Health Canada's Policy Rationale Behind the Development of the *Marihuana for Medical Purposes Regulations* (MMPR)

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Introduction – Lets Set the Context

Governments will always play a huge part in solving big problems. They set public policy and are uniquely able to provide the resources to make sure solutions reach everyone who needs them. They also fund basic research, which is a crucial component of the innovation that improves life for everyone.

Bill Gates

The one who adapts his policy to the times prospers, and likewise that the one whose policy clashes with the demands of the times does not.

Niccolo Machiavelli

Avoid any specific discussion of public policy at public meetings.

Quintus Tullius Cicero

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So What Was The Big Problem?

- Since 2000 Canadian courts across the country have consistently ruled that marihuana must be available for therapeutic use.
- In subsequent court challenges, strain, medical reason of use and amount was not allowed to be specified by the government.
- The response by the government was to create a small program – the *Marihuana Medical Access Regulations* (MMAR) – to address the needs (at that time) of a small population.
- Over the next 10 years the solution became unworkable as additional issues started to clog the government's policy capacity and desire to deal with the problem.

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Why Change Was Needed

- Exponential population growth in the program for which the Department was not prepared.
- Issues with supply.
- Safety concerns expressed by Fire, Police and Municipalities.
- Scientific concerns raised by medical practitioners.
- Various court challenges – constantly losing on appeal.
- Cost and role of the Department.
- Constant reaction by the Department as opposed to developing new pro-active policies.

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Why Change Was Needed (continued)

- In the meantime other countries started to quickly develop new and different policies allowing for the therapeutic use of marihuana.

- For example:
  - Norfolk Island (an overseas territory of Australia);
  - Australia;
  - Belgium;
  - The Czech Republic;
  - Germany;
  - Uruguay;
  - The Netherlands;
  - Israel;
  - Austria;
  - Mexico; and of course
  - The United States.

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The Government's Objectives

- Get the Department out of providing supply.
- Get the Department out of authorizing individuals to consume.
- Strike a balance between providing legal access for medical use while ensuring compliance with the *Controlled Drugs and Substances Act*.
- Improve the fiscal and organizational operations of the program.
- Comply with international agreements.
- Respond to the criticisms and observations from all stakeholders.

The Policy Debate

- Still a controlled substance as per the *Controlled Drugs and Substances Act*.
- Scientific research/evidence lacking.
- Fear of diversion to the illegal market.
- Inspections for safety, quality and security of MMAR participants practically impossible.
- The Department could not ensure quality – duty to do so given the *Food and Drugs Act*.
- Therefore, treat it as any other medicine.

The Policy Debate – Numbers

- In 2002 only 477 persons were allowed to legally obtain marihuana for medical purposes in Canada.
- By the end of 2014 the number would have grown to approximately 50,000 individuals worth (conservatively) $180 million per year.
- Health Canada estimated that by 2024 the market will have grown to 400,000 patients worth an estimated $1.3 billion per year.
- By comparison California's market (with roughly the same population as Canada) in 2012 was worth $1.3 billion per year.

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The Policy Debate (continued)

- How to treat it as any other medicine?
- Use the regulated health products industry as a model – to a point.
- No need for the Department to provide supply.
- No need for the Department to authorize patients.
- Can control and regulate for quality.
- Can inspect for safety and security.
- Can determine supply at any given time.
- Allows the Department to go back to its core mandate to ensure: "*The people of Canada maintain and improve their health*."

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Challenges – Health Canada

- Drastically underestimated those willing to supply the market.

- For example on June 23, *City News Toronto* reported:
  - Health Canada has received 920 applications since June 14;
  - Only 20 applicants have been issued licenses including 13 that currently sell to the public;
  - About 18-25 applications are still being received each week; and
  - Ontario has the most applications under review at approximately 200 compared with:
    - 176 in British Columbia;
    - 36 in Quebec;
    - 24 in Alberta;
    - 15 in both Manitoba and Nova Scotia;
    - 12 in New Brunswick;
    - 8 in Saskatchewan;
    - 4 in Newfoundland and Labrador; and
    - 2 in Prince Edward Island.

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Challenges – Health Canada (continued)

- For the last six months ongoing reorganization at Health Canada.
- By their own admission, Health Canada has reduced the staff of the Bureau of Medical Cannabis by almost 50% (as of February 2014).
- Current vacancy in the position of Executive Director – Market Development.
- No published service standards on how long it takes to review an entire application.
- Lack of consistency in review process.
- Longer then expected timelines for RCMP review of Criminal Record checks.

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Challenges – Legal and Political

- Decriminalization, legalization, therapeutic use – separate or are all issues one in the same?

- Allard:
  - The government could win the appeal – in which case there might be no further legal challenges to the MMPR; or
  - The government loses the appeal – in which case it would have to amend the MMPR (which could take up-to a year) to allow for the existence of previously sanctioned individuals to continue to grow their own product – creating a two tier regime that would certainly be challenged in the courts.

- Smith:
  - Ruling applies to the MMAR it does seem to indicate that producing extracts could be a viable option for the MMPR;
  - certain the government will appeal; and
  - Potential to expand the industry, however, any extract product developed will have to be approved by Health Canada.

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Challenges – Rumours

- The Government of Canada can initiate any legislative or regulatory changes it deems necessary – but:
  - Has stated on numerous occasions that there is no intent to limit the number of Licensed Producers;
  - Has publicly maintained that supply can only meet demand if the market is open for competition;
  - The government's legal argument for its appeal regarding the Allard Decision is based on the premise that the cost of marihuana for medical purposes is not prohibitive given that competition should ensure competitive pricing; and
  - The government's own legal advice would point out the significant litigation risks and costs that would occur.

- In the worst case – a proper regulatory process would have to be followed – a change to the MMPR – consultation process.

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– Then What?

- Each Licensed Producer has to be renewed by Health Canada.

- What will that process look like?
  - Legislative change;
  - Regulatory amendments;
  - Inspections;
  - New application process;
  - Supply and demand issues;
  - Size and worth of the industry;
  - Import and export;
  - Science and R&D;
  - Extracts – other products;
  - Medical Practitioners; and
  - Costs for industry and patients.

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Conclusion(s)

- The MMPR is a good first regulatory step.
- Implementation is another matter – there has to be recognition of the significant start up costs (time and financial).
- Further transparency required.
- The courts will still have an active role in how the industry develops and how the government responds with its policies.
- Different from the dot.com craze in that there is an actual product to sell and consume.

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