A Roadmap to Compassion

The Implementation of a Working Medicinal Cannabis Program in Canada

By the Canadians for Safe Access,
the B.C. Compassion Club Society, and the
Victoria Island Compassion Society:
Philippe Lucas, Hilary Black, and Rielle Capler

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For over five years, the Canadian federal government has been struggling with the development and implementation of a national medicinal marijuana program. Although Health Canada has taken some progressive policy steps, many improvements are still needed.

This document identifies many of the roadblocks Canadians have been facing with the MMAR program, and proposes solutions to overcoming them. These solutions focus on the already existing and successful medical cannabis distribution system in Canada, the compassion societies.

The courts have acknowledged that compassion societies have been filling in the holes left by Health Canada's inadequate program. Many government bodies, including the Senate Special Committee on Illegal Drugs, the Ontario Court of Appeals and the BC Provincial Court have also recognized the key role of the Compassion Societies in a viable national program.

Senate Special Committee on Illegal Drugs

Conclusions of Chapter 9:

- People who smoke marijuana for therapeutic purposes prefer to have a choice as to methods of use;
- Measures should be taken to support and encourage the development of alternative practices, such as the establishment of compassion clubs;
- The practices of these organizations are in line with the therapeutic indications arising from clinical studies and meet the strict rules on quality and safety;
- The qualities of the marijuana used in those studies must meet the standards of current practice in compassion clubs, not NIDA standards;
- The studies should focus on applications and the specific doses for various medical conditions;
- Health Canada should, at the earliest possible opportunity, undertake a clinical study in cooperation with Canadian compassion clubs.

From the Ontario Court of Appeal in regards to the Hitzig Decision:

"A central component of the Government's case is that there is an established part of the black market, which has historically provided a safe source of marihuana to those with the medical need for it, and that there is therefore no supply issue. The Government says that these "unlicensed suppliers" should continue to serve as the source of supply for those with a medical exemption. Since our remedy in effect simply clears the way for a licensing of these suppliers, the Government cannot be heard to argue that our remedy is unworkable."

Problems with the MMAR

The Canadian government was ordered by the courts to amend the cannabis prohibition laws to allow Canadians in medical need to access cannabis without fear of legal repercussion. The response was the creation of the MMAR. Since its implementation over 5 years ago, Health Canada's medicinal cannabis program has completely failed to live up to its mandate. Numerous courts have found both the MMAR and its predecessor, the Section 56 Exemption, unconstitutional. More tellingly, the critically and chronically ill Canadians who have been diligent and determined enough to join the MMAR have also been its most vocal and vociferous critics.

Obstacles to Access

While Health Canada's own polls suggest that over 400,000 Canadians currently claim to use cannabis for medicinal purposes, its program has registered a mere 700 applicants over 4 years. Unjustified bureaucratic obstacles to accessing the program, such as yearly renewals and the requirements of support from a medical specialist, have created an oxymoron out of Health Canada's Office of Cannabis Medical Access.

Both the Canadian Medical Association and the Canadian Medical Protection Association have issued notices to the medical community instructing them not to participate in the federal medicinal cannabis program for fear of potential legal liability. This has effectively stymied the proper implementation of the MMAR.

A centralized approval and registration system is in itself an unnecessary obstacle to access. Such a system is far more extensive, expensive, and difficult to administer and enforce than regulations for any other medicine. Cannabis simply does not warrant such restrictive and invasive measures.

Supply and Distribution

Once a patient has obtained an MMAR license, their choices for accessing a legal supply are severely limited. They may either produce it themselves or apply to have a third party grow for them. Many patients are not able to produce their own medicine nor do they have feasible options for a third party-grower.

A more recent court-ordered option provides for license holders to apply to receive their cannabis directly from Prairie Plant System. This half-hazard option is problematic for several reasons:

- Health Canada's attempts to produce medicinal grade cannabis have been an embarrassing and expensive ($5 million +) failure, resulting in a non-organic product that is of poor quality and potentially dangerous to medicinal users. The product may be unsafe due to heavy metal contamination and the use of gamma irradiation. Even those who so desperately need this herb have rejected the product;
- The undeniable importance of making a variety of different strains of cannabis products available in many different forms has been ignored;
- A monopoly on production prevents the potential benefit to medicinal cannabis users from the reduced cost, increased quality and wider range of varieties that would prevail with free-market competition;
- Current distribution possibilities completely ignore the educational component necessary for the safe and successful use of cannabis products.

Most importantly, the costs of this medicine are not yet covered. The price of medicinal cannabis is artificially inflated due to its illegal status. As with other prescribed medicines, cannabis should be covered through the provincial health insurance system.

Research

Although Health Canada claims to be promoting research into this area of medicine, it has only approved and fully funded one clinical protocol since the implementation of this program. Experts in the field of medicinal cannabis are concerned about skewed research outcomes resulting from the government's crop, which is below average quality cannabis.

In addition, Health Canada has inexplicably ignored the recommendations of the Special Senate Committee to undertake research in collaboration with the compassion societies.

Recommendations: A Roadmap for Change

What is readily apparent to all is that for a cost of over $3 million a year, Canadians who could benefit from the use of medicinal cannabis are being drastically underserved by the OCMA.

The following recommendations are based on the experience and expertise of medicinal cannabis users and distributors, and are intended to:

- Help Health Canada finally address its many court obligations as well its responsibilities to Canada's critically and chronically ill;
- Put in place a community-based system for the safe and effective non-profit cultivation and distribution of medicinal cannabis.
- Create a system that is easier to understand and implement - for both patients and physicians - than the current system.;
- Allow Health Canada to use its resources more effectively and thus reduce costs;
- Financially support patients in accessing their supply of medicine;
- Create a program that is both in line with Canada's Constitution, Canada's international obligations that merits the support of the Canadian courts, press, and public;
- Create a well funded research program using high quality cannabis;.
- And address concerns about black-market re-distribution.

The Role of Health Canada

Health Canada must abandon its role in the approval process of potential medicinal cannabis users. This role creates a burden of wasted time and unnecessary bureaucracy for applicants; and of expense and wasted resources for Health Canada.

Health Canada should allow access to medicinal cannabis solely with a confirmation of diagnosis from an appropriate health practitioner Physicians are currently able to prescribe many controlled substances that are addictive and potentially dangerous without onerous government oversight; there simply is no logical or scientific reason to place cannabis under a stricter regulatory regime. Although the effectiveness of cannabis in treating certain ailments may not yet be fully conclusive, its remarkable safety profile is well established and accepted within the scientific community.

In order to ensure the success of this program, The OCMA's role should more closely resemble the Dutch Office of Medicinal Cannabis. Its roles would include:

- Working with provincial health care programs to ensure cost coverage of medicinal cannabis and harm reduction devices such as vaporizers, and for cultivation equipment where applicable;
- Creating national standards in collaboration with the existing Compassion Societies for the operation and licensing of community-based cannabis distribution centres;
- Establishing guidelines for site inspections and the testing of cannabis for strength and safety;
- Creating system to ensure protection of medicinal cannabis users from police interference;
- Providing appropriate information to consumers, healthcare providers, and law enforcement.

The Role of Physicians and other Health Care Practitioners

The involvement of physicians in the process is not questioned – what must be determined is their proper role with respect to use of cannabis for therapeutic purposes.

Health Canada should reconsider the role of the physician in the context of this program. The Senate Special Committee on Illegal Drugs recognized some of the concerns with prescribing an illegal herbal medication, but concluded that these can be addressed by replacing the role of the physician as gatekeeper with that of diagnostician:

" The involvement of physicians in the process is not questioned – what must be determined is their proper role with respect to use of cannabis for therapeutic purposes. Physicians are trained to provide a diagnosis of a person's medical conditions and symptoms and to determine how to treat these conditions and symptoms medically. Most do not have, however, adequate knowledge of the therapeutic benefits of cannabis and are reluctant to associate themselves with this product for a variety of reasons, including its illegality.

In these circumstances, the proper role of the physician should be to make a diagnosis of the patient's medical conditions or symptoms. If the condition or symptom is one where cannabis has potential therapeutic applications, the patient would be authorized to use the therapeutic product of his or her choice, including cannabis. This would also mean eliminating the current requirement that all other ""conventional treatments" have been tried or considered before the use of cannabis is authorized. There is no justification for making cannabis an option of "last resort."

These recommendations mirror the procedures already being carried out by physicians in order to register their patients at Compassion Societies. Compassion Societies require health care practitioners to confirm their patients' diagnoses and symptoms, and to "recommend" rather than prescribe cannabis. Any patient who has a confirmation of any condition or symptom for which cannabis is an effective treatment should have the right to choose to utilize this medicine within the health care system without further authorization. The decision to use medicinal cannabis should be between a patient and their healthcare practitioner, as it is with all pharmaceutical and natural health products.

Cannabis is an herb; therefore the authorization to recommend access must be given to those health care practitioners most experienced with herbal medicine and should not be limited to allopathic physicians. The BC Compassion Club Society currently accepts confirmations of diagnosis and recommendations from physicians (GP or specialist), Naturopathic Doctors, or Doctors of Traditional Chinese Medicine. Clinical Herbalists will be added to this list once they have the licensing bodies and associations necessary to be legally regulated.

The Role of the Compassion Societies

In the state of California, where over 70,000 registered users gain legal access solely through compassion clubs, a recent Field poll suggests that support for the program has grown from about 56% in 1996, to 74% today.

The compassion societies have been successfully meeting the needs of medicinal cannabis users across the country for seven years. These not-for-profit compassion societies currently supply over 6000 critically and chronically ill Canadians with a safe supply of cannabis at no cost to Health Canada or the taxpayers. They have been risking arrest, criminal records and imprisonment for this important work.

Compassion societies have long ago recognized that different conditions respond better to different varieties of cannabis and modes of administration. They therefore stock numerous strains and offer this medicine as loose-leaf product, or in the form of tinctures, oral sprays, edible oils, concentrates and baked goods.

Similar to Health Canada's program, compassion societies oversee membership requirements, confirm diagnoses and recommedations with approved health care practitioners and keep careful files on each member, tracking their use of cannabis.

There are many additional services provided which are outside of Health Canada's mandate:

- Education regarding harm reduction strategies and information on strains, proper dosages and methods of ingestion;
- A community environment, providing valuable social support and safe space;
- Low cost complimentary healthcare, such as herbalism, counselling, acupuncture, nutritional counselling, massage and yoga;
- Outreach designed to address the questions and concerns of physicians and of law enforcement officials;

Under a new regulatory and licensing regime, the role of Compassion Societies would remain much the same. Compassion Societies would continue to be responsible for maintaining transparency and for accurate and accountable record keeping. The Vancouver Island Compassion Society and the BC Compassion Society are successful socially accepted and integrated models of such organizations.

The Role of Private Cultivators

Sensibly regulated, not-for-profit organic cultivation of cannabis would allow a safe and steady supply of medicine. Community based cultivation would take advantage of the extensive genetic pool and knowledge residing within those currently engaged in the grey-market production and distribution of therapeutic cannabis. This would significantly improve the quality, expand the selection and lower the cost of the supply.

Furthermore, it would relieve the federal government of the onerous and clearly unwanted responsibility cultivating a Canadian supply of therapeutic cannabis.

Criteria for the licensing of compassion societies and community-based cultivators:

An excellent guidance document for the regulation of the services provided by compassion societies titled "Operational Standards for the Distribution of Medicinal Cannabis" has been drafted by the British Columbia Compassion Club Society - Canada's oldest and largest compassion club - and should be used as the basis for the development and implementation of further regulations[1].

Some recommended standards are:

- Non-profit incorporation to guarantee financial transparency and ensure responsibility to the consumer;
- A minimum level of production and distribution standards based on Good Lab Practices (GLP) and Good Agricultural Practices (GMP) guidelines;
- The exclusive use of organic cultivation practices;
- Participation in inspections to ensure standards are being met.

Compassion Society-Based Research

Compassion societies are uniquely suited to participate in research projects. They have extensive experience in the application of cannabis as a medicine, and their collective national membership are an untapped resource of potential study participants.

Over the last 2 years, compassion societies have been at the forefront of research into the safety and effectiveness of medicinal cannabis. They have conducted research protocols regarding the effects of cannabis on Hep-C with the University of California San Francisco and regarding nausea and pregnancy with UBC. The VICS has received independent funding to study the effects of smoked cannabis on chronic pain. All of this research is peer-reviewed and publishable, and is being conducted at no cost to the taxpayer.

Health Canada must expanded its research agenda and funding to include compassion societies and university partnerships.

Potential Concerns With a Decentralized Program

There have been some concerns vocalized by various government and enforcement agencies regarding a decentralized program.

International Treaties: In the past, Health Canada has implied that the decentralization of this program is restricted by our international treaty obligations, the most significant of which are the Single Convention on Narcotic Drugs [(1961)], the Convention on Psychotropic Substances [(1971)] and the relevant portions of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances [(1988)].

According to section (c) of the original 1961 treaty, a signing country has the right to produce any drug or substance so long as its use and distribution is: "Subject to the provisions of this Convention, to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs." In other words, there should be no doubt that the trade, use and possession of drugs for medical or scientific purposes is permitted by the terms of this Convention.

Re-distribution: The fear of illicit re-distribution has been cited as a main reason to maintain centralized federal control over the cultivation and distribution of cannabis. No scientific data has ever been presented to suggest that the re-distribution of cannabis would increase or be more of a concern than it is under the current system. The same measures can be taken as are currently in place for alcohol, cigarettes, or prescription and over-the-counter pharmaceuticals.

The responsibility to dissuade the re-distribution of cannabis should fall on the individual compassion societies. Currently the practice of compassion societies includes clear and firm rules against diversion or re-distribution; memberships have been revoked for the re-distribution of cannabis.

Increased Use: There may be a concern that legitimizing the compassion societies would increase or promote the use of cannabis. Evidence from other jurisdictions with medicinal cannabis programs would appear to counter this claim. After the state of California passed medicinal cannabis legislation in 1996, high school drug use surveys (conducted by the state every 2 years) have shown that the rate of cannabis use has remained steady or has decreased[2].
Increased use is not necessarily a problem. Many people who need medicinal cannabis are currently prevented from accessing the medicine they require. What would undoubtedly result from the decentralization of this program would be a visible shift by medicinal users away from black-market sources to licensed distributors.

Timeline for Implementation

The relationship between Health Canada and the nation's medicinal cannabis users, cultivators and distributors has unfortunately suffered as a result of broken promises, lengthy litigation, and a lack of cooperation and trust. We are compelled to suggest a timeline for the implementation of these necessary changes with the hope of allowing the government to fulfill its obligation in a timely manner and to restore good faith between all parties.

3 months - The MMAR is changed to allow for the legal use of medicinal cannabis with the diagnosis and recommendation of either a physician or other qualified health care practitioner such as a Doctor of Traditional Chinese Medicine or Naturopathic Doctor. Consultations with compassion societies and medicinal users are initiated to produce a regulatory scheme for the community based, not-for profit distribution of medicinal cannabis.

6 months - Licensing scheme is in place for compassion societies. Private cultivators can bid for local, small-scale non-profit cultivation contracts from Compassion Societies. Physician or health care practitioner diagnosis and recommendation allows legal access to medicinal cannabis through compassion societies.

9 months - Health Canada has expanded its research agenda and funding to include compassion societies and university partnerships.
12 months - The program is fully decentralized. National standards in have been collaboratively established for site inspections and the testing of cannabis for strength and safety. Compassion societies are licensed.

Conclusion:

The future of a successful medicinal cannabis program in this country should focus on the distribution model that has already proven itself to be safe and successful: not-for profit distribution by community-based compassion societies.

For over seven years, national compassion clubs and societies have been risking arrest and prosecution in order to address the pressing medicinal needs of Canada's critically and chronically ill, all at no cost to the taxpayer. This vital work has been recognized by numerous Canadian courts, as well as governmental bodies such as the Senate Special Committee on Illegal Drugs. Compassion societies serve a clear and necessary purpose, and benefit from the support of their local communities and of the Canadian public as a whole.

The decentralization of the Office of Cannabis Medical Access program and the legitimization of these compassionate organizations will not only save Health Canada both time and money, it will also address many of the concerns expressed by those who could benefit from medicinal access to this herb. For the thousands of Canadians who could alleviate their chronic and debilitating symptoms, while staying productive and maintaining a level of hope and happiness despite their serious condition, decentralization is simply the right thing for Health Canada to do.

1 http://thecompassionclub.org/club/standardsapr30.pdf
2 http://www.safestate.org/index.cfm?navID=254