuring compliance with regulations, especially if there is a need for suspension or revocation of licences. Should a cap be introduced to the number of plants one person can grow or a designated grower can grow on behalf of others, inspections will be important to maintain the integrity of the program.

With most marihuana production done within a private residence of the licensed individual, the ability of a Health Canada inspector to enter and inspect is dependent on the consent of the occupant and the perceived safety of the inspector during the inspection.

An inspector cannot enter a dwelling place without consent, except under the authority of a warrant, and it is unlikely that a judge/justice would consent to a warrant. The introduction of an inspection capability would mitigate this need. Training, safety, security and cost of such a regime would have to be considered, therefore, it is not clear whether a full inspection regime could be undertaken.

Legal Considerations
To be provided.

Section B Options – Long Term:

Section B represents a longer term solution to the issues associated with the MMAP. Current evidence suggests that personal production has been the root of many of the problems and challenges the MMAP is facing (please see Appendix A for further information). Two options are for consideration which are separate of one another. The distinguishing feature between the two options is the factor of how much the Government of Canada wants to be involved in the actual production of marihuana for medical purposes. It is estimated that both options would take two to three years to implement.

The background for both options is the same: The MMAR enables a situation in which individuals can be licensed to produce large numbers of marihuana plants in "legal" production operations in the absence of the tight controls applied to the production and handling of other controlled substances regulated under the CDSA. Given there are limited authorities to inspect personal dwellings, this could potentially result in large quantities of marihuana being produced in unsuitable locations or environments. This also increases the risk that marihuana produced for medical purposes could be potentially diverted to illicit markets; and/or, compromising the health of licensed persons, other inhabitants of the same or neighbouring dwellings and/or surrounding community members, as a result of mould, infrastructure damage and fire hazards associated with the cultivation of a significant number of plants in a single location.

1. Exclusive Health Canada Production.

Description
All forms of personal production are eliminated and the Government of Canada would become the only supplier and distributor of legal marihuana available for medical purposes. Health Canada would contract the production to a small number of suppliers and distributors and impose strict requirements for the sites, quality control of the manufacturing process and secured storage and distribution of the product to authorized persons.

A full cost recovery system would need to be implemented in parallel to address the ongoing increase in MMAP participants and to ensure program stability.

Considerations
Environmental health and safety concerns arising from residential personal production are eliminated while many of the stakeholder concerns (Fire, Police, Municipal) regarding production safety and security are addressed. This option would also reduce potential risk of diversion of the product.

Health Canada would ensure that marihuana produced under contract is compliant with good manufacturing practices and subjected to stringent quality controls, manufacturing and testing processes and given such central control and ease of inspection that minimal inspection resources would be required.

This option also satisfies international commitments (similar to some of the features implemented in the Netherlands) made through the International Narcotics Control Board.

However, costs to the MMAP are unclear and they could be significant since Health Canada would be required to meet the entire demand (versus only 20% presently ordering from Health Canada).

Public Works and Treasury Board Policies would need to be properly followed, making it difficult to regularly renew contracts with suppliers given the nature of the product and the small market. There would be a perceived conflict of interest given Health Canada is both the regulator and producer/distributor of the product. As the sole supplier, but dependent on a small number of contractors, a stable and predictable supply is not always guaranteed (e.g. crop wiped out due to disease, natural or man-made disasters).

Legal Considerations
To be provided.

2. Commercial Production.

Description
The Government of Canada production and distribution and all personal/designated production is terminated. Commercial sector providers would be granted a license (created in regulations) to establish a nongovernmental supply.

Commercial providers would be required to meet a series of comprehensive manufacturing requirements such as: good manufacturing practices; appropriate site zoning; proper security; safe packaging/labelling; proper recordkeeping; and ensuring the health and safety of the employees. Commercial providers could operate for profit or could operate as a non-profit organization.

Considerations
If implemented, this option would demonstrate the Government of Canada's commitment to address public health, safety and security issues by eliminating personal production and increasing the effectiveness of the MMAP by defining an appropriate oversight role for Health Canada.

It clearly establishes the parameters between licit and illicit marihuana production and leaves the marihuana market (for medical purposes) in the hands of a regulated private sector. Regulatory controls over the production and distribution of marihuana for medical purposes would be enhanced via greater ability to ensure compliance with the MMAR.

Cost savings for Health Canada may be significant given Health Canada would only administer the MMAP rather than supplying and distributing marihuana. This would allow for the reallocation of funds currently allocated to Health Canada production to other functions such as licensing, compliance, monitoring and streamlining of program delivery.

Stakeholders' demands for increased options to different marihuana varieties would be met. Compliance under existing inspection authorities (i.e. no administrative warrants or consent to enter personal dwellings required) would be easier to implement since the number of sites would be reduced from thousands of personal/designated producers (given residential sites no longer allowed to grow marihuana) to a smaller number of medium to larger producers.

Legal Considerations
To be provided.

Appendix A – Evidence

Blair, J. & Wedman, G. (2009). *Residual pesticides in former marijuana grow-operations: Determining safe levels*. Pacific Environmental Consulting.

- Grow operations can damage properties in a number of ways including:
  - Structural Damage
  - Faulty Wiring
  - Venting Furnace Exhaust Indoors
  - High Humidity
  - Pooling Water
  - Plumbing Modifications
  - Fertilizer Contamination
  - Pesticide Contamination
  - Fungal Growth
  - Electrical Modifications
- The results of pesticide swab samples collected in 139 homes identified 15 different pesticides.
- Permethrin is the most commonly identified pesticide in former illegal grow operations. The average concentrations of Permethrin and Malathion identified in homes were just below, and just at, the suggested acceptable levels; therefore, there is a high likelihood of finding elevated levels of these two pesticides in former grow operations.

British Columbia Safety Authority. (2005). *Information Bulletin: Electrical Hazards Resulting from Marijuana Grow Operations.*

- The British Columbia Safety Authority has determined that electrical installations associated with indoor residential marijuana grow operations typically present a significant risk to public safety, especially in residential neighbourhoods (p. 1).
- Considering this fact, the British Columbia Safety Authority has issued a warning to inspectors due to the potentially dangerous nature of an inspection of a marijuana grow operation. Before approaching a residential property where you suspect the presence of a marijuana grow operation, authorities are advised to request assistance from a police officer who will provide security and keep the peace (p. 2).

Fire Chiefs Association of British Columbia. (2004). *Report to the Government of British Columbia on an Urgent Matter of Public Safety.* Government of British Columbia.

- 3.5 % of illicit grow operations were discovered as a result of a fire. It is believed that the misuse of electrical energy resulted in most, if not all cases (p. 4)
- The Fire Chiefs Association of British Columbia neither finds that the current methods of dealing with marihuana grow operations as effective or acceptable in terms of reducing fire related occurrences nor is it respectful of the risk to the health and safety of the public and firefighters due to electrocution.

Garis, L. (2008). ***Eliminating Residential Hazards Associated with Marijuana Grow Operations and the Regulation of Hydroponics Equipment: A brief on, British Columbia's Public Safety Electrical Fire and Safety Initiative.*** **City of Surrey Fire Service**

- The risk of fire and serious damage to private property resulting from marijuana grow operations in part relates to the propensity for marijuana grow operators tampering with electrical equipment to obtain electricity required to cultivate marijuana (p. 2).
- Common hazards found in grow operations:
  - Inadequate electrical protection of fuses and circuit breakers;
  - Electrical energizing of the ground within 10 metres of the ground rod, typically placed at the side of the grow operation when a by-pass is utilized;
  - Improper installation of electrical systems resulting in tripping, shock and fire hazards;
  - Failure to properly enclose electrical bypasses resulting in exposed fire and shock hazards;
  - Overloading of electrical conductors resulting in an increased risk of electrocution to individuals standing in water at the site, such as fire protection personnel, police officers, by-law officers, etc.;
  - Lack of monitoring of grow operations which can result in fires being well established before they are noticed. This poses additional dangers to neighbouring properties (p. 2).

Garis, L. (2005). ***Eliminating Residential Marijuana Grow Operations – An Alternate Approach: A report on Surrey, British Columbia's Electrical Fire and Safety Investigation Initiative.*** **City of Surrey Fire Service.**

- Indoor marijuana grow operations tend to share similar characteristics.
- To power their equipment, grow operations can consume two to five times more electricity than a typical home (p. 7).
- Grow operations typically overload the electrical circuits, which could cause short circuits or electrification of adjacent metal. This brings with it a significant electrocution hazard for unsuspecting electrical professionals or firefighters (p.8).
- A home with a grow operation is 24 times more likely to catch fire than a typical home (p.8).

- 8.7% of Surrey's 173 house fires in 2003, were directly attributed to grow operation electrical problems, and the average value of property loss in grow operation electrical fires was nearly twice as high as for typical house fires in Surrey (p. 8).
- The humidity required for an optimal growing environment frequently leads to mould and fungus – a health hazard – while the buildings' structural integrity can be compromised by unapproved renovations and sloppy irrigation practices that rot flooring. The operations can also create a low-oxygen environment, and gases from chemicals used in the process can build up in the home (p. 9).

Garis, L. & Jessop, J. (2008). *Regulations to Produce Medical Marihuana.* Niagara Falls Fire Service, Ontario Association of Fire Chiefs, City of Surrey Fire Service, & Fire Chiefs Association of British Columbia.

- There is no mechanism in place to ensure that participants are adhering to provincial, regional and municipal fire, safety and electrical regulations. The result is increased and unaddressed fire, health and safety risks to the building occupants and emergency responders (p. 1).
- Canadian fire departments are finding that licensed growers are not adhering to zoning, fire and safety regulations. For example: A grow operation in Niagara Falls was inspected by the fire service and they discovered violations to the provincial fire code, building code, and electrical safety code (p. 1).
- Sites inspected by the Surrey Electrical Fire Safety Team, were using 5 times the average daily electricity usage. Violations of municipal regulations were found at all sites as well as violations to the provincial electric code, building code and fire code. Some of the sites also contained improper chemical storage, mould, excess moisture, and fire hazards (p. 1).
- Growing marihuana (legally or illegally), tends to result in health, fire and safety hazards due to electrical reconfiguring, structural changes, and excessive moisture (p. 1).

Ontario Association of Chiefs of Police. (2003) *Green Tide: Indoor Marijuana Cultivation and its Impact on Ontario.*

- The likelihood of fire in a grow operation may be as much as 40 times greater than the likelihood of fire in a typical private dwelling in Ontario (p. 2).
- The potential for violence in and around grow operations is also very real: in York Region there have been at least two homicides directly related to grow operations (p. 2).
- Human health risks can result from the mould sometimes associated with marihuana hydroponic cultivation, the chemicals used to foster plant growth, and the relatively high concentration of carbon dioxide

(CO2) and carbon monoxide (CO) suspected to exist in some grow operations (p. 2).

- The large amounts of electric power required to operate the high-wattage grow lights can deteriorate the wiring in a dwelling, rendering it unsafe for normal usage (p. 18).
- The high degree of humidity and moisture produced by a grow operation can engender significant amounts of mould development on the walls and ceilings (p. 22).
- Approximately four percent of grow operations (1 in 25) in Ontario experienced fire in 2001-2002. This is consistent with fire rates in British Columbia, where 3.5 percent of grow ops reportedly experienced fire in the 1997-2000 period (p. 24).
- In 2001 in Ontario, there were 4,183 fires in private dwellings and a total of 4,556,240 private dwellings. The general probability of fire in a private dwelling in Ontario, in 2001, may be approximately .09 percent (1 in 1,089 houses). Thus, assuming 2001 is a typical year with regard to fire rates, the likelihood of fire in an Ontario grow operation could be as much as 40 times greater than the likelihood of fire in a typical private dwelling in Ontario (p. 24).
- Because grow operations contain a high level of relative humidity, they are prone to the build-up of various moulds. At high concentrations, these moulds can be damaging to human health, causing and/or exacerbating immunological diseases such as hay fever, allergies, and asthma, as well as causing infections and even cancer (p. 29).
- In addition to the problem of mould, grow operations also raise the spectre of toxic smoke as well as land and groundwater contamination. Operators often store large quantities of chemicals such as liquid nutrients, pesticides, and fungicides on the premises. If ignited, some of these chemicals could engender toxic smoke. If spilled in the grounds surrounding a dwelling, the liquid nutrients and fertilizers could engender land and water pollution (p. 30).
- As well, carbon dioxide (CO2), which is sometimes used to enhance plant growth, can have serious human health risks. CO2 is naturally present in the atmosphere at levels of approximately .035 percent. Higher concentrations can affect respiratory function and cause excitation followed by depression of the central nervous system. High concentrations of CO2 can displace oxygen in the air, resulting in lower oxygen concentrations for breathing. Therefore, effects of oxygen deficiency may be combined with effects of CO2 toxicity (p. 30).
- In order to vent the pungent smell of the marihuana plants, operators sometimes purposely disconnect furnace piping, allowing the emission of carbon monoxide (CO). They also sometimes erroneously believe that CO emitted by furnaces fosters plant growth (p. 30).

Health Canada Meeting with Ontario Fire Marshals. (March 30, 2009).

- In a Health Canada meeting with the Fire Marshal of Ontario and the Manager of Operational Support Fire Investigations Services, certain public safety issues were highlighted:
  - Inappropriate venting of gases (e.g. heat and humidity), which may damage infrastructure and make the structure unsafe (e.g. rot supporting frame or foster mould formation)
  - Overload circuits which can lead to fire (bypass and steal electricity with unsafe connections).
  - Use and storage of chemicals and pesticides to accelerate plant growth (not intended for domestic use).
  - Compressed gas cylinders on site (e.g. carbon dioxide also used to facilitate plant growth).
  - Changes to Municipal Act in Ontario - Law Enforcement and Forfeited Property Management Statute Law Amendment Act, 2005 – municipal officials to determine if marihuana grow operation property is safe or if it would require remedial work.
- The Ontario Fire Marshal also noted that in many cases, they have seen similar production set-ups for licensed production.

LeForte, N. (2009). *Inter-Office Memo RE: Electrical Concerns Relating To Medicinal Marihuana Grow Operations.* Surrey City of Parks.

- Electrical inspectors in the City of Surrey have stated that in many cases there is little difference in the electrical installations between legal medicinal grow operations and illegal grow operations. In both types of installations, there has been little regard to proper or safe installations, thus exposing the occupants and their neighbours to a real electrical fire safety hazard (p. 1).
- In most cases, the electrical inspectors noted that installation is done without good knowledge of the electrical trade to provide for a safe installation (p. 1).
- Tenants will sometimes apply for and obtain a license to grow marihuana for medicinal purposes. The licensee installs the operation in a leased or rented premise without the owner's knowledge. This can have serious impacts on the safety, future value and or insurability of the premise all without the owner's knowledge (p. 1).

Little, W. & Nash, E. (2004). *The Reality of Safely Cultivating – Legal, Organic and safe.* Island Harvest Certified Organic Cannabis.

- The cultivation of cannabis is the same as other agricultural crops. The plant requires light, water and food - preferably in an optimal environment to achieve a good consistent quality product. Growing cannabis has very basic cultivation, safety and environmental requirements. Thus, if the house is not properly equipped, a grow operation can inflict significant structural damage on the dwellings in which the operation is housed (p. 3).

Markham Ontario. *Marijuana Grow Operations Information Page.* (June 18, 2009). http://www.markham.ca/Markham/Departments/BldStd/BldInsp/MarijuanaGrow.htm

- According to the Insurance Bureau of Canada (2004), the average claim to repair the damage caused by a grow operation was $41,000, not including lost rent.

National Collaborating Centre for Environmental Health. (2009) *Recommendations for Safe Re-Occupancy of Marijuana Grow Operations.* Public Health Agency of Canada.

- Grow operations can cause several health and safety problems including:
  - The presence of biological hazards such as mould due to excess moisture (p. 1).
  - The presence of chemical hazards related to chemical spills and residues from the use of pesticides, fertilizers, and solvents used for the extraction of tetrahydracannibol (THC) (p. 2).
  - In grow operations, bypasses and additional wiring necessary to produce the extra light required for optimal plant growth can overload the electrical system if not repaired (p. 2).
  - All houses and buildings have a background concentration of settled spores. Spores result in mould growth if there is suitable temperature, humidity and substrate. As adequate temperatures and the presence of nutrients are usually met in indoor environments, fungal growth usually results from a moisture problem (p. 2).
  - Investigators of grow operations may find signs of chemical spills or residues such as staining, odours, or mineral deposits. These residues may be present near drains, floor areas where water traveled towards drains, or in bathrooms and kitchens that have served as chemical mixing rooms for THC extraction, pesticides, fertilizers, and acids and bases (p. 3).
- If there is a makeshift ventilation system to either vent the odour of the plants or to collect CO2 from furnace and hot water flues to improve plant growth, there is a risk of CO poisoning.

Plecas, D., Diplock, J. & Garis, L. (2009). *Commercially Viable Indoor Marihuana Growing Operations in British Columbia: What Makes them such a Serious Issue?* The Ministry of the Attorney General Province of British Columbia

- The changes made to facilitate the growing of marihuana involve practices that generally require specific training, certification, and inspection to ensure proper function and safety (p. 6).

- When a marihuana growing site is located within a residential neighbourhood, the risks associated to errors in, or abuses of, construction, ventilation, chemical usage, waste disposal, plumbing, electrical work, and security are assumed by others without their knowledge and consent (p. 6).
- According to a focus group on illicit marihuana grow operations, 90% had improper ventilation, leading to high levels of humidity and thus exposure to mould (p. 6).
- Growers may also try to improve the yield of their operation by using CO2 and chemicals (Surrey Fire Service focus group, July 10, 2009). CO2 is used to increase the rate of growth and tolerance to higher temperatures in growing sites. Exposure to higher than normal levels of CO2 can be dangerous, and the problem may be further compounded when the increase of the gas coincides with displacement of oxygen (p. 6).
- Chemical residues are almost always left behind by marihuana growing operations (p. 7).
- Because indoor marihuana grow operations require a great deal of electricity to power the typically 1000 watt bulbs used to provide the plants with light, these operations are susceptible to serious electrical hazards including fire. Risks include inadequate electrical protection of fuses and circuit breakers, improper installation of electrical systems, failure to enclose electrical by-passes, and improper monitoring of grow sites (p. 7).
- These dangers are not limited to only the grow operators, but pose a serious threat to neighbours and first responders. Contamination from the chemicals used in the growing process is a major health concern for people in neighbouring properties. According to the focus group, there is a real risk of drinking water contamination in the neighbourhood as a result of back flushing (p. 8).

Plecas, D. & Malm, A. *The Connection Between Marihuana Growing Operations and House Fires in British Columbia*. Centre for Criminal Justice Research and Department of Criminology and Criminal Justice, University College of the Fraser Valley.

- We know that the average illicit indoor marihuana grow operation involves the production of 192 plants per crop (several MMAP participants can grow close to, or more, than this amount) and to do that, a grower (if using electrical power) would either have to be diverting electricity or be using excessive amounts of electricity relative to what would ordinarily be required to power the average single family residence (p. 10).
- In considering the risk of fire associated to grow operations, it is important to keep in mind that not all fires involving grow operations (as indicated by province-wide data presented earlier) are associated to an electrical by-pass issue. Rather, it would appear that most fires

are associated to the overloading of electrical circuits and poor wiring (p. 8).

- The results of our study show that grow operations in single family dwellings are a fire risk. This is assumed given that 1 in 22 grow operations resulted in a house fire within a community where the normal likelihood of fire over a seven year window averaged 1 in 525 (p. 9).
- The property damage involved in a grow operation fire was nearly double the damage assessed for house fires generally in the same community (p. 9).
- The source of grow operation fires are clearly associated with electrical problems caused by cultivation. Some of those problems involve hydro by-passes, while others were related to relatively excessive hydro consumption. In either case, the blame for these fires can be traced back to the failure of the individuals in control of grow operations to comply with electrical standards (p. 9).

Royal Canadian Mounted Police Criminal Intelligence, (2009). *Criminal Intelligence Brief: A Review of Cases Related to the Medical Marihuana Access Regulations.*

- 70 Marihuana Medical Access Regulations (MMAR) violations reported to the Royal Canadian Mounted Police (RCMP) were examined. Of the 70 cases, 40 were for production and trafficking violations, which exceeded the terms of the participants' permits (p. 1).
- Of the 70 cases, 6 also involved a participant with a prior drug conviction or charge (p. 1).
- Cases reviewed identified community safety issues regarding medical marihuana grow houses such as increased risk of break-ins and home invasions because of the potential profits associated with the illicit sale of marihuana (p. 4).
- Children can live in a residence where a license holder is growing and storing marihuana. A child living with a licensed user or grower has increased access to marihuana, which has potential negative ramifications. In British Columbia, a recent examination of the health of children living in houses where marihuana is grown raised serious concerns. Most of these children were found to have respiratory problems in reaction to mould and pesticides used to grow marihuana. These children are also at risk of residential fires and violence due to "grow-rips" (p. 5).
- Licensed growers can choose whatever technique they want to grow the plants. Certain techniques used by licensed growers reviewed for this report required special lighting, chemicals and irrigation systems. The same techniques are used by illicit marihuana growers to increase plant growth. These techniques are potentially hazardous and can result in residential fires, spilling of chemicals in sewer systems and injuries to growers and their families (p. 5).

- A major issue is the number of plants a licensed producer can grow as it has been determined that a single marihuana plant grown with seeds provided under the MMAR can produce 30 times more dried marihuana than estimated by Health Canada. Some permit holders are growing marihuana for medicinal purposes and selling the excess for personal gain (p. 2).
- The dwellings of licensed marihuana producers under the MMAR are not being adequately inspected. The current ratio of Health Canada inspectors to licensees across Canada is 1 to 257. Permit holders are expected to destroy excess dried marihuana. This regulation relies on the good faith of the license holder which is not effective given the numerous cases of diversion encountered thus far. The powers of Health Canada inspectors are very limited. They can only enter a dwelling with consent, and can only inspect the building that the license holder has designated as the growing area.
- Police officers do not have the authority to inspect license holders in their jurisdiction without the suspicion of criminal activity and a search warrant. This has made it difficult to determine if a licensed producer has more marihuana plants/dried marihuana in their possession than they have authorization to produce (p. 3).
- MMAR policy specifies that security measures against loss or theft of growing or storing marihuana are left to the applicant. Cases reviewed have identified community safety issues regarding medical marihuana grow houses such as increased risk of break-ins and home invasions because of the potential profits associated with the illicit sale of marihuana. The activities of licensed growers cause worries to unsuspecting citizens and the current regulations do not give police the necessary tools to ensure the safety, security and trust in the protection it is supposed to provide for citizens.

The Canadian Real Estate Association. (2004). *Grow Ops: What Realtors Need to Know.*
http://www.schumacherrealty.com/pdfs/realtor_toolbox/GROW%20OPS.pdf

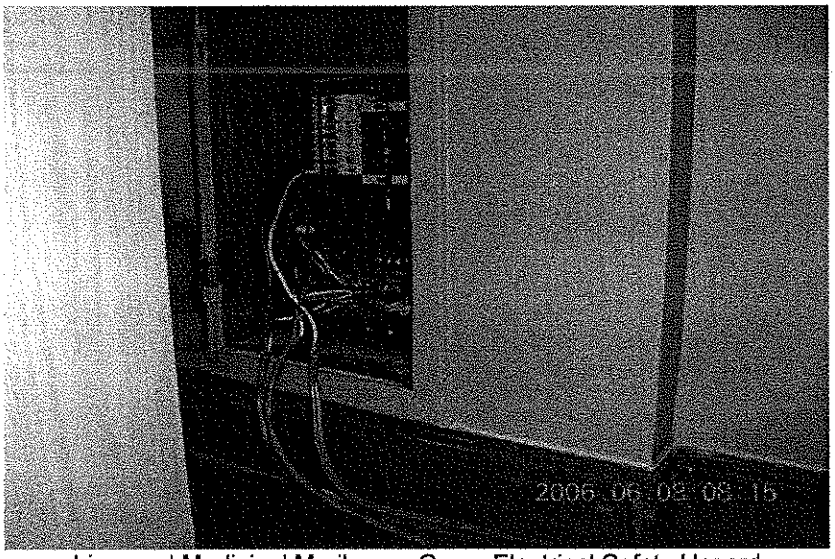
- To grow a hydroponic marijuana crop indoors, a number of renovations to the property may be required. These renovations have the potential to cause defects to the housing structure of the grow operation. Repairs can cost several thousand dollars, and in extreme cases, the house has to be completely torn down (p. 3).
- Large amounts of water are required to grow a marijuana crop. A custom hook-up in the basement is often installed. Growers need some form of ventilation to handle the excess moisture generated. This may require modifications to the drain system, or venting through the roof (p. 3).
- The large amounts of moisture required to grow indoors can generate a considerable amount of mould and spores. There are a number of

noxious gases that develop in the process. It's also not unusual to find that pesticides have been used on the crops (p. 3).
- If electrical standards are not met, connected cables can create fire hazards. Additionally, heavy power usage wears out the transformers prematurely, which can result in fires even months or years down the road (p. 3).
- Wiring and lighting may be modified, thus overloading electrical systems and making the houses hazardous to entire neighbourhoods (p. 3).

Van Leeuwen, R. (2004). *Marihuana Grow Operations and Hydro Bypasses Report: Draft.* Surrey Fire Department.

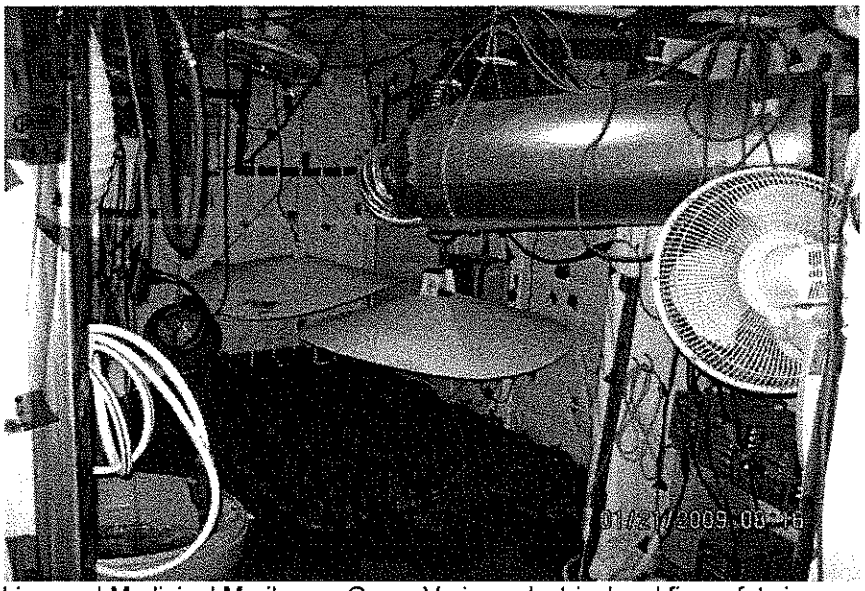
- Grow operations may overload electrical conductors. This tends to melt the insulation, causing short circuits or inadvertent electrification of metal devices that they pass by. An unsuspecting fire official could easily be electrocuted if he or she is standing in water used in the fire fighting effort, and touching the metal object (p. 3).
- Since electrical installations are rarely done by electrical professionals, the wiring to all of the equipment in the grow operation is vulnerable to electrical faults due to inadequate installation. This can present a tripping hazard, a shock hazard, and a fire hazard (p. 3)
- Electrical installations are not subjected to an inspection; therefore grow operations are an electrical safety hazard and a fire hazard to:
  - The occupants.
  - The unsuspecting public who access the property.
  - Adjacent properties.

The following pictures represent a very small sample of licensed marihuana grow operations to reflect the concerns and to demonstrate the hazards associated with both.

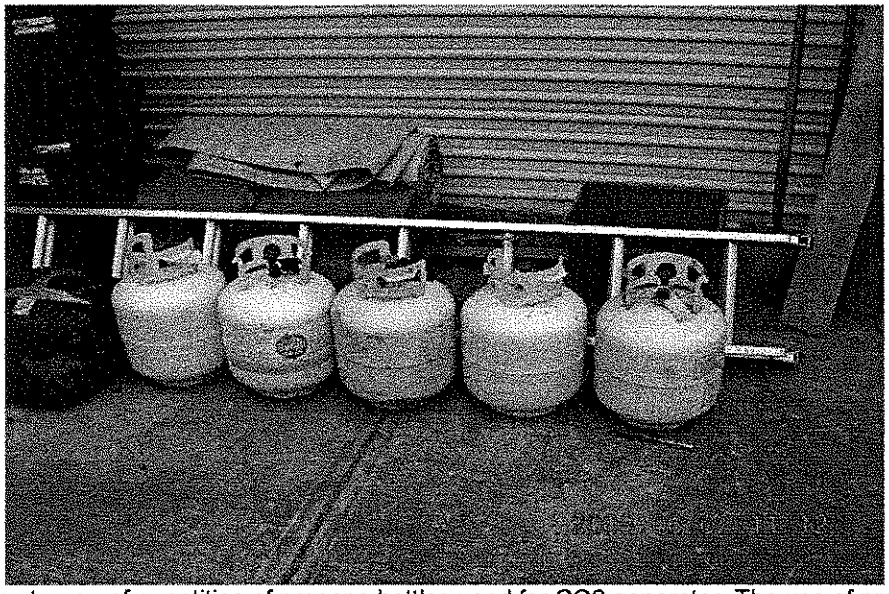


Licensed Medicinal Marihuana Grow- Electrical Safety Hazard
Work performed without permit or inspection.

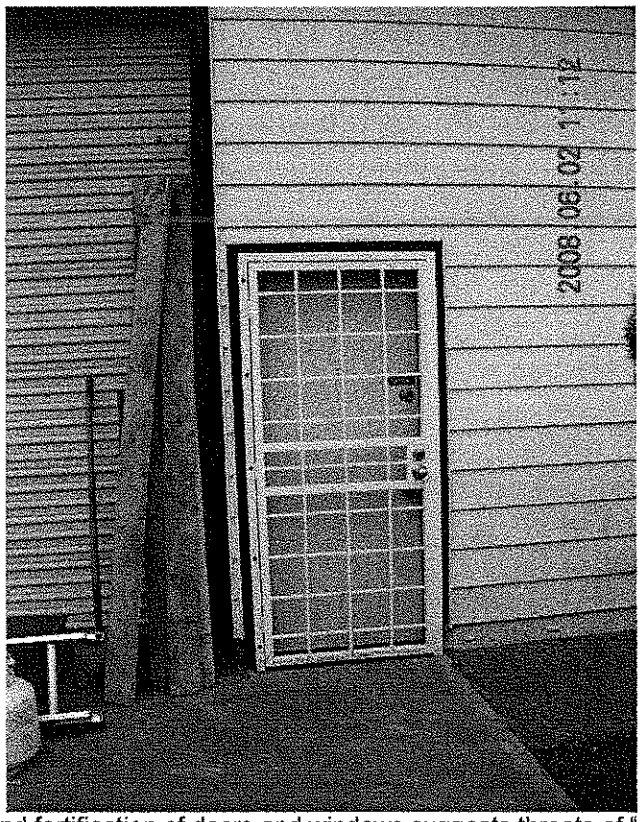
Licensed Medicinal Marihuana Grow- mould and electrical safety issues.



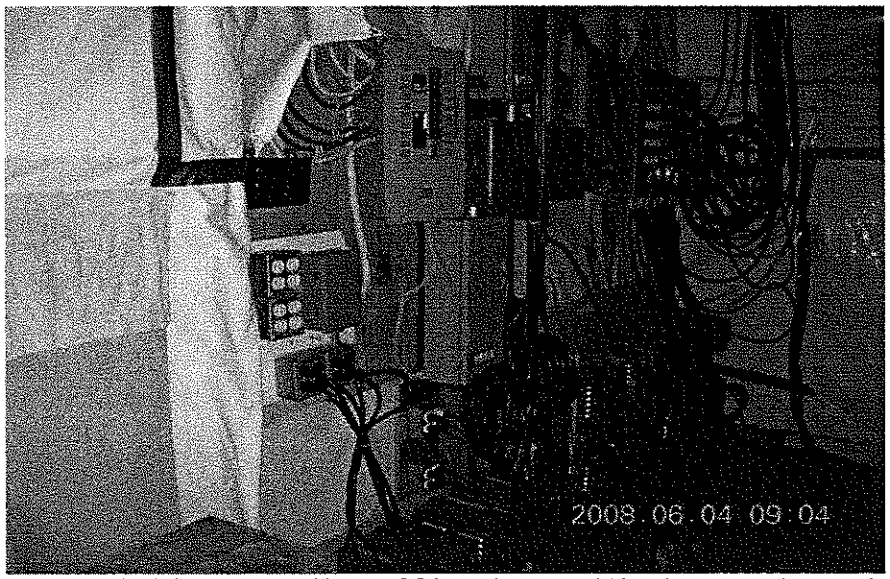
Licensed Medicinal Marihuana Grow- Various electrical and fire safety issues.



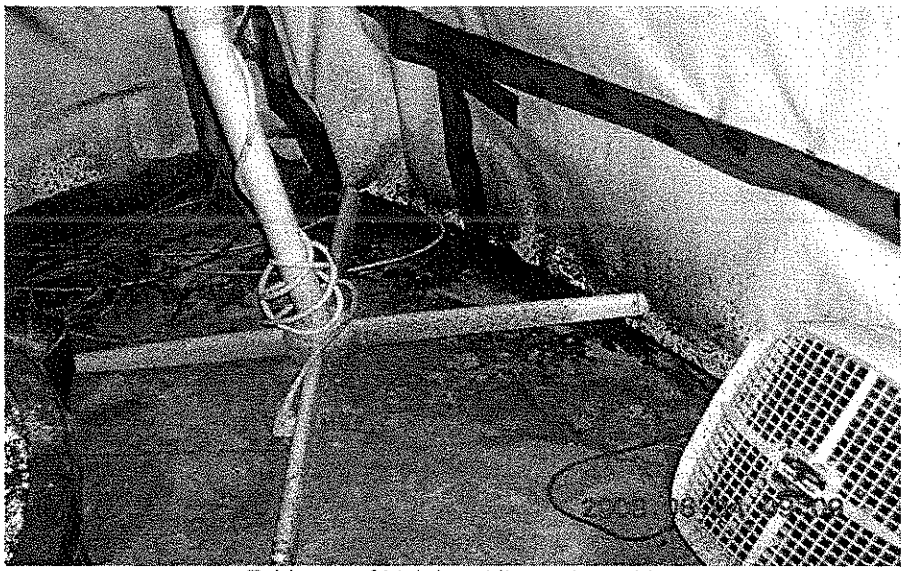
Unsafe storage of quantities of propane bottles used for CO2 generator. The use of propane to introduce C02 into the grow room is common practice. Quantity and storage of tanks is of concern, as is the excess CO2 in the residence.



Security and fortification of doors and windows suggests threats of "grow rips".



Unapproved electrical distribution with non CSA equipment. 110 volt receptacles used with 240 volt equipment. Electrical equipment suggests a very large quantity of plants, considering one ballast per light and one light handling from 12-16 plants



Evidence of high humidity and mould.

Unsafe storage and use of chemicals.

Brief Web Scan of Available Compassion Clubs in Canada:

1. BC Medical Marijuana (mail order)
2. British Columbia Compassion Club Society (BCCCS)
3. Calgary Medicinal Marijuana Center
4. Cannabis As Living Medicine (CALM)
5. Cannabis Buyers Club of Canada
6. Cannabis Buyers Clubs of Canada
7. Centre Compassion Quebec
8. Club Compassion de Montreal
9. Green Cross Society of B.C.
10. Hemp Users Medical Access Network (HUMAN)
11. Le Centre Compassion de Montreal
12. London Compassion Society
13. Marijuana Home Delivery (medical use only)
14. Marsh Marijuana Club
15. Medical Cannabis Club of Guelph (MCCG)
16. Medical Compassion Clinic
17. MedMe (CMMS)
18. Mid-Island Compassion Club
19. Mobile Access Compassionate Resources Organization Society
20. Okanagan Compassion Club Society
21. Rainbow Medicinal Cannabis
22. The Halifax Compassionate Club Society
23. The Vancouver Medicinal Cannabis Dispensary
24. Toronto Compassion Centre
25. Treating Yourself Medical Marijuana Club
26. Vancouver Island Compassion Society

This is **Exhibit "N"** 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

Medical Marihuana Program

The Medical Marihuana program was created in 2001 in response to a court case that found the criminal prohibition on marihuana use was invalid without provision for a medical exemption. The court found that there was ample evidence of therapeutic benefit to some patients for some conditions. This therapeutic benefit is recognized in the international convention limiting marihuana use to which Canada is a party. Of all of the drugs with potential therapeutic effects, marihuana stood out as the only one subject to a complete prohibition. Far more dangerous drugs, such as morphine and heroin, were subject to regulation with regard to their medical uses, not complete prohibition, and could be obtained by physician prescription in appropriate cases.

Thus a program providing for legal medical use is required in order to maintain the criminalization of marihuana.

The current program has been subject to a number of court challenges over the years and has been modified to meet the various court decisions as well other difficulties that have arisen. There remain however a number of issues.

Other jurisdictions are dealing with similar issues. Fourteen states in the US have some law allowing the medical use of marijuana and 2 others have provided either prescription powers to doctors or a defence on medical grounds. Other countries such as Austria, Israel and the Netherlands have also enacted various regimes to accommodate the medical use of marihuana.

Legal Parameters

Various court decisions over the years have given rise to a number of principles, some of which support the controls implemented by the government program and others that have invalidated certain provisions.

- The constitutional legitimacy of the criminal prohibition on the possession, sale and production of marihuana has been upheld - i.e. the courts have rejected arguments that individuals have a general right to use marihuana.

- There is a legal right for individuals who have demonstrated a medical need to have access to a legal supply of marihuana. Any regime of criminalization that does not provide for this will be struck down.

- The use of doctors as gatekeepers and to set the daily dosage has been supported by the courts, as was the requirement in non-end of life cases for a declaration by a doctor (in that case a specialist) that all conventional treatments for the symptom have been tried or considered. In summary, provided there is a reasonable medical justification, requirements around access and use are likely to be upheld. Requirements that are analogous to those on other drugs are likely to be easier to defend.

- The government is <u>not</u> required to supply marihuana to medical users. However it must ensure that any state barriers to a licit supply for authorized users are removed. In other words, if the overall effect of the regime is to require the authorized medical user to go to the black market for supply, the regime, or at least the offending parts of it, will be struck down.

Issues

The current regime has a number of practical, legal and medical issues in 3 main categories:

1.Supply

The company under contract to Health Canada supplies about 20% of medical use marihuana. Over 70% of the supply comes from individual growers - either patients or "designated persons". As there are regulatory limits on how much can be grown by 1 person or in 1 place, this means that a considerable amount of growth takes place in small locations, including private homes. This has resulted in a number of challenges:

1) The same health and safety risks of illegal grow ops are quite prevalent - e.g. fire risk due to improper electrical usage, mould contaminated air.
2) Security issues are also of concern. The value of the crop can attract criminal elements with attendant risks of home invasions and robbery.
3) There are few regulations regarding sites beyond limits on the number of licences at 1 site and the amount that can be possessed at one time. As a practical matter it may be difficult for small individual producers to comply with many security and safety regulations.
4) It is questionable whether the current limits on how many patients can be grown for at one site will survive a court challenge. The courts struck down as arbitrary the limit of 1 patient per designated grower. For such a regulation to survive it must not unduly restrict the ability of organizations to take advantage of economies of scale, carry out research on the efficacy of varying strains of cannabis and/or other activities directed towards improving medical treatment to eligible patients.
5) The supply from the government contractor is sold below cost. The original reason for that was to encourage access through that legal supply. However, given that the proportion supplied via that source has remained steady for the last few years, there seems little reason to continue this subsidy.

2. Usage

There are a number of issues related to the conditions for which marihuana is authorized, the dosages and methods of use:

1) While there is considerable evidence that marihuana provides health benefits to some patients, this does not meet the normal standards of drug testing and approval. The range of conditions for which marihuana has been approved has grown including some conditions for which there is little evidence of efficacy. There is little if any evidence with regard to appropriate dosages for different conditions and different delivery mechanisms.
2) Doctors have received little education in the medical use of marihuana. Recently some material has been available but a considerable gap remains.

3. Regulatory Regime

The regime has faced a number of court challenges but also faces practical issues:

1) There is no effective inspection capacity. Thus it is impossible to say whether the requirements that do exist are being followed or are effective in achieving their aims. As long as there are many small growers any effective inspection capacity will probably be difficult and expensive to achieve.
2) Lack of scientific research has hampered the ability to contain the number of conditions for which marihuana is authorized or the individual dosages. Clearly some in the medical community who have spent time on this issue are skeptical about some uses but the lack of scientific research (coupled with the lack of physician education) has made it as difficult to justify limitations on the conditions for which it is used.

Way Ahead

The biggest immediate challenge is with the **production facilities** of marihuana for medical use.

Most marihuana for medical use is produced in small facilities, often private homes. From a security and health point of view, small growers seem to present the greatest risks. Both police and fire officials are concerned with the challenges to their responsibilities presented by such facilities. The police indicate that fewer facilities with more security regulations (coupled with regulatory enforcement) would considerably reduce their concerns.

Regulatory inspection is a great challenge with regard to such facilities - the numbers greatly augment the resources that would be required for an effective effort and the constitutional limitations with regard to inspecting homes further complicate the issue.

There are 2 options for the way forward with regard to production facilities:

1. **Continue on the current path,** amending the regulations as required from time to time by court decisions. There are several implications to this option:
   i. The next amendments likely to be required are with regard to the limits on the number of authorized users a designated person can grow for - it is not at all clear how the rationale for the latest revisions differs from that which was struck down.

   ii. The health and security concerns of police and fire officials would remain unaddressed.

   iii. Regulatory inspection, even if additional resources are added, is unlikely to be very effective in view of the number of sites and legal challenges re inspecting dwelling houses.

2. **Move towards production at fewer but larger facilities,** with increased security, health and safety requirements.
This could be done either by moving to all supply through a government contractor(s) (increasing significantly the amount and number of different strains of supply), or by eliminating the limit on the number of authorized users a supplier can serve and enacting regulations with stringent security and health requirements.
I do not favour a sole government supply. It moves marihuana one further step away from the way in which other medical therapies are treated, government would take even further ownership of the issue (and perhaps risk further legal exposure) and finally it gets government into business, not usually a strength of government.

There are several implications of moving towards fewer but larger facilities:

(i) The capacity to introduce stringent security, health and safety measures is enhanced with a concurrent reduction in the risks that currently concern police and fire officials. The closer such measures can come to those in place for other controlled drugs that also have medical uses the easier the defence of any court challenge is likely to be.

(ii) Establishing an effective regulatory inspection regime becomes more feasible - there are fewer sites to oversee and the legal challenge with regard to dwelling houses is removed.

(iii) An effective transition regime would be required in order to ensure that court cases are not lost due to an inadequate supply. Such cases might risk impairment of the more stringent security and health measures. Following an appropriate transition period consideration could be given to banning production in homes.

Note: Option 1 may also lead to larger production facilities. Unless a justification for limits on numbers at sites is developed and accepted by the courts, all such limits may be ruled unconstitutional. Without development of the security, health and safety regulations referred to under option 2, the result may be legal large sites with no such requirements, at least for a certain period.

Other Issues

Regardless of the option choice with regard to supply there are several other issues:

1. **Education of doctors** The CMA has introduced some training recently and there is now a group of researchers trying to raise the level of physician knowledge, but it is apparent that most doctors know relatively little about appropriate use and dosages. Increased education may reduce both the dosage levels and the number of conditions marihuana is authorized for. The government role in this could vary from simply showing connections to the training now available on its web site, to actively reaching out to all physicians authorizing medical use of marihuana to inform them of available education material, to providing some funding for the development of education programs. This latter option would probably be best considered once additional research has had been done. (see below).

2. **Research** There is much less research available on the medical effects and usage of marihuana than is the case with other drugs. Further research could reduce the number of conditions marihuana is being authorized for and the dosages. It could also affect the delivery mechanisms.
Even gathering all the known scientific knowledge in one scientifically recognized format would help ensure that usage is contained to conditions and dosages with some evidence of effectiveness.
There is a publicly funded credible organization that could do this - the Council of Canadian Academies. The Council conducts assessments of the state of knowledge of scientific issues related to public policy. To do so they convene panels of experts - Canadians and non-Canadians. The government has the right to request 5 such assessments per year.
There is also a possibility of conducting research in partnership with other countries that also have an interest in this area. The Canadian Consortium for the Investigation of Cannabinoids is a group of Canadian researchers with international connections.
There is already government funding directed towards medical research. Some of this could be tapped for research in this area and/or additional funding could be directed. There is some suggestion that the major health research funder (CIHR) has not been interested in funding research in this area since the government cut the specific program so it might have to be made clear that research in this area was wanted.

3. Limits on where to use marihuana for medical purposes There is some suggestion that the government should enact regulations governing where medical marihuana can be used. I am advised by government lawyers that the provinces already have jurisdiction to regulate this area and I would recommend it be left to them. This is likely to be a contentious and complicated area with variations across the country.

4. Costs At the moment the cost of the medical marihuana provided by the government contractor is below cost and reportedly below the costs of other supplies as well. I see no reason to keep the low price and would recommend the price be raised in the near future in order to reduce the cost of the program to the taxpayers.

5. Inspection regime I am doubtful of the ability to create an effective regulatory enforcement regime under the current program of many small production sites, many of which are in homes. The integrity of any regulatory regime is questionable without some form of enforcement. Effective enforcement is probably the most compelling reason in favour of option 2 above (i.e. moving to fewer, larger sites with more stringent security and health measures). If the choice is to stay with the current path then any additional inspection measures should be modest.

This is **Exhibit "O"** 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 2011-80

Field C

News Release

Government of Canada Considers Improvements to the Marihuana Medical Access Program to Reduce the Risk of Abuse and Keep our Children and Communities Safe

June 17, 2011
For immediate release

Backgrounder: Marihuana Medical Access Program

OTTAWA –To reduce the risk of abuse and exploitation by criminal elements and keep our children and communities safe, the Honourable Leona Aglukkaq, Minister of Health, today announced that the Government of Canada is considering improvements to the Marihuana Medical Access Program.

"Our Government is very concerned that the current Marihuana Medical Access Program is open to abuse and exploitation by criminal elements," said Minister Aglukkaq. "That is why we are proposing improvements to the program that will reduce the risk of abuse and keep our children and communities safe, while significantly improving the way program participants access marihuana for medical purposes."

The Government is launching public consultations today with Canadians on the proposed improvements. A consultation document has been posted on the Health Canada website which contains the proposed improvements. Interested Canadians are invited to provide comments until July 31, 2011. Input from these consultations will be considered in the development of new regulations, which Canadians will again have an opportunity to comment on when the proposed regulations appear in *Canada Gazette*, Part I, in 2012.

"These proposed improvements reflect concerns we have heard from all kinds of Canadians including law enforcement, fire officials, municipalities, program participants and the medical profession," said Minister Aglukkaq.

It is important to note that the legalization or decriminalization of marihuana is not a part of these improvements. Marihuana will continue to be regulated as a controlled substance under the *Controlled Drugs and Substances Act*.

Until improvements to the program are in place, the process for applying for an authorization to possess and/or a license to produce marihuana for medical purposes under the *Marihuana Medical Access Regulations* will remain the same.

.../2

Canadian Courts have established that individuals who have demonstrated a medical need for marihuana have a right under the *Canadian Charter of Rights and Freedoms* to possess and access a legal supply of marihuana. In recognition of a need for a process to provide seriously ill Canadians with access to marihuana for medical purposes, the Government introduced the *Marihuana Medical Access Regulations* in 2001. Activities including possession, production and trafficking of marihuana other than as authorized under the regulations remain illegal.

- 30 -

To view the Consultation document: "*Proposed Changes to Health Canada's Marihuana Medical Access Program,*" please click on: http://www.hc-sc.gc.ca/dhp-mps/consultation/index-eng.php

A summary of the proposed changes can be found in the attached backgrounder.

Media Enquiries:
Health Canada
(613) 957-2983

Cailin Rodgers
Office of the Honourable Leona Aglukkaq
Federal Minister of Health
(613) 957-0200

Public Enquiries:
(613) 957-2991
1-866 225-0709

This is **Exhibit "P"** 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

Issue Analysis Summary
ADVERSE REACTIONS REPORTING

FINAL (Protected B)

ISSUE

HC will need to determine what provisions should be made in new regulations for the reporting of adverse reactions related to the use of marihuana for medical purposes.

CONTEXT

Current Status:

Marihuana (cannabis) is an unapproved drug and as such has not been comprehensively evaluated in terms of safety, efficacy, quality and therapeutic usefulness as required under the *Food and Drugs Act* for other medications. Despite this, Health Canada's Marihuana Medical Access Program provides access to marihuana for Canadians who suffer from serious medical conditions.

Health Canada has developed an information sheet for patients authorized to possess dried marihuana which currently includes information and contact details for reporting serious side effects to the product to the Marketed Health Products Directorate (Health Products and Food Branch) MedEffect Program and the Canada Vigilance database [1]. While MedEffect receives these reports and enters them into their database, the Marketed Health Products Directorate does not conduct post-market surveillance for marihuana for medical purposes, and does not regularly review the case reports, other than possibly reviewing reports which list other medications as suspect products in the context of safety assessments for these other drugs.

An April 2012 search of the online Canada Vigilance database for adverse reactions reported since 2001 and listing cannabis or marihuana as a suspect drug returned 215 adverse reactions, of which 201 were considered serious. Only two of these reports specifically indicated that the suspect product was Health Canada-supplied marihuana (adverse reactions listed as "drug ineffective" and "convulsion"). The vast majority of the reports listed "drug dependence" or "substance abuse" as the primary reaction term, and all but one report had a number of other controlled substances (primarily oxycontin) as co-suspect drugs. It should be noted that a report in the database does not necessarily mean a causal relationship has been established.

Standard post-market surveillance of drugs by the review bureau in the Marketed Health Products Directorate relies on a number of different sources of data, including adverse reaction reports from the Canada Vigilance database. Canada Vigilance, however, is only one source of data, as it only includes Canadian reports. While serious adverse reactions known to the manufacturer of the product must be reported to Health

1 http://www.hc-sc.gc.ca/dhp-mps/medeff/vigilance-eng.php

Issue Analysis Summary
ADVERSE REACTIONS REPORTING

FINAL (Protected B)

Canada under the *Food and Drug Regulations*, healthcare practitioners and consumers can also report directly. Adverse reactions are known to be substantially underreported, and for medications which are used by small populations, rare adverse events in the Canadian population alone are unlikely to provide enough of a signal to be detected. Ongoing review of the safety of drugs generally relies on a combination of international data, annual summary reports (generally in a standard format known as a Periodic Safety Update Reports [PSUR] [2]) prepared by the manufacturer, published medical literature and safety data from clinical trials. None of these other sources of safety information are currently available for marihuana.

The analysis of all of these sources of data is used by Health Canada to periodically re-assess the benefit-risk profile of authorized products. Should new safety issues be identified, manufacturers can be requested by Health Canada to update their authorized Canadian Product Monographs to reflect the safety profile, or other regulatory actions can be taken. Note that Health Canada does not currently have regulatory authority to require monograph changes. Substantial changes to the product monograph will often be associated with the issuance of a risk communication, often directed to both patients and healthcare professionals. These communications are usually issued by the manufacturer, with review of the information by Health Canada.

Proposed Changes:

For context on the proposed changes to the MMAP, please refer to Health Canada's consultation document entitled *Proposed Improvements to Health Canada's Marihuana Medical Access Program.*

Product quality requirements for the medical marihuana will be based on the good manufacturing practices requirements included in the current *Natural Health Products Regulations* (NHPR) [3], and technical specifications relating to purity in a related Natural Health Products guidance document [4]. Included in the NHPR are provisions for product recall (generally related to product quality issues). Adverse reaction reporting is a separate section of the NHPR and *Food and Drug Regulations* (FDR) [5], but is included in this section of the project for completeness.

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2 http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2C/Step4/E2C_R1__Guideline.pdf

3 http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/

4 http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/eq-paq-eng.pdf

5 http://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/

Issue Analysis Summary
FINAL (Protected B)

ADVERSE REACTIONS REPORTING

IDENTIFICATION AND ANALYSIS OF OPTIONS

Criteria:

- There is an expectation on the part of Canadians that a regulated product is safe for consumption, and if not, that they should have a mechanism to report safety issues.
- Requirements imposed by the regulations must be clearly linked to potential health risks so as not to create an undue regulatory burden, which in turn could result in high costs or access issues.
- The program overall should treat marihuana as much as possible like any other drug.

Options:

- One option was set aside:
    - The option of not requiring any reporting of adverse reactions was set aside, as there will be an expectation on the part of the consumers that, as the regulator of the marihuana for medical purposes industry, Health Canada should have a system in place to monitor the safety of the products and to receive complaints.

Option 1: Drug/NHP Reporting Requirements

LPs would be required to report all non-serious and serious Canadian adverse reactions, and all serious unexpected adverse reactions to Health Canada, as well as prepare an annual summary report to be submitted to Health Canada upon request.

PROS

- Treats marihuana like any other drug.

CONS

- By definition, this reporting system relies on an extensive pre-authorization review of the safety of the product in order to define what adverse events are to be considered expected. There will be no such pre-authorization review of marihuana for medical purposes.

Both the FDR and NHPR have similar requirements with respect to adverse reaction reporting, which include:

- reporting to Health Canada every serious adverse reaction to the product that

occurs in Canada within 15 days of the manufacturer becoming aware of the reaction.
- reporting to Health Canada every serious unexpected reaction to the product that occurs inside or outside Canada within 15 days of the manufacturer becoming aware of the reaction.

Additionally, recent modifications to the FDR also require the manufacturer to prepare an annual summary report containing a critical analysis of the reported adverse reactions, and in so doing, to make a conclusion as to whether the benefit-risk balance of the drug has changed.

"Adverse drug reaction" is defined in the FDR as:
"a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function"

"Serious adverse drug reaction" is defined as:
"a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death."

"Serious unexpected drug reaction" is defined as:
"a serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug"

The adverse drug reaction definition would need to be modified slightly, given that there is no dose of marihuana "normally used" for medical purposes.

By definition, an unexpected adverse reaction is not labeled in the product monograph. Since marihuana does not have a Health Canada authorized, product-specific monograph based on a review of clinical trial data, this requirement cannot apply.

Finally, as Health Canada is required by the courts to provide access to marihuana, and has not made a formal determination of a positive benefit-risk balance for the product, the concept of requiring the manufacturer to make this assessment as part of an annual reassessment does not apply.

Option 2: Develop modified requirements specifically for dried marihuana

HC would develop minimum reporting requirements for marihuana, while maintaining any applicable requirements in place for other drugs, for consistency. These would include:

- modification of the adverse event definition, as indicated above
- regulatory requirements to report any serious Canadian and international adverse reactions to Health Canada (no requirement for reporting of non-serious adverse reactions).
- annual summary report to be prepared and available for inspection – this should include both adverse events, and any quality related issues which could affect safety, similar to the PSUR format, which requires a report of actions taken by the manufacturer for safety reasons.

PROS

- Requirements would be tailored to this program and limited to what is necessary to avoid placing consumers at risk due to inadequate product quality.

CONS

- Requirements would be slightly different from drugs or natural health products, in order to reflect the unique marihuana situation.

CONSIDERATIONS

- Unlike for other drugs, the Government has an obligation under the *Charter of Rights and Freedoms* to ensure that there is reasonable access to marihuana for medical purposes in Canada, even though it has not been scientifically demonstrated that its benefits outweigh its risks. While being required to provide access, Health Canada is not authorizing marihuana on the basis of an assessment of safety, quality and efficacy in the same way in which Health Canada authorizes a pharmaceutical or biologic drug.
- Safety of medical marihuana – in the context of being an unauthorized product for which a benefit-risk assessment has not been done – can primarily be defined on the basis of health risks related to product quality, as for example, mould or microbial content could be a safety risk for immunosuppressed patients.

CONSULTATIONS

Adverse reaction reporting has not been specifically discussed in stakeholder consultations.

Issue Analysis Summary
ADVERSE REACTIONS REPORTING

FINAL (Protected B)

RECOMMENDATION

Option 2 is recommended because requirements would be tailored to this program and limited to what is necessary to avoid placing consumers at risk due to inadequate product quality.

NEXT STEPS

Drafting instructions will reflect this policy direction.

Internal Health Canada consultations (Marketed Health Products Directorate, Office of Controlled Substances) will be required to define how an adverse reaction reporting requirement should be operationalized.

This is **Exhibit "Q"** 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

Solicitor-Client Privilege/Protected

Issue Analysis Summary

FINAL (Protected B)

Advertising

ISSUE

HC will need to determine whether licensed producers will be permitted to advertise marihuana for medical purposes to the general public.

CONTEXT

Current Status:

Currently, Health Canada makes limited information about the dried marihuana product sold and distributed by the Crown available on the Health Canada website. Information available online includes how to order the product, it's price, and a product information sheet containing factual information about the product, e.g., the fact that it consists of milled dried flower heads of female cannabis plants, the fact that it is irradiated, etc.

Narcotic Control Regulations (NCR)

The NCR prohibits advertising a narcotic to the general public, where "advertisement means any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of a narcotic". In practical terms, this means that licensed dealers typically advertise by direct mail to physicians, and in trade or professional journals. Advertisements for narcotics are also required to bear an 'N' symbol.

Food and Drugs Act (FDA) and *Food and Drug Regulations* (FDR)

The FDR governs advertising of therapeutic products. These requirements vary according to the regulatory classification of the product. For prescription drugs, included on Part I of Schedule F of the FDR, advertising to the public is limited to the name, price and quantity of the product. Advertising is further limited by indication. That is, generally a person cannot advertise drugs to the public as treatments, preventatives or cures for a range of diseases, disorders or abnormal physical states; including cancer, acute inflammatory and debilitating arthritis, and glaucoma (see s.3 and Sch. A of the FDA and s.A.01.068 of the FDR). However, natural health products and most non-prescription drugs are exempted from the prohibition on advertising them as preventatives for Schedule A diseases. In addition, a person cannot advertise drugs in

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Issue Analysis Summary

FINAL (Protected B)

Advertising

a manner that is false, misleading or deceptive or that is likely to create an erroneous impression regarding the character, value, quantity, composition, merit or safety of the drug (s.9 of the FDA).

For prescription drugs, i.e., drugs listed in Schedule F to the FDR, C.01.044 of the FDR limits the promotion of a prescription drug (Schedule F) to the general public to name, price and quantity. C.01.044 was introduced in 1953, and at the time, completely prohibited advertising prescription drugs to the general public. In the 1970's, in response to period of very high drug costs, the FDR was amended so as to allow for the name, price, and quantity of drugs to be advertised to the general public. Parliament's concern was not only the cost of drugs (which at the time were largely borne by consumers) but also on the demands on physicians' time, wasting of resources and effects on prescribing. More recently, Health Canada has conducted preliminary consultations on returning to an outright ban on the advertising of Schedule F drugs. However, no final decisions as to the outcome of those consultations have been made.

The advertising that is permitted – of OTC drugs and NHPs, and some vaccines; advertising to medical professionals; and non-promotional messages to the public – ensure the public receives appropriate, valuable information which optimizes patient participation in their health management, encourages patients to visit their physicians, when appropriate, and preserves the very important doctor/patient relationship.

Furthermore, section C.08.002 of the FDR stipulates that new drugs cannot be advertised unless the manufacturer holds a valid Notice of Compliance and has submitted specimens of labels, inserts, brochures and file cards to be used in connection with that drug.

The Health Products and Food Branch policy on *The Distinction between Advertising and Other Activities* provides further guidance regarding the dissemination of non-promotional information.

Table 1 shows regulatory requirements for the advertising of health products.

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Issue Analysis Summary

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Advertising

Advertising Guidelines

Table 1: General Advertising Requirements for Health Products (Not Exhaustive)

Product	Requirements
All drugs, (FDA)	**S.3(1)** *"No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A."* **S.9.(1)** *"No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."*
Natural Health Products (NHPR)	**s.103.2** *"A natural health product is exempt from subsection 3(1) of the Act with respect to its advertisement to the general public as a preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.*
Narcotics (NCR)	**70.** *"No person shall* ***(b)*** *publish or cause to be published or furnish any advertisement to the general public respecting a narcotic"*
Prescription Drugs (FDR)	***C.01.044.*** *(1) Where a person advertises to the general public a Schedule F Drug, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug.*
New Drugs (FDR)	***C.08.002.*** *(1) No person shall sell or advertise a new drug unless* *(a) the manufacturer of the new drug has filed with the Minister a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission or an abbreviated extraordinary use new drug submission relating to the new drug that is satisfactory to the Minister;* *(b) the Minister has issued, under section C.08.004 or C.08.004.01, a notice of compliance to the manufacturer of the new drug in respect of the submission;* *(c) the notice of compliance in respect of the submission has not been suspended pursuant to section C.08.006; and* *(d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any labels, including package inserts, product brochures and file cards, intended for use in connection with that new drug, and a statement setting out the proposed date on which those labels will first be used.*

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Advertising

Over the Counter Drugs (FDR)	**A.01.068.** *"A drug is exempt from subsection 3(2) of the Act with respect to its sale by a person where the drug is represented by label or is advertised by that person to the general public as a preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act".*

Proposed Changes:

Under the proposed changes, an individual who requires marihuana for medical purposes would receive a document from their health care practitioner and use that document to register with an LP. LPs will be allowed to grow any strain of marihuana they choose. Individuals will need to know what LPs exist and what range of products they offer before they are able to register.

Product review and licensing is not contemplated under the proposed changes.

For further details on the proposed changes to the MMAP, please refer to Health Canada's consultation document entitled *Proposed Improvements to Health Canada's Marihuana Medical Access Program.*

CONSULTATIONS

In consultations with Bedrocan BV, representatives indicated that that there was overlap between advertising and informing that is difficult to navigate when dealing with a controlled substance. Bedrocan felt that product advertising should not be allowed, but wondered whether sales representatives would be permitted visit doctors. They highlighted that it is important that firms retain the ability to communicate openly with stakeholders without interference.

In technical meetings with individuals interested in becoming LPs, questions were raised about whether or not advertising of products would be permitted. Participants indicated that customers would need basic information to be able to select an LP.

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Issue Analysis Summary

FINAL (Protected B)

Advertising

IDENTIFICATION AND ANALYSIS OF OPTIONS

Criteria:

The recommendation should:

- be consistent with the process of accessing marihuana outlined under the proposed reform; in other words the recommendation should facilitate the practitioner/patient relationship for decision-making and ensure the patient has the right information to select a product/strain;
- treat marihuana as much as possible like a medication;
- not incite the recreational use of marihuana.

Options

The option of not regulating advertising was set aside, because advertising without restriction would not meet several of the criteria above in the following ways:

- It would be inconsistent with the principle that the decision to use marihuana is best made between the patient and their health care practitioner, as advertising may prompt the patient to enter into the discussion with their health care practitioner already convinced that it is the only or most appropriate treatment for their particular condition or symptom.
- It would be inconsistent with treating marihuana as much as possible like a medication. Advertising of all medication is subject to the *Food and Drugs Act*.
- Unregulated advertising might include representations that medicalize the recreational use of marihuana.

Option 1: Name, price and quantity only could be advertised to the general public

LPs would be permitted to advertise only with representations of the brand name, the proper or common name of the strain, the price per gram and the cannabinoid content. This is consistent with what is permitted for Schedule F (prescription) drugs. However, licensed producers would also be permitted to include their name and contact information in light of the difference in the distribution scheme.

Health Canada would publish a list of LPs to ensure that patients would be able find out about the full range of product offering on the Canadian market by making inquiries, if

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they chose.

Pros:

- Allows LPs to publish/advertise information that is relevant for product or strain selection.
- Allows LPs to compete within the market of prospective clients, but limits their ability to increase the market of prospective clients by means of marketing, e.g., suggesting marihuana is medically appropriate for a new symptom or condition.
- May result in more competitive pricing.
- Facilitates the involvement of the health care practitioner in the determination as to whether the use of marihuana for medical purposes is appropriate for a given individual.
- There is precedent for limiting advertising to name, price and quantity for medications. (While this may change in the future, the arguments for providing this information directly to patients for dried marihuana would be unaltered.)
- Advertising would be limited to simple factual information, rather than confusing or misleading claims or statements about the product and/or its benefits.

Cons:

- Inconsistent with the ban on advertising to the general public for other narcotics. However, it could be argued that because dried marihuana products are distributed differently, differences are justified.
- The selection of a product by program participants may be driven by the quantity and quality, e.g., visual appeal, of advertising they are exposed to.
- Some members of the general public and/or groups may find marihuana advertisements objectionable.
- Compliance monitoring of advertising may be required. Health Canada may need to engage the Pharmaceutical Advertising Advisory Board.

Option 2: Advertising to the general public would be prohibited. Name price and quantity could optionally be published on the Health Canada website.

LPs would be permitted to advertise, provided they do not advertise to the general public. In practice this means that LPs could distribute promotional materials to health care practitioners, which could in turn be distributed to a patient under the care of that practitioner. They could also advertise to other groups, such as pharmacists, their own registered clients, e.g., via an email list. In addition, as with any drug, prospective

clients would be able to receive inquire and receive information directly from LPs without this being considered advertising.

LPs would have the option of providing Health Canada with information for publication on its website.

Pros:

- A ban on advertising to the general public would treat marihuana like other narcotics.
- Facilitates the involvement of health care practitioners in product selection.
- Licensed producers would still have a means of informing prospective clients about their products.
- The quantity of information available about a given product would be limited. In other words, the 'advertising exposure units' would be consistent for all dried marihuana products.

Cons:

- May make the market less attractive to some prospective LPs.
- Imposes another role on healthcare professionals in relation to access to marihuana for medical purposes, which they may or may not be reluctant to fulfill. It is also unlikely that they will keep and disseminate information provided by LPs.
- Health Canada would be accountable for the information posted on the Health Canada website. Updating the website periodically would be time consuming, and information published may become outdated quickly. The website would have to carry a caveat indicating that it reflects information received from LPs and it may not be updated in real time.
- Inconsistent with the government's role as a regulator of LPs.

CONSIDERATIONS

- Consideration should be given to maintaining the FDA prohibitions on advertising (i.e. advertising untruthfully, or advertising treatments or cures for certain diseases) under either option, because ensuring these prohibitions remain in effect for marihuana would contribute to the goal of treating marihuana as much as possible like other medications, and avoid inconsistencies with other health products.
- Under either of the listed options, HC should give serious consideration to publishing a guideline on advertising. Under option 1, a guideline might further interpret information advertising and describe best practices for compliance with advertising

provisions in the regulations. Under option 2, a guideline would likely look very much like the current circular letter on Publicity that is provided to licensed dealers under the NCR. The circular letter provides guidance on the size and quantity of advertisements for narcotics, as well as the distribution of those advertisements. While the circular letter provides some meaningful guidance it was developed for advertising narcotic pharmaceuticals to physicians only, and distributed in 1983. It's relevance to the proposed changes to the MMAP is limited.

- Health care practitioners should be consulted to determine their perspectives on whether LPs should be permitted to advertise directly to patients. This is because they may be faced with patients who have been influenced by advertising, and have to navigate this in their interaction with the patient.
- The Pharmaceutical Advertising Advisory Board should be consulted if/when HC develops a guideline on advertising.

RECOMMENDATION

Option 1 is recommended because it ensures that licensed producers can communicate information that patients require to select a product, and thus select an LP. However, it limits the influence advertising has on patients before they see their doctor, by preventing representations in advertising about the value or efficacy of the product. This places the decision-making as to the value of marihuana for that particular individual between the patient and the health care practitioner.

This is **Exhibit "R"** 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

Issue Analysis Summary
Dispensing through pharmacists

PROTECTED B

ISSUE

Whether or not to maintain the ability of pharmacists to dispense marihuana for medical purposes, if authorized by their province or territory, in the proposed *Marihuana for Medical Purposes Regulations* (MMPR).

BACKGROUND

In December 2010, the Minister of Health was authorized by Cabinet to develop a new regulatory system for marihuana for medical purposes. The policy direction that was approved by Cabinet was clear with respect to not allowing storefront retail operations. Instead, licensed producers would distribute marihuana directly to their clients using a secure shipping method.

The original reform proposal did not include a role for pharmacists. However, during pre-regulatory development consultations in 2011, Health Canada was asked by some provincial/territorial (P/T) ministries of health, law enforcement, fire officials, municipalities and medical associations to examine the benefits of dispensing marihuana for medical purposes by pharmacists. P/Ts noted that they are responsible for regulating the practice of pharmacy in Canada, and some suggested that flexibility be incorporated into the regulations so that they could design their health care systems to best meet their needs. Law enforcement, local governments and fire officials noted that pharmacies already have security measures and systems in place to dispense other narcotics, thus providing a secure distribution method. Therefore, in May 2012, the Minister sought and was granted authority from Cabinet to amend the original proposal to allow pharmacists to dispense marihuana for medical purposes, but only if this activity was authorized under P/T legislation.

CONSIDERATIONS

Certain stakeholders (interested licensed producers, compassion clubs and individuals) have indicated that store-fronts are valuable not only because an individual could access marihuana immediately, but also because alternative services, such as counseling, education and dissemination of information, could be provided. These comments were received during the pre-regulatory development consultations in 2011, and again following publication of the proposed MMPR in *Canada Gazette,* Part I (CGI) in late 2012. Other stakeholders, mainly law enforcement, municipalities and fire officials, were not supportive of dispensing through store-fronts other than pharmacies as they believe that this could increase the risk of diversion. They also cited concerns from citizens if marihuana were to be distributed in their communities through a

storefront.

Other CGI comments, particularly those received from potential licensed producers (LPs), suggest that there could be a way to work around providing marihuana through secure shipping methods by simply hiring a pharmacist to dispense on-site. Such an outcome would be inconsistent with the framework approved by Cabinet in 2010.

Despite earlier consultations, CGI comments received from P/Ts and pharmacists are consistently negative about the possibility of pharmacists dispensing. Both P/Ts and pharmacist associations/regulators note that dried marihuana should not be dispensed through pharmacies because it is not a therapeutic product approved for sale under the *Food and Drugs Regulations* (FDR). As such, it should not be dispensed by pharmacists. Given these positions, it is unlikely that, even with enabling provisions in the MMPR, this option would be implemented by the P/Ts.

IDENTIFICATION AND ANALYSIS OF OPTIONS

Option 1: Status quo - Pharmacists may dispense dried marihuana as authorized by provinces/territories

Under this option, the proposed MMPR would remain as currently drafted, and pharmacists would be permitted to dispense dried marihuana as regulated under P/T jurisdiction. Both the practice of pharmacy (i.e. the qualifications of a pharmacist and how these professionals should conduct business), and the requirements for the licensing or accreditation of a facility designated as a pharmacy, are well-defined under P/T regulation.

PROS

- Treats marihuana as much as possible like other narcotics used for medical purposes, in that it could be dispensed by pharmacists.
- Pharmacists have experience in handling, storing, tracking and dispensing other controlled substances.
- Having a pharmacist dispense dried marihuana in a pharmacy could mean that patients could receive direct counseling and education on the use of dried marihuana from a trained professional, assuming that pharmacists received sufficient information in order to be confortable with this role.

CONS

- Could possibly lead to the development of marihuana-specific pharmacies, if licensed by the P/T.
- Marihuana-specific store-fronts are viewed as a risk by a majority of

municipalities, law enforcement agencies and fire officials who view this as the least secure distribution option.

Option 2: Remove pharmacists' ability to dispense dried marihuana from the proposed MMPR.

PROS

- Would eliminate the potential dispensing of dried marihuana through store-fronts, while secure shipping direct from LPs to their registered clients would still be maintained as a distribution option.
- It would be clear for law enforcement that any storefronts or retail outlets that sell marihuana for medical purposes are doing so illegally.
- Responds to concerns raised by P/Ts and pharmacist associations/regulators regarding the ability of pharmacists to dispense marihuana for medical purposes.

CONS

- Does not treat marihuana exactly like other narcotics used for medical purposes.
- Does not provide P/Ts with the flexibility to design their health care delivery services, although this could be addressed through regulatory amendments at a future date if P/Ts determine that they wish to authorize pharmacists to dispense marihuana for medical purposes.
- Other health care practitioners, in particular physicians, may question why Health Canada is responding to the concern raised by pharmacists regarding their role but not to the concerns that they have raised about supporting access for an unapproved drug.

RECOMMENDATION

Option 2 is recommended. This option responds to stakeholder concerns regarding the role of pharmacists. It also prevents the possibility of retail storefront distribution, either in the case of a licensed producer who hires a pharmacist, or in the case of a marihuana-only pharmacy becoming authorized under P/T legislation.

Prepared by: Valerie Anderson, Project Officer, MMRR

Approvals:
Megan Bettie, Associate Director, MMPR (Approved)
Sarah Geh, Legal Services (Approved)
Jeannine Ritchot, Director, MMPR (Approved)
Robert Ianiro, DG, CSTD (Approved)
Hilary Geller, HECS ADM (Pending)

This is **Exhibit "S"** 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

Issue Analysis Summary
Health Care Practitioners

FINAL (Protected B)

ISSUE

Health Canada (HC) will need to determine whether other health care practitioners other than physicians should be authorised through regulation to support access to marihuana for medical purposes under a reformed Marihuana Medical Access Program (MMAP).

CONTEXT

Current Status:

Marihuana is not an approved therapeutic product under the *Food and Drug Regulations* (FDR) because its efficacy and safety have not been sufficiently demonstrated. As such, it has never been issued a Notice of Compliance (NOC) or drug identification number (DIN) and cannot generally be prescribed in Canada. The *Marihuana Medical Access Regulations* (MMAR) provide a legal framework by which individuals can obtain dried marihuana for medical purposes.

The MMAR require that only a medical practitioner who is licensed to practice in Canada and who is able to prescribe narcotics can support an application for an authorization to possess marihuana for medical purposes. This is because Health Canada believes that the determination as to whether marihuana should be used as a therapy for a particular health condition is best made by a physician. They are trained to diagnose and treat patients and to prescribe and administer medical treatments, including the use of controlled substances for medical purposes.

Under the MMAR, there are two categories of symptoms or conditions. Category 1 refers to both symptoms within the context of compassionate end-of-life care and specific symptoms related to specific conditions as outlined in the Regulations (e.g. seizures caused by epilepsy, or chronic pain caused by severe arthritis). In such instances, a program participant requires the support of one medical practitioner. All debilitating symptoms associated with medical conditions or the medical treatment of conditions that are not listed in Category 1 fall under Category 2, and require that the supporting medical practitioner consult with a specialist in the field which is relevant to the treatment of the applicant's medical condition.

Since the beginning of the program, medical associations have expressed discomfort with the role of physicians in supporting an application to Health Canada. This concern stems from the lack of scientific evidence regarding the risks and benefits of the use of marihuana for medical purposes, and the lack of clinical guidelines to assist physicians in making this determination. Over the years, Health Canada has recognized these concerns and amended the MMAR so that physicians are required to sign a declaration

stating that they understand that their patient wishes to use a particular amount of dried marihuana, that conventional treatments for the symptom have been tried or considered and have been found to be ineffective or medically inappropriate for the treatment of the patient, and that they understand that marihuana has never been issued a NOC under the FDR. Physicians are not required to make definitive statements regarding benefits outweighing risks, or, in practice, to make specific recommendations regarding the daily dosage of marihuana to be used by their patient.

Despite concerns raised by physicians and their associations over the duration of the program, the number of program participants has continued to rise steadily, particularly in the past two years. This rise in participation would not be possible without the support of physicians. Indeed, the number of physicians supporting applications to the program has also risen. In 2001, 727 doctors supported at least one application for an authorization to possess marihuana (which includes those doctors who supported an exemption under s. 56), whereas between January 1 and October 25, 2010, 2,351 doctors supported at least one application for an authorization to possess.

The MMAR have been challenged in the courts due to the requirement for a medical declaration by a physician to support an individual's application to Health Canada to obtain access to marihuana for medical purposes. Specifically, in April 2011, the Ontario Superior Court found, in the case of *R. v. Mernagh*, that sections 4 and 7 of the *Controlled Drugs and Substances Act* (CDSA) and the MMAR in its entirety as they pertain to the possession and production of marihuana were constitutionally invalid. This decision was based on the judge's interpretation that doctors were "boycotting" the MMAR process, that there was a general lack of knowledge about the medical use of marihuana and that the specialist requirement was an additional barrier to access. These reasons, combined with what the court referred to as "the widespread shortage of doctors in Canada", led to the conclusion that the requirement for physician participation in the MMAR has rendered legal access to marihuana for medical purposes illusory and therefore violated s. 7 of the *Charter*. In his decision, the judge cited Health Canada's inaction in extending the role of supporting applications to health care practitioners other than physicians as one of the reasons for this situation. This case is currently before the Ontario Court of Appeal.

Beyond the MMAR, in some jurisdictions, midwives, nurse practitioners and podiatrists are authorized to prescribe controlled substances within their scope of practice as set out in their provincial/territorial (P/T) legislation. However, they cannot actually do so as the CDSA and its regulations authorize only doctors of medicine, dentists and doctors of veterinary medicine to conduct activities with controlled substances. As a result, patients treated by midwives, nurse practitioners and podiatrists must be referred to a doctor of medicine or dentist to obtain medications containing controlled substances, thereby hampering flexibility and timeliness in delivery of health care services.

Issue Analysis Summary
Health Care Practitioners

FINAL (Protected B)

To address this, Health Canada is preparing to publish in *Canada Gazette, Part II* the *New Classes of Practitioners Regulations* (NCPR). These regulations will include midwives, nurse practitioners and podiatrists within the definition of practitioner as defined in the *Controlled Drugs and Substances Act* (CDSA) so that they would be authorized to prescribe, administer and provide certain controlled substances – including narcotics – as listed in Schedules to the *Narcotic Control Regulations* (NCR), the *Benzodiazepines and Other Targeted Substances Regulations* (BOTSR) and Part G to the FDR. In order to be able to conduct activities with named substances, these new classes would already have to be authorized do so within their P/T scope of practice as set out in P/T legislation. Health Canada has also developed a designation framework that outlines the process of designating additional classes of health professionals under the NCPR in the future. [1]

Notwithstanding the above, the NCPR will also exclude a specific set of controlled substances with which each of the new classes of practitioners are not authorized to conduct activities. Among other substances, none of the new classes of practitioners would be allowed to conduct activities with marihuana. While some representatives of P/T ministries of health initially questioned why Health Canada wished to exclude marihuana from the NCPR, the provinces and territories expressed their overall support for the revised NCPR, including its list of exclusions.

Proposed Changes:

For further background, please see the consultation document entitled *Proposed Improvements to Health Canada's Marihuana Medical Access Program*.

CONSULTATIONS

During consultations for the MMPR, medical associations and P/T regulatory bodies expressed concern about physician liability in supporting a patient's access to an "unapproved therapeutic". One of their major concerns was related to the lack of scientific evidence, information and guidance available for the treating physician on the risks and benefits of marihuana for medical purposes. They also emphasized that some medical practitioners feel pressured by patients to support their use of this product, despite limited scientific and medical information about its risks and benefits. One solution put forward by medical associations and regulatory bodies was to invest more in research so that there is a better understanding of the use of marihuana for medical

1 Note that at the time of updating, the NCPR have not yet been published in Canada Gazette II, although this is expected to occur before the MMPR are pre-published in Canada Gazette I.

purposes. Such research could also potentially lead to the authorization of marihuana as a therapeutic drug under the FDR, which would in turn lead to greater physician comfort in supporting its use.

Physicians themselves have indicated that they also need to have better knowledge about what is already known regarding the use of marihuana for medical purposes, so that they are better informed when their patients ask them about it. Further consultations are planned with individual physicians, particularly through the administration of a needs assessment survey, which aims to seek information from physicians regarding what they would want to know regarding the use of marihuana for medical purposes, and what information (and in what format) they would like to receive.

All stakeholder groups, including program participants, welcomed the creation of an Expert Advisory Committee as a means to assist Health Canada in supporting physician education about the use of marihuana for medical purposes.

Finally, program participants and cannabis dispensaries requested that Health Canada consider expanding the role of supporting access to other health care professionals, including naturopaths, herbalists, and practitioners of Chinese traditional medicine. Some P/T ministry of health officials also asked whether or not Health Canada would consider allowing other regulated professions with prescription authority (i.e. nurse practitioners) to support an individual's access to marihuana for medical purposes, although all acknowledged that they do not currently allow other classes of practitioners to play such a role under P/T legislation, and there was no consensus regarding whether or not this role should be extended to other practitioners. Physician associations and regulatory bodies noted that in some cases, it could be appropriate for other health care practitioners such as nurse practitioners to share the responsibility of supporting access.

On the other hand, law enforcement has expressed significant concern that there are already insufficient controls around the prescribing practices of physicians who participate in the current program. In a report produced by the Canadian Association of Chiefs of Police (CACP) and submitted to the Minister of Health in 2010, police provided case evidence of diversion by program participants who were authorized by Health Canada to possess large daily amounts of marihuana for medical purposes. The CACP drew particular attention to the fact that in many of the cases they enumerated, physicians were not aware of appropriate dosages of marihuana and relied on the recommendation of their patients. They provided two specific recommendations to the Minister of Health:

- That the daily amount of marihuana recommended by a physician should be based on recognized training and scientific literature versus the demand of the patient; and

- That 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.

When asked if Health Canada should consider allowing other health care practitioners to support access to marihuana for medical purposes, law enforcement expressed significant reservations with allowing other professions to play a role absent appropriate training and controls.

IDENTIFICATION AND ANALYSIS OF OPTIONS

Criteria:

The recommended option should:

- not unduly impede access to marihuana for medical purposes;
- should respect P/Ts jurisdiction to choose scope of practice;
- treat marihuana as much as possible like any other drug.

Option 1: Allowing those HCPs who are authorized to administer and prescribe other narcotics to also support access to MM

Under this option, Health Canada would authorize those HCPs who can currently prescribe narcotics to also be able to support access to MM. This includes those professions captured under the definition of "practitioner" in the *Controlled Drugs and Substances Act* (CDSA) (i.e. physicians, veterinarians and dentists), as well as any other professions added to this definition under the NCPR. Currently, nurse practitioners have the greatest scope of practice to the professions being added to the list of practitioners able to prescribe narcotics. Nurse practitioners already have the appropriate competencies. Providing them with the ability to support access would provide P/Ts with flexibility in the design of their health care delivery systems, as well as potentially provide better access to health care in remote communities where there are a limited number of physicians.

To achieve this, it is recommended that the MMPR not limit the definition of "health care practitioner" to licensed physician, as does the current MMAR. Instead, the CDSA definition would apply. This means that any time that a new class of practitioner is added to the definition of "practitioner", these new classes of practitioners would also be able to support access to marihuana for medical purposes pending an amendment to the MMPR.

This would also require either a consequential amendment to the NCPR to remove the prohibition on marihuana, or a change to the draft regulations prior to publication in CGII.

Issue Analysis Summary
Health Care Practitioners

FINAL (Protected B)

PROS

- Expanding the authority to support access to marihuana for medical purposes to only those practitioners allowed to prescribe under the CDSA is in keeping with the principle to treat marihuana like any other drug. This is because it is not just any HCP can prescribe a narcotic; only those as defined in the CDSA/NCPR can do so;
- HCPs would have to comply with requirements set out in the NCR for practitioners with respect to keeping records on MM prescribed, received or provided; ensuring proper security and reporting on loss or theft within a specific timeframe to law enforcement and HC;
- Respects P/T jurisdiction for scope of practice as HCPs would have to be authorized to prescribe under their P/T legislation in their jurisdiction;
- Mechanisms agreed to by P/Ts are already in place under the NCPR to allow this to happen;
- Allows for more flexibility and timeliness in delivery of health care services with respect to MM in remote areas where physicians may not be as accessible;
- In some P/Ts (e.g. Ontario), models of patient care have expanded beyond a role for only a physician to diagnose and treat patients. This gives P/Ts the flexibility to treat marihuana as much as possible like other drugs as well by allowing it to be supported by HCPs who play an important role in models of care.
- Reduces the burden on patients as they would be able to seek the support of other HCPs;
- P/Ts have indicated their support for expanding the scope of practice of certain HCPs with prescribing authority to include supporting access to marihuana for medical purposes. This allows them a vehicle to do so.
- Addresses immediate stakeholder concerns to allow access via other HCPs once the NCPR are promulgated.
- Allowing nurse practitioners, in addition to physicians, to support access to dried marihuana for medical purposes addresses a key recommendation of many stakeholders for enhanced access by patients.

CONS

- This does not include authority for other HCPs to support access to marihuana for medical purposes under the new MMPR, and instead leaves this authority in the NCPR. It could be more clear to define classes allowed to support marihuana for medical purposes in that regulation.
- Would require an amendment to the MMPR each time that a new class is added to the definition of practitioner under the CDSA, which can cause an

administrative burden to Health Canada.

Option 2: Allow P/Ts to determine any HCP as being able to administer and prescribe MM

Under this option, P/Ts would have full authority to expand the scope of practice of any HCP – including those that do not have authority under the CDSA/NCPR to prescribe narcotics, to include support for marihuana for medical purposes. This would be achieved by defining medical practitioner in the MMPR as a licensed physician, but by also including an enabling clause that would allow allow P/Ts to determine which HCPs should be able to prescribe MM and thus including them in the MMPR definition.

PROS

- Respects P/T jurisdiction to choose scope of practice with respect to prescribing of MM. Some jurisdictions (i.e. Ontario), have asked that Health Canada give them full flexibility to determine the appropriate HCPs rather than limiting to the same included in the NCPR/CDSA framework
- May be more clear to use just one regulation to define those HCPs able to support access to marihuana for medical purposes rather than two.

CONS

- Does not respect the principle of treating marihuana as much as possible like a medication for two reasons:
  - The NCPR is the vehicle that HC has chosen to expand the classes of practitioners able to prescribe narcotics, not the MMPR;
  - May result in a situation where HCPs who do not have authority to prescribe other narcotics have the ability to support marihuana for medical purposes.
- May have impact on HC's ability to control MM as is the mandate of the CDSA, given that a full range of HCPs who are not allowed to prescribe narcotics may now be able to do so with marihuana;
- Does not immediately address stakeholder concerns to HC regarding other HCPs being allowed to prescribe and administer (i.e. dependent on when and if a P/T would change the scope of practice of a particular profession);
- If HC were to object to a specific group of HCPs from prescribing MM, [redacted] – could create disagreements between HC and P/Ts.

Option 3: Nurse Practitioners and Physicians Only

Issue Analysis Summary

FINAL (Protected B)

Health Care Practitioners

Under this option Health Canada would define health care practitioner as a medical practitioner or nurse practitioner. Nurse practitioners would only be defined as a nurse practitioner within the meaning of section 1 of the *New Classes of Practitioners Regulations* who is permitted to support access to dried marihuana in their practice under the laws of the province in which they are registered and entitled to practise and who is not named in a notice issued under section 59 of the *Narcotic Control Regulations*.

Once the MMPR come into force and a consequential amendment is made to the NCPR to remove cannabis from the list of excluded substances, no other federal action would be required to authorize nurse practitioners to support access to marihuana for medical purposes. If a P/T has already included cannabis on the list of authorized substances for nurse practitioners to 'prescribe', the MMPR would allow them to do so as soon as it comes into force - assuming that marihuana would be considered a 'drug' and the medical document would be considered a 'prescription' under provincial or territorial law.

PROS

- Physicians and nurse practitioners belong to national associations and regulatory bodies that apply stringent rules and disciplinary actions for cases of inappropriate action with a controlled substance. This is congruent with Health Canada's objective of limiting diversion of marihuana to the extent possible;
- Continues to maintain control over marihuana by not allowing it to be administered by anyone;
- HCPs would have to comply with requirements set out in the NCR for practitioners with respect to keeping records on MM prescribed, received or provided; ensuring proper security and reporting on loss or theft within a specific timeframe to law enforcement and to HC;
- Respects P/T jurisdiction for scope of practice as HCPs would have to be authorized to support access to marihuana for medical purposes under their P/T legislation in their jurisdiction;
- Reduce the burden on patients as they would be able to seek the support of other HCPs;
- Allowing nurse practitioners, in addition to physicians, to support access to dried marihuana for medical purposes addresses a key recommendation of many stakeholders for enhanced access by patients.

CONS

- Added burden on HC if in future, we decide to allow other HCPs to support access to MM, there would have to be regulatory amendments to possibly a number of regulations (NCPR, MMPR);

Issue Analysis Summary
Health Care Practitioners

FINAL (Protected B)

Option 4: Status quo

Health Canada would not expand the role of supporting access to marihuana for medical purposes to any other health care practitioners. "Practitioner" in the MMPR would be defined as a licensed physician, and no amendments would be made to the NCPR.

PROS

- By restricting the role to only one health care profession, it could be argued that HC maintains tighter controls on MM;
- Physicians belong to national associations and regulatory bodies that apply stringent rules and disciplinary actions for cases of inappropriate action with a controlled substance. This is congruent with Health Canada's objective of limiting diversion of marihuana to the extent possible;
- Restricting the role of supporting access to physicians is well received by stakeholder groups who want to minimize the possibility of diversion (i.e. law enforcement).

CONS

- The status quo in this new regulation does not address concerns regarding physician access raised by stakeholders, including program participants and physician associations and the Ontario Court in the case of *R. v. Mernagh*
- [redacted]
- Added burden on HC if in future, we decide to allow other HCPs to support access to MM, there would have to be lengthy regulatory amendments to possibly a number of regulations (NCPR, MMPR);
- Inconsistent with treatment of marihuana like a medication in that there are other HCPs that are able to prescribe narcotics (under NCPR);
- Does not respect P/T jurisdiction over scope of practice;
- Does not address the immediate stakeholder concern to include other HCPs in the regulatory framework as it is still dependent on whether or not P/Ts permit under their legislation;
- Does not address access in remote areas where there may be not physicians available – may be seen to impede access in these cases.

Issue Analysis Summary
Health Care Practitioners

FINAL (Protected B)

CONSIDERATIONS

- The NCPR facilitate the adoption of an expanded scope of practice to include the "prescription of marihuana for medical purposes" to other health care practitioners. Should a P/T allow such an expanded scope of practice, a F/P/T discussion would be held to prepare the required regulatory amendment to the NCPR.
- Regardless of who is eventually able to support access to marihuana for medical purposes, a common concern among all stakeholders is that better access to information and educational material is needed to assist in the decision regarding the use of marihuana for medical purposes. The recommendations stemming from the Expert Advisory Committee could be expanded to target all health care practitioners who could eventually have a role in supporting access.
- There are accredited courses on the use of cannabis and other cannabinoids which are available to physicians. These courses are offered through the Canadian Consortium on the Investigation into Cannabinoids (CCIC).
- The newly created Expert Advisory Committee will provide recommendations to Health Canada on how best to communicate information about the use of marihuana for medical purposes to the medical community. This will enable Health Canada to address the concerns raised by physicians and their associations.

RECOMMENDATION

Option 3 is recommended as it aligns most closely with the objectives of reform. This option:

- Respects P/T jurisdiction over scope of practice;
- Expands access options for patients
- Treats marihuana as much as possible like a prescription narcotic.

This is **Exhibit "T"** 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

Issue Analysis Summary
Indoor/Outdoor Cultivation

DRAFT (Protected B)

ISSUE

Whether or not to allow outdoor cultivation of marihuana for medical purposes by licensed commercial producers (LCPs) under the new Program.

CONTEXT

Current Status:

Under the *Marihuana Medical Access Regulations* (MMAR), holders of a valid personal-use production licence (PUPL) or a designated person production licence (DPPL) have the option of having either an outdoor or indoor cultivation site to grow marihuana for medical purposes. Under Section 28 (1) (g) of the MMAR, the only requirement is that outdoor cultivation sites cannot be adjacent to any public property that is mainly frequented by persons 18 years of age or younger, such as a public playground, school or a day care. This requirement also mirrors that of the *Industrial Hemp Regulations* (IHR) with respect to outdoor cultivation. However, this requirement has been difficult to enforce as Health Canada (HC) does not proactively monitor these sites.

Proposed Changes:

Under the proposed changes, HC would cease to allow outdoor cultivation of marihuana for medical purposes. Cultivation would be limited to indoor sites only, which also includes greenhouses.

For context on the proposed changes to the MMAP, please refer to HC's consultation document entitled *Proposed Improvements to Health Canada's Marihuana Medical Access Program.*

CONSULTATIONS

Potential LCPs expressed that they were not overly concerned with the cost of securing an outdoor cultivation site, as they felt that the cost associated with indoor cultivation in terms of electricity and equipment would be about the same as costs of securing an outdoor cultivation facility. However, very few interested producers anticipate that they would grow outdoors because of product quality issues. Marihuana grown outdoors is of lower quality when compared to that grown indoors due to exposure to the elements such as temperature, air quality, bugs/pests, etc.

Issue Analysis Summary
Indoor/Outdoor Cultivation

DRAFT (Protected B)

IDENTIFICATION AND ANALYSIS OF OPTIONS

Option 1: Indoor cultivation only

LCPs would only be permitted to cultivate marihuana for medical purposes indoors only. Indoor would also include a greenhouse.

PROS

- Industrial hemp producers have expressed concerns that outdoor production of marihuana as allowed under the current program could lead to cross-pollination with their own industrial hemp crops, thus resulting in higher THC potency of hemp and a lower potency of marihuana. Although this would still be possible due to outdoor production of illicit crops, restricting producers of marihuana for medical purposes to indoor grow sites would address a concern of another Health Canada stakeholder group;
- Health Canada will require that LCPs maintain consistency across batches of product sold to registered individuals (i.e. if a product is marketed as 12% THC, LCPs will have to remain within a reasonable variation on either side of that in order to sell a particular harvest). It would be difficult to ensure batch consistency in an outdoor environment, where product quality would be less consistent due to environmental factors beyond a producer's control;
- Ability to produce maximum harvests and have plants at varying stages of growth growing concurrently – important when being a commercial entity to be able to consistently produce product all year around;
- Health Canada inspectors already have knowledge of how to inspect an indoor cultivation site because of the PPS contract, but have no such knowledge of outdoor cultivation sites;
- Easier and less costly to the LCP to secure an indoor facility as it is not visible to the public, contained within reinforced walls.

CONS

- Does not allow LCPs to make their own choice regarding cultivation site;
- Could lead to increased costs for light, water etc. to maintain an indoor cultivation site.

Option 2: Allowing outdoor cultivation

LCPs would be permitted to cultivate marihuana for medical purposes either indoors or outdoors. Sites would have to be appropriately secured based on selected mode of cultivation. As in the current MMAR and *Industrial Hemp Regulations* (IHR), outdoor production could not occur on a site adjacent to a school, public playground, day care facility or other place frequented mainly by persons under the age of 18 years of age.

Issue Analysis Summary

DRAFT (Protected B)

Indoor/Outdoor Cultivation

PROS

- Allows the LCP to make their own choice regarding cultivation site, as long as they are able to demonstrate that they can meet all security and quality requirements;
- LCP is able to significantly reduce some cultivation costs, such as hydro;
- May lead to higher yield than indoor plants as the plants are able to grow larger outside.

CONS

- Industrial hemp producers would continue to express concerns with respect to cross-pollination;
- A higher likelihood of batch inconsistency, as quality is highly dependent on environmental factors which LCPs would have little to no control over such as amount/intensity of light, amount of water and nutrients, temperature control and control over bugs and pests. While Health Canada will be able to inspect for quality, it will be difficult to monitor every harvest of an LCP producing outside to ensure that they are indeed compliant with the quality requirements;
- Outdoor production is not conducive to year-round production as it is dependent on the growing season;
- Likely higher costs for LCPs to secure the premises as they would require features such as barb wire/electric fencing, additional FT staff such as security guards;
- Poses a greater risk to diversion as marihuana plants are visible to members of the public;
- Law enforcement has advised that outdoor cultivation sites are easier to rig with "booby traps" to keep intruders out. While this evidence is in reference to illicit production, there could be increased safety risks to inspectors and law enforcement ;
- Added burden on HC as we would need to develop both indoor and outdoor cultivation security requirements/guidance for which we currently have no expertise.

Issue Analysis Summary
Indoor/Outdoor Cultivation

DRAFT (Protected B)

CONSIDERATIONS

- HC has previously allowed marihuana for medical purposes to be cultivated outdoors under MMAR. However, this was allowed for production on a much smaller scale for individuals with a PUPL or DPPL and has been highly criticized by many stakeholders, including industrial hemp producers.

- HC will be working with the RCMP to conduct an overall Threat Risk Assessment to assist in the development of an overall security framework. This security framework will be incorporated into regulation and will dictate the precise requirements that LCPs must have in place in order to be licensed, depending on a number of factors, including proximity to high-crime areas, potential for diversion, and value of the asset. This work is currently ongoing and will be examined under separate cover.

- With outdoor cultivation, it would likely be impossible to produce consistent crops due to the inability to control inputs. The amount of water and light each plant is exposed to is not standardized.

RECOMMENDATION

Option 1 is recommended because it ensures that there is little risk to neighboring crops, provides consistent access to a year round supply of marihuana for patients, a consistent product quality, would not be openly visible to members of the public and would be easier to physically secure than an outdoor cultivation site. Furthermore, since outdoor cultivation is more visible to the public, LCPs would need to meet rigorous physical security requirements set out by HC to ensure public health and safety.

NEXT STEPS

Consultation with the RCMP and other individuals with appropriate expertise will be engaged.

This is **Exhibit "U"** 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

Issue Analysis Summary FINAL (Protected B)
International Trade – Marihuana for medical purposes
Solicitor-Client Privilege/Protected

ISSUE:

Should the Marihuana for Medical Purposes Regulations (MMPR) provide an enabling mechanism to allow LPs to engage in the international trade of dried marihuana for medical purposes? [1]

CONTEXT:

International Drugs Conventions

Canada is party to the *United Nations Single Convention on Narcotic Drugs, 1961* (the *Convention).* As a party to the *Convention*, Canada must take measures to give effect to and carry out the provisions of the Convention. These measures include limits on the quantity of drug [2] that may be imported or manufactured (determined based on estimates supplied to the International Narcotics Control Board ([NCB] by the Government of Canada), as well as controls on import, manufacture and distribution. Article 23 of the Convention requires that a party that permits the cultivation of the cannabis plant [3] establish a national agency that purchases and takes physical possession of all stock and have exclusive rights to importing, exporting, wholesale trading, and maintaining stocks.

It should be noted that Health Canada is designated as the agency for this purpose but it does not purchase and take physical possession of the cannabis plant produced by individuals pursuant to a production license issued under the Marihuana Medical Access Regulations (MMAR). However, the underlying objective of article 23 of the Convention is to ensure that there is effective government control over the cultivation, production and distribution of marihuana to prevent misuse and diversion. To that end, the MMAR establish a licensing regime with controls and inspection provisions to help prevent diversion of marihuana for medical purposes into the illicit market. While the

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1 For the purposes of this analysis, international trade refers to importation/exportation activities that are undertaken for commercial reasons, and not for intended personal use. For example, a LP could not import from an individual in another country or export to an individual in another country. Transactions would have to take place between appropriately licensed and permitted entities.

2 The term "drug" in the Single Convention on Narcotic Drugs, 1961, includes cannabis and cannabis resin and extracts and tinctures of cannabis. The term "cannabis" is defined in the Single Convention on Narcotic Drugs, 1961, as "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated).

3 The term "cannabis plant" is defined in the Single Convention on Narcotic Drugs, 1961, to mean any plant of the genus Cannabis.

Issue Analysis Summary FINAL (Protected B)
International Trade – Marihuana for medical purposes
Solicitor-Client Privilege/Protected

MMAR may not strictly comply with the technical requirements of article 23 that a government central purchasing and distribution agency receive and take possession of the crop, the regime puts in place strict measures to limit the production, use and distribution of marihuana to medical purposes and to prevent misuse and diversion, consistent with Canada's legal obligation under the *Single Convention* . Health Canada also keeps track of the number of authorized and licensed individuals under the program, and provides annual consumption estimates annually to the INCB.

Import/Export process

Currently under the *Narcotic Control Regulations (NCR)*, only a licensed dealer who has been issued a permit may import or export a narcotic including marihuana. In addition to their licence, a licensed dealer requires an import or export permit. A permit specifies the name and quantity of the narcotic, the importer, the exporter, the method of transportation and the port of entry into Canada. A permit is valid for one transaction only.

Upon issuance, a copy of the import permit is typically supplied to the exporter of the narcotic, who in turn supplies it to the government of the country of export. That government would be able to issue a corresponding export permit, based on both the import permit and the importing country's total estimated requirement for that narcotic. In addition, the *Convention* requires that a copy of the export permit accompany the shipment, and that the government issuing the export permit send a copy to the Government of the importing country.

Current Program

Under the *Marihuana Medical Access Regulations* (MMAR), marihuana for medical purposes is produced in Canada, either by Prairie Plant Systems (PPS), a private company under contract to Health Canada, or by individuals (or their designates) licensed by Health Canada to produce marihuana for their personal medical purposes.

The MMAR also authorizes the Minister to import and possess viable cannabis seed for the purpose of selling, providing, transporting, sending or delivering the seed to the holder of a license to produce or to a licensed dealer. However, in practice, PPS domestically produces cannabis seeds that could be purchased by holders of a personal or designated production license so that they may cultivate their own marihuana. Canada does not currently import marihuana for medical purposes, either

dried or in starting material form.

Importing dried marihuana has, however, been considered as an alternative to the current domestic contract. In 2003, when the Government was instructed by the courts to ensure that Canadians have access to a legal supply of marihuana for medical purposes, the Government looked to other jurisdictions. The National Institute of Drug Abuse (NIDA) in the United States sold dried marihuana cigarettes at $2 CDN per gram, but would agree to sell to Canada for research purposes only. The Netherlands, the only other Government running a national program at the time, estimated their price at $13 CDN per gram.

The Netherlands therefore offered the only possible source, but was not considered feasible due in part to its cost (which exceeded the price on the Canadian black market, estimated at the time to be within the range of $10 to $20). Furthermore, Health Canada had a limited amount of time to procure a legal source of marihuana due to the Court decision, and import from the Netherlands presented too many time constraints. Health Canada also considered that it would be necessary to perform further quality testing on the Dutch product prior to distributing it, which would have resulted in additional expense and which would have required a distribution contract with another entity. Finally, because the Netherlands offered the only import option at the time, a sole source contract would have been required [redacted]

Proposed changes:

The proposal to reform the current Marihuana Medical Access Program (MMAP) is silent on the issue of import and export.

Consultations:

The issue of import and export did not come up during consultations with potential domestic LPs.

Issue Analysis Summary FINAL (Protected B)
International Trade – Marihuana for medical purposes
Solicitor-Client Privilege/Protected

Bedrocan, the producer of marihuana for medical purposes for the Netherlands government, was consulted to determine their interest in becoming a LP under this framework. Bedrocan expressed an interest in observing the market in its first few years before deciding whether or not it would be a successful business venture for them. They did, however, indicate an interest in exporting their starting materials (i.e. cannabis seeds) to either the Government of Canada or to interested LPs.

[redacted]

ANALYSIS

Legal issues: Access

Canadian courts have established that the Government must allow for reasonable access to a legal supply of marihuana for medical purposes. The creation and regulation of an industry of licensed producers, as proposed through this initiative, should help achieve this objective. [redacted]

One of the keys to success for future licensed producers will be the ability to secure appropriate starting materials from which to begin to cultivate marihuana for medical purposes. Through an examination done under separate cover (see Seeds IAS), it was determined that importation from jurisdictions with similar programs could be an option for LPs to obtain their starting materials. This could provide for a greater variety of strains for the consumer.

There may also be other conditions under which LPs would need to look to alternative sources to obtain marihuana, for example, should a LP suffer a crop failure. The

regulations will contain provisions that allow LPs to sell product to one another. Enabling LPs to import marihuana from international sources could improve licensed producers' capacity to supply registered clients with a broad range of dried marihuana strains for medical purposes.

Legal issues: Other regulations to be considered

Licensed dealers who import or export therapeutic products containing narcotics are subject to the applicable requirements of the CDSA and the NCR. They are also subject to the applicable requirements of the Food and Drugs Act (FDA) and the Food and Drug Regulations (FDR). As such, currently a licensed dealer (other than PPS who is exempted from most requirements of the FDA/FDR under the Marihuana Exemption Regulations) who would be issued a permit to import or export dried marihuana for medical purposes would also be subject to the applicable requirements of the FDA and the FDR. Should it be decided that the MMPR would not enable LPs to import or export dried marihuana and should HC wish to allow licensed dealers to do so, one option to be considered would be to exempt licensed dealers, when importing or exporting dried marihuana for medical purposes, from certain requirements of the FDA and the FDR and subjecting them instead to the certain requirements of MMPR as they relate, for instances, to product quality and record keeping.

Also, since licensed dealers are not authorized under the NCR to sell directly to individuals for their medical use, regulatory changes would be required to either allow licensed dealers to provide imported dried marihuana to LPs for further sale or to authorize licensed dealers to sell dried marihuana directly to patient under certain terms and conditions.

Economic issues:

A key factor in providing reasonable access to a legal source of dried marihuana for medical purpose is to ensure that there are a sufficient number of interested LPs who can become licensed and who are capable of producing and distributing enough dried marihuana for medical purposes to supply all registered clients. It is therefore in Health Canada's interest to attract a sufficient number of LPs.

Providing for an enabling export mechanism through this new regulation may attract LPs interested in exploring international markets. Indeed, countries which are establishing programs, such as Israel, have indicated that they are looking for

international sources of marihuana for medical purposes as opposed to domestic ones.[4]

International Obligations

The 1961 Convention provides a framework for limiting the possession, use, trade in, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes. It also provides a framework to address drug trafficking through mechanisms for international cooperation which are aimed at deterring and discouraging drug traffickers. As Canada is a party to the Convention, any consideration to allow LPs to produce, distribute, import or export marihuana must be done so in compliance with its international obligations as noted above.

As noted above, the import/export process currently provided for under the NCR requires that only licensed dealers under that regulatory framework are permitted to import or export and that appropriate permits from Health Canada are required in order to undertake this type of transaction, consistent with Canada's international legal obligations with respect to international trade in narcotics. The proposed import-export provisions in the MMPR will maintain this process.

[redacted]

Administrative burden:

As indicated above, absent a specific requirement in the MMPR that permits LPs to import/export marihuana for medical purposes, interested LPs would have this avenue open to them under the existing NCR framework. However, one key aspect of the NCR which will not be included in the MMPR framework is the notion of the "qualified person in charge" or QPIC. Under the NCR, a licensed dealer is required to designate a QPIC to have overall responsibility for licensed activities. The QPIC is required to be a

4 Based on conversation between representatives of Canada and Israel at the 2012 Vienna meeting.

pharmacist, practitioner, or to have a degree in an applicable science. Based on stakeholder consultations, this requirement is likely to be burdensome for small LPs, and given the differences between the skills and qualifications needed to grow marihuana, and those required for pharmaceutical drug production, this requirement for the QPIC would likely not add value. A more suitable model to follow for marihuana would be to include a requirement for a senior person in charge/responsible person in charge, as described in the Precursor Regulations, thus still requiring designated personnel to be responsible for activities, while not specifying their professional qualifications.

Without the inclusion of enabling import-export provisions in the MMPR, LPs wishing to import or export would therefore be required to also become licensed dealers under the NCPR, which would create additional administrative burden for the LP, and additional resource implications for Health Canada for application processing and inspections, with no additional benefit in the form of security controls.

CONSIDERATIONS

Quality monitoring

Regardless of the framework chosen to permit import and export of marihuana for medical purposes, there are implications with respect to quality of the product. Specifically, under the MMPR, quality standards will apply to the end product (i.e. dried marihuana) being produced and distributed to clients. As an eligibility requirement for application, LPs will have to demonstrate how they will meet the standards set out by Health Canada. Quality standards in the regulations will describe Good Manufacturing Practices, similar to those currently in place for Natural Health Products, such as for record keeping and manufacturing conditions that will ensure a consistent final product. Specific finished product requirements, for example, for microbial and heavy metal testing, will be set out in technical documents. There will be no requirement for a specific cannabinoid content.

For drugs other than marihuana for medical purposes, Canada is a participant to Mutual Recognition Agreements (MRAs), which cover good manufacturing practices (GMP) Compliance Programs with the European Community, the European Economic Area, Australia and Switzerland. MRAs allow an importer of a drug that is fabricated, packaged, labelled or tested in a building recognized by an MRA country to

demonstrate to Health Canada compliance with GMP standards, without having to be inspected or having to submit evidence establishing compliance with GMP standards. In countries where HC does not have an MRA, or for activities conducted in a building not recognized by an MRA country, the importer could submit a certificate from a Canadian inspector or other evidence establishing compliance with GMP standards.

There are no such reciprocal agreements for marihuana, although there are international standards such as the World Health Organization Quality Control Methods for Medicinal Plant Materials and the WHO Guidelines on Good Agricultural and Collection Practices which could serve as guides to ensure quality of imported marihuana.

To ensure that imported marihuana meets the quality requirements under the MMPR, one option could include a border monitoring program, which would be resource intensive for Health Canada and its partners. A second option could be to, through regulation, require that LPs who import dried marihuana for the purposes of distribution ensure that it is compliant with the MMPR quality standards, within a specified period of time, prior to its distribution. They could in turn be required to provide evidence to Health Canada (i.e. test results or Good Manufacturing Practices certification) to demonstrate compliance with the MMPR quality standards.

Security:

The MMPR will include physical security requirements which will have to be met by LPs prior to obtaining a license. These measures are meant to reduce the risk of diversion (i.e. to protect large amounts of marihuana from potential threats). For marihuana imported from an international source, Health Canada would not require a site inspection to ensure that the marihuana is produced in a secure location. As for other controlled substances, import or export will be limited to a single transaction per permit, and will not be allowed without the appropriate authorization and permit from the other country's competent authority.

RECOMMENDATION

It is recommended that the MMPR include a mechanism to enable importation and exportation of starting material and dried marihuana. This option is recommended for the following reasons:

- LPs will be required to demonstrate compliance with strict security and quality requirements, including the requirement to have security measures in place, and to have gone through appropriate criminal record checks prior to obtaining a licence. These provisions are similar to the requirements outlined in the NCR, BOTSR, PCR and FDA5 to obtain a dealer's licence. [redacted]
- To meet market demand in time to allow for the elimination of personal and designated production by March of 2014, licensed producers will have to begin production as soon as they become licensed by Health Canada. They will first have to obtain starting materials (i.e. seeds). To prevent them from turning to illegal sources, Health Canada would like to facilitate access to the widest possible number of legal avenues. This could include importation from legitimate markets abroad, such as countries which operate similar programs. Furthermore, providing licensed producers with the opportunity to import finished product could mitigate against risks of domestic shortage in the case of extenuating circumstances (such as crop failure). Allowing licensed producers to obtain a contingency source to sell and distribute could prevent individuals requiring access from turning to illicit sources to obtain their dried marihuana. This could also help to ensure that reasonable access to marihuana for medical purposes is not interrupted even though personal and designated production have been eliminated.
- Security and record keeping requirements to be included in the regulatory framework will address Canada's international obligations under the Single Convention.
- This option would not limit the market to Canadian sources, which would help satisfy international trade requirements, in a manner similar to OTC drugs and prescription medications.
- It may help to provide additional legal sources of marihuana, thus supporting the argument that Health Canada is taking appropriate steps to ensure reasonable access to a legal source of marihuana for medical purposes.
- It supports the reduction of administrative burden to small businesses by not requiring that they undertake additional steps to be able to import or export.
- It may encourage interest in becoming a LP by giving entities an option of looking

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5 Narcotic Control Regulations; Benzodiazepines and Other Targeted Substances Regulations; Precursor Control Regulations; Food and Drug Regulations

for international markets, thus helping to promote the viability of the domestic market.

- A viable Canadian industry requires sufficient interest from businesses in becoming licensed. In recent discussions with Health Canada, Israel noted that it is looking to reform its own marihuana program by replacing small-scale domestic production with import from foreign sources. Allowing licensed producers to take advantage of such export opportunities to legitimate markets could provide additional incentive to entities considering entering this market.

This is **Exhibit "V"** 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

Issue Analysis Summary

FINAL

(Protected B)
Labelling

ISSUE

Under a reformed Marihuana Medical Access Program, licensed producers (LPs) are responsible for the labelling of marihuana packages prior to shipping via secure courier to clients. This IAS outlines the proposed labelling requirements for LPs.

CONTEXT

In Canada, marihuana that is manufactured, sold or represented for medical purposes meets the definition of a drug under the *Food and Drugs Act* (FDA). As with other drugs, a Drug Identification Number (DIN) would generally be needed before marihuana could be legally sold in Canada for medical purposes. However, under the current MMAP, dried marihuana can be produced and sold by Prairie Plant Systems (PPS) and holders of designated-person production licences. With the exception of clinical trials, marihuana produced and sold under these circumstances is exempt from the FDA and its regulations, due to the *Marihuana Exemption (Food and Drugs Act) Regulations* (MER):

> Marihuana is exempt from the application of the *Food and Drugs Act* and the regulations made under it, other than these Regulations, if it is produced:
> (a) under contract with Her Majesty in right of Canada; or
> (b) under a designated-person production licence, as defined in subsection 1(1) of the *Marihuana Medical Access Regulations*.

The above MER exemption from the application of the FDA and its regulations includes activities such as labelling. In the case of PPS, specific labelling requirements were described in the contract. With respect to designated-person production, there are no labelling requirements.

Under section 2 of the *Food and Drugs Act*, a label is defined as "including any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package". Drug labeling also refers to all of the printed information that accompanies a drug, including the label, the wrapping and the package insert. In Canada, depending on which schedule the drug falls under, drug labeling for over-the-counter, prescription and narcotic drugs must comply with the *Food and Drugs Act,* as well as related provisions of the *Food and Drug Regulations,* and the *Controlled Drugs and Substances Act,* and its related *Regulations* including the *Narcotic Control Regulations,* Part G and J of the *Food and Drug Regulations* and the *Benzodiazepines and Other Targeted Substances Regulations*.

Current Status:

Except as authorized by regulation, the possession of cannabis is prohibited under the *Controlled Drugs and Substances Act*. Individuals who wish to have access to dried marihuana for medical

Issue Analysis Summary

FINAL

(Protected B)
Labelling

purposes must apply to Health Canada. As part of the approval process, Health Canada allows program participants to choose one of three supply options; personal production, designated production and a Health Canada supply. The Health Canada supply is currently contracted out to PPS.

PPS is required to meet all labeling requirements described under the contract with Her Majesty in right of Canada. These requirements include: the product name, the plant scientific name and form, the lot number from which the product is harvested, the date harvested, the package contents, storage information, product content (THC etc), the expiry date, a general statement advising to "Keep out of reach of children" and a statement which indicates that the marihuana was produced and packaged for Health Canada. Health Canada also provides detailed information about the strain available from PPS on its website. In addition, two Health Canada inserts are also included in the package; a notice to applicants (annex A) and a product information insert (annex B). The notice to applicants details risks and recommendations about dried marihuana for medical use, while the product insert details generic information about the use of marihuana for medical purposes, including warnings, precautions, interactions, use, side effects, storage information, and instructions for reporting adverse reactions.

In contrast, personal and designated production do not require any form of labeling. However, program participants would receive much of the above information when they purchase their initial seed supply from PPS to begin growing.

Currently for other narcotics, the pharmacist provides the client with the prescribed narcotic and an information package with directions for use, contraindications, side effects, etc. This package is often not standardized and may vary from pharmacy to pharmacy. With respect to dispensing, the narcotic is provided to the client according to the directions of the physician and in a container with a standardized label. This label includes the client's name, physician's name, pharmacy name and address, date the drug was dispensed, a DIN, prescription number, name of the substance, number of tablets dispensed and directions for use.

Proposed Changes:

Under the proposed changes, LPs would be permitted to produce any strain of marihuana. Health Canada would require that all LPs comply with specific labelling requirements as outlined in regulation, so that LPs would be providing appropriate information about the product to consumers. Such information would be captured in three ways: the consumer package itself, an additional proof of possession label that would be affixed to the package, and a generic product information insert.

For additional context on the proposed changes to the MMAP, please refer to Health Canada's consultation document entitled *Proposed Improvements to Health Canada's Marihuana Medical*

Issue Analysis Summary

FINAL

(Protected B)
Labelling

Access Program.

Consultations:

Given that there is limited scientific research and knowledge regarding the risks and benefits of consuming marihuana for medical purposes, some prospective LPs have indicated that they are concerned that they would be held liable should an individual suffer an adverse reaction from consuming their product. Some LPs have suggested that they would require clients to sign some form of waiver, perhaps in the form of a signed declaration.

Law enforcement is supportive of the overall framework, but asked that Health Canada consider measures in regulation to guard against the possibility of diversion or criminal involvement in the production of marihuana. This could include measures to ensure that labels and packages cannot easily be counterfeit.

PROPOSED REQUIREMENTS FOR LABELING

Criteria:

The labelling of dried marihuana for medical purposes by the LP must contribute to the goals of the reform. The requirements to be imposed by regulations should:

- treat marihuana as much as possible like a medication, and individuals have access to information about the known characteristics and risks associated with the product, as well as an avenue for the reporting of adverse reactions;
- not significantly increase the administrative burden for the LP;
- mitigate potential risks to public health, safety and security from permissible use;
- not inhibit government's ability to control non-medical use as provided for under the CDSA and its regulations; and
- provide clear and concise information about the product, including risks and uses to the consumer.

Proposed requirements:

The regulations will set out the information that LPs are required or prohibited to display for clients. The regulations will also set out three media to display labeling information: the consumer package itself, a proof of possession label that will be affixed to the package when an LP fills a client-specific order, and generic information about the product, to be included as a package insert. The approach outlined below is consistent with the principle of treating marihuana as much as possible like a medication, as it will ensure that LPs provide clients with the same type of information that they could expect if they were purchasing a medication. Furthermore, label information must appear on packages in both English and French and must be readily discernable.

Issue Analysis Summary

FINAL

(Protected B)
Labelling

Product Label

Once the LP has gone through the processing and manufacturing of the plant material into dried marihuana, including the required testing, dried marihuana would be packaged and stored until such a time as an order needs to be filled. The consumer package (also known as the immediate container) must contain information that is specific to its contents:

- licensed producer's name;
- include words dried marihuana/marihuana séchée;
- brand name;
- lot number from which the product was harvested;
- cannabinoid profile, specifically the percentage of tetrahydrocannabinol w/w, and the percentage of cannabidiol;
- net weight (g);
- recommended storage conditions;
- packaging date;
- either: A) its expiry date or;
  B) statement to the effect that no expiry date based on stability data has been determined for the dried marihuana;
- the symbol "N" set out in the upper left corner of the label in a colour contrasting with the rest of the label or in type not less than half the size of any other letters used on the label;
- the warning "KEEP OUT OF REACH OF CHILDREN";
- the statement "Important: Please read the Health Canada document provided with this package before using dried marihuana

Client Label

Once a registered client places an order, the LP will need to prepare a package for shipping. Part of this process will affix a label that includes more personalized consumer information onto the package as well as a product receipt. As per a previous IAS, this label will also serve as proof of possession so that program participants may demonstrate that they are in lawful possession of marihuana. The label and product receipt would include:

- the given name and surname of the client;
- the given name, surname and profession of the health care practitioner who provided the client's medical document;
- the name of the licensed producer;

- the daily quantity of dried marihuana indicated on the client's medical document;
- expiry date of the client's registration;
- date shipped by LP

The product label and client label may be combined into one label, however a separate receipt containing the information for proof of possession must be provided to the client. All information required on both labels must appear on the label in English and French, be displayed clearly and prominently, and be readily discernible under the customary conditions of purchase and use.

Information on the Use of Marihuana for Medical Purposes

LPs will also be required to provide generic information regarding the use of marihuana for medical purposes. Such information must be included in the final package being shipped to the consumer, and includes:

- known warnings/precautions;
- known interactions with the product;
- instructions on how not use the product;
- known side effects;
- instructions on how to report adverse side effects; and
- potential known risks.

Such product information is generally developed by a product manufacturer based on information gathered during a clinical trial. Such evidence does not exist for dried marihuana, and LPs will not be required under regulations to develop this information as they cannot do so without conducting a clinical trial. Health Canada has already prepared two product information inserts, based on its *Information for Health Care Practitioners* document, which PPS must include in each package. It is recommended that Health Canada update these current documents and require LPs to use them. Health Canada would also keep these documents up to date as additional evidence or information becomes available.

CONSIDERATIONS

- Requiring LPs to provide complete product information to their clients will ensure that the consumer is aware that there are certain risks associated with the use of marihuana for medical purposes, and that marihuana has not been authorized for therapeutic use under the FDA. This may not address all liability concerns raised by potential LPs; however, this is a natural business risk for an entity to assume if they wish to become an LP. For example, Health Canada would not prevent, through this regulation, LPs from requiring

that their customers sign a declaration indicating that they are aware that there are no known studies demonstrating that risks of marihuana consumption outweigh the benefits or other statements similar to those in the current declaration.

- Regulations will stipulate that all required information must be prominently displayed. Therefore, a proof of possession label could not be affixed over key information on the consumer package.

- The proposed labeling requirements are consistent with other regulatory frameworks, including the *Food and Drugs Regulations* and the *Natural Health Product Regulations*. They are also consistent with the type of information that PPS is required to display under its contract with the Crown.

RECOMMENDATION:

As described above, all three types of mechanisms for displaying labeling information; product label, client label and Information on the Use of Marihuana for Medical Purposes ensure that individuals have access to information about the product which they are purchasing for their medical use, as well as being able to prove legal possession of medical marihuana. This approach is consistent with the principle of treating marihuana as much as possible like a medication.

This is **Exhibit "W"** 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

Issue Analysis Summary FINAL (Protected B)
Interaction with local authorities

Solicitor-Client Privilege/Protected

Issue

Whether to require, through regulation, that licensed producers (LPs) obtain appropriate approvals from and/or notify local authorities (i.e. local governments, law enforcement and fire officials) prior to obtaining a license to produce and distribute marihuana from Health Canada, and whether to prohibit, through regulation, LPs from operating in a dwelling-place.

Context

The Current Program

Under the current *Marihuana Medical Access Regulations* (MMAR), Health Canada licenses individuals to produce marihuana for medical purposes. License holders either produce for themselves with a personal use production license (PUPL), or for a maximum of two authorised persons with a designated person production license (DPPL). While applicants must provide a description of the security measures that they intend to implement in order to protect the production and storage sites, the MMAR do not prescribe any specific security measures. Nor do they require holders of PUPLs and DPPLs to adhere to any specific quality control measures for the production of marihuana for medical purposes.

With respect to information sharing, the MMAR include a provision that allows Health Canada to communicate limited information to a Canadian police force if such information is requested in the course of an investigation under the *Controlled Drugs and Substances Act* (CDSA) or under the regulations. The MMAR do not, however, enable Health Canada to share information about production site locations proactively with law enforcement. Nor does Health Canada have the authority through regulation to proactively share information such as the location of production sites with local governments or local fire services.

In recent years, a wide range of stakeholders including police and law enforcement, fire officials, physicians, municipalities, and program participants and groups representing their interests, has identified concerns with the current program. Some of the key concerns are related to the ability of individuals to produce marihuana in homes, and include:

- 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 in private dwellings;

- public safety risks, including electrical and fire hazards, stemming from the cultivation of marihuana in homes that were not designed for the scale of production currently being undertaken;
- public health risks due to the presence of excess mould and poor air quality associated with the cultivation of marihuana plants in homes that were not designed for the scale of production currently being undertaken; and
- the inability of Health Canada to proactively share information regarding the location of production sites with local authorities, including municipal governments, fire services and law enforcement.

The MMAR authorize Health Canada to inspect production sites to ensure that marihuana is being produced as per the regulations and the conditions of their license. However, s.57(2) states that "an inspector may not enter a dwelling-place without the consent of an occupant of the dwelling-place." In May and June of 2010, the Controlled Substances Program of Health Canada's Regions and Programs Branch identified 35 sites in British Columbia and 40 in Ontario to inspect. Specific findings include:

- a success-rate (measured in terms of numbers of individuals who permitted Health Canada to conduct a compliance verification and/or voluntary compliance promotion) of 36% (27 out of 75 doors answered);
- the operation of a compliance and enforcement program specific to Health Canada would be costly, estimated, in May 2010 (when there were approximately 3,300 production licenses) to cost $27.4M.

This exercise demonstrated the difficulties that Health Canada has in effectively inspecting marihuana production sites that are located in residences. A summary of the inspection initiative, which includes more detailed findings, can be found in Annex A.

Proposed changes

Under the proposed redesigned program, the Marihuana for Medical Purposes Regulations (MMPR), Health Canada would no longer authorise individuals to produce their own marihuana or to have it produced by a designated person for medical purposes. The only legal source of dried marihuana would be LPs, who would be licensed and regulated by Health Canada to produce and distribute dried marihuana. These producers would be subject to inspection and audit to ensure that they are compliant with the new regulations.

Because local zoning and bylaw application is a municipal responsibility, the proposed changes do not contemplate restricting licensed commercial production to specific zones or locations. Municipalities retain the ability to decide if a

business should be established within its community, as well as to determine where businesses should be located (i.e. in commercial or industrial sectors). This would be the case with licensed producers as well. Municipal governments could decide to restrict them to certain locations, and would be able to inspect and enforce all applicable bylaws (i.e. inspections for compliance with fire codes) for licensed producers, as they do with all other businesses located within their area of jurisdiction.

The proposed regulations would prohibit the production of marihuana in dwelling places. They would also require producers to meet strict security, quality and record-keeping requirements. Entities unable to demonstrate how they meet these requirements would not be able to obtain a license to produce. A pre-condition for licensing would also be to consent to an inspection by a Health Canada inspector.

For more context on the proposed changes, please see http://www.hc-sc.gc.ca/dhp-mps/consultation/marihuana/ 2011/program/consult-eng.php

Consultations

Federal and provincial public safety officials, municipalities, law enforcement and fire officials are highly supportive of the proposed phase-out of personal and designated production, indicating that this measure would address most of their concerns regarding public safety, security and public health risks. They indicated that they would like to know the location of production sites as licit production sites, although less risky due to proposed quality and security guidelines, could still pose health and safety risks to both first responders and the general public, particularly in instances where first responders are called to deal with an emergency at a production site. During consultations, these groups presented many suggestions for Health Canada's consideration in order to ensure that licensed commercial production is undertaken in the safest of conditions. These suggestions include:

- a requirement that LPs obtain a business license from their local government;
- a requirement that LPs provide proof to Health Canada that they have received all necessary approvals from municipal governments prior to being granted a license;
- a requirement that law enforcement and fire officials be given the address and blueprints of all licensed commercial producers.

Issue Analysis Summary FINAL (Protected B)
Interaction with local authorities

With respect to the production of marihuana in dwelling places, law enforcement[1] has provided Health Canada with evidence demonstrating the potential for harm as a result. Specifically, with respect to the location of these production sites in a dwelling site, law enforcement has provided the following information:

- Production sites can be targeted by criminals who commit an invasion in order to steal or destroy a crop ("grow-rips"). When a production site is in a dwelling place, this exposes all family members, including children, to violence. Of the cases examined, the CACP noted that children were present during a home invasion in 15 cases (Canadian Association of Chiefs of Police 2010: 20).
- Grow-rips often lead to the violent victimization of producer or of unrelated and innocent bystanders, including neighbours who reside in close proximity to a production site. The CACP has provided case evidence of individuals whose dwelling place was invaded because of mistaken identity or a mistaken address (Canadian Association of Chiefs of Police 2010: 21-22).
- Grow-rips often involve the use of weapons, including firearms, knives, and instruments that can be used as weapons (i.e. pepper spray, baseball bats, blunt instruments) (Royal Canadian Mounted Police 2012: 3).

Recommended approach

Health Canada's objective through this new regulation is to reduce the risks to public health, safety and security that may stem from the production of marihuana by individuals in homes. These risks are exacerbated by a series of factors: (1) the location of production sites is not known to local authorities; (2) dwelling places are not typically designed for the large scale production of marihuana for medical purposes; (3) inspection of a dwelling-place requires the consent of an owner, which, based on recent experience, is not always granted; and (4) dwellings which are the site of a marihuana production operation can be targeted for invasion, thus exposing residents and their neighbours to violence.

In order to meet this objective, Health Canada is proposing the following:

The regulations would explicitly prohibit licensed producers from operation in a dwelling-place.

As a condition of receiving a license, producers would be required to provide proof of notification to local government, law enforcement and fire officials of their application to Health Canada and of their production address. This will respond

[1] See Annex B, Canadian Association of Chiefs of Police. 2010. *An Analysis of National Cases Related to the* Marihuana Medical Access Regulations, and Annex C, Royal Canadian Mounted Police. 2012. *Marihuana Grow Operations and Related Violence in Canada.*

to the concerns from local governments and first responders that they are not aware of the location of marihuana production sites in their areas. While not required to be explicitly outlined in regulation, Health Canada could also, in the processing of an LP application, conduct a verification with local government to ensure that they were indeed properly notified and that the proof of notification is legitimate.

The regulations would also provide Health Canada with the ability to share information with local government, if it is necessary to communicate that information for the proper administration or enforcement of the Act or the regulations. With respect to information-sharing with law enforcement, information gathered during an inspection could be shared in specific circumstances with any Canadian police force or member thereof for the purposes of a criminal investigation. The specific issue of information sharing with all possible entities will be examined in further detail under separate cover.

The regulations would contain provisions that allow Health Canada to suspend or revoke a license from an LP if it is found that continuation of that license would likely create a risk to public health safety or security (including a risk of diversion), or if it is found that the license was issued on the basis of false or misleading information. In the case of the latter, if it were later found by Health Canada that the LP did not indeed notify the municipality as required, the license could be revoked.

Health Canada would be authorized to conduct an inspection of a production site as required, including prior to licensing. As production sites would not be in dwellings, Health Canada would not require the consent of an owner prior to entering the premises.

Other options considered but not recommended

Option 1: Prohibit under the new regulations, the production of marihuana in residential areas.

The Federal Government does not have jurisdiction on where a business can operate within a municipality. If municipalities want to prohibit an activity from taking place in a certain area they need to pass their own by-laws to that effect. The proposed MMPR would require a prospective LP to notify the municipality which would enable the municipality to verify compliance with applicable by-laws.

Option 2: Set minimum and/or maximum production requirements.

This option was considered as a method to curb production in residential areas and dwelling units, to ensure that LPs are not an extension of current PUPLs or DPPLs and to maintain an adequate supply of dried marihuana to meet market demands. However, imposing maximum or minimum requirements on production runs counter to Health Canada's goals of treating marihuana as much as possible like any other medication and of creating a free-market industry. The risk of production in residential areas and dwelling units is mitigated by minimum quality and security requirements that will make at-home production and the concerns surrounding it unfeasible.

Option 3: Require a copy of a business license.

To establish a business, many local governments require the issuance of a business license. Generally speaking, an entity wishing to obtain a business license must register with the province and adhere to municipal by-laws and regulations. This includes registering their address and type of business (i.e. commercial, agricultural or industrial) and in many cases obtaining permits from the municipality for compliance with fire code, health and safety requirements etc. In so doing, these entities are known to their municipal governments and local authorities.

Unfortunately, the practice of requiring registration of businesses and the issuance of business licenses is not one that is consistent across jurisdictions. Every province and every municipality has different rules, and in some cases (i.e. organized territories – an area that does have local government services), there may not be a requirement for a business license at all. In a case where an LP wishes to establish in an area that does not require a business license, inclusion of this requirement in the proposed regulatory framework would in fact be prohibitive. It should also be noted that there is no requirement under the *Narcotic Control Regulations* (NCR) to provide Health Canada with a copy of a business license prior to being issued a dealer's license. Nor do the *Food and Drugs Regulations* require a copy of a business license as a requirement for applying for an establishment license.

This option would make Health Canada's issuance of a licence contingent on a third party's approval [redacted]. The proposed reform must allow for reasonable access to marihuana for medical purposes under the *Charter*. If, for example, a municipality, once informed of the location of the production site, cannot provide a reasonable justification for their actions in withholding or delaying the appropriate licence, [redacted]

[redacted]

It should be noted, however, that municipalities could still create by-laws that would restrict the location of an LP, or even prohibit them altogether. [redacted]

Option 4: Requiring that LPs demonstrate proof that they have obtained all municipal approvals prior to issuing a license

Some stakeholders have suggested that Health Canada should not consider issuing a license until an LP has obtained all necessary approvals (i.e. fire inspections) from its local government.

Health Canada does not recommend that such a requirement be included in the new regulations by a similar rational to option 3 where Health Canada's licence would be contingent on a third party's approval, leaving Health Canada vulnerable to legal challenges.

Recommendation: A combination of modified option 1 and option 4 is recommended. Residential area zoning is beyond HC jurisdiction however, safety/security of Canadians is not and therefore preventing production in dwelling place provides adequate mitigating strategies to health safety and security risk. In addition, requesting that potential LP provide proof that they have notified local government, police and fire department (not obtain approval) seems prudent and also helps mitigate risk and address comments from consultation.

Issue Analysis Summary FINAL (Protected B)
Interaction with local authorities

Annex A: Risk matrix

Potential risks associated with production in homes under current regime	Potential causes under MMAR	Proposed measures to address risks in proposed MMPR
Risk of fire	- source of heat from lights - electrical hazards - minimal fire/ building code inspections because no knowledge of the address of the site by fire department and municipalities	- Ensure that fire department and municipalities have knowledge of address of site - Provide the Minister with the authority to suspend or revoke a licence to produce if the continuation of the licence would likely create a risk to public health, safety or security including the risk of marihuana being diverted to an illicit market of use.
Violence (including home invasion)	- absence of prescriptive security measures - criminal activities - no knowledge of the address by police so no surveillance	- Require security measures (including criminal record checks [CRC]) - Ensure that police departments have knowledge of address of site - Provide the Minister with the authority to suspend or revoke a licence to produce if the continuation of the licence would likely create a risk to public health, safety or security including the risk of marihuana being diverted to an illicit market of use - Absence of cultivation in dwelling places removes risk of home invasion

Issue Analysis Summary FINAL (Protected B)
Interaction with local authorities

Potential risks associated with production in homes under current regime	Potential causes under MMAR	Proposed measures to address risks in proposed MMPR
Theft or loss (including diversion)	- absence of prescriptive security measures - criminal activities - absence of record keeping - minimal inspection by HC (too many sites, consent required and limited ability to obtain administrative warrant)	- Require security measures (including CRC) - Require detailed record keeping - Perform compliance inspections in accordance with Part IV of the CDSA - Ensure that police departments have knowledge of address of site - Provide the Minister with the authority to suspend or revoke a licence to produce if the continuation of the licence would likely create a risk to public health, safety or security including the risk of marihuana being diverted to an illicit market of use
Mould/Toxic chemicals	- absence of GMP - minimal building code inspection because no knowledge of the address of the site -Location not designed for large production operations	- Require Good Production Practices (GPP), including limits on contamination - Require record keeping - Ensure that municipalities have knowledge of address of site - Perform compliance inspections in accordance with Part IV of the CDSA to verify compliance with GMP (- Provide the Minister with the authority to suspend or revoke a licence to produce if the continuation of the licence would likely create a risk to public health, safety or security including the risk of marihuana being diverted to an illicit market of use

Issue Analysis Summary FINAL (Protected B)
Interaction with local authorities

Potential risks associated with production in homes under current regime	Potential causes under MMAR	Proposed measures to address risks in proposed MMPR
Security of first responders	- booby traps, fire arms due to criminal activities - electrical hazards - mould and toxic chemicals - minimal fire/ building code inspections because no knowledge of the address of the site - no knowledge of the address of the site by fire department - no knowledge of the address by police - minimal inspections by HC (too many sites, consent required and limited ability to obtain administrative warrant)	- Ensure that fire department, police and municipalities have knowledge of address of site. - Perform compliance inspections in accordance with Part IV of the CDSA - Provide the Minister with the authority to suspend or revoke a licence to produce if the continuation of the licence would likely create a risk to public health, safety or security including the risk of marihuana being diverted to an illicit market of use. - See measures to address mould and toxic chemicals above.

This is **Exhibit "X"** 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

Issue Analysis Summary
Potential Business Models for Licensed Producers

FINAL

ISSUE:

Should licensed producers (LPs) under the *Marihuana for Medical Purposes Regulations* (MMPR) be required to directly undertake all aspects of production from seed to sale or could different business and licensing models be used?

CONTEXT:

In November 2010 the Minister of Health was authorized to develop a new regulatory framework for providing Canadians with access to marihuana for medical purposes, eliminating personal and designated production in favour of licensed producers. Key principles of the new framework are to treat marihuana as much as possible like a medication, while reducing risks to public safety, health, and security, and reducing risk of diversion. As approved by cabinet, the new program design described that "Health Canada will develop and administer regulations that will govern the activities of LPs. The new regulations will specify, for example, requirements for:

- security;
- product quality;
- distribution (e.g. direct from licensed producer without storefront);
- packaging (type and size) and labeling;
- licensed producer location (e.g. must be located in Canada, not allowed in residential neighborhoods);
- personnel (e.g. education, criminal reference check);
- production limits;
- import/export
- record keeping and reporting (e.g. customer database, supply records);
- inspection and compliance monitoring;
- conditions under which a licensed producer can supply dried marihuana to an authorized individual; and
- advertising (e.g. no ability to make health claims)."

While not stated explicitly in the 2010 Memorandum to Cabinet, the above text could be read to suggest that a LP should be responsible for all activities from seed to sale. Being responsible, however, does not necessarily require that all activities be conducted by a single entity, or that all activities be conducted on a single site. Strict controls on record keeping and transactions could achieve the same end. The applicability of various business and licensing models will be discussed below.

Issue Analysis Summary — FINAL
Potential Business Models for Licensed Producers

Supply Chain

The supply chain for marihuana refers to the steps in the production cycle from initial seed to final sale to an end user. The steps in the cycle include:

- Obtaining starting materials
- cultivation (from seed or clone)
- harvest
- drying
- further processing such as irradiation or milling (if applicable)
- testing
- packaging/labelling
- distribution of dried material to consumers or other LPs, of seeds/clones to other LPs
- destruction of waste material

Current Program

Prairie Plants Systems (PPS), the company which produces marihuana for medical purposes under contract to the Government, handles all aspects of production from seed to sale. They do however contract out testing and irradiation functions to licensed dealers.

Proposed Changes

Under the proposed framework, LPs will be the sole suppliers of seeds/clones/dried marihuana to other LPs, for export, and dried marihuana only to consumers. LPs who choose to only produce seeds/clones only must meet all relevant requirements under the new regulations including requirements for personnel, security and record-keeping. In all proposed business models, LPs would be able to obtain and distribute dried marihuana from other LPs.

Consultations

Stakeholders welcomed clear regulations that outlined requirements for commercial producers; however, some parties interested in becoming LPs highlighted that the requirements should not be so complex that only large businesses could become licensed. Parties felt that if they are required to undertake all aspects of the supply chain then the start up costs would be overly burdensome and unrealistic. Potential LPs want the option to contract out certain elements e.g.

testing, packaging and labeling.
OPTIONS:

Option 1: The license would require LPs to undertake all activities along the supply chain. LPs will not be licensed to undertake individual activities (e.g. grow or distribute only). With respect to the LP whose final product is seeds/clones only, all applicable requirements for licensing must also be met as set out in the regulations.

Pros:

- By requiring that LPs directly control the growth, processing and distribution of their products, the potential for diversions along the supply chain due to many intermediary transactions taking place in the market is minimized.
- This model over time could result in lower production, distribution and selling costs, resulting in lower costs for participants as all functions are undertaken by the same entity saving costs that associated with contracting out services.
- LPs will have direct contact with their customers through telephone and Internet orders. This information will help them to plan their production for the next year, while current clients who reorder or fail to reorder from the same LP will provide important information to the LP on whether product quality and customer service are meeting the needs of their customers.
- Could improve business efficiency and the chances of success of the regulated market. From a cost control perspective, it may force business to consolidate all operations and minimize duplicative set-up costs such as for security.

Cons:

- High start up costs may limit the number of LPs who enter the market resulting in potential access issues for Canadians.
- Reduces or limits business choices.
- Other manufactures are not treated this way.
- Potentially reduces competition between suppliers.
- Labs for testing are costly, could impact on the number of LPs able to enter the market if they must specialize in everything.
- Is not consistent with the idea of allowing certain LPs to produce starting materials (seeds and clones) only for sale to other LPs.
- Not consistent with NCR.

Option 2: All LPs import, grow, process, and distribute but may or may not package, label or test.) Sale would be conditional on growing.

Certain activities requiring specialized equipment or personnel could be contracted out, but the product would be returned to the LP, which would then be responsible for final distribution. Only one licensing process would be necessary and the LP would be fully responsible for record keeping and reporting of transactions. Entities responsible for the contracted activities (which would be limited to testing and/or packaging/labelling, and specialized processing such as irradiation, if applicable) would be required to be licenced dealers (LDs) under the NCR.

Pros:

- Provides greater options for LPs to set up and operate their business in a manner in which they choose. (less restrictive)
- Minimizes start-up costs and may contribute to greater access if more LPs can realistically enter the market.
- The LP is ultimately accountable for the sale of the product they produce or import. Record keeping practices from the LD's along the way provide a chain-of-custody for the product. Preventing contract growing and distributing activities from occurring in isolation of each other reduces the number of entry points into the market, meaning that marihuana is easier to track through the supply chain.

Cons:

- A supply chain that involves multiple stages and companies may increase the risk of diversion to the illegal market and related abuses of the new regulatory regime.
- International trade implications. As above, unless specific exemptions were created in the regulations to allow import only in exceptional circumstances, this business model would also preclude import and distribution. Is not consistent with the idea of allowing certain LPs to produce starting materials (seeds and clones) only for sale to other LPs.
- Does not treat marihuana like a medication as there are sale restrictions tied to production (import, grow process) cycle that are not imposed on other drugs.
- Not consistent with NCR.

Option 3: LP may be licensed for any activity.

Similar to the current LD model, LPs would be licensed to engage in any combination of activities along the supply chain, and would be required to meet the specific requirements (e.g. security) for only the activities that they are conducting.

Pros:

- Treats marihuana as much as possible like a medication.
- Existing infrastructure of LD model works for other narcotics and controlled substances.
- Permits importing dried marihuana to a Canadian distributor.

Cons:

- Licensing LPs to undertake each activity separately will create multiple market entry points in the new industry which may complicate reporting the production and international trade of marihuana. However, this risk, similar to that for other narcotic drugs, can be mitigated through record keeping requirements and requirements for the reporting of activities to Health Canada.

CONSIDERATIONS:

Colorado

Vertical integration in the marihuana for medical purposes market is not without precedent. In the state of Colorado, businesses are licensed as Medical Marihuana Center, which process and distribute marihuana. Medical Marihuana Center license holders cannot source more than 30% of their annual inventory from other Centers. Once licensed as centers, these businesses can also obtain an Optional Growing Premises license. Thus effectively, licensees are required to maintain control not only over the sale of finished products but also over majority of their supply of raw marihuana.

Multiple LP site locations

Consistent with existing frameworks for narcotic drugs, licensing of LP activities will be tied to the premises specified in the application. Under the MMAR, however, PUPLs and DPPLs are allowed to indicate as part of their application for their license, a location for keeping dried marihuana that can be different from the site where growing takes place. Although it is feasible and may be financially more attractive to confine growing, processing and distribution of dried marihuana to a single location, an LP may conceivably choose to carry out the different activities at different locations for business or convenience reasons. In this case, it may be necessary to allow the applicant to declare more than one premise to which the license would apply, providing that all sites meet all applicable requirements. Additional location(s) must be an integral part of the applicant's business and will each require their own license, only one license will be granted per site. As well, all sites must meet the regulatory requirements for security for the license(s) to be issued.

It should be noted that concerns about security risks and the possibility of diversion are increased if there is movement of the marihuana between different sites. Therefore, if multiple sites under one LP are permitted under the MMPR – and there is currently no recommendation to require all activities at a single site – then the question of whether to allow multiple activities to be licensed individually is less of an issue.

Testing

Testing for product quality and composition is an area of the supply chain that requires specialized training and equipment, and may require accreditation. Therefore this is an expensive process that would be difficult to impose on all LPs.

Import/Export

Import and export provisions are now proposed to be included in the MMPR. Part of the rationale to include provisions for import was to have a contingency plan in the event of a domestic crop failure or supply shortage. Import provisions were not intended to open the door to Canadian LPs who did not want to grow but rather import and sell (distributor).

RECOMMENDATION:

The policy authority derived from the 2010 Memorandum to Cabinet requires the MMPR to provide a system where there is accountability for all stages of the marihuana supply chain. Such accountability can be achieved in multiple fashions, but a balance between the idea of control and accountability with developing a viable marketplace that will fulfil the goals of providing access to marihuana for medical purposes for consumers needs to be found. The recommended option therefore is Option 3, that is, to use the Licensed Dealer model from the NCR, where specific activities are licensed, and there is no limitation on the business structure. Record keeping and security requirements will provide adequate controls of the flow of raw materials and finished product, just as they currently provide control for other narcotic drugs, and this model provides adequate flexibility for LPs to conduct their activities within the regulated marketplace.

This is **Exhibit "Y"** 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