CONCERN IS ACCESSIBILITY AND AFFORDABILITY.

I WANT TO BE ABLE TO PURCHASE CONSISTENCY IN THE PRODUCT

it's not for everybody but it is for me

to be able to afford it and do this legally

Cannabis as Therapy for People Living with HIV/AIDS

"Our Right, Our Choice"

some people are very suspicious when you tell them

I WANT TO DO IT SAFELY

barriers to access

worry about who is going to know, am I going to get caught?

misunderstand

We are driven by our community action principles of empowerment

CANNABIS AS THERAPY

June 2006

CANADIAN AIDS SOCIETY
SOCIÉTÉ CANADIENNE DU SIDA

Cannabis as Therapy for People Living with HIV/AIDS:
"Our Right, Our Choice"

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Solvay Pharma

PREFACE

Voices of People Living with HIV/AIDS on the Use of Cannabis for Medicinal Purposes

"I've been HIV [positive] since 1983 so I mean I've used marijuana for a long time, especially to stimulate my appetite. My meds have changed over the years and you know [the use of marijuana for medicinal purposes] is an issue that I find dear because I've seen how a lot of people suffer and it seems to be one of the only things that seems to eradicate that and make life a little better."

"I use marijuana for appetite because when I was first diagnosed, I was diagnosed with PCP pneumonia and I only had 16 fighter cells left. The meds were hell on me for the first three months that I took them and if it hadn't have been for smoking marijuana… My husband had to be constantly readily available for me, and it was getting to the point that my 2 year old was handing me the garbage can saying: "Mommy's gonna be sick again". So it was that or me running to the bathroom you know because of the diarrhea so the bathroom was almost my condominium, as horrible as that is. And then who the heck really wants to eat if you puke 2 or 3 times in a day. I don't want to eat after. I have a real problem with that and I actually get depressed about it. I start crying, and I get really pissed off about it, and marijuana is the only thing that helps me. And I told my family doctor about it and her response was: "I'm open to it, however I think you look fine right now and when you're ready to come back to me, let's say you drop a whole bunch of weight like you did when you had PCP pneumonia, then we could talk about it then."… So I'm getting the impression that she's saying that I have to wait until I'm practically dying to get it. And I don't think that's fair."

"Those persons in our lives that we met that think it's all about getting high often misunderstand that that high often relieves us of the tears, of hurt, of stress, of living with a terminal illness and a lot of other things in our daily lives. It's a very special plant that nature is offering us. Somehow, the society has to come to grips with freeing nature to man."

"I would also like to have it paid for or be reimbursed because we have to take it out of the food budget. They could at least replace the food budget or give us the money upfront. It would be nice if they did that."

"I want to be able to purchase consistency in the product. I want to do it safely… If there is a better way to be able to afford it and do this legally… I worry about who's going to know, am I going to get caught, you know, and especially living in a small town."

"I think that the concern is accessibility and affordability. If you are using it for medicinal reasons, well, like with my other medications, my HIV drugs are all covered, the stuff I need for side effects are all covered… So if we are going to talk about medicinal cannabis, then let's treat it like any other medicine that we take."

"I believe strongly in the right for humans to have access to what nature provides… It's not for everybody but it's for me."

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Executive Summary

Who We Are

The Canadian AIDS Society is a national coalition of 125 community-based AIDS service organizations across Canada. We are dedicated to strengthening the response to HIV/AIDS across all sectors of society, and to enriching the lives of people and communities living with HIV/AIDS.

Description of the Project

We received funding from the Public Health Agency of Canada to study the barriers to access to cannabis for medicinal purposes for people living with HIV/AIDS. We conducted an extensive consultation of people living with HIV/AIDS from across Canada through focus groups and a widely distributed questionnaire. This executive summary provides an overview of a policy paper[1] that outlines the barriers to access to the federal medical cannabis program, to a legal source of cannabis, and to adequate information and services. Recommendations are made to address these barriers so that people living with HIV/AIDS can treat themselves without fear of criminal prosecution, with a safe and affordable source of cannabis, with adequate information to make informed decisions, and with the necessary support to optimize their health.

"Our Right"

Legal, Regulatory and Policy Complexities

In Canada, cannabis (marijuana) remains a controlled substance subject to the *Controlled Drugs and Substances Act*, which prohibits possession, cultivation, trafficking, possession for the purpose of trafficking, importation and exportation.

Cannabis is a plant and would normally be considered a natural health product subject to the *Natural Health Products Regulations* were it not for its designation as a controlled substance. Law reform regarding personal adult use of cannabis has been considered in Canada but has yet to manifest. The only other option for herbal cannabis to become widely available for medical use would be for it to be subjected to the drug approval process. If approved as a drug, cannabis could then be prescribed by physicians and reimbursement of costs to seriously ill Canadians could be considered under provincial health insurance programs.

However, the approval of herbal cannabis as a drug is unlikely so long as a criminal prohibition on cannabis use is maintained. The drug approval process is governed by the *Food and Drug Regulations* (FDR). The typical process by which new drugs enter the therapeutic marketplace involves a "drug sponsor" who has identified a potentially therapeutic molecular compound from which the sponsor ultimately hopes to profit. Bringing a new drug to market is expensive, and both the criminal law and the law of intellectual property (i.e. patents on plant products) have served as disincentives for the initiation of drug development and approval by drug sponsors.

However, some pharmaceutical companies have shown an interest in developing cannabis-based products. The focus of research and development has been on synthetic derivatives, and in the next decade one may expect to see a variety of synthetic cannabis-based medicines on the market. Regardless of the

> *"I believe strongly in the right for humans to have access to what nature provides… It's not for everybody but it's for me."*
>
> *"I believe we all have a right to our own therapy, whether it's medical marijuana or whether it's narcotics prescribed by our doctors."*
>
> —*Focus group participants*

availability of pharmaceutical products derived from cannabis, some seriously ill Canadians will continue to opt for herbal cannabis, thus the importance of addressing the barriers to access to the federal medical cannabis program.

Use of Cannabis for Medicinal Purposes

As many as 14% to 37% of people living with HIV/AIDS use cannabis to help manage symptoms such as appetite loss, wasting, nausea and vomiting, pain, anxiety, depression and stress, among others. It is also estimated that several thousand Canadians use cannabis for medicinal purposes for conditions such as multiple sclerosis, side effects of chemotherapy for cancer, severe pain due to arthritis or spinal cord injury or disease, seizures due to epilepsy and others.

The Federal Medical Cannabis Program

As a result of a legal challenge, our courts have ruled that a person has a constitutional right to access cannabis for medical purposes without fear of criminal prosecution, and that a person has the freedom to make decisions that are of fundamental personal importance without interference from the state. In response to this court decision, Health Canada introduced the *Marihuana Medical Access Regulations (MMAR)* in 2001, which enable compassionate access to cannabis for people who are suffering from serious illnesses and related symptoms. Canada is among a handful of countries that have made cannabis available to its seriously ill citizens. The learning curve has been steep and groundbreaking.

Barriers to Legal Access

Despite estimates that thousands of seriously ill Canadians use cannabis for medicinal purposes, only 1399 persons are currently legally authorized to possess cannabis for medical purposes. Only 26% of the medicinal users of cannabis we consulted had obtained an authorization to possess cannabis for medical purposes. Access to the federal program remains hindered by barriers such as a lack of awareness of the program's existence, mistrust in the government, misinformation about the program and difficulty in finding a physician to support their application. Thousands of seriously ill Canadians must therefore choose between breaking the law to use the therapy of their choice, or going without, which in many cases compromises their well-being and quality of life.

Access to a legal, safe and affordable source of cannabis is also severely hindered due to the limited options available to people who obtain the legal authorization to possess cannabis for medical purposes. Access to adequate information and services related to this treatment is minimal to non-existent, making it difficult for people to make informed decisions about their therapy and to optimize their care.

The Medical Profession's Reluctant Participation

The medical community has been reluctant to participate in the federal medical cannabis program because of the lack of information it has regarding the medical use of cannabis. Until adequate research is conducted and the arduous drug approval process is undertaken, participation by physicians in the federal medical cannabis program will remain severely hampered. Drug approval would facilitate physicians' support of cannabis use, access to cannabis for medical purposes, and reimbursement of costs for medical users.

It is critical that clinical research be conducted, otherwise the federal medical cannabis program will remain a special access program rife with unnecessary regulatory and bureaucratic barriers. Special access programs are used extensively for physicians to obtain experimental drugs for people living with HIV/AIDS. They are designed to allow physicians to secure unapproved drugs for seriously ill patients. The application process requires physicians to outline why the unapproved drug is the "best choice" and whether other therapies have been "considered, ruled out and/or failed to achieve an adequate choice". The federal medical cannabis program is designed along the same lines.

Thwarting of Research

Prohibition has thwarted research into the therapeutic properties of cannabis in its herbal form. Researchers

have been reluctant to initiate studies due to the burdensome regulatory and bureaucratic processes required to gain access to a legal source of cannabis with which to conduct their research, as well as the stigma associated with cannabis use, especially in smoked form.

More research is needed regarding the management of HIV/AIDS related symptoms with cannabis, cannabis versus pharmaceutical products, adherence to antiretroviral therapy, and long term effects of cannabis use. It is clear that more research is needed using cannabis in either smoked or vaporized form. Long-term studies on the effects of cannabis on the immune system and on antiretroviral medications, as well as studies on the direct effects of cannabinoids on the CD4 cell counts and viral loads need to be conducted to determine the long term safety of cannabis use for people living with HIV/AIDS. The effects of different strains must also be studied.

Research can greatly be enhanced by involving community groups or organizations such as AIDS service organizations or compassion clubs, from the development of the research protocol to the dissemination of results from a clinical trial. An innovative approach to clinical trials entails creating a community advisory committee to obtain input directly from the population one wishes to study. Such a committee can also assist with recruitment. Community-based research also has an important role to play in contributing to the greater body of knowledge.

"Our Choice"

Limited Choices of Product

Despite the existence of the federal medical cannabis program and of the MMAR, legal choices for authorized persons to have access to a safe and affordable source of cannabis remain severely limited: they can purchase the cannabis grown by the government, they can purchase seeds from the government and grow their own cannabis, or they can designate a person to grow for them and only them. The majority of the people we consulted relied on illegal sources for their supply of medicinal cannabis: 62.5% of respondents obtained cannabis from "a friend or someone they know", 35.9% from a compassion club, 30.8% from street dealers, and 8.5% grew their own cannabis without a license. Note that almost half the respondents reported that they obtain cannabis from more than one source.

The Government's Cannabis

The cannabis grown under contract for the government has received much media attention and has been subject to much criticism. Changes to the product continue to be made based on feedback received from the people who are using the product. The number of people ordering cannabis from the government remains low. Only 1.7% of the medicinal users of cannabis we consulted reported that they obtain their supply from the government. Considering the current public attitude towards the government's cannabis, the fact that the government only provides one strain of cannabis to authorized persons, and the government's expressed intention to eventually phase out licenses to produce, we are concerned that people living with HIV/AIDS will have to continue to break the law to supply themselves with cannabis for their medicinal purposes, perhaps at an even greater proportion than is currently the case. We favour providing authorized persons with a variety of legal options and products. Offering only one legal source and only one strain of cannabis for distribution to authorized Canadians may not be a constitutionally adequate alternative to the diverse supply currently available to them through licenses to produce, unauthorized compassion clubs, or within the black market.

Licenses to Produce

Our consultation revealed that 8.5% of medicinal cannabis users had obtained a license to produce cannabis for medical purposes, and 4.3% had a designated producer. Health Canada has stated that its vision is to eventually phase out licenses to produce cannabis for medical purposes and to make the government's cannabis available through Canadian pharmacies. While we support the development of pharmacy distribution of medical cannabis, we do not support eliminating legal options for authorized persons. We support a person's choice as to how they wish to obtain cannabis for their medicinal needs, according to what best suits their individual needs.

For many, the decision to grow their own cannabis is purely economical, and they are likely to continue growing their own until other provisions are made to assist them with the costs. Producing their own cannabis also enables people to choose the strains that work for them and to control the conditions under which the cannabis is grown. Some people tell us that they will continue to produce cannabis for themselves regardless of whether or not they can obtain a license, which is also alarming. Seriously ill Canadians should not be forced to hide and 'go underground' to have access to the therapy of their choice. Moving toward further limiting legal options for seriously ill Canadians without financial compensation is a step backward in ensuring legal access to the treatment of their choice without fear of prosecution, and we question the constitutionality of doing so.

Community-Based Distribution of Cannabis

Eventually, Canada has to develop an adequate model for the distribution of legal, safe and affordable medical cannabis to ensure that seriously ill Canadians do not continue to rely on the black market as their source of cannabis. Based on our community action principles[2] of empowerment, community support, self-help, holistic approach, accountability, harm reduction and greater involvement of people living with HIV/AIDS, we favour a not-for-profit, community-based model of distribution of medicinal cannabis and of its related services. Some compassion clubs (medicinal cannabis dispensaries) in Canada meet these principles, and the more established clubs have developed guidelines for operational standards that all clubs can voluntarily adhere to. These organizations also offer a number of different strains and alternatives to smoking, and are currently serving more than 10,000 Canadians. Other models, such as community gardens run by and for people who use cannabis as therapy, could also be considered. We will continue to advocate for operational standards of compassion clubs, especially with regard to quality control of the cannabis they provide, and for their inclusion in a legal system of distribution of cannabis for medical purposes. We do not exclude other ways of distributing cannabis for medical purposes, for example through the pharmacy distribution model proposed by Health Canada. However, we believe in providing options to people to best suit their needs.

Informed Choice

The Canadian AIDS Society is driven by community action principles. People living with HIV/AIDS must be directly involved in the decisions that affect their lives and in the organizations that serve their needs. Canadians told Commissioner Romanow[3] that they want to take charge of their health care. We need to provide them with the resources to make informed choices, and with safe and affordable products.

> *"Many people are in a situation where they have to break the rules to be able to supply themselves."*
>
> *—Focus group participant*

As with any activity that is forced underground, the prohibition on cannabis has resulted in a societal silence on the subject its use for medicinal purposes. People do not discuss the use of cannabis openly, except in closed circles, for fear of criminal prosecution. Prohibition has an impact on the everyday life of a person who uses cannabis for medicinal purposes. The silence that surrounds cannabis use results in a lack of information for people who use it for medicinal purposes.

The people we consulted expressed their need for information when it came to all aspects of the use of cannabis for medicinal purposes: scientific and medical evidence of the therapeutic effects of cannabis, how to access cannabis for medicinal purposes, the MMAR and the federal medical cannabis program, alternatives to smoking, harm reduction strategies, and more.

We have answered some of this call for information by producing a series of fact sheets on Cannabis and HIV/AIDS, available on our web site at <www.cdnaids.ca/cannabis>.

Stigma and Discrimination

The use of cannabis is associated with stigma in Canadian society. Medicinal users of cannabis are often met with laughter, scepticism, or with negative reactions, all of which may have negative consequences

on their everyday life. The federal medical cannabis program and the ID cards that are issued to authorized persons have helped to facilitate an acceptance of the medicinal use of cannabis. They have also brought some credibility and legitimacy to the use of cannabis for medical purposes and helped improve the image of cannabis use. These positive aspects of enabling legal access to cannabis for medical purposes are slowly shifting Canadians' perceptions of medicinal cannabis use, which in turn contributes to the quality of life of the people who use it.

However, too many seriously ill Canadians remain marginalized for the medicinal use of cannabis. When people are forced into hiding for fear of stigmatization or criminal repercussions, the unspoken becomes a dark cloud over their lives. The fear-mongering that has taken place around cannabis use in this climate of prohibition has also fed the beast. Breaking this silence and encouraging dialogue can be challenging, and can go a long way to lifting the smoke screen.

During our consultations, people described instances when they felt discriminated against for their medicinal use of cannabis both by their peers who do not use cannabis for medicinal purposes and by the medical system in general. Denying a seriously ill person access to health care services is not only unethical, it also violates the very essence of our universal health care system. In some cases, people can be legally protected from certain forms of discrimination.

The Canadian AIDS Society is committed to disseminating information about the use of cannabis for medicinal purposes, to bringing forward the voices of people living with HIV/AIDS and the realities they face when they choose cannabis as part of their therapy, and to encouraging dialogue on these important public health issues. We invite all of the key stakeholders, including the government, to join our efforts.

Purpose of this Policy Paper

The Canadian AIDS Society remains committed to participating in consultations with the government and other key stakeholders. Based on our ongoing consultations with people living with HIV/AIDS, we will continue to work with Health Canada and provide input into the federal medical cannabis program so that it may better meet the needs of seriously ill Canadians.

This paper is our call to action to all key stakeholders. We must, as a collective, find a way to address the barriers that prevent seriously ill Canadians from having access to cannabis for their medicinal needs without fear of prosecution, as is their right, and if it is their informed choice.

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1 Canadian AIDS Society. Cannabis as Therapy for People Living with HIV/AIDS: "Our Right, Our Choice." Full report available from <www.cdnaids.ca/cannabis>.

2 Canadian AIDS Society. The Community Action Principles of the Canadian AIDS Society. Adopted by the CAS Board of Directors, May 1991. Amended December 2005. Available at <www.cdnaids.ca/web/casmisc.nsf/cl/cas-gen-0051>

3 Romanow, Roy J. Commission on the Future of Health Care in Canada. Building on Values: The Future of Health Care in Canada. Final Report, November 2002.

INTRODUCTION

As many as 14% to 37% of people living with HIV/AIDS use cannabis[1] (marijuana) to help manage symptoms such as appetite loss, wasting, nausea and vomiting, pain, anxiety, depression and stress.[2,3,4,5] In Canada, as there are about 58,000 people living with HIV/AIDS[6], this represents about 8,000 to 21,000 people. Other surveys reveal that as many as 14%-16% of people with multiple sclerosis,[78] about 10% of people living with chronic pain,[9] and 21% of people with epilepsy[10] use cannabis as part of their therapy. Some people with severe arthritis and other on chemotherapy for cancer treatment are also benefit from the use of cannabis. It is often cited that there are approximately 400,000 Canadians currently using cannabis for therapeutic purposes.[11]

Cannabis remains a controlled substance subject to the *Controlled Drugs and Substances Act*, which prohibits possession, cultivation, trafficking, possession for the purpose of trafficking, importation, and exportation. The Canadian government had proposed a bill dictating that possession of under 15 grams of cannabis would be subject only to the penalty of a fine, but the bill was never passed and the current Conservative government has no plans to reform cannabis laws.

Our courts have ruled that a person has a constitutional right to access medical treatment for a condition representing a danger to life or health, without fear of criminal sanction, and that a person has the freedom to make decisions that are of fundamental personal importance without interference from the state.[12] In response to a court decision in *R. v. Parker*[13], Health Canada introduced the *Marihuana Medical Access Regulations*, which were created to enable compassionate access to cannabis for people who are suffering from serious illnesses and related symptoms and to meet constitutional needs. Canada is the first country to establish such a program and is among a handful of countries that has made cannabis available to its seriously ill citizens. The learning curve has been steep and groundbreaking.

Despite the fact that the Canadian government has put in place a process through which people can apply to use cannabis legally for their medical[14] needs, access to the federal program and to a legal source of cannabis remains hindered by barriers. Access to information and services related to this treatment is minimal to non-existent, making it difficult for people to make informed decisions and to optimize their care. There are currently 1399 people authorized to possess cannabis through the federal program, a proportion of which are people living with HIV/AIDS.[15] Most people who use cannabis for medicinal purposes have not yet applied to the program for various reasons which will be elaborated on in this document.

Despite the existence of the federal medical cannabis program and of the MMAR, legal choices for authorized persons to have access to a safe, legal and affordable source of cannabis remain severely limited: they can purchase the cannabis grown by the government, they can purchase seeds from the government and grow their own cannabis, or they can designate a person to grow for them and only them. The government offers only one strain of cannabis, and plans on phasing out licenses to produce, further limiting legal options for authorized persons. Uptake of the government's cannabis remains low. Cannabis clubs (compassion clubs) are not recognized as part of a legal distribution system of cannabis, despite the fact that they currently supply about 10,000 people. Most medicinal users of cannabis, whether they are authorized under the MMAR or not, continue to rely on the black market for their source of cannabis. This is an unacceptable source for their therapy of choices as it places them at risk for their personal safety and for criminal prosecution.

We, the Canadian AIDS Society, are a national coalition of 126 community-based AIDS service organizations across Canada. We are dedicated to strengthening the response to HIV/AIDS across all sectors of society, and to enriching the lives of people and communities living with HIV/AIDS. We

are driven by community action principles of empowerment, community support, self-help, holistic approach, accountability, harm reduction and greater involvement of people living with HIV/AIDS[16]. We were a member of Health Canada's Stakeholder Advisory Committee on Medical Marihuana, which was established in October 2002 to provide its Drug Strategy and Controlled Substances Programme with timely advice on medical, scientific, regulatory, policy and operational issues related to cannabis for medical purposes. It was comprised of patient representatives, medical professionals, law enforcement officers, and researchers. The committee reviewed the regulations and policies related to the MMAR. Some changes were made to the federal program as a result of these consultations.

Unfortunately, Health Canada disbanded the Stakeholder Advisory Committee on Medical Marihuana in October 2005, claiming that the committee's mandate had been fulfilled as the MMAR had been reviewed and amended. Our National Steering Committee for this project has expressed great concern about no longer having a venue through which to provide input into Health Canada's regulations, policies and operational issues related to the federal medical cannabis program. This concern is compounded by the fact that most developments to the program have occurred as a result of litigation through the courts rather than in consultations with the government, which is not an efficient process for developing public policy.

We set out on a journey across Canada to speak directly to people living with HIV/AIDS about the use of cannabis for medicinal purposes. We conducted an extensive consultation to understand first hand what it is like for a person who is living with HIV/AIDS in Canada when they choose to use cannabis as part of their therapy, and documented their stories. This policy paper provides a voice for people living with HIV/AIDS who use, or want to use, cannabis as part of their therapy, as well as the perspective of other key stakeholders. Specifically, it outlines the barriers to access to the federal program, to a legal source of cannabis, and to required information and services. Recommendations are made to address these barriers so that people living with HIV/AIDS can treat themselves without fear of criminal prosecution, have access to a legal, safe and affordable source of cannabis, with adequate information to make informed decisions about their therapy, and with the necessary support to optimize their health.

Whether you are a person living with HIV/AIDS, a front line worker in an AIDS service organization, a volunteer with a community-based organization, a policy maker, a law enforcement officer, a health care professional, a public servant, an elected official, a lawyer, or a person who is simply interested in this issue, we trust that this document will be useful for your purposes. More broadly, this document is a call to action to all key stakeholders. We must, as a collective, find a way to address the barriers that prevent seriously ill Canadians from having access to cannabis for their medicinal needs without fear of prosecution, as is their right, and if it is their informed choice.

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1 The terms 'cannabis' and 'marijuana' are used interchangeably throughout this document. Health Canada uses the term 'marihuana'. This spelling will be used when referring to Health Canada documents or communications. We favour the term 'cannabis', as it is the name of the plant.

2 Furler MD, Einarson TR, Millson M, Walmsley S, Bendayan R. Medicinal and Recreational Marijuana Use by Patients Infected with HIV. AIDS Patient Care and STDs. 2004;18(4):215-28.

3 Braitstein P, Kendall T, Chan K, Wood E, Montaner JS, O'Shaughnessy MV, Hogg RS. Mary-Jane and her patients: sociodemographic and clinical characteristics of HIV-positive individuals using medicinal marijuana and antiretroviral agents. AIDS. 2001 Mar 9;15(4):532-3.

4 Ware M, Rueda S, Singer J, Kilby D. Cannabis use by persons living with HIV/AIDS: Patterns and prevalence of use. Journal of Cannabis Therapeutics. 2003;2:3-15.

5 Wesner B. The medicinal marijuana issue among PWAS: Reports of therapeutic use and attitudes towards legal reform. Working Paper No.3, Working Paper Series. Drug Research Unit, Social Science Institute, University of Hawaii, Manoa; 1996.; Dansak DA. Medical use of recreational drugs by AIDS patients. J Addict Dis. 1997;16(3):25-30. ; Fairfield KM, Eisenberg DM, Davis RB, Libman H, Phillips RS. Patterns of use, expenditures, and perceived efficacy of complementary and alternative therapies in HIV-infected patients. Arch Intern Med. 1998 Nov 9;158(20):2257-64.; Sidney S, Quesenberry CP Jr, Friedman GD, Tekawa IS.. Marijuana use and cancer incidence (California, United States). Cancer Causes Control. 1997 Sep;8(5):722-8.; Prentiss D, Power R, Balmas G, Tzuang G,

Israelski DM. Patterns of marijuana use among patients with HIV/AIDS *followed in a public health care setting*. J Acquir Immune Defic Syndr. 2004 Jan 1;35(1):38-45.

6 Public Health Agency of Canada. HIV and AIDS in Canada: Surveillance Report to December 31, 2004. April 2005.

7 Clark AJ, Ware MA, Yazer E, Murray TJ, Lynch ME. Patterns of cannabis use among patients with multiple sclerosis. Neurology. 2004 Jun 8;62(11):2098-100.

8 Page SA, Verhoef MJ, STebbins RA, Metz LM, Levy JC. Cannabis use as described by people with multiple sclerosis. Can J Neurol Sci. 2003 Aug;30(3):181-2.

9 Ware MA, Doyle CR, Woods R, Lynch ME, Clark AJ. Cannabis use for chronic non-cancer pain: results of a prospective study. Pain. 2003 Mar;102(1-2):211-6.

10 Gross DW, Hamm J, Ashworth NL, Quigley D. Marijuana use and epilepsy: prevalence in patients of a tertiary care epilepsy centre. Neurology. 2004 Jun 8;62(11):1924-5.

11 This estimate is based on one study conducted in Ontario that found that 1.9% of the population aged 18 years and over reported that they use marijuana for medical purposes (Ogborne AC, Smart RG, Adlaf EM. Self-reported medical use of marijuana: a survey of the general population. CMAJ. 2000 Jun 13;162(12):1685-6). This is most likely an underestimate. In British Columbia alone, it is estimated that about 7%, or 290,000 people, use cannabis for therapeutic purposes (Robin O'Brien, Member of Health Canada's Stakeholder Advisory Committee on Medical Marihuana, Personal Communication, February 2004).

12 *R. v. Morgentaler* (1988), 37 C.C.C. (3d) 449,485 (S.C.C)

13 *R. v. Parker* (1997), 12 C.R. (5th) 251 (Ont. Prov. Ct.).

14 In this document, the term 'medicinal' is used to mean 'having value for healing, helping and relieving'. The term 'medical' is used to refer to having to do with the science and art of medicine. Admittedly, these terms tend to be used interchangeably.

15 The only available statistics provided from the government's medical cannabis program indicate that people living with HIV/AIDS represented the largest patient group under the former Category 1 (terminal illness) of the program (38%), and people living with HIV/AIDS were the second largest group under the former Category 2 (various illnesses and related symptoms), at 24%, with people living with multiple sclerosis patients representing 27%.

16 Canadian AIDS Society. The Community Action Principles of the Canadian AIDS Society. Adopted by the CAS Board of Directors, May 1991. Amended December 2005. Available at http://www.cdnaids.ca/web/casmisc.nsf/cl/cas-gen-0051

Brief Overview of the Methodology

A. Purpose of the Project

Under the Canadian Strategy on HIV/AIDS (now called the Federal Initiative on HIV/AIDS), a "Legal, Ethical and Human Rights Fund" was set up to fund projects that promote social justice through legal and policy approaches to HIV/AIDS that respect, protect and fulfill the rights of people living with HIV/AIDS and that facilitate prevention, care, treatment and support. This project on cannabis as therapy examines the legal, ethical and human rights issues related to access to medicinal cannabis, as well as the effects of the current regulatory environment on the everyday life of people living with HIV/AIDS. The results of this work will contribute to the design of programs that are developed along the prevention care continuum for people living with HIV/AIDS.

This project gives people with HIV/AIDS a voice to express the realities in terms of facilitators and barriers they face when choosing to use cannabis as part of their treatment and care. Its goals are:

- to examine the issues related to the use of cannabis as therapy that people living with HIV/AIDS face, and make recommendations for addressing those concerns through the legislative and related policy initiatives; and
- to develop a resource for use by people living with HIV/AIDS and the HIV/AIDS community that outlines the current regulations regarding access to medicinal cannabis based on existing national and international legislation and regulation.

To meet these goals, the Canadian AIDS Society, in collaboration with the National Steering Committee and the legal consultant, have used the information collected:

- to produce a report on the legal, ethical and human rights issues related to the use of cannabis as therapy for people living with HIV/AIDS;
- to develop a series of fact sheets for people living with HIV/AIDS, which will also be useful in building the capacity of CAS' member organizations to provide information to people living with HIV/AIDS regarding the use of cannabis as therapy; and
- to develop a plan of action to address the barriers to access and the effects of the current regulatory environment on people living with HIV/AIDS.

B. Guiding Principles

At the core of our principles, the Canadian AIDS Society believes that people living with HIV/AIDS should have access to cannabis for therapeutic purposes in the treatment of HIV/AIDS[1] without fear of prosecution. From the point of view of constitutional rights, it is not necessary to find extensive clinical research proving that cannabis is therapeutically effective, although the evidence regarding cannabis efficacy in managing HIV/AIDS-related symptoms is mounting. It is sufficient that a person's choice is reasonable.[2] Guarantees of human rights and personal safety are critical to the development and maintenance of good health.[3]

We see health as more than the absence of symptoms or disease. Good health encompasses physical, emotional, mental and spiritual well-being, and is an important dimension of the quality of life as well as a major resource for the social, economic and personal development of individuals. Some uses of cannabis may be therapeutic or beneficial for the person using it but may not yet be recognized by the medical community.

We believe that persons living with HIV/AIDS have the right to be directly involved in all decisions that affect their lives. As such, it is in everyone's best interests to obtain accurate information, to the best of available knowledge, about the therapeutic properties and potential risks of using cannabis. Each person needs to analyze the benefits they get and the risks they take when it comes to cannabis use. Providing ple with tools for this self-assessment falls within a

harm reduction and health optimization approach favoured by the Canadian AIDS Society.

We believe that everyone must have equal access to the therapies and services that they trust will provide the most benefit to them, free from all forms of discrimination and barriers. Access to cannabis for therapeutic purposes is laden with barriers due to legislative and policy complexities.

We are driven by our community action principles of empowerment, community support, self-help, holistic approach, accountability, harm reduction and greater involvement of people living with HIV/AIDS.[4] People living with HIV/AIDS must be directly involved in the decisions that affect their lives and in the organizations that serve their needs. We accept and endorse the Principles of Greater Involvement of People Living with or Affected by HIV/AIDS (GIPA) as stated in the UNAIDS working definition.[5] We have consulted people living with HIV/AIDS in the context of this project and plan on their continued involvement in future actions related to addressing the barriers to access to cannabis for medicinal purposes.

As members of the voluntary sector, the Canadian AIDS Society is committed to assisting the federal government in identifying issues and in achieving its public policy objectives, as per the *Accord Between the Government of Canada and the Voluntary Sector*.[6] We recognize the importance of dialogue between the two sectors and have included government representatives in our consultations and as ex-officio members on our National Steering Committee for this project.

With these guiding principles in mind, the Canadian AIDS Society has taken on the challenge of examining the legal, ethical and human rights issues related to access to cannabis for medicinal purposes, as well as issues related to the regulation of medicinal cannabis. We put forward recommendations to be considered regarding legislative and policy processes.

C. Methodology

i. National Steering Committee

A National Steering Committee was established to bring together representatives from key stakeholder groups. It was composed of 5 regional representatives (Pacific, Prairies, Ontario, Quebec and Atlantic), a representative from a compassion club[7], representatives from the cannabis community, two medicinal cannabis users, a lawyer, a physician, a pharmacist, and two ex-officio members. Some of these representatives were members of our national partners: Canadian HIV/AIDS Legal Network, Canadian Treatment Action Council, and the Canadian Aboriginal AIDS Network. The ex-officio members included a representative from Health Canada's Marihuana Medical Access Division and a representative from the Public Health Agency of Canada's HIV/AIDS Policy, Coordination and Programs Division. Law enforcement organizations were also invited but did not put forth a representative. The National Steering Committee's mandate was to direct and provide recommendations on the development and content of all aspects of the project.

ii. Legal Analysis

A legal consultant was hired under contract to conduct a legislative and policy review and analysis of the current legal context that people living with HIV/AIDS have to work with to make decisions regarding their care and treatment. The analysis included strategic directions and recommendations for possible future actions that the Canadian AIDS Society could pursue to address the barriers to access to medicinal cannabis for people living with HIV/AIDS. The legal consultant's recommendations were taken into consideration when putting forth the Canadian AIDS Society's recommendations. Excerpts from the consultant's report are included in this document.

iii. Consultations

People living with HIV/AIDS were widely consulted though focus groups and a consultation questionnaire. The purpose of this consultation was:

- To identify the barriers to access to medicinal cannabis and the effects of the regulation of cannabis on their everyday lives;

- To document the realities that people living with HIV/AIDS face with regard to the use of cannabis as part of their therapy; and
- To identify their information needs regarding the use of cannabis for medicinal purposes.

A consultation report which provides detailed results of the responses to the questionnaire and the focus groups consultations is available as a complement to this policy paper.

a. Focus Groups

Focus groups were conducted across Canada in cities in each of the 5 regions: Victoria, Saskatoon, Toronto, Montreal and Halifax, as well as at the Annual Forum for People Living with HIV/AIDS, which was held in Ottawa. During the focus groups, some people were brought in from outside the cities that were visited to get better representation from outside urban centres. The focus groups followed a single-category design whereby participants had to be people living with HIV/AIDS. A total of 42 people participated in the focus groups. Most were medicinal users of cannabis, although a few were not.

The focus group sessions were facilitated and recorded for transcription purposes. The questioning route used to guide the discussion during the focus groups included questions on:

- how they use cannabis medicinally;
- how it has been for them to get cannabis for medicinal purposes;
- whether they had applied to the federal medical cannabis program and how that process was for them; whether they have considered obtaining their cannabis from the government's source;
- what they think of the government's plan to distribute cannabis through pharmacies;
- what their thoughts are on the new product "Sativex®";
- whether they have discussed the use of cannabis for medicinal purposes with their physician;
- how people react to their use of cannabis for medicinal purposes;
- how the laws regarding cannabis affect their everyday life;
- whether there are social, cultural or spiritual aspects to their use; and
- what their thoughts are as to what an ideal system for medicinal cannabis in Canada could be.

The discussions were transcribed and analyzed by the project consultant, with input from the National Steering Committee. The main messages extracted from these focus groups guided the development of this report.

b. Consultation Questionnaire

A questionnaire was developed to collect information on the medicinal use of cannabis from across the country, to obtain better representation of views, and to reach people living with HIV/AIDS who were not currently using cannabis for medicinal purposes. This was done to identify potential barriers that may be preventing them from using cannabis should they want to, in order to address these barriers in our plan of action.

The questionnaire was widely distributed to the Canadian AIDS Society's member organizations, participants at the annual Forum for People Living with HIV/AIDS, compassion clubs across Canada, and email lists pertaining to medicinal cannabis as well as issues related to HIV/AIDS. It was also posted and available on the Canadian AIDS Society's web site. An article appeared in an issue of Cannabis Health magazine describing the project and inviting people to participate in the focus groups and questionnaire. Each participant of the focus groups also completed the questionnaire. Some physicians displayed the questionnaire in their office for their patients. We compiled a total of 197 completed questionnaires. We do not claim to have a random sample of people living with HIV/AIDS. We consulted as many people as possible through a convenience sample within the constraints of our resources. The questionnaire was also available online. The questionnaire results were analyzed using SPSS 13.0 for Windows software to generate proportions and conduct cross-tabulations. The focus group transcripts were used to complement the data collected with the questionnaire. The transcripts added depth and personal stories behind the issues and identified additional issues not captured by the questionnaire.

iv. Key Stakeholder Interviews

Key stakeholders in the context of medicinal cannabis for people living with HIV/AIDS were identified and interviewed. The list of people interviewed is available in Appendix A. Questions specific to each key stakeholder were developed. The interviews were recorded and transcribed, and were considered in the development of our recommendations. Excerpts from these interviews are included throughout this document.

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3 Canadian AIDS Society. Our Core Beliefs and Values. Available from: <www.cdnaids.ca/web/casmisc.nsf/cl/cas-gen-0050>.

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7 Compassion clubs or cannabis clubs are establishments that provide cannabis for medicinal purposes to seriously ill Canadians, usually with proof of diagnosis and/or a physician's signature on the application form. These clubs vary in size, organizational structure, and in the services they provide. They are currently not officially recognized and are not legal establishments, though clubs that adhere to certain procedures have yet to be successful prosecuted.

Brief Overview of the Science

Cannabis has been used for millennia for a variety of medicinal purposes. The earliest well-documented evidence of cannabis use dates back to 4000 BCE. In Asian and Middle Eastern countries, cannabis has been used for at least 2,500 years. It was introduced into Western medicine in the late 1830s. Cannabis had been widely used as a medicine until the pharmaceutical revolution of the 20th century, combined with a criminal prohibition, obscured the therapeutic benefits of the plant. The criminalization of cannabis in Canada in 1923 effectively put an end to the medical applications of this plant, and its continued criminalization has effectively thwarted research into its effects, with the exception of research designed to investigate the alleged harms of the plant in hopes of justifying the prohibition. However, since the 1970s, there has been a resurgence of interest in the use of cannabis for medicinal purposes, as people discovered its capacity to control some of the symptoms associated with major debilitating illnesses.[1]

A. Management of HIV/AIDS Related Symptoms

The scientific literature exploring the therapeutic potential of cannabis for symptom management related to HIV/AIDS is growing. We provide a brief summary of the current scientific literature regarding the use of cannabis by persons living with HIV/AIDS as it relates to appetite stimulation, nausea, and neuropathic pain. This is not an exhaustive review and is meant to provide the reader with some context. For the latest summary of published research on cannabis and cannabinoids[2] from the international literature, we invite you to consult the Canadian Consortium for the Investigation of Cannabinoids' Web site at <www.ccicnewsletter.com>.

i. Appetite Loss

Appetite loss often results from HIV/AIDS or from medications. Severe appetite loss can lead to significant weight loss and wasting. Wasting syndrome is one of the primary killers of people with AIDS. It is defined as the involuntary loss of more than 10% of baseline bodyweight and results from cachexia (wasting), which causes a disproportionate loss of lean tissue mass and starvation resulting from food or nutrient deprivation. In 1991, an open pilot study was published which revealed that Marinol® (synthetic THC) led to increased weight gain in a majority of subjects.[3] These findings were supported by a controlled trial of 88 people with AIDS that found that Marinol® was significantly superior to placebo in improving appetite, with a tendency toward weight gain, with 75% of adverse effects falling within the mild/moderate categories[4].

Although there is a wealth of anecdotal evidence which suggests the success of smoked cannabis in appetite stimulation (i.e. "the munchies"), few scientific studies have been conducted on this relationship. Those studies which have been published have been limited to laboratory settings with few patients, and have found significant increases in body weight, appetite, and food intake[5]. The Ontario HIV Trial Network has recently provided funding for a study on the effects of smoked cannabis on body weight, food intake, and appetite stimulation in HIV/AIDS. The researchers had suggested an open-label, single-arm, dose titration study. Since the approval by the OHTN, the importance of conducting a larger clinical trial has lead the investigators to rework the protocol.[6]

ii. Nausea and Vomiting

The severity of AIDS wasting syndrome is compounded by the fact that the protease inhibitors (antiretroviral drugs) which form an integral part of the current treatment of the disease often lead to extreme bouts of nausea and vomiting, similar to that experienced by cancer patients following chemotherapy. Cannabis has been found to act as an efficacious antiemetic. In fact, in a 1991 study, Doblin found that 44% of surveyed oncologists had recommended the use of cannabis as a treatment for nausea.[7] In a review

of six separate studies conducted by in the U.S., cannabis was found to be "effective in reducing or eliminating nausea and vomiting following cancer chemotherapy."[8] Moreover, the studies showed smoked cannabis to be equal to, or more effective, than Marinol® for this indication. Similarly, in a non-randomized trial with subjective assessment of nausea/vomiting, smoked cannabis was found to be very effective (34%) or moderately effective (44%).[9]

iii. Neuropathic Pain

Anecdotal evidence supports the view that cannabis does have positive benefits for neuropathic pain. This form of pain is defined as follows:

> Neuropathic pain occurs when nerves themselves sustain injury. It is often experienced as a burning sensation that can occur in response to even a gentle touch. Neuropathic pain does not usually respond to narcotic painkillers, which may relieve other types of pain. Antidepressant or anticonvulsant drugs, as well as certain surgical procedures, may improve some cases of neuropathy.[10]

As was noted by the 1997 National Institute on Drug Abuse (NIDA) workshop on medical cannabis: "Neuropathic pain represents a treatment problem for which currently available analgesics are, at best, marginally effective. Since delta-9-THC is not acting by the same mechanism as either opioids or non-steroidal anti-inflammatory drugs, it may be useful in this inadequately treated type of pain."[11] Although one study found that Marinol® (synthetic THC) was largely ineffective in treating patients with refractory neuropathy,[12] it has been criticized as it did not consider the possible therapeutic effect of the other cannabinoids. In this vein, a series of double-blind, randomized, placebo-controlled single-patient crossover studies, which compared three different whole-plant extracts against placebo for patients with intractable neurogenic symptoms, concluded that cannabis extracts can improve neurogenic symptoms that are unresponsive to standard treatments, with well-tolerated adverse effects.[13] Other recent short-term studies found similar promising results with Sativex® on neuropathic pain.[14] Moreover, a recent two-week study of a synthetically manufactured cannabinoid (CT-3) proved efficacious in treating neuropathic pain, which is significant since this particular cannabinoid was designed to function without psychoactive effects.[15]

One study which was recently completed by Dr. Donald Abrams studied the effect of smoked cannabis on sixteen people living with HIV/AIDS with painful nerve damage in their hands and feet. Abrams has reported that the preliminary findings "are very suggestive that there was a benefit to smoked marijuana."[16]

B. Herbal Cannabis versus Pharmaceutical Products

Synthetic THC, in the form of Marinol® (dronabinol) and Cesamet® (nabilone), has been indicated for nausea and vomiting resulting from chemotherapy. Moreover, Marinol® has been further indicated for appetite stimulation in the treatment of AIDS wasting syndrome. Many of the early studies on the antiemetic and appetite stimulant properties of cannabis were conducted solely with Marinol®. However, more recently, under a more sympathetic climate, studies have begun to investigate the safety and efficacy of smoked cannabis, on its own and in relation to Marinol® and other traditional drugs.

Although studies have shown that Marinol® and smoked cannabis are similarly efficacious in treating nausea and stimulating appetite, people living with HIV/AIDS have been clear in their preference for smoked cannabis.[17] In a recent questionnaire study of 160 HIV clinic patients and 19 compassion club members in Toronto, Ottawa, and Montreal, 93% of those patients who used both Marinol® and cannabis (n=57) reported that they preferred cannabis.[18] A number of reasons for this preference have been advanced, including:

- the high expense of Marinol® in relation to cannabis, which makes long-term use financially unfeasible;[19]
- the ability for patients to titrate their doses using cannabis;[20]
- the rapid onset of smoking the drug versus oral ingestion;
- the difficulty of swallowing Marinol® during

bouts of nausea;[21]

- and the possible synergistic effect of the whole cannabis plant, with the interaction of its numerous cannabinoids, particularly cannabidiol (CBD), which is absent from the THC-exclusive Marinol®.[22]

A critical difference between the therapeutic applications of marijuana and of Marinol® lies in the route of administration. Smoking cannabis has the advantage of rapid onset and efficient bioavailability. Rapid onset is highly desirable in terms of combating waves of nausea. More importantly, Marinol® is absorbed through the gastro-intestinal tract, which presents certain problems for patients in terms of variable bio-availability. The metabolization of THC produces a more psychoactive substance which tends to induce dysphoria in patients.[23]

C. Adherence to Drug Therapy

Adherence to medications is of utmost importance to HIV positive individuals in order to ensure long-term suppression of the virus. As the medication is often accompanied by unpleasant side effects, sticking to a drug regimen can be a challenge for a chronically ill person. Anecdotes of increased adherence with the help of cannabis abound.[24]

Research has been done in this area and shows that mental health, substance use and adherence to medication are closely linked. One study found that people living with HIV/AIDS who are depressed, suffering from an anxiety disorder or panic disorder, and who used drugs such as cocaine, cannabis, amphetamines or sedatives, were more likely to be non-adherent to their antiretroviral medication than those without these mental health issues.[25] Similarly, another study showed that people on antiretroviral medications who had missed at least one dose of their medication in the past week scored significantly higher on a hopelessness scale and reported more current use of cannabis.[26] However, these studies did not focus on people living with HIV/AIDS who specifically use cannabis to help with the side effects of their medication. Another study specifically sought to identify the effects of cannabis use on adherence to antiretroviral therapy (ART). It found that the "medicinal use of marijuana may facilitate, rather than impede, ART adherence for patients with nausea, in contrast to the use of other illicit substances, which were associated with lower rates of ART adherence."[27] These findings suggest that the use of smoked cannabis to specifically help with nausea may be associated with adherence to ART among people living with HIV/AIDS.

D. Long Term Effects of Cannabis

Scientists have spent a great amount of time searching for suspected harms associated with the use of cannabis in order to provide a foundation for current prohibition policies. The war on drugs has made it difficult to distinguish between legitimate and skewed scientific study. Researchers have been able to find ailments and diseases in rats exposed to high amounts of cannabis, but, more often than not, these findings are not replicated in human population studies, nor are they reflected in epidemiological evidence in an aging population of cannabis smokers.[28]

The fact that there may be harm associated with the use of cannabis should not prevent cannabis from being considered an important medicine. All drugs have side-effects and in the realm of medicine, the critical question is whether the harms outweigh the benefits. Given the political nature of the debate, no consensus has been reached with respect to the harms associated with cannabis. Suffice it to say, even when one takes the various claims of harm at face-value, it is clear that cannabis has a wide margin of safety. There has never been a recorded death directly attributed to cannabis use and most of the documented side-effects are not so grave so as to render cannabis unsuitable for medical use. In fact, there is no known lethal dose for cannabis or its major components in humans.[29,30,31,32,33] It is estimated that one would need to consume 1500 pounds of cannabis in 15 minutes to die from it, and this has never been proven.

i. Effects on the Lungs

However, there are two suspected harms which need to be explored in greater depth: effects on the pulmonary system, and impairment of the immune system. Since the evidence in support of these claims is tenuous and speculative, there is a need to conduct further research. The need for confirmatory research

is especially relevant with respect to effects on the immune system and the potential impact of cannabis use on persons already suffering from a compromised immune system.

As for pulmonary risks, there is documented evidence that chronic smoking of cannabis will lead to bronchial impairment; however, there is no hard evidence of emphysema or lung cancer.[34] Most of the research on pulmonary harm has been conducted by Dr. Tashkin at UCLA. He has recently completed a study examining over 64,000 patient files in which he concluded that cannabis users did not develop lung cancer at a higher rate nor die earlier than non-users. The paper has yet to be published. At the July 2005 International Cannabinoid Research Society, Dr. Tashkin presented his findings which showed that even long-term use of cannabis does not cause cancer of the lungs, upper airwaves or esophagus.[35] Tashkin's findings echo the findings of a large-scale 2004 study which found no increased risk of oral cancer for cannabis smokers.[36]

Even if cancer is not a consequence of long-term use of cannabis, the non-cancerous forms of pulmonary impairment from long-term smoking still present a risk for people living with HIV/AIDS. Frequent use can cause airway injury, lung inflammation and impaired defence against infection, which could be serious in immunocompromised individuals.[37]

Pulmonary risks are increased when the cannabinoids are delivered by combustion and smoking. However, there are measures of harm reduction for those who choose to smoke cannabis. One interesting option is the use of vaporizers, which release cannabinoids by heating cannabis to a temperature short of combustion, thereby eliminating or substantially reducing harmful toxins that are present in cannabis smoke.[38, 39]

ii. Effects of Contaminated Cannabis

The risk of pulmonary infection is heightened when patients smoke cannabis which may contain microbiological contaminants, opportunistic fungi and other adulterants.[40] Microbiological contamination is an important factor to consider during the cultivation of cannabis. Some measures exist to prevent the growth of microbiological contaminants.

iii. Effects on the Immune System

With respect to risks to the immune system from smoking cannabis, one commentator has noted that, "despite the many claims that marijuana suppresses the human immune system, the health effects of marijuana-induced immunomodulation are still unclear."[41] With respect to persons living with HIV/AIDS, the issue of immune suppression must be studied further if cannabis is to be used for medical purposes. There is an additional concern over the drug interaction between cannabis and the protease inhibitors used in AIDS treatment, since both drugs are metabolized by the same systems in the liver.[42]

However, in the most comprehensive study of the issue,[43] involving 62 subjects who were taking protease inhibitors (either indinavir or nelfinavir), Dr. Abrams found that these patients did not experience significant virologic effects from cannabinoid treatment (either smoked or oral) over the three week study. "Our short duration clinical trial suggests acceptable safety in a vulnerable immune-compromised patient population." Moreover, patients who were treated with cannabinoids actually gained more weight than those who were on placebo. In concomitant studies, Bredt[44] found that there was no change in immune system phenotypes or functions and Kosel[45] found no effect on the metabolism of protease inhibitors. Similar conclusions were reached through oncological studies, which analyzed immunologic markers in cannabis users.[46] Nonetheless, despite these initial positive results, all of the authors cautioned that longer-term studies were necessary.

While some research scientists continue to express concern about cannabis and immune suppression, other scientists are reaching the conclusion that cannabis has actually become an indispensable treatment component for maintaining high adherence to antiretroviral drug regimens which are needed to suppress viral loads. Unfortunately, adherence to the drug regimen is difficult for many patients. As Bayer notes, "patients with AIDS often find that the medicines they need to sustain their lives can produce side

effects so intolerable that they become reluctant to maintain their treatments, or fail to take treatment regularly."[47] One study of 160 HIV clinic patients found that 71.3% suffered from adverse effects from their antiretroviral drugs, causing 14.4% of them to miss their doses. However, 27.5% of the patients reported using cannabis or dronabinol to counteract these adverse effects.[48] In a survey study within a public health care system for HIV/AIDS in northern California, de Jong found that patients who suffered from moderate to severe nausea and used cannabis were more likely to adhere to their drug regimen than those patients who similarly suffered from nausea but did not use cannabis.[49] This is particularly significant since nausea and anorexia are frequently cited as reasons for delayed or missed doses and discontinuation of antiretroviral therapy.[50]

E. Cannabis as Therapy for People Living with HIV/AIDS

Out of these studies, it has become apparent that cannabis could be an essential complement to HIV/AIDS therapy on account of its anti-emetic, appetite stimulant, analgesic properties and others – so much so that the 1999 report on medical cannabis by the Institute of Medicine (IOM) in the United States declared that:

> "For patients such as those with AIDS or who are undergoing chemotherapy, and who suffer simultaneously from severe pain, nausea, and appetite loss, cannabinoid drugs might offer broad-spectrum relief not found in any other single medication."[51]

However, liberal access to cannabis as therapy will always remain underdeveloped until the requisite clinical research is conducted to uncover the ways in which cannabis is therapeutically active and effective. Both the historical record and current scientific understanding support the assertion that cannabis has therapeutic value. However, there is a divergence of opinion as to whether cannabis is a superior, inferior, or even equally effective treatment for appetite loss, nausea, cachexia (wasting) or neuropathic pain when compared to other conventional pharmaceuticals. While the renewed interest in the therapeutic properties of cannabinoids is promising, there remain important gaps in the research, especially when it comes to the therapeutic effects of smoked cannabis.

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Legal Access to Cannabis for Medical Purposes in Canada

In Canada, seriously ill Canadians can apply to the federal government to obtain legal authorization to possess and cultivate cannabis for medical purposes. As Canada has been a leader in enabling legal access to medical cannabis, we outline in considerable detail how the federal program came to exist. Access to cannabis for medical purposes was primarily developed in Canadian courts. As such, we present the legal history that resulted in the current regulations and policies. This section sets the stage for the current regulatory and policy environment that people have to manoeuvre in order to use cannabis legally as part of their treatment.

A. The Canadian Constitution

The Canadian Constitution does not explicitly guarantee a "right to health" or a "right to healthcare" as is found in numerous international treaties and conventions. Nonetheless, depriving someone of health care may constitute a violation of equality rights under section 15 of the *Canadian Charter of Rights and Freedoms,* as well as a violation of the right to life, liberty and security under section 7 of the Charter. To date, there has been little success in utilizing the *Charter of Rights* to secure health care entitlement; however, in the late 1990s, seriously ill people did manage to secure a constitutional entitlement to use cannabis as therapy.

Prior to the medical cannabis breakthrough of the late 1990s, the developing jurisprudence under the Charter did not lay a promising foundation for an entitlement to use cannabis as therapy. Without an emerging constitutional right to health, the strategy in the medical cannabis cases was to develop a "right to choose medical treatment", based upon notions of autonomy and dignity already recognized in common law and constitutional jurisprudence. At common law, the doctrine of informed consent was predicated on the notion that patients must have a right to self-determination with respect to treatment and that doctors serve the function of providing the requisite information to facilitate an independent choice by the patient. Ultimately, the patient could make a foolish choice as long as the physician provided the patient will full disclosure of the risks and benefits of a proposed treatment.

This deeply-rooted conception of autonomy in the common law has crystallized into a constitutional right under section 7. Autonomy in the choice of medical treatment engages consideration of the "security interest", which is protected under section 7. The inclusion of the right to make autonomous decisions as they relate to one's bodily integrity within the section 7 right to security of the person has been supported by the Supreme Court of Canada. In the *Rodriguez* case, dealing with the constitutionality of the assisted-suicide prohibition, the Court stated:

> There is no question, then, that personal autonomy, at least with respect to the right to make choices concerning one's own body, control over one's physical and psychological integrity, and basic human dignity are encompassed within security of the person, at least to the extent of freedom from criminal prohibitions which interfere with these.[1]

In the *Morgentaler* case, dealing with the constitutionality of the abortion prohibition, the Court stated:

> "Security of the person" within the meaning of s. 7 of the Charter **must include a right of access to medical treatment for a condition representing a danger to life or health without fear of criminal sanction** *(emphasis added).*[2]

Autonomous choice with respect to medical treatment also falls within the protection of a broader conception of the liberty interest contained within section 7 of the Charter. This broader conception has been characterized as a freedom to make decisions of a fundamental personal nature without undue state

interference. The Supreme Court of Canada has articulated this broader conception in the following manner:

> Freedom of the individual to do what he or she wishes must, in any organized society, be subjected to numerous constraints for the common good. The state undoubtedly has the right to impose many types of restraints on individual behaviour, and not all limitations will attract Charter scrutiny. On the other hand, liberty does not mean mere freedom from physical restraint. In a free and democratic society, the individual must be **left room for personal autonomy to live his or her own life to make decisions that are of fundamental personal importance** *(emphasis added)*.[3]

By elevating the common law right to make an autonomous decision concerning one's bodily integrity into a constitutionally-entrenched right to liberty and/or security, it is clear that the state must now have a compelling reason to override the individual's autonomous choice of treatment. Although little success had been achieved in elevating a general right to effective health care into a constitutional right, the elucidation of the right to "liberty" and "security" in section 7 of the Charter laid a strong foundation for constitutionalizing the right to self-medicate with cannabis. Liberty had been expanded to include the right to make fundamental personal decisions (choice of medical care) without unjustified government interference (i.e. criminal charges), and security was understood as the right to be free from state-induced psychological stress (i.e. fearing that one's choice of treatment will occasion state punishment). With cannabis remaining a controlled substance, people who used cannabis for medicinal purposes faced the possibility that their choice would be met with criminal sanction, and it was clear that this state interference constituted a violation of both liberty and security. The only remaining uncertainty surrounded the question of whether this violation was "in accordance with the principles of fundamental justice."

B. The Birth of the Marihuana Medical Access Regulations (MMAR)

In 1997, in the *Clay* case, the first claim relating to the constitutional dimensions of medical cannabis use was brought in the context of a broader constitutional challenge to the prohibition of cannabis. The trial judge declined to address the constitutional arguments relating to medical use on the basis that the applicant in that case was not a medical user. However, the judge stated:

> As an aside, Parliament may wish to take a serious look at easing the restrictions that apply to the use of marijuana for the medical uses as outlined above as well as for alleviating some of the symptoms associated with multiple sclerosis, such as pain and muscle spasm. There appears to be no merit to the widespread claim that marijuana has no therapeutic value whatsoever.[4]

Later that year, an Ontario Court judge issued a stay of proceedings in relation to cultivation and possession charges brought against an epileptic, Terry Parker, who had been using cannabis for therapeutic purposes.[5] As a remedy for the constitutional violation of Parker's section 7 rights, the judge "read-in" to the legislation a constitutional exemption for individuals possessing and cultivating cannabis for their personal medical use. Undoubtedly the case was a resounding victory for medical cannabis advocates; however, an appeal was quickly launched and the status of the ruling was left in doubt.

Meanwhile, on September 8, 1998, an Ontario Superior Court judge dismissed an application by James Wakeford, a person living with HIV/AIDS, who was seeking a constitutional exemption to permit him to use cannabis medicinally. That judge agreed with the trial judge in *Parker* that the criminalization of the medicinal use of cannabis was not in accordance with the principles of fundamental justice.[6] Nonetheless, the judge in *Wakeford* dismissed the application on the basis that the Crown had asserted that there was a process by which Wakeford could obtain an exemption for medicinal use. The Crown took the position that section 56 of the *Controlled Drugs and Substances Act* (CDSA) provided a valid exempting process to enable him to legally possess cannabis

for medicinal purposes, and that Mr. Wakeford had failed to avail himself of this opportunity. The judge accepted the Crown's assertion despite Wakeford's submission that the section 56 exemption process was nothing more than an illusion. Although he dismissed that first application by Wakeford, the judge noted:

> It should be obvious by now that our society must begin to seriously give consideration to the medicinal benefits of marijuana. Medical evidence and opinion, albeit not complete, clearly indicate that the time has come to examine this sincerely. In the case at bar, anecdotal evidence was submitted that attempts to demonstrate the many ways in which marijuana has brought medical assistance and relief to persons suffering debilitating and deadly ailments. These include prominent professionals and others who suffer from cancer, AIDS and epilepsy, to mention only some. All speak of the relief and benefits obtained from marijuana smoking during their illnesses and treatment, all of which is described as painful and debilitating until then. In this regard they express the same concerns as Mr. Wakeford as to the availability of "clean" and affordable marijuana. All of these concerns are, in my view, valid and ought to be dealt with by Parliament if it has not done so or is not doing so. If such is not the case, the courts of this land will, without question, continue to be called upon and expected to provide a remedy for this very pressing and fundamentally important issue. Unlike government, the courts do not have the luxury of avoiding this difficult and sensitive matter until a more suitable time. Our duty is to decide such issues as they are presented to us on a case by case basis. Such an approach, in my opinion, cannot be either satisfactory or the most beneficial to the interests of our society.[7]

Six months later, in March 1999, Wakeford sought a re-hearing of his first application on the basis that the judge had been misled by the Crown as to the relevance and operation of section 56 of the CDSA. After hearing Wakeford's fresh evidence, the judge concluded that the section 56 exemption process was indeed an illusory process. He stated:

> At the time Mr. Wakeford filed his original application in this matter, namely, February 1998, there was no process whereby the Minister of Health could have granted him an exemption. This continued to be the case on September 8, 1998 when I released my judgment ... What is clear is that: (i) no process existed within the Ministry of Health such that an application for exemption by someone in the circumstances of Mr. Wakeford could have been considered at the time of the original hearing in this matter; and (ii) had Mr. Wakeford formally applied for an exemption, the Minister of Health had no real and meaningful way of considering his application.[8]

The judge concluded that the exempting process under section 56 was only now being developed as a result of the original application brought by Wakeford; that is, it was in response to Wakeford's application that the "Interim Guidance Document" was created. The Interim Guidance Document outlined a rudimentary procedure whereby a physician would submit a patient's medical records to Health Canada for evaluation. The physician did not necessarily make any recommendation and medical examiners at Health Canada, on behalf of the Minister of Health, would determine whether it was medically sound to authorize the person to use cannabis for medical purposes. The judge ordered that Wakeford be granted an interim constitutional exemption while his application for an exemption was being processed under the terms of the newly-created Interim Guidance Document. The judge noted that "I continue to be unable to decide whether the process is real in the sense that it complies with the principles of fundamental justice."

On June 9, 1999, Mr. Wakeford became the first recipient of an exemption under section 56. From that time, Wakeford began to repeatedly request that Health Canada provide him with a supply of medical cannabis and that the Government exempt his caregivers from the operation of the criminal law. On May 1, 2000, Ontario Superior Court Justice Wright dismissed an application by Wakeford for relief under section 24(1) of the Charter. The judge dismissed the claim on the basis that Wakeford's section 7 rights had not been violated because Wakeford had always been able to secure a supply of medicine. The judge stated:

> In view of the fact that the Government does not have, within Canada, a source of licit marijuana, and that the Government is moving at a reasonable pace to provide clinical trials of marijuana, and that marijuana is not the only avenue by which Mr. Wakeford may improve his quality of life, the principles of fundamental justice are not infringed by the failure of the Government to supply marijuana directly to Mr. Wakeford.[9]

In constructing the first regulatory regime, Health Canada held multi-stakeholder consultations. In the first consultation in February 2000, the following issues were identified to be priorities:

1. obtaining a legal source of marijuana for section 56 exemptees;
2. exemptions for caregivers;
3. addressing the need for more information on the use of marijuana for medical purposes;
4. addressing concerns of law enforcement agencies;
5. improvement of the process and tools for section 56 applications;
6. communication regarding the section 56 process and Health Canada's activities regarding marijuana for medical purposes.[10]

Despite the stated priority of obtaining a legal source, the issue unsuccessfully raised in the *Wakeford* case, the MMAR were silent on this issue. Although the new regime did permit exempted persons to grown their own cannabis, or to designate a producer to do so without compensation, the regulatory scheme did not authorize any other form of organized distribution. Although Mr. Wakeford did not succeed in obtaining a court order for the government to distribute medical cannabis, his case prompted the Minister of Health in December 2000 to award a contract to Prairie Plant Systems (PPS), making it the only licensed dealer allowed to produce a domestic source of cannabis. However, Health Canada took the position that this source was destined solely for research purposes and not for medical use by those authorized under the MMAR.

While Mr. Wakeford was pursuing issues relating to access and supply, the appeal in the *Parker* case had been finally resolved. In July 2000, the Court of Appeal confirmed that a constitutional right to choose cannabis as medicine did in fact exist, although the precise contours of the right still remain a matter of debate. The government chose not to appeal this decision and the *Parker* case became the seminal case on the constitutional dimensions of the therapeutic choice to use cannabis as a means of treating serious illnesses. In light of the precedential significance of this judgment, this report provides excerpts from the decision on the key components of the ruling in R. v. Parker (2000) in Appendix B.

In the *Parker* case, the Court of Appeal agreed that a medical patient's rights were violated by criminalizing the patient's choice, but the Court did not agree with the trial judge in *Parker*, and the application judge in *Wakeford*, that the proper remedy was a constitutional exemption for the individual litigant before the court. Instead, the Court held that there must be an effective government program whereby all patients can seek exemption from the law in order to be authorized to use cannabis as medicine. Without an effective medical program, the Court declared that the government would lose the constitutional authority to retain the criminal prohibition on the use of cannabis. In other words, if medical users were not adequately protected from the criminal law, then the criminal law ceases to apply to *all* users, whether medical or recreational.

The Court of Appeal also concluded that the existing program governed by the Interim Guidance Document was unconstitutional because it lacked concrete guidelines and vested too much discretion with the Minister of Health. With the invalidation of the Interim Guidance Document, the government was compelled to construct a meaningful exempting program. The Court suspended their ruling, thus providing the government one year to construct an effective program, and on August 1, 2001, the *Marihuana Medical Access Regulations* (MMAR)[11] came into effect. Despite the invalidation of the s.56 Interim Guidance Document, exemptions continued to be granted to patients under s.56, independently of

the MMAR; however, Health Canada will eventually phase out s.56 applications by directing all applicants to apply under the terms of the MMAR.

Thus, the *Marihuana Medical Access Regulations* were prepared by the Government in direct response to the decision of the Ontario Court of Appeal in *Regina v. Parker*. The Government's stated purpose in creating the Regulations was to bring greater clarity and transparency to the process of exempting the medical use of cannabis. Under the old regime (the Interim Guidance Document), an exemption to possess and/or cultivate medical cannabis under section 56 was dependant on the unfettered discretion of the Minister. On behalf of their patients, physicians would supply the Minister with information demonstrating that a patient had been suffering from a serious illness and that conventional medical treatments had been ineffective. Based on the information supplied by the physician, the Minister would then render a decision on the merits of the patient's exemption application. Under the new regime, however, physicians simply produce signed declarations relating to medical necessity without having to file any supporting documentation with the Ministry. Once these declarations have been made, the Minister must grant the authorization, subject to very narrow exceptions. In essence, the criteria for granting an exemption under the MMAR's regime is similar to the criteria under the former regime (as set out in the section 56 Interim Guidance Document), but the new regulatory regime has shifted the decision-making power to the applicant's physician, as opposed to the Minister.

Under the original draft of the MMAR, every applicant who sought an authorization to possess needed to provide medical declarations in support of the application. The nature of these requisite medical declarations depended upon the particular category in which the applicant was situated. Category 1 covered those illnesses which are terminal and for which there is a prognosis of death within 12 months. Category 2 related to serious illnesses such as cancer, HIV/AIDS, Multiple Sclerosis, spinal cord injury or disease, epilepsy, severe forms of arthritis and specific symptoms associated therewith. Category 3 related to other illnesses and/or symptoms not specifically enumerated in the other categories. An applicant under Category 1 needed a declaration from his or her medical practitioner, whereas Category 2 applicants needed to provide a medical declaration from a physician and a specialist and Category 3 applicants needed medical declarations from the physician and two specialists.

Medical declarations under each category of application were required to state that all conventional treatments for the symptoms had been tried or at least been considered. In the case of Category 2 applicants, the medical declaration was required to state that *all* conventional treatments were medically inappropriate for reasons specified in the Regulations. Category 3 applications required further explanation from a medical specialist as to why all other treatments were deemed medically inappropriate. In addition, a second specialist was required to review the applicant's medical file and discuss the applicant's case with the first specialist. Patients authorized under the program were allowed to produce their own cannabis or recruit the services of a designated producer. This designated producer was only allowed to grow for one patient and could not be compensated for this service.

C. Physicians as Gatekeepers to the Program

Prior to the enactment of the MMAR, it became apparent that physicians had indicated strong opposition to the proposed regulations. In fact, on May 7, 2001 the Canadian Medical Association wrote to the Minister of Health and clearly stated that "physicians must not be expected to act as gatekeepers to this therapy,"[12] yet that is precisely the role Health Canada had thrust upon them. In general, physicians around the country were cautioned by their professional associations to not lend support to the authorization process due to a perceived lack of scientific evidence supporting the medical benefits of cannabis. In particular, the Alberta Medical Association cautioned its doctors against completing the forms necessary to prescribe medical cannabis. In his President's Letter, released on July 27th, 2001, Dr. Clayne A. Steed advised Alberta physicians to "think twice" before completing any forms for the use of cannabis.[13] Similar cautions have been issued

by the Quebec and Manitoba Associations, while the Ontario Medical Association has advised their physicians not to complete the forms required for their patients to lawfully obtain medical cannabis.

To further complicate matters, the Canadian Medical Protective Association (CMPA – the insurer for the medical profession) issued an information sheet, dated October 2001, advising doctors not to complete the requisite MMAR declarations unless they had "detailed knowledge" relating to cannabis. The CMPA represents 60,000 of Canada's doctors, approximately 95% of all who practice in Canada. On November 8, 2001, the Association wrote to the Minister of Health expressing concern about "the medico-legal difficulties that may face members that choose to follow Health Canada's *Marihuana Medical Access Regulations*."[14] Accordingly, some physicians have declined to even consider the merits of an application simply because of the admonitions of their medical associations and their insurer. Thus, from the outset, the resistance of the medical profession has posed problems for the effective implementation of the MMAR and for people to obtain legal access to cannabis for their medical needs.

D. The Reform of the MMAR

The *Parker* case established that section 7 of the Charter includes a constitutional right to choose alternative forms of medicine without undue state interference. It also established that Parliament loses the constitutional authority to prohibit possession (and perhaps cultivation) of cannabis in the absence of a constitutionally valid exempting process to allow seriously-ill Canadians to access medical cannabis without fear of criminal prosecution. However, with the enactment of the MMAR, new questions arose which had not been addressed in *Parker*. In particular, there was concern that the MMAR constituted an "illusory exemption" and thus didn't qualify as a constitutionally valid exempting scheme. Such an analysis was based on two separate critiques of the regime: a) it contained unnecessary administrative and procedural restrictions such that it was "practically unavailable" for many seriously ill individuals, and b) it did not provide any mechanism for access to a lawful supply of medical cannabis for seriously ill Canadians who cannot cultivate their own cannabis.

Within one year, the growing dissatisfaction with the MMAR led to another court challenge. In the *Hitzig* case, a number of patients and caregivers sought invalidation of the MMAR (and, as a consequence, the CDSA prohibition on possession of cannabis as per the *Parker* case) on the basis that the regulatory regime imposed many arbitrary obstacles for people seeking authorization to use cannabis as therapy. In a nutshell, the requirement of obtaining the concurrence of one or two specialists, combined with the stated resistance of the medical associations, made it virtually impossible for many, if not most, people to enter the program. Moreover, beyond the obstacles placed upon eligibility for entry into the program, those who did secure authorization were still left without a lawful and safe supply of cannabis, unless they were able to cultivate themselves, or were able to find a designated producer to cultivate without compensation.

Thus, in *Hitzig*, it was argued that the legislative and regulatory provisions of the MMAR interfered with decisions of fundamental personal importance (the "liberty" interest) and the ability to access effective medical treatment (the "security of the person" interest). Moreover, these deprivations were not in accordance with the principles of fundamental justice, since the MMAR's restrictions on access to medical treatment were arbitrary and did not advance any compelling state interest. In fact, in *Parker*, the Ontario Court of Appeal noted that, "an administrative structure made up of unnecessary rules that results in an additional risk to the health of the person is manifestly unfair and does not comport to the principles of fundamental justice."[15] In effect, the regulatory regime operated as an illusory exemption because its restrictions on access to medicinal cannabis excluded a large sector of eligible seriously ill Canadians who were still exposed to the risk of criminal prosecution for therapeutic use of cannabis. Further, it was argued that the regulatory regime was also illusory because, while putatively authorizing the choice of some seriously ill Canadians to use cannabis medicinally, the regime denied them access to a safe and lawful supply of cannabis.

The *Hitzig* case gained great momentum on September 4, 2002, with the release of the *Report of the Senate Special Committee on Illegal Drugs*. In its Report, the Senate Special Committee reached conclusions with respect to Health Canada's medical cannabis program which perfectly expressed the position taken by the Applicants in the *Hitzig* case. The Senate concluded:

> The MMAR are not providing a compassionate framework for access to marijuana for therapeutic purposes and are unduly restricting the availability of marijuana for patients who may receive health benefits from its use.
>
> The refusal of the medical community to act as gatekeepers and the lack of access to legal sources of cannabis appear to make the current regulatory regime an "illusory" legislative exemption and raises serious Charter implications.[16]

In January 2003, the decision in *Hitzig* was released by the Ontario Superior Court. The application court judge did not agree that the restrictions on eligibility amounted to a constitutional violation. He stated that:

> while the application process specified by the MMAR might be cumbersome, and the specialist requirement onerous for many seriously ill applicants, especially in light of the medical associations' stance, I do not find these aspects of the MMAR to be inconsistent with the principles of fundamental justice.[17]

However, he did find that restrictions upon lawful access did engage the constitution and concluded that:

> it is inconsistent with the principles of fundamental justice to deny a legal source of marijuana to people who have been granted ATPs [Authorizations to Possess] ... Laws which put seriously-ill, vulnerable people in a position where they have to deal with the criminal underworld to obtain medicine they have been authorized to take, violate the constitutional right to security of the person. The MMAR expose the applicants, who all have serious medical conditions, to further risk to their personal safety. Not only do they face the risks associated with consorting with criminals, and the possibility of prosecution should they breach the terms of their ATP or production licence, but they have to deal with the uncertain quality of the product they are getting on the street.[18]

In light of this violation of section 7 of the Charter, the judge invalidated the entire MMAR, but suspended the invalidation for six months (until July 9, 2003) to provide the government with the opportunity to address the deficiency with respect to access to a lawful supply. The Government appealed this ruling. The Government then attempted to obtain an 11th hour reprieve from this decision by asking the Court of Appeal to stay execution of the judgment, but the Court of Appeal refused.[19] Accordingly, on July 8, 2003, Health Canada announced an interim policy under which authorized Canadians could purchase medicine from the only licensed dealer, Prairie Plant Systems. In addition, the regulatory change allowed patients who wished to produce their own medicine to purchase seeds from Prairie Plant Systems. On this date a regulation was also passed exempting cannabis produced by the licensed dealer and by designated producers from the operation of the *Food and Drugs Act* so that this product could be distributed and sold without first obtaining drug approval.[20]

The judge's conclusion that the failure to provide a lawful source violated constitutional rights was foreshadowed by the Alberta Court of Appeal a few months earlier. In a case involving an epileptic, Grant Kreiger, who produced cannabis for his medical purposes, and was charged with unlawful production, the Court invalidated the production offence in the CDSA, on the basis that the law prevented seriously ill people from producing their own medicine despite the absence of a lawful government supply. The trial judge stated:

> Obtaining a s. 56 exemption from the Minister of Health triggers the absurdity that an individual who has been granted an exemption has the legal right to produce, possess and use cannabis marijuana. However, in order to obtain the product, that individual is required to participate in an illegal act, since whoever sells the exempted person either the raw cannabis marihuana or the seeds to grow their own, does so in breach of s. 5(2) of the CDSA .... I am not satisfied that the absurdity that I mentioned above has been properly ad-

> dressed. In my view, when a minister has the discretion to allow someone an exemption to produce and use a substance for proper medical purposes, that substance must be something that is available to the individual by legal means at the time exemption is granted. As a s. 56 exemption has no practical purpose without a legal source for cannabis marijuana, s. 56 cannot serve to delineate the boundaries of the Applicant's s. 7 rights or to justify violation of those boundaries. [Note: S.56 is a reference to the regime governed by the Interim Guidance Document, since at the time of this case the MMAR had not yet been enacted]. [21]

Upon reasoning similar to the *Parker* case, in which the Court found the possession offence constitutionally overbroad by failing to exempt medical users from its scope, the Alberta Court of Appeal declared that the production offence was similarly overbroad, since many medical users were compelled to illegally produce because the government had not established a lawful supply for the medical user. The Court stated:

> We agree with the trial judge that s. 56 [CDSA] creates an absurdity because there was no legal source of cannabis. That absurdity is not removed by the fact that the Respondent had a personal supply at the time the charge was laid. There was no evidence as to how long the supply would last nor as to the duration of the potential s. 56 exemption.[22]

On October 7, 2003, the Ontario Court of Appeal released its decision in *Hitzig*.[23] The Court concluded that the requirement that Category 3 patients obtain the declarations of two specialists was a violation of section 7 of the Charter, and it also agreed with the trial judge that the failure to provide a lawful source violated section 7. However, the Court did not agree that the proper remedy was invalidation of the entire MMAR, but instead chose to invalidate specific, offending provisions. Accordingly, the Court invalidated the provisions requiring second specialist approval for Category 3 patients, as well as those provisions which prevented designated growers from receiving compensation, from growing for more than one authorized person, and from growing in combination with more than two other designated growers. By invalidating these impugned provisions, the Court concluded that the remaining provisions of the MMAR could continue to operate in a constitutionally sound manner. As the *Hitzig* case now represents the last word from an appellate court on the scope of the right to choose cannabis as therapy, this report provides critical excerpts from the decision in *Hitzig et.al. v. Canada* (2003) in Appendix C.

E. The Current Status of the MMAR

Health Canada has responded to the constitutional demands of *Hitzig* in two phases. In the first phase of regulatory amendment[24] in December 2003, the department accomplished three objectives:

1. it removed the second specialist requirement for Category 3 patients;
2. the interim policy for distribution of the government's marijuana was entrenched and reformed;
3. and it reinstated the very restrictions on designated producers which the Ontario Court of Appeal had invalidated as unconstitutional obstacles to access and supply.

In the second phase of regulatory amendment[25] in June 2005, Health Canada further amended the MMAR by streamlining the application process and paving the way for distribution of medical cannabis through the pharmacies. In this second phase of amendments, Health Canada articulated in its Regulatory Impact Statement its vision for the future direction of the program:

> To enhance protection of the health and safety of Canadians, Health Canada's strategic direction for the medical marihuana program envisions the program taking on, to the extent possible, the features of the traditional health care model employed for other medicinal agents available in Canada. Such a model would include:
>
> - continued support for research and enrolment of patients in clinical or open-label trials as the first consideration of patients and physicians;
> - centralized source(s) of marihuana that comply with product standards applied under the Food and Drugs Act and its Regulations to ensure the safety and quality of drug products marketed in

Canada, accompanied in the longer-term, by a phase-out of personal cultivation;

- distribution of marihuana for medical purposes to authorized persons through pharmacies;
- updated information stemming from research into the risks and benefits of marihuana when used for medical purposes, and education of patients and physicians; and
- improved surveillance of the use to monitor safety and efficacy of marihuana when used for medical purposes.[26]

The program, as amended in the past two years, appears to have become more responsive to the needs of patients; however, puzzling features within the amended program still remain. As for the eligibility requirements (in effect June 2005), the amendments have addressed the letter and spirit of the *Hitzig* case in a meaningful fashion. First, the previous categories 1 and 2 have been merged into one category (see Table 1), such that the enumerated illnesses of Category 1 and 2 have been listed in the new Category 1 and an authorization for these stated illnesses can be obtained upon the declaration of one family physician.

Table 1. Category 1 Symptoms

Symptom	Associated Medical Condition
compassionate end-of-life care	
severe nausea	cancer, HIV/AIDS
cachexia, anorexia, weight loss	cancer, HIV/AIDS
persistent muscle spasms	multiple sclerosis, spinal cord injury or disease
Seizures	epilepsy
severe pain	cancer, HIV/AIDS, MS, spinal cord injury or disease, arthritis

The new Category 2 relates to debilitating conditions and related symptoms that are not specifically enumerated in Category 1, for which an authorization can be obtained upon the declaration of a family physician. There is no longer a need to obtain a declaration from a specialist for Category 2; however, the case must be assessed by a specialist in consultation with the signing physician. In addition, the process has been streamlined by reducing the scope and definitive nature of the physician's declaration. As noted in the Regulatory Impact Statement:

> Physicians are no longer required, in their declarations, to make definitive statements regarding benefits outweighing risks, or to make specific recommendations regarding the daily dosage of marihuana to be used by the applicant. In addition, the information that the physician is required to provide in the medical declaration has been reduced to only those elements essential to confirm that the applicant suffers from a serious medical condition and that conventional treatments are inappropriate or ineffective. For example, physicians are no longer required to list conventional therapies that have been tried or considered, or to provide their reasons for finding those therapies to be ineffective or inappropriate.[27]

Although these eligibility amendments should be viewed as progressive, Health Canada's response to the issue of access and supply is more problematic. Contrary to the direction of the Ontario Court of Appeal in *Hitzig*, Health Canada has reinstated most of the restrictions initially placed upon designated producers. The producers can now be compensated for their efforts, but they cannot grow for more than one authorized person and cannot grow in common with more than two other designated producers. In the Regulatory Impact Statement, accompanying the 2003 Phase I amendments, Health Canada provides four reasons for reinstating the restrictions on designated producers:

> These limits on the production of marihuana are necessary to:
>
> - maintain control over distribution of an unapproved drug product, which has not yet been demonstrated to comply with the requirements of the FDA/FDR;
> - minimize the risk of diversion of marihuana for non-medical use;
> - be consistent with the obligations imposed on Canada as a signatory to the United Nations' *Single Convention on Narcotic Drugs*, 1961 as amended in 1972 (the 1961 Convention), in respect of

cultivation and distribution of cannabis; and

- maintain an approach that is consistent with movement toward a supply model whereby marihuana for medical purposes would be: subject to product standards; produced under regulated conditions; and distributed through pharmacies, on the advice of physicians, to patients with serious illnesses, when conventional therapies are unsuccessful. Such a model would also include a program of education and market surveillance.[28]

Much of the impetus behind restricting the designated producer option lies with Health Canada's interpretation of its obligations under the United Nations *Single Convention on Narcotic Drugs*, 1961. The department's stated understanding of the treaty obligations is as follows:

> Removing the limits on the number of holders of an ATP [Authorization to Possess] for whom a DPL [Designated Person Production License] holder can produce, and permitting the pooling of multiple DPLs, have the effect of expanding the production and distribution of marihuana to an extent which, when combined with the declaration of invalidity of the restriction on DPL holders from obtaining consideration, facilitates the development of commercial activity that would move Canada away from compliance with its international obligations under the United Nations 1961 Convention. Articles 23 and 28 of the Convention require signatory countries who permit the cultivation of marihuana, to create a national government agency that has exclusive right on import, export, wholesale trade and maintenance of stocks of marihuana. Provisions within Article 23, as they apply to cannabis [marihuana], include obligations such as the requirement for all cultivators of marihuana to deliver their total crops of marihuana to the agency for distribution. The Government of Canada has been compelled by the courts to develop a system to provide for a legal supply of marihuana for medical purposes. In doing so, the Government has made every effort to implement a system that will meet its international obligations to the fullest extent possible. By permitting only limited production of marihuana by persons authorized to possess for medical purposes, or limited production of marihuana by a designated person on their behalf, that is carried out within the terms and conditions of their licences to produce, the supply of marihuana for medical purposes in Canada is not inconsistent with the intention of the Convention to prevent illicit trade in marihuana. To expand the number of ATP holders that a DPL holder can produce for beyond the current 1:1 ratio, would obligate the Government to implement a system to collect all marihuana produced in order to comply with the 1961 Convention.[29]

Recognizing that reinstating restrictions on designated producers would serve to impede access to a lawful supply, Health Canada needed to provide an acceptable alternative for access and supply so it entrenched the interim policy for distribution of medical cannabis produced by their licensed dealer as its preferred option for distribution. The licensed dealer has been given authority to distribute, on a cost-recovery basis, cannabis seeds for those who wish to produce their own, and dried cannabis for those who cannot produce their own. Authorized persons who purchase seeds for self-production are also entitled to purchase an interim, four month, supply of dried cannabis pending their first harvest. Dried cannabis is shipped by courier directly to the authorized person or to their physician. Ultimately, Health Canada envisions the product being shipped to local pharmacies, as well as the phasing out of licenses to produce. The most recent statistics on the operation of the MMAR, as of April 7th, 2006, are as follows:

- **Possession of Dried Marihuana**

  1399 persons are currently allowed to possess marihuana for medical purposes

  - ➥ 1391 hold an *Authorization to Possess* dried marihuana under the *Marihuana Medical Access Regulations* (MMAR)
  - ➥ 8 hold an Exemption for possession under Section 56 of the *Controlled Drugs and Substances Act* (CDSA)

- **Cultivation/Production of Marihuana**

  1005 persons are currently allowed to cultivate/produce marihuana for medical purposes

  - ➥ 890 hold a *Personal-Use Production Licence* under the *Marihuana Medical Access Regula-*

tions (MMAR)

- ➥ 109 hold a *Designated-Person Production Licence* under the *Marihuana Medical Access Regulations* (MMAR)
- ➥ 5 hold an Exemption for cultivation/production under Section 56 of the *Controlled Drugs and Substances Act* (CDSA)
- ➥ 1 holds a designated person Exemption for cultivation/production under Section 56 of the *Controlled Drugs and Substances Act* (CDSA)

- **Distribution of Dried Marihuana and Marihuana Seeds**

  266 persons are currently accessing dried marihuana for medical purposes under the *Policy on Supply of Marihuana Seeds and Dried Marihuana for Medical Purposes*

  - ➥ 190 persons have received marihuana seeds for medical purposes under the *Policy on Supply of Marihuana Seeds and Dried Marihuana for Medical Purposes*
  - ➥ 72 persons are receiving dried marihuana (for up to four (4) months) and have received marihuana seeds for medical purposes under the *Policy on Supply of Marihuana Seeds and Dried Marihuana for Medical Purposes*[30]

1 *Rodriguez v. B.C.* (A.G.) (1993), 85 C.C.C. (3d) 15, 63 (S.C.C.).

2 *R. v. Morgentaler* (1988), 37 C.C.C. (3d) 449, 485 (S.C.C.).

3 *B.(R). v. Children's Aid* [1995] 1 S.C.R. 315, 340.

4 *R. v. Clay* (1997), 9 C.R. (5th) 349, 363 (Ont. Gen. Div.).

5 *R. v. Parker* (1997), 12 C.R. (5th) 251 (Ont. Prov. Ct.).

6 *Wakeford v. Canada* (1998), 166 D.L.R. (4th) 131, 147 (Ont. Gen. Div.)

7 *Wakeford v. Canada* (1998), 166 D.L.R. (4th) 131, 151 (Ont. Gen. Div.).

8 *Wakeford v. Canada* (1999), 173 D.L.R. (4th) 726, 731-732 (Ont. Sup. Ct.).

9 *Wakeford v. Canada* (2000), 187 D.L.R. (4th) 175, 185 (Ont. Sup. Ct.). On January 17, 2002, the Ontario Court of Appeal dismissed Mr. Wakeford's appeal, essentially for the reasons given by the trial judge - *Wakeford v. Canada* (2002), 162 C.C.C. (3d) 51, (Ont. C.A.).

10 *Marihuana Medical Access Regulations*, Regulatory Impact Analysis Statement. Canada Gazette. 2001 Jul 4;135(14). SOR 2001-227

11 *Marihuana Medical Access Regulations*, Regulatory Impact Analysis Statement. Canada Gazette, Part II. 2001 Jul 4;135(14). SOR 2001-227.

12 Letter dated May 7, 2001 from Dr. P. Barrett to Minister of Health Alan Rock. This letter was part of the court record in *R. v. Hitzig* – Letter on file with legal consultant.

13 Letter dated July 27th, 2001 from Dr. Clayne A. Steed - This letter was part of the court record in *R. v. Hitzig* – Letter on file with legal consultant.

14 Information Sheet of Canadian Medical Protective Association (CMPA) dated October 2001 - This letter was part of the court record in *R. v. Hitzig* – Letter on file with legal consultant.

15 *R. v. Parker* (2000), 49 O.R. (3d) 481, 521 (Ont. C.A.).

16 Nolin PC, Kenny C. Cannabis: Our Position for a Canadian Public Policy, Report of the Senate Special Committee on Illegal Drugs, September 2002. Available from: <www.parl.gc.ca/illegal-drugs.asp>.

17 *Hitzig et. al. v. Canada* (2003), 171 C.C.C. (3d) 18, (Ont. S.C.).

18 *Ibid.* at 58.

19 *R. v. Parker et. al.* [2003] O.J. No. 5966.

20 SOR/2003-261.

21 *R. v. Krieger* (2000), 225 D.L.R. (4th) 164, 178-179 (Alta. Q.B.).

22 *R. v. Krieger* (2002) AJ No. 44 at para. 5 (Alta. C.A.).

23 *Hitzig et. al. v. Canada* (2003), 177 C.C.C. (3d) 449, (Ont. C.A.).

24 SOR/2003-387.

25 SOR/2005-177.

26 *Regulations Amending the Marihuana Medical Access Regulations* P.C. 2005-1124 June 7, 2005. Regulatory Impact Analysis Statement, 2. Canada Gazette, Part II. 2003 Dec 17;137(26). SOR/2003 – 387.

27 *Ibid.* at 3.

28 *Ibid.* at 5.

29 *Ibid*, at 5.

30 Valerie Lasher, Manager, Marihuana Medical Access Division, Health Canada. Personal communication, April 12, 2006. More detailed information is available from: <www.healthcanada.gc.ca/mma>.

Policy Considerations and Recommendations

We provide the following considerations and recommendations for all key stakeholders to ponder on the issue of cannabis as therapy. As cannabis is a controlled substance, legal access to cannabis for medical use has required that regulations be developed to set up a framework to enable compassionate access. The *Marihuana Medical Access Regulations* were established as a result of a court decision. We would much rather see legislative, regulatory and policy developments occur as a result of dialogue between the government and the key stakeholders, rather than through Canadian courts. We will continue to work with the government to provide our input into the federal medical cannabis program.

Despite the fact that Canada has a process through which people can obtain legal authorization to possess and cultivate cannabis for medical purposes, access to the federal program and to a legal source of cannabis remains hindered by barriers. Access to information and services related to this treatment is minimal to non-existent, making it difficult for people to make informed decisions and to optimize their care. Most people who use cannabis for medicinal purposes have not yet applied to the program. As a result, thousands of Canadians are not currently protected from the law for using their therapy of choice, nor do they have access to a legal, safe, reliable and affordable source of cannabis, nor to adequate information and related services. Our consultations revealed a series of barriers that will be explored in this section of the report.

A. Evaluation and Accountability of The Federal Medical Cannabis Program

Health Canada has invested over $24 million[1] into the MMAR program, including a contract valued at $5,751,250 with a licensed dealer to produce cannabis for medical purposes.[2] This contract has since expired, and a capital expenditure by the government in this area is expected in the near future. There are currently only 1399 persons authorized to possess cannabis for medical purposes under the MMAR, a fraction of the estimated thousands of medicinal users of cannabis in Canada. Only about 14% of them have ordered their cannabis from the government.

We know that people living with HIV/AIDS represent the largest group of seriously ill persons who use cannabis as part of their therapy. For example, people living with HIV/AIDS represented the largest group under the former Category 1 (terminal illness) of the federal program (38%), and were the second largest group under the former Category 2 (various illnesses and related symptoms), at 24%. In consultation with a few compassion clubs, which serve more than 6,450 people, it was revealed that for some clubs, people living with HIV/AIDS represent as much as 58% of their clientèle. We also know that about 14% to 37% of people living with HIV/AIDS use cannabis as part of their therapy to manage appetite loss, wasting, nausea and vomiting, pain, anxiety, depression and stress, among others.[3,4,5,6] However, only 36% of the people we talked to reported that they had applied to the federal program, despite the fact that about nearly two thirds of them use cannabis as part of their therapy. Only 26% of respondents to our questionnaire had obtained their Authorization to Possess.

Based on the Conservative government's vision, cannabis law reform will not be an option. We fear that people who use cannabis for medicinal purposes will increasingly fall to the attention of law enforcement. The government cannot repeal the MMAR and eliminate the federal medical cannabis program, as this would result in prohibition on cannabis being unconstitutional.[7] The MMAR will continue to be the only legal way seriously ill Canadians can obtain legal access to cannabis for their medical purposes. We anticipate that applications to the MMAR program will significantly increase as people fear criminal repercussions. As such, the government of Canada will need to ensure that adequate resources are allocated to the federal medical cannabis program to meet the

"The fact that I would have an exemption from the government, that would be like a security. It would make me feel more secure in the sense that if the police stop me, I could have a criminal record. A criminal record, well that doesn't really interest me."

"I had 7 cells last year. With my doctor exempting me, allowing me not to have as much anxiety to smoke pot, with having a few plants in my house and not worrying about police breaking in my door. I have myself at 140 [pounds] as of last week. My viral load went from a million to undetectable."

"I want to get rid of the guilt, of the stigma and the fear. . . . I think about well I'm doing it illegally and it just compounds everything."

—Focus group participants

anticipated increase in applications and ongoing renewals, and to better meet the needs of seriously ill Canadians.

Investing in this program will contribute to the health and well-being of Canadians. The people we consulted who have obtained an Authorization to Possess report feelings of protection, safety and stability. They also report that an authorization from the government brings recognition, legitimacy and credibility to their medicinal use of cannabis, thereby reducing the stigma they are subjected to for their use of cannabis.

In addition, the issue of legal sources of cannabis for authorized person will need to be better addressed. Authorized persons currently have three legal options under the MMAR: they can order the government's cannabis, grow their own, or designate someone to grow for them. The government wants to phase out licenses to produce. The number of authorized persons currently ordering cannabis from the government remains low. Out of the 1399 people that are currently authorized to possess cannabis for medical purposes, only 266 are ordering their cannabis from the government, which represents less than 20% of authorized persons. This number includes 72 people who are temporarily ordering dried cannabis from the government while they wait for their first crop to be ready for harvest. In essence, about 14% of authorized persons have ordered the government's cannabis as their main source of supply.

We question the spending on a multi-million dollar contract to supply relatively few authorized persons, and believe that authorized persons would be better served if restrictions on licenses to produce were lifted. Many authorized persons continue to access other sources of cannabis. Cannabis is widely available in the black market in Canada. The Fraser Institute, an independent Canadian economic and social research and educational organization, estimates that Canadians spend anywhere from $1.8 billion to $4.4 billion for cannabis in 2000 (compared to $2.3 billion for tobacco).[8] They report:

> What the analysis reveals is how widespread marijuana use is in Canada… As a consequence, the broader social question becomes less about whether we approve or disapprove of local production, but rather who shall enjoy the spoils. As it stands now, growers and distributors pay some of the costs and reap all of the benefits of the multi-billion dollar marijuana industry, while the non-marijuana-smoking taxpayer sees only the costs. --The Fraser Institute, 2004

The government needs to explore options for the distribution of medicinal cannabis to ensure taxpayer dollars are being spent efficiently. Polls reveal that as many as 90%-92% of Canadians support the use of cannabis for medicinal purposes.[9] The Conservative Party of Canada has made restoring the government's accountability a top policy priority. In an effort to gain Canadians' trust in knowing that tax dollars are well spent, the new government stands for:

> "Giving more power and teeth to independent watchdogs such as the Auditor General and Ethics Commissioner, protecting whistleblowers from reprisal, and strengthening

> access to information laws to give citizens the right to know."[10]

We call on the Auditor General to conduct a performance audit of all aspects of the current federal medical cannabis program, including the Health Canada's Marihuana Medical Access Division and the contract with the current licensed dealer which produces cannabis for the government. This investigation was already requested by the Honourable Libby Davies, MP for Vancouver East, and by Senator Pierre Claude Nolin, in a letter to the Auditor General and to the then Minister of Health, Ujjal Dosanjh.[11]

Recommendation

We recommend that the Auditor General conduct a performance audit of all aspects of the current federal medical cannabis program, including the Health Canada's Marihuana Medical Access Division and the contract with the current licensed dealer which produces cannabis for the government, to ensure that resources are adequately allocated to address the needs of seriously ill Canadians.

B. Involvement of Key Stakeholders in the Policy Dialogue

The Canadian AIDS Society was a member of Health Canada's Stakeholder Advisory Committee on Medical Marihuana, which was established in October 2002 to provide its Drug Strategy and Controlled Substances Programme with timely advice on medical, scientific, regulatory, policy and operational issues related to cannabis for medical purposes. This committee provided a forum for policy dialogue between the voluntary sector and the government of Canada. Unfortunately, Health Canada disbanded the committee. The government must consider re-establishing such a committee. We would much rather see ongoing policy dialogue between the government and other key stakeholders rather than fragmented changes to the program resulting from litigation through the courts.

Action by the Canadian AIDS Society

We will continue to work with Health Canada and to provide input into the federal medical cannabis program so that it may better meet the needs of seriously ill Canadians, based on our ongoing consultations with people living with HIV/AIDS. We will also continue to raise awareness about the existence of the program so that people living with HIV/AIDS who use cannabis for medicinal purposes can be protected from criminal prosecution in an environment of increased enforcement of cannabis laws.

Recommendation

We recommend that the government re-establish a Stakeholder Advisory Committee on Medical Cannabis to provide a forum for all key stakeholders[12] to exchange information and provide ongoing input into the federal medical cannabis program and the policies, regulations and legislation that govern it.

C. Lack of Awareness and Misinformation about the Federal Medical Cannabis Program

Our consultations revealed that some people living with HIV/AIDS were not aware of or were misinformed about the federal medical cannabis program Throughout our consultations, almost 9% of the participants reported that they were not aware that the program existed, or that they didn't know how to go about applying for legal access. There were also indications that there was misinformation about the program, and about the legal issues regarding the medicinal use of cannabis. For example, some people were under the impression that compassion clubs are part of the federal program. This is not the case as access to cannabis through these clubs remains illegal. Another misconception among people living with HIV/AIDS is that some believe they cannot apply to the federal program if they have a criminal record. This is not the case, as a criminal record does not preclude a person's medicinal need. This lack of awareness and misinformation about the program results in people not applying to the program, therefore not benefiting from accessing cannabis for medicinal purposes without fear of legal prosecution.

"No, I have not applied to the government program. There is a lack of information, of course, and for me I did not see that it would make a big difference. I have never been stopped by the police, I have always had easy access. The forms are too complicated, too long. I did not want to identify myself to the government either. It was new, I feared that I would be considered a drug addict."

"You get the medical marijuana exemption. What's that going to do when you want to go get your passport and get out of the country? They can't refuse you your passport because you are a Canadian, but who do they share that information with? When you are crossing a border, what happens then?"

"I authorize myself to possess and my social network facilitates this. The government is wasting tax dollars. The Feds should legalize and move on to more important issues like AIDS in Africa and third world debt."

—Focus group participants

Some people are choosing not to apply to the federal program because of their fear or mistrust of the government, and do not wish to be identified to the government as medicinal cannabis users. Others have concerns about the impact of providing this information to the government if they travel abroad or if they wish to obtain their Canadian citizenship. They fear that this information may get into the wrong hands or will be used to target people who use cannabis for medicinal purposes.

Some people living with HIV/AIDS do not see a need to obtain authorization to possess cannabis for medicinal purposes as they have been accessing it through their own means for years without encountering difficulties with the authorities. They therefore see no real benefit or advantage in doing so, and do not want to bother with the application process. Others feel that the use of cannabis for medicinal purposes is their right and ask that the government reconsider the prohibition on cannabis. Although the perceived risks of legal prosecution may not be enough to convince some people to seek authorization to possess medical cannabis legally, the fact remains that it is currently illegal to possess cannabis for medicinal reasons without an Authorization to Possess in Canada. We have concerns about the current political climate in Canada, and the new conservative government's reluctance to consider alternatives for the legislation of cannabis.[13] This may have a negative and serious impact on people who currently use cannabis for medicinal purposes without the legal authorization to do so. The government has a responsibility to disseminate information about the federal medical cannabis program widely to ensure that the constitutional right of seriously ill Canadians to access the therapy of their choice without fear of criminal prosecution is respected.

Action by the Canadian AIDS Society

The Canadian AIDS Society remains committed to raising awareness about the federal medical cannabis program and the *Marihuana Medical Access Regulations* to people living with HIV/AIDS across Canada, and to building the capacity of its member organizations to respond to information request and assist people living with HIV/AIDS with the application process. We will achieve this by offering workshops and materials, by posting this information on our web site, and by presenting this information at venues where people living with HIV/AIDS gather (conferences, symposia, etc.), within the constraints of available resources. Disseminating this information will contribute to reducing the misinformation and fears among the HIV/AIDS community, and will result in more people living with HIV/AIDS being protected from legal repercussions.

Recommendation

We recommend that Health Canada and organizations such as the Multiple Sclerosis Society, the Arthritis Society, the Canadian Cancer Society and others dis-

seminate accurate and up-to-date information about the federal medical cannabis program and the Marihuana Medical Access Regulations to the people they serve, and that they build the capacity of their member organizations, if this applies, to respond to information requests and to assist them with the application process. We are open to collaborating on these efforts, within the confines of available resources.

D. Federal Medical Cannabis Program's Application Renewal Process

The most frequently reported reason for not applying to the program was the onerous application process. Almost 16% of respondents to our questionnaire feel it is complicated, intimidating and overwhelming, and that there is too much paperwork involved. They feel that the time it takes to process application is long and often with gaps or delays in follow up. Yearly renewals are seen as unnecessary and cumbersome for people who are living with a life-long disease. The application process can be daunting for many people, especially if their health is compromised. Obtaining the forms and deciphering which forms apply to an individual situation, completing them, obtaining photos and seeking the necessary signatures from a physician are time-consuming activities that require planning, coordinating, scheduling and sometimes support and assistance. Some costs are involved for the photos, the traveling to appointments, and sometimes for the physician's completion of the medical declaration, and for postage, with no compensation to the applicant. Yearly renewals require planning and forethought to allow for enough time for processing before the expiry of an authorization or license. Delays and periods between applications can be very stressful for people when their authorization and license have expired, and has sometimes resulted in police intervention despite people's efforts to comply with the law and the process.

We point out that our consultations took place in May and June of 2005, just before the MMAR were amended on June 29th, 2005. Health Canada has streamlined the new forms so that they are somewhat more user-friendly. Once everyone in the program has applied or renewed their authorization under the new MMAR, the renewal process will be simpler as Health Canada reports that the new renewal form will be one page long and will simply require the applicant's and the physician's signatures if the applicant's situation has not changed. Despite the new forms, the fact remains that most people are simply overwhelmed by such a bureaucratic process and this often keeps them from applying. Our consultations also reveal many mentions of delayed paperwork, despite the fact that the program currently only serves 1399 people. The expected increase in applications will exacerbate the situation.

Under the MMAR, Authorizations to Possess and Licenses to Produce must be renewed yearly, and there are sometimes gaps between expired cards and receipt of renewed ones. The MMAR have provided a framework within which seriously ill Canadians can have legal access to cannabis for medical purposes. The ID cards provided by the federal medical cannabis program enable police to be able to verify whether a person is authorized to possess and licensed to produce cannabis for medical purposes. They provide information as to how much cannabis a person is authorized to possess and how many plants they are allowed to produce. Police also have access to Health Canada to verify the validity of these cards when they are investigating someone.

When there are delays in processing applications or in renewing a person's authorization to possess and

> *"Meanwhile my exemption is not any good right now I don't think, and I've got 20 plants growing still. . . Now I'm worrying about everything, I'm all stressed out about it but I'm sure they probably wouldn't do anything as long as I keep doing what I've been doing. I've got a letter, I've got everything here, my exemptions and everything. And when you try to call Health Canada, it takes like two weeks to get a response, even. And it's like "Well, we have to get in touch with the doctor" and whatever. They're just very slow there."*
>
> —*Focus group participant*

license to produce, a person lives under stressful conditions of not being protected by the law. The potential for police intervention exists during that period of time. When it comes to producing their own cannabis, some people are forced to decide to continue to grow while they wait for their renewed ID card, or to not take any chances and destroy the garden they have invested in and worked hard to establish. Should police intervention occur, the police officers are placed in an awkward position of either enforcing the letter of the law or going by the spirit of the law. New applications must be processed expediently to maximize protection from the law and minimize the negative health impact on seriously ill Canadians. Authorized persons that adhere to the process and ensure that their renewal application is submitted on time must be protected under the law and must not be exposed to legal repercussions due to bureaucratic delays. The process must be improved to ensure that it is seamless.

Action by the Canadian AIDS Society

The Canadian AIDS Society will continue to disseminate information about the MMAR, the requirements of the federal medical cannabis program and its processes as widely as possible to its membership and to people living with HIV/AIDS. We will provide accurate and up-to-date information to ensure that our stakeholders are aware of the procedures so that they can respect them and avoid problematic situations with police.

Recommendation

We recommend that Health Canada evaluate its resource needs to ensure that applications and renewals are processed in a timely manner to avoid gaps in a person's legal authority to possess and produce cannabis.

We recommend that Health Canada address delays in the renewal of Authorizations to Possess and Licenses to Produce by providing an acknowledgement of receipt of the renewal application, which could temporarily extend the authorization period until such a time as a new authorization and license are issued.

E. Reluctance of Physicians to Participate in the Program

During our consultations, the majority of people (68.9%) stated that their physician was supportive of their use of cannabis for medical purposes, while 16% stated that their physician was not. Some physicians are not comfortable with smoking as a mode of delivery for a medicine, or have other concerns about the use of cannabis, such as the effects of cannabis on depression or on the immune system. Some participants mentioned that their doctor was concerned about repercussions from the medical associations. The lack of information available to doctors, especially from clinical trials, clearly emerges as an issue based on the participants' testimonials and on our own discussions with physicians.

> *"And I told my family doctor about [my marijuana use] and her response is "I'm open to it, however I think you look fine right now and when you're ready to come back to me, let's say you drop a whole bunch of weight like you did when you had PCP pneumonia, then we could talk about it then. But until then, I don't think it's an issue for you or something you should worry about right now". So I'm getting the impression that she's saying that I have to wait until I'm practically dying to get it. And I don't think that's fair."*
>
> —*Focus group participant*

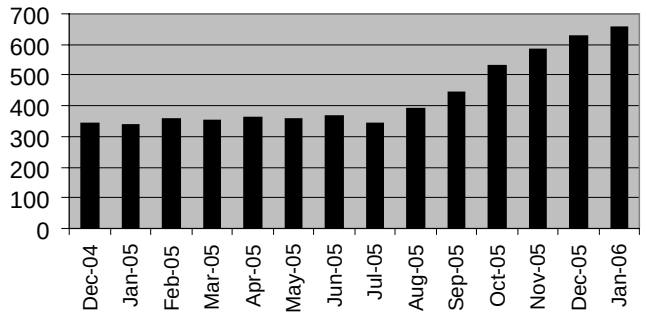
Almost 9% of respondents mentioned that their doctor refused to sign their application form. When a physician refuses to sign an application form for a patient who wishes to have legal access to cannabis for medical purposes, they are in a position of authority over a person's decision of utmost personal importance, which is in conflict with section 7 of the Canadian Charter of Rights and Freedoms (see Section 4A of this report). Though we support the need for people living with HIV/AIDS to discuss any therapy with their physician, we reiterate that a person has a constitutional right to the treatment of their choice

without fear of prosecution, and to make decisions of fundamental personal importance. People report that refusal by one physician leads to doctor shopping, and that people find supportive physicians through word of mouth, if they are in a position where they have several physicians to choose from where they live. We have concerns about doctor shopping. Ideally, we would like to see some continuity of care and see to it that physicians have the maximum amount of information about their patient to ensure they are providing the best care. We also realize that physicians are the gatekeepers to the federal medical cannabis program and that this is the only legal recourse for people living with HIV/AIDS who wish to use cannabis to manage their symptoms.

It is worth noting that since the amendments to the MMAR in June 2005, and the changes that now allow family physicians to sign the application forms instead of a specialist, the number of physicians supporting their patients' applications has gradually been increasing (see Figure 1). This may also be due to the shift of responsibility from the physician to the patient in terms of the requisite declarations on the application forms (see section 4E). Whatever the reason, the rise in support coincides with the amendments that took place in June 2005, indicating better access to the program for seriously ill Canadians. This is encouraging, as physicians are the gatekeepers to access to the program. Their participation is essential.

However, the reluctance of physicians to sign their patients' application forms to the federal program remains one of the most significant barriers to access to the program. One designated grower, who has also been assisting people with their applications to the MMAR, reports that he has received over 2500 emails from people requesting assistance, about 40% of which are requests for help to find a physician that will support their application.[14] This section therefore presents the various factors that contribute to the reluctance of physicians to support such applications: cannabis is not approved as a drug, they have a lack of information regarding the safety and efficacy of cannabis, they have received warnings from their medical associations, and they have their own attitudes and knowledge regarding the use of cannabis for medical purposes.

Figure 1. Number of Physicians Who Support Authorizations to Possess
(source of data: Health Canada's Web site at hc-sc.gc.ca)



In an ideal world, the decision to try cannabis for therapeutic purposes would be made solely by the seriously ill person and a health care practitioner; however, in light of the fact that cannabis is still an unapproved, illegal substance, there will continue to be restrictions on eligibility which do not exist for most other treatment options.

i. Cannabis is Not an Approved Drug

Most of the restrictions upon eligibility and access to the medical cannabis program arise from the fact that cannabis is not an approved substance. Despite the long-standing and wide-ranging therapeutic use of cannabis in past centuries, both the criminal law and the law of intellectual property have served as disincentives for the initiation of clinical testing needed for drug development and approval.

On the application forms to the federal medical cannabis program, the medical declaration is consistent with the general program for access to all unapproved drugs. The Special Access Program (SAP) is designed to allow physicians to secure unapproved drugs for seriously ill patients and this program has been used extensively for physicians to obtain experimental drugs for people living with HIV/AIDS. The application process for SAP requires the physician to outline why the unapproved drug is the "best choice" and whether other therapies have been "considered, ruled out and/or failed to achieve an adequate choice". Accordingly, it cannot be said that the government has set out greater restrictions for access to cannabis than it has set out for other unapproved drugs.

Dr. Isra Levy, Director of the Office of Public Health at the Canadian Medical Association, mentioned that physicians are in a particular quandary with regard to cannabis. They rely on peer-reviewed medical and scientific journals to determine the body of evidence when it comes to a product's safety and efficacy. The process by which drugs are approved by the regulators, and the notices of compliance that accompany approved drugs, provide physicians with information they can use to determine a product's safety, efficacy and good manufacturing practices.

The drug approval process is governed by the *Food and Drug Regulations* (FDR). The typical process by which new drugs enter the therapeutic marketplace involves a "drug sponsor" who has identified a potentially therapeutic molecular compound from which the sponsor ultimately hopes to profit. The sponsor then undertakes three phases of clinical trials before submitting its application to Health Canada for drug approval. Health Canada does not take a proactive role in this process and simply reviews the conclusions and findings of drug sponsors; that is, Health Canada does not initiate nor does it become involved in drug research. It has been said that bringing a new drug to market can take up to fifteen years and costs drug sponsors an average of $1.3 billion per drug.[15]

> *Here is a practicing clinician faced with this . . . natural health product about which health claims have been made but about which there is a reasonable doubt that the use will cause harm, and the regulatory agency hasn't done its bit. That's the bottom line of it."*
>
> *—Isra Levy, Director of the Office of Public Health at the Canadian Medical Association*

There may be a great deal of research and development taking place with synthetic cannabinoid derivatives, but little clinical research is taking place in Canada with herbal cannabis. Despite the MMAR program, there are no drug sponsors who are currently poised to apply for such approval for herbal cannabis. Until this arduous process is undertaken, the chance for physicians to fully buy into the program and eventually for MMAR participants to receive compensation for their medicine remains severely hampered. Drug approval would facilitate physicians' support of its use, access to cannabis for medical purposes, and reimbursement of costs for medical users. It is unlikely that, in the near future, there will emerge many drug sponsors willing to undertake the clinical process with herbal cannabis, especially with cannabis owned by the government. Nonetheless, it is critical that clinical research be developed or the medical cannabis program will always remain within a special access program rife with unnecessary regulatory and bureaucratic barriers.

Since cannabis is not an approved drug, it does not have a Notice of Compliance (NOC) or Notice of Compliance with Conditions (NOC/c). A complete Notice of Compliance requires extensive clinical testing for both safety and efficacy, whereas a Notice of Compliance with conditions only requires promising evidence of clinical effectiveness. The NOC/c process was designed to expedite the process by which new drugs would be available for distribution. The Government's policy statement on the NOC/c classification notes that its purpose is to: (a) provide patients suffering from serious, life-threatening or severely debilitating diseases or conditions with earlier access to promising new drugs, and to (b) create a mechanism to ensure that a manufacturer that has a drug approved under this policy conducts confirmatory studies to verify the clinical benefit of the drug and further establish the safety profile.

Accordingly, in order to allow compassionate access, the federal government initiated the distribution of cannabis produced under contract for them after changes were made to the FDR. The government exempted cannabis produced under contract for the government from certain requirements of the *Food and Drug Regulations* – an exemption which allowed for distribution of medical cannabis without the necessity of having all the data required under the drug approval process required by legislation.

The only current option for cannabis to obtain a NOC/c would be for the only current licensed dealer under contract to Health Canada to apply to Health Canada for a NOC/c for this product. However, the

current licensed dealer does not own the cannabis they grow and the application to obtain a NOC/c would require that Health Canada take the initiative to commence this process. However, as stated above, Health Canada does not initiate nor become involved in this process. Obviously something will need to change for this process to move forward.

Recommendation

We call on the government and the medical and scientific communities to take the necessary steps to facilitate the process of obtaining drug approval, or conditional drug approval, for cannabis so that physicians can prescribe it and consideration can be given to having the costs of the product covered under provincial drug plans.

ii. Safety and Efficacy of Cannabis

Physicians want to see clinical data, preferably from randomized clinical trials, about the safety and efficacy of cannabis for medical purposes. This is the evidence they require to feel they can assist their patients with decisions regarding their health care. They also want evidence regarding the long-term effects of cannabis use, especially in smoked form, to determine whether the benefits outweigh the risks for their patients. If cannabis was approved as a drug, this information would be readily available to physicians.

For herbal cannabis to be approved as a drug, it must be tested extensively for both safety and efficacy through clinical trials. Human trials conducted to gain market authorization are usually performed in three phases. Phase I trials are the "first in human" trials in which an experimental drug is usually given to a small number of healthy volunteers. The goal of a Phase I trial is to determine how the drug is absorbed, distributed in the body, metabolized and excreted, as well to estimate the initial safety and tolerability of the drug at different dosages. Phase II trials are the initial trials to assess efficacy in patients for a specific indication. Due to their preliminary nature, they are also called "therapeutic exploratory studies". Some of the information gained in Phase II trials includes the best dose and frequency of the drug, the target population (i.e. those with mild or severe disease) and the best outcome measures to assess efficacy. The objective of Phase III trials, also called "therapeutic confirmatory studies", is to demonstrate the safety and efficacy of the drug in the intended patient population under the intended conditions of use.

Phase IV clinical trials, which lean towards an open-label design, are traditionally undertaken after drug approval as a means of conducting a wide-ranging safety review and as a way to determine if the approved drug may have other medical applications. Health Canada has consistently suggested that a Phase IV trial design would be appropriate for cannabis. This concession opens the door for large-scale production and distribution. Perhaps Health Canada believes that the initial phases of drug approval are redundant because there is already a sufficient body of evidence to meet their objectives. As Dr. Mark Ware testified before the Senate Special Committee on Illegal Drugs,

> "the safety of cannabis in humans has been extensively studied, thanks in part to the massive Western cohort of healthy human volunteers of the last 40 years. Cannabis may have undergone the most extensive and un-

"...we're cops, OK? So if the medical community says to us that this is a drug that will aid or assist people who are suffering from illness, it's not for us to say that that is not correct. Our concern is more about how do you put a system in place that doesn't allow the illegal diversion of an illicit drug... We do have problems with the way the system is put together. If it is a drug that can aid patients, it should be distributed like all drugs, in our view, through pharmacies."

—Deputy Chief Christopher McNeil, Deputy Chief of Operations in Halifax, and Chair of the Drug Abuse Committee at the Canadian Chiefs of Police Association

> orthodox Phase I clinical trials of any drug in history."[16]

Therefore, it is more important to understand and study medical efficacy in light of the known safety risks. Open-label clinical trials provide an ideal opportunity to achieve wide-ranging distribution of the product with far fewer formal requirements than would be needed for most clinical trials. An open-label clinical trial is defined as a trial "used to expose a medicine to a broad patient population, in order to gain information on the efficacy and safety of the medicine for situations in which it will be used."[17] A trial of this nature closely approximates traditional medical treatment because there is no control group, no placebo, and the study is not blinded (i.e. all the parties know the identity of the substance).

The notion of an open-label clinical trial first arose as part of Health Canada's explanation for why it originally refused to release the cannabis grown for them under contract for direct medical use. Health Canada explained that it was essential to first conduct clinical trials before commencing any form of medical distribution. However, in an effort to accommodate the medical needs of individuals already authorized to use cannabis, Health Canada stated it would encourage and facilitate open-label clinical trials if private researchers would come forward with appropriate protocols. As open-label clinical trials most closely approximate ordinary medical use, without the restrictions commonly accompanying participation in randomized, control-group trials, Health Canada concluded that the open-label trials could satisfy the medical needs of patients while still generating clinical data as patients are monitored by their physicians.[18]

Health Canada and the Canadian Institutes of Health Research (CIHR) have made some efforts through the Medical Marihuana Research Program to stimulate such research – an initiative that offered successful applicants the possibility of $1.5 million of funding per year, with a maximum duration of three years, to run open-label clinical trials. In its Request for Proposals, CIHR stated:

> In the absence of a commercial sponsor, potential researchers have been required to assume all of the responsibility for the development of the necessary regulatory documentation to support the conduct of clinical studies. Health Canada recognizes this is an onerous burden to place on researchers and is therefore taking this into consideration for the new Marijuana Open Label Safety Initiative.[19]

We now know that very little interest was generated by this Request for Proposals, with only one applicant being approved. Dr. Mark Ware from the McGill Pain Centre is currently investigating the safety and efficacy of smoked cannabis on chronic neuropathic pain in people living with multiple sclerosis. The existence of the program showed that the government was committed to this type of wide ranging research. However, funding for this research program is no longer available. It remains to be seen whether this funding will be reinstated.

In an interview with the Canadian AIDS Society, Beth Pieterson, Director General of the Drug Strategy and Controlled Substances Programme at Health Canada, states:

> "We have not encouraged as much research as we would have liked. There hasn't been as much uptake on research, but we have not given up. … We have money allocated each year for research. We are going to be trying to do more contract research so that it's more targeted. We solicit and invite people, and we would have the protocols developed or do more basic research to get to meet our needs rather than just going to CIHR."

An open-label clinical trial is both necessary and desirable for the use of smoked cannabis in the treatment and management of HIV/AIDS related symptoms. First, patients will receive immediate access to cannabis without enrolling in the MMAR and it is conceivable that this access will be funded for participants in the trial. Second, the open-label trial provides an opportunity for physician education. Third, the modest monitoring which accompanies these trials could provide definitive resolution of critical questions about the use of cannabis for medical purposes. Whatever mechanism is used to make this research happen, it is of utmost importance that this research be done.

"So if we are going to talk about medicinal cannabis, then let's treat it like any other medicine that we take."

"Fortunately, I can afford it but I thoroughly believe that this should not be an issue for people, even if you can afford it. That's not the way our health care system works. It's not fair to provide medicine for some people but not to others."

"I would also like to have it paid for or be reimbursed because we have to take it out of the food budget."

—Focus group participants

Recommendation

We recommend that the Canadian Institutes for Health Research, through the Medical Marijuana Research Program, issue a Request for Proposals for a Marijuana Open Label Safety Initiative for a trial to assess the safety and efficacy of smoked cannabis on appetite stimulation, nausea and vomiting, pain, and other HIV/AIDS related symptoms.

If researcher interest is still low or non-existent, we recommend that Health Canada actively solicit research in this area through targeted contracts.

iii. Medical Associations' Communications to Physicians

The medical associations have been active in expressing their concerns about physicians participating in the federal medical cannabis program. In fact, on May 7, 2001 the Canadian Medical Association wrote to the Minister of Health and clearly stated that "physicians must not be expected to act as gatekeepers to this therapy,"[20] They feel there is not enough clinical evidence for physicians to properly advise their patients about the use of cannabis for medical purposes, as cannabis has not been subjected to the rigorous clinical trial processes needed for drug approval. In addition, the Canadian Medical Protective Association (CMPA), the insurer for the medical profession, issued an information sheet dated October 2001, advising doctors not to complete the requisite MMAR declarations unless they had "detailed knowledge" relating to cannabis. The CMPA represents 60,000 of Canada's doctors, approximately 95% of all who practice in Canada. On November 8, 2001, the Association wrote to the Minister of Health expressing concern about "the medico-legal difficulties that may face members that choose to follow Health Canada's *Marihuana Medical Access Regulations*."[21] These cautions have put off many doctors who fear reprisal and do not feel they have the necessary knowledge to support their patients' applications. The number of people enrolled in the MMAR is 1399, and in light of estimates of hundreds of thousands of medical users[22], it is clear that most medical users have either chosen not to enrol, or have been unable to find a physician willing to authorize their medical cannabis use.

The Canadian Medical Protective Association has recently provided an option for physicians to address liability concerns. They have made available a Release Form for Medical Practitioners[23]. They recommend that physicians who complete the medical declaration for a patient's application to the federal medical cannabis program ask the applicant to sign this release from liability, and that they keep copies of this form on hand for future use.

Action by the Canadian AIDS Society

The Canadian AIDS Society will take every opportunity it can to disseminate information regarding the medicinal use of cannabis and the *Marihuana Medical Access Regulations* to people living with HIV/AIDS. Fact sheets prepared as part of this project include an information sheet for physicians. This sheet can be taken to physicians by their patients. It includes information about the amendments to the MMAR and practical information about cannabis use, which may make physicians more comfortable to support their

patient's application. It also includes information about the Release Form for Medical Practitioners from the Canadian Medical Protective Association.

Recommendations

If they have not already done so, we recommend that the Canadian Medical Association and other medical associations communicate the changes made to the MMAR to their member physicians to ensure that they have the latest information and are aware that family physicians can now sign their patients' application forms, and that there has bee a shift of responsibility from the physician to the patient in accepting the potential risks and benefits of using cannabis for medical purposes.

If they have not already done so, we recommend that the Canadian Medical Protective Association communicate with their member physicians to inform them of the Release Form for Medical Practitioners and its purpose with regard to liability.

iv. Physicians' Attitudes and Knowledge Regarding Medical Cannabis Use

Some people we consulted report some judgmental reactions from their physicians when they brought up the subject of cannabis for medical purposes. Others fear their doctor's reactions and have therefore not discussed their cannabis use with their physician. In some cases, discussing this topic has resulted in tense patient-doctor relationships. We feel that prohibition on cannabis and the mainstream messages regarding drug use and 'drug users' have contributed to this barrier. Information dissemination to physicians about the medical use of cannabis is crucial.

As cannabis is not an approved drug and is not part of the current pharmacopeia, physicians do not have access to information regarding cannabis' therapeutic applications and safety and efficacy, as discussed previously. As such, physicians do not feel that they are in a position to assist their patients with their application to the MMAR. In order to ensure that seriously ill Canadians are protected under the law when they use cannabis as part of their therapy, physician support is required. Physicians will need to be informed. The education and information needs of physicians will need to be assessed to develop the proper tools to address general attitudes and information gaps.

> *"I really don't care what other people think except the people that can have an effect on my life, [like] my doctor, he doesn't approve so I don't share it with him and that means I'm denying him, I'm denying myself having a doctor that fully knows the medicines that I use. I'm denying myself a doctor who agrees to treat the whole me with HIV. It's unfortunate. He's such an excellent doctor in so many other ways and is compassionate in so many other ways. But I don't share with him that I smoke because I know what his issues are so I couldn't turn to him to sign the license and I can't share with him the whole extent of the medicine I use. And that's how it affects me."*
>
> —*Focus group participant*

Action by the Canadian AIDS Society

We are exploring the possibility of developing and managing a referral list of physicians for people living with HIV/AIDS who seek doctors who are ready, willing, and able to sign applications to the federal medical cannabis program. For this, we require more information about physicians' willingness to be on such a list. We will consult with medical colleges to determine the role they could play in establishing this referral list.

Recommendations

We recommend that researchers conduct a survey of physicians to obtain information about their attitudes toward the use of cannabis for medical purposes, as well as to assess their knowledge of medical applications of cannabis in the treatment and symptom management of HIV/AIDS. This type of research should be solicited through the CIHR Medical Marijuana Research Program or other funding agencies. Once this information is available, a continuing education

module can be developed to provide proper training to physicians about the use of cannabis for medical purposes.

We recommend that, as part of a survey of physicians about their attitudes and knowledge related to the medical use of cannabis, physicians be asked about their willingness to be included on a referral list for patients seeking physicians who support applications to the federal medical cannabis program.

F. Stigma and Discrimination

Stigma is defined as "an unfavourable mark placed on a person or a group", and is "made up of attitudes, beliefs, and policies directed toward that person or group by others because of a perceived characteristic of the person or group."[24] The use of cannabis is associated with stigma in our society. Medicinal users of cannabis are often met with laughter, scepticism, or with negative reactions, all of which may have negative consequences on their everyday life. The federal medical cannabis program, and the ID cards that are issued to authorized persons, have helped to facilitate a growing acceptance of the medicinal use of cannabis. It has brought some credibility and legitimacy to the use of cannabis for medicinal purposes and helped improve the image of cannabis use. These positive aspects of enabling legal access to cannabis for medical purposes are slowly shifting Canadians' perception of medicinal cannabis use, which in turn contributes to the quality of life of the people who use it.

When a society perpetuates negative, judgemental attitudes toward any group of people, especially with regard to their different values, beliefs and ways of life, it is being oppressive. This oppression results in people being stigmatized, marginalized and ostracized for their beliefs or actions. This oppression, in turns, gets internalized by the people who experience it, resulting in feelings of fear, self-hatred and shame. A lack of understanding or awareness about the realities of the marginalized group contributes to this stigma. When people are forced into hiding for fear of stigmatization or criminal repercussions, the unspoken becomes a dark cloud over their lives. The fear-mongering that has taken place about cannabis use in this climate of prohibition has also fed the beast. Breaking this silence and encouraging dialogue can be challenging, and can go a long way to lifting the smoke screen.

Discrimination occurs when a person is treated unfairly or unjustly on the basis of belonging or being perceived to belong to a particular group.[25] During our consultations, some people described instances when they felt discriminated against for their medicinal use of cannabis. They felt discrimination for their choice of therapy, both by their peers who do not use cannabis for medicinal purposes and by the medical system in general. Denying a seriously ill person of health care services is not only unethical,

"Some people… are very suspicious when you tell them that there are some benefits to its use and it's not just because you want to get stoned. [With an Authorization to Possess], maybe they would not see it that way anymore. It's not so much for me but for how it is seen by others."

"I believe that the social stigma on anybody using cannabis is just horrendous. Being a parent myself I have that stigma two times dealing with the school board etc and I am trying to knock down some of the barriers and I'm trying to educate the public as to what the government's stance is on cannabis as a therapy… if they are going to condone that I believe that they should educate the public a little better which would reduce the stigma."

—Focus group participants

"The hardest thing for me is still paying for it and feeling so discriminated against because it's my drug of choice. It's discriminated by the tax system, by society in general, by the medical system, by everybody."

"I just want to reiterate how angry I am with how long it's taking to get this all sorted out and how terribly discriminated against I feel. It's had enough feeling discriminated against because you are HIV positive but going through all of this hassle to try to get your medicine, and the extra expense, it's just ludicrous that we are having to go through this and have a half assed attempt in providing us with our medication. I'm really sick of it."

"I could be denied a liver transplant because I am using medicinal marijuana. It comes into play when you want to go for an organ transplant. They're not going to transplant you if you smoke or do drugs, or certain things. So we face some hurdles which I think are probably unbeknownst to ourselves and just being discovered, that are really going to prevent us from being open and telling everybody."

"And also I find that if you are smoking medicinal marijuana, it's been my experience that I don't get treated the same way at a hospital. My pain is not taken seriously. . . . Somewhere I need some supplement and they won't give it to me. They won't give me anything that has any kind of pain relief in conjunction with my medical marijuana so the only place that will do that is my specialist who did sign my form so it's really a catch 22 in some cases."

"I had to switch family doctors and when I was trying to find a new family doctor, I was actually denied service specifically because I use medical marijuana, was the exact excuse. Which I did by the way report to the College of Physicians and Surgeons because I thought it was somewhat discriminatory."

—Focus group participants

but it violates the very essence of our universal health care system. In some cases, people can be legally protected from certain forms of discrimination.

Action by the Canadian AIDS Society

The Canadian AIDS Society is committed to disseminating information about the use of cannabis for medicinal purposes, to bringing forward the voices of people living with HIV/AIDS and the realities they face when choosing cannabis as part of their therapy, and to encouraging dialogue on these issues. We will continue to offer workshops, discussion groups, and presentations and we will strive to have a presence at relevant events, within the confines of the resources available to us. We developed a fact sheet on "Stigma and Discrimination of Cannabis Use" as part of our fact sheets series. We provide information about how people can deal with various situations of stigma and discrimination, as well as information on where people can turn to pursue action should they be subjected to discrimination because of their medicinal use of cannabis. We will disseminate this report and the fact sheets widely, and we will continue to advocate on behalf of people living with HIV/AIDS who use cannabis for medicinal purposes.

Recommendations

We recommend that all the key stakeholders, including the government, join our efforts in disseminating information about the medicinal use of cannabis and the federal medical cannabis program. We must also find opportunities to engage others in a dialogue about the use of cannabis for medicinal purposes in an effort to reduce the stigma associated with the medicinal use of cannabis.

We call on all levels of government and on the medical and scientific communities to take measures to ensure that there is adequate research, information dissemination, and related services so that seriously ill Canadians are provided with standards of care around their treatment of choice, without discrimination.

G. Thwarting of Research

In 1972, the LeDain Commission completed its review and assessment of the prohibitory policy with respect to cannabis and, in the course of recommending that the government decriminalize the use of cannabis, the Commission also recommended that research be conducted into the plant's therapeutic potential.[27] The efforts to evaluate the therapeutic claims of medical cannabis users were bolstered in 1988, when investigators discovered the biological basis of cannabis' mechanism of action. The discovery of two separate cannabinoid receptors in the central nervous system and the peripheral organ systems managed to ground cannabis therapeutics in the Western medical paradigm, and resulted in an explosion of research into the plant's medical potentials. Accordingly, these discoveries have "re-established the basis for the restoration of cannabis as a medicine."[28] In 2002, the Senate Special Committee on Illegal Drugs reiterated the need for research into the therapeutic applications of cannabis and recommended that the Government of Canada create a national fund for this research.[29]

Health Canada and the Canadian Institutes of Health Research established a five-year Medical Marihuana Research Program, a research fund of up to $7.5 million, to encourage research on the safety and efficacy of smoked and non-smoked cannabis and cannabinoids. Only one research project has received funding, under the direction of Dr. Mark Ware, McGill Pain Centre of the Montreal General Hospital, McGill University Health Centre. The study will investigate the safety and efficacy of smoked cannabis on chronic neuropathic pain. The funding period for this program has since elapsed and it is unclear whether it will be reinstated.

The climate for researchers is still very much affected by the current regulatory environment. One cannabis researcher, Dr. Mark Ware, speaks of the challenges that researchers face if they wish to pursue research on cannabis:

> "As a researcher, the challenges were convincing the granting agencies that this is a worthwhile area to study and that the designs of the projects could be valid enough to make them fundable… There's a lot of embitterment about the inability of grant reviewers to recognize the need for what is being done… it's frustrating to have to wait as long as one does for some of the approvals to get the licenses [and] permits and to have to go back and forth to committee after committee to get projects moving."

It is regrettable that the criminal prohibition on cannabis has significantly limited medical research to date. There are over 60 active compounds called "cannabinoids" present in cannabis and scientists know very little about the activity of most of these compounds. Most of the research to date has fo-

"Cannabis is remarkably safe. Although not harmless, it is surely less toxic than most of the conventional medicines it could replace if it were legally available. Despite its use by millions of people over thousands of years, cannabis has never caused an overdose death. The most serious concern is respiratory system damage from smoking, but that can easily be addressed by increasing the potency of cannabis and by developing the technology to separate the particulate matter in marihuana smoke from its active ingredients, the cannabinoids. Once cannabis regains the place in the [pharmacopoeia], it will be among the least toxic substances in that compendium. Right now the greatest danger in using marihuana medically is the illegality that imposes a great deal of anxiety and expense on people who are already suffering." [26]

—Dr. Lester Grinspoon, October 1, 1997

cused upon THC (delta-9-tetrahydrocannabinol) and cannabidiol (CBD). Research scientists know little about the interplay of the 60 cannabinoids and other unique compounds found in cannabis. Some scientists do not believe that the entire therapeutic impact of cannabis is found solely in the interplay of the two primary cannabinoids (THC and CBD), and it has been asserted that there is a synergistic interplay among all the cannabinoids,[30] in that the whole is greater than the sum of its parts. Different strains of cannabis have different cannabinoid profiles and the "entourage effect" for plant medicines (i.e. the medical effect which is derived from synergistic interplay) would dictate that these different strains have distinctive therapeutic applications. Preliminary research has indicated that the different cannabinoids may indeed have different therapeutic applications. For example, it has become fairly clear that the anti-seizure and anti-spasmodic properties of cannabis may relate more to the presence of the cannabinoid CBD than the presence of THC. As Professor Richard Musty has noted: "thus far, THC and CBD ratios have been administered to a maximum 1:1 ratio, yet the studies cited above suggest that alternative ratios of CBD:THC should be tested for their pharmacological and clinical efforts."[31] A great deal of research needs to be conducted to explore the interplay of diverse cannabinoid profiles found in the various strains of cannabis, in order to gain a clearer scientific understanding of the medical potential and properties of cannabis.

Accordingly, the direction of contemporary cannabis research concerns the production of a multitude of diverse strains with varying cannabinoid profiles, in order to assist in selecting one strain with the greatest therapeutic potential for symptom control. It is clear that THC and CBD are not the only pharmacologically active constituents and that the presence of these other constituent elements can modify the overall effect of cannabis. As noted by Wilkinson, *et. al.*:

> This work suggested that medicinal preparations of cannabis should be characterized chemically to a greater degree than simply specifying the concentration of THC and CBD, to maximize efficacy and minimize side effects....It also suggests that other non-psychoactive compounds might be discovered, and by selecting a suitable ratio of constituents it might also be possible to minimize side effects and increase efficacy. It is therefore likely that preparations containing different cannabinoid ratios will be developed for different therapeutic applications in the future, but determining the effective composition of these will require further basic research, in addition to clinical investigation.[32]

Accordingly, there is an unresolved debate as to 1) whether or not cannabis-based medicine should be a delivered as a whole plant product, either in extract form or in herbal form, and 2) whether or not the hundreds of strains of cannabis available in the black market all have different therapeutic effects, as has been suggested by its users. There has been a great deal of clinical research done using synthetic can-

"Without the medical marijuana, I would have a very difficult time eating a substantial amount of food without becoming nauseous, simply from the heat, the smell, the taste."

"It relieves the nausea from the meds and allows me to have an appetite and to stick to the regimen of taking pills. And certain strains work better for the pain."

"Medications turn my appetite off and make me sluggish so using helps me want to eat and gives me drive to go out."

"It allows me to have a much improved quality of life, I can eat like a horse and my CD4 counts have risen from a low of 20 (when I was diagnosed with full blown AIDS) to today where it is approaching 500 CD4 cell count."

—Focus group participants

nabinoid derivatives, but little with smoking or ingesting the whole plant product to determine if there is strain-specific therapeutic response. It is critical to resolve the strain-specific issue because of the government's "one-size-fits-all" approach of only offering one strain of cannabis despite the different needs.

We have already presented a brief overview of the existing research with regard to the management of HIV/AIDS related symptoms with cannabis, cannabis versus pharmaceutical products, adherence to antiretroviral therapy, and long term effects of cannabis use (see section 3). It is clear that more research is needed using cannabis in either smoked or vaporized form. Long-term studies on the effects of cannabis on the immune system and on antiretroviral medications, as well as studies on the direct effects of cannabinoids on the CD4 cell counts and viral loads need to be conducted to determine the long term safety of cannabis use for people living with HIV/AIDS. The effects of different strains must also be studied.

Research can greatly be enhanced by involving community groups or organizations from the development of the research protocol to the dissemination of results from a clinical trial. An innovative approach to clinical trials entails creating a community advisory committee to obtain input directly from the population one wishes to study. Such a committee can also assist with recruitment. Community-based research also has an important role to play in contributing to the greater body of knowledge.

Action by the Canadian AIDS Society

The Canadian AIDS Society has provided letters of support to researchers and has participated in community advisory committees for research proposals that were submitted for funding. We would be willing to collaborate to assist in the development of research protocols and with the recruitment of participants, within the confines of available resources.

Recommendations

We recommend that funding bodies such as the Canadian Institutes for Health Research and Health Canada solicit research proposals in the following areas:

- Randomized controlled trials comparing smoked and vaporized cannabis to pharmaceutical products currently available for stimulating appetite, managing nausea and vomiting, and managing pain
- Long-term effects of cannabis on the immune system and on antiretroviral medications
- Therapeutic effects of various strains of cannabis and cannabinoid profiles on specific symptoms
- Research into the direct effects of cannabinoids on CD4 cell counts and viral load
- Research into alternative modes of delivery such as vaporizers
- Community-based research

H. Thwarting of Information Regarding the Medicinal Use of Cannabis

As with any activity that is forced underground, prohibition on cannabis has resulted in the stigmatization of its use and in a societal silence on the subject. People do not discuss the use of cannabis openly, except in closed circles, for fear of judgement or criminal prosecution. Prohibition has an impact on the everyday life of a person who uses cannabis for medicinal purposes. The silence that surrounds cannabis use results in a lack of information for people who use it for medicinal purposes.

Participants in the consultations were asked what type of information they would like to have access to regarding the use of cannabis for medicinal purposes. Table 2 shows the main categories of information needs identified.

Under "Scientific and Medical Evidence", people asked for information on health benefits, efficacy, effectiveness, on health risks, safety issues, long term effects , strains, scientific studies, clinical trials, and research, interactions with medications, how to use cannabis medicinally, dosage, health issues related to

Table 2. Information Needs of People Living with HIV/AIDS

Information Need Identified	Number of Responses	Percent
Scientific and Medical Evidence	74	42.5
Access to Cannabis/Information on Cannabis	36	20.7
General Information	23	13.2
Marihuana Medical Access Regulations	22	12.6
No Information Needs – fine with information that exists	11	6.3
Harm Reduction – Alternatives to Smoking	8	4.6
Alternatives to Current Legal Options	2	1.1

the production of cannabis, addictive patterns, and on economic savings for medications not dispensed due to cannabis use. Under "Access to Cannabis/Information on Cannabis", people wanted information on availability, access (i.e.where and how to obtain cannabis safely and easily), costs and how to get it at affordable cost, information on growing cannabis, potency and THC percentage, health insurance coverage, quality, and how to store and handle cannabis. Under "General Information", they wanted all information or any information, web sites, more public and accessible information, testimonials from users, information in French, and the truth! Under the "Marihuana Medical Access Regulations", they sought information regarding the federal program, legal issues and understanding of the law and regulations, how to obtain authorization and access cannabis legally if their doctor will not sign their application, a list of physicians open to the idea of signing forms, pharmacy distribution, and how to get their doctor to sign their application for authorization. For "Harm reduction – Alternatives to Smoking" they asked for information on how to cook with cannabis, and information on pharmaceutical options. As for "Alternative to Current Legal Options", they wanted information on commercial licenses for producing cannabis for medicinal purposes, and how to start up a compassion club.

The people we consulted clearly stated their information needs when it came to all aspects regarding the use of cannabis for medicinal purposes. They asked for information on the scientific and medical evidence of the therapeutic effects of cannabis, how to access cannabis for medicinal purposes, the MMAR and the federal medical cannabis program, alternatives to smoking and harm reduction strategies, and more.

Action by the Canadian AIDS Society

To address many of the information needs expressed by the people living with HIV/AIDS, the Canadian AIDS Society has prepared a series of fact sheets[33] to provide information about the various aspects of the medicinal use of cannabis, as well as listing resources where they can find more information. These sheets will be disseminated widely to our membership and at various events relevant to people living with HIV/AIDS, within the confines of available resources.

We call on our member organizations to assist us in disseminating the fact sheets on Cannabis and HIV/AIDS, to develop position statements on the use of cannabis as therapy for people living with HIV/AIDS and to support our advocacy efforts with regard to the use of cannabis for medicinal purposes by people living with HIV/AIDS.

Recommendation

We recommend that all key stakeholders, including Health Canada, engage in the gathering and dissemination of information regarding the use of cannabis for medicinal purposes to people living with HIV/AIDS and other seriously ill Canadians.

I. Access to a Source of Cannabis

On the consultation questionnaire, respondents were asked where they obtained their cannabis for medicinal purposes. The most commonly reported

source by far, by 62.5% of respondents, was "a friend or someone they know", hinting at the broad network that exists to obtain cannabis in Canada. The next most common source, by 35.9% of respondents, was a compassion club, followed by street dealers (30.8%). Some people grew their own cannabis (17%) or had someone grow it for them (4.3%). Half of the people who grew their own had obtained a license to do so. The least frequently reported source was the government product (1.7%). Many (44.4%) respondents reported that they obtained cannabis from more than one source.

> *"Many people are in a situation where they have to break the rules to be able to supply themselves."*
>
> *—Focus group participant*

When a person obtains an Authorization to Possess cannabis for medical purposes, they have three legal options to obtain cannabis. They can order the cannabis produced under contract for the government, obtain a Personal License to Produce cannabis, or designate a person to produce cannabis for them. This designated person must obtain a Designated Person License to Produce. Designated producers are also limited to grow for only one authorized person, which means that each authorized person who chooses this option must find their own designated producer. Many people are not in a position to grow cannabis and may not know of someone who would be willing to grow it for them.

This section explores access to medicinal cannabis through various sources and provides recommendations to ensure that seriously ill Canadians are provided with more legal choices to supply themselves with medicinal cannabis.

i. The Cannabis Grown for the Government

The government has contracted a licensed dealer to produce and distribute cannabis for medical purposes to authorized persons. The product has received much media attention and has been subject to much criticism. Changes to the product have been continuously made based on feedback received from the people who are using the product. The cannabis produced for the government is sold to authorized persons for $5 a gram, plus applicable taxes.

The number of people ordering cannabis from the government remains low. Out of the 1399 people who are currently authorized to possess cannabis for medical purposes, only 266 have ordered their cannabis from the government, which represents less than 20% of authorized persons. This number includes 72 people who have a license to produce and who are temporarily ordering dried cannabis from the government while they wait for their first crop to be ready to harvest. Essentially, only 14% of authorized persons have actually ordered their cannabis from the government as their main source of cannabis for their medicinal purposes.

It was clear from our consultations that people had heard unfavourable comments and reports about the medical cannabis produced for the government. Very few people we consulted had actually tried the product, and even fewer were ordering their cannabis from the government. People who had tried the government's cannabis most frequently reported that the product was too dry and too finely ground. Improvements regarding the grind size and moisture content have been made to the government's product. Despite Health Canada's efforts to improve the product based on feedback, uptake by authorized persons remains low. This is a concern, especially if the government is moving toward making the government product the only legal source of cannabis for medical purposes, along with their plan to phase out licenses to produce and to eventually distribute cannabis through Canadian pharmacies. We strongly oppose this vision of phasing out licenses to produce as it is not in the best interest of seriously ill Canadians who use cannabis for medicinal purposes. People have told us that if the government moves toward phasing out licenses to produce, they will seek other sources, which means that they will resort back to the black market, or that they will continue to produce their own cannabis without a license.

Given the current public perception of the government's cannabis, the fact that the government only

provides one strain to authorized persons, and the government's vision to phase out licenses to produce, we are concerned that people living with HIV/AIDS will further have to break the law in order to supply themselves with cannabis for their medicinal purposes. We favour providing authorized persons with a variety of legal options and medicinal cannabis products.

This said, the government will have to take measures to increase buy-in from authorized persons. To address the negative perception that currently exists regarding the government's cannabis, people will have to try it for themselves. We suggest that Health Canada distribute small samples, perhaps 5 grams, of their product to newly authorized persons to enable them to try the product and to determine for themselves whether or not it is effective for their symptom management. This practice is widely used in physicians' offices when patients are prescribed medications.

Recommendation

Given the low uptake of the government's cannabis by authorized persons, we recommend that Health Canada provide 5g samples of cannabis to newly authorized persons to encourage more authorized persons to try the government's product and subsequently order it, to minimize the number of authorized persons that depend on an illegal source of cannabis.

ii. Personal Licenses to Produce Cannabis for Medical Purposes

Ideally, authorized persons should have legal access to a safe and affordable supply of cannabis for their medical purposes. Canada has been facing some challenges in providing adequate access to a legal source of cannabis for medical purposes while working its way through the complex legal issues. There is no doubt that providing an authorized person with a license to produce cannabis for their own medical use facilitates access to cannabis. Many people welcome the fact that they can grow their own cannabis legally. This gives them control over the selection of the strain of cannabis and the conditions in which their cannabis is cultivated. It also cuts the costs of obtaining cannabis, once their garden is established and the crop is stable. Barriers with regard to Personal Licenses to Produce need to be addressed.

> *"In the beginning it was really difficult because I really didn't have a great deal of an idea how to grow it and grow it properly. So I went through a few trials and I had friends who grew before indoors. And they came in and we bought the equipment. That's the worst part of it is buying the equipment to grow it. . . [it] is very expensive and now what you are being forced to do is 1) take time to grow this, and 2) to pay for the equipment so it takes quite a while before you recoup your money. It takes at least two crops really to make your money back for what you spent on the equipment. But once you get it going, you save a lot of money, but it's a real big hassle. One thing, it can destroy your home if you don't have the proper ventilation and ventilation costs a lot of money. I need to buy the proper strain that is going to be satisfactory for me."*
>
> —Focus group participant

a. Costs to Set Up, with No Financial Compensation

As many people reported, the initial costs of setting up a home garden can be steep. The costs of getting all of the proper equipment and supplies can be a barrier for some to start producing for themselves. There is also a steep learning curve for people who have never grown cannabis.

In its March 2005 budget, the federal government announced that a medical expense tax credit (METC) had been granted for drugs purchased under Health Canada's Special Access Programme, and for medical cannabis. These two types of medication are available only upon the recommendation of a physician. However, to be an eligible expense under the METC, medical cannabis has to be purchased from either Health Canada or a designated grower by an

individual authorized to use cannabis for medical purposes under Health Canada's Medical Marihuana Access Regulations or by exemption under Section 56 of the Controlled Drug and Substances Act.

For authorized persons who grow their own cannabis with a Personal License to Produce, production costs are not eligible under the METC, with the exception of the cost of seeds purchased from Health Canada. According to the government, individuals who have eligible medical expenses (now including medical cannabis) in excess of a certain threshold (the lesser of 3% of their net income for tax purposes or $1,844) are now able to claim those expenses and receive tax relief of up to 16% of those expenses. The medical expense tax credit is not intended to reimburse individuals for the costs they incur, but rather to recognize their reduced ability to pay tax as a result of incurring those expenses. The Canadian AIDS Society has asked the federal government about the rationale for excluding expenses incurred by authorized persons who have a license to produce. We were told that the Minister of Finance made a decision not to grant a tax credit to people who grow their own cannabis for medical purposes on the basis that it would be almost impossible to calculate the expenses incurred. [34] We challenge this explanation. It would be simple for holders of licenses to produce to submit receipts for their costs as they would for any other medical expense.

Recommendation

We recommend that the Minister of Finance revise the medical expense tax credit to allow authorized persons who have a License to Produce cannabis for medical purposes to claim expenses incurred in producing cannabis for their medical purposes. These costs include a portion of their electricity bills, based on the square footage of their cultivation area, costs for equipment and supplies purchased to start up and maintain their production of medical cannabis and the costs of seeds required to start their home garden. All of these costs should be allowable under this tax credit.

b. No Other Legal Option Should Crops Fail

Currently, authorized persons have three legal options to obtain cannabis for medical purposes. They can buy the government's product, grow their own, or designate someone to grow for them. Authorized persons cannot use more than one of these options at a time. There are provisions made within the MMAR that allow a person to order medical cannabis from the government for a period of four months while they are setting up their home garden. However, should a person's crop fail, not yield the expected amount of cannabis needed, or should a person's crop be destroyed by pests, a home invasion, or police intervention, an authorized person has no immediate legal option available to them. There must be a mechanism in place to account for such situations in the event that someone is left with no immediate access to a legal source of cannabis.

Recommendation

We recommend that Health Canada establish a mechanism through which a person can report a loss of crop and obtain immediate authorization to have access to the government's supply until such a time as they are able to supply themselves adequately through their home garden.

c. No Access to Testing to Ensure the Cannabis is Safe

Cultivating cannabis requires knowledge and skills. Cannabis plants are not necessarily that different from other household plants. However, extra care and knowledge are required to tend to plants used for medicinal purposes. There are specific considerations to ensure that a crop is free of microbiological or heavy metal contamination.

There is currently no legal way for a grower to get their cannabis tested to verify its potency in terms of THC content nor to ensure it is safe for consumption. As Richard Viau, Director of Drug Analysis Service at Health Canada, reports:

> "It is still buyer beware because the buyer has no way of checking that [the product is safe]… Because growing marihuana is illegal, those growing it do so in a hidden fashion and

> there is no authority verifying what they are doing… a license is required to test a controlled substance like marihuana and Health Canada is the one issuing licenses. We have not received any applications from any recognised labs to test marihuana… Other than at Health Canada, no Canadian laboratories are currently authorized to test cannabis."[35]

Licensed laboratory testing for heavy metal contamination and biological impurities must be authorized for all authorized persons under the MMAR to ensure their cannabis' safety, regardless of the source they obtained it from.

Action by the Canadian AIDS Society

The Canadian AIDS Society strives to provide relevant health information to people living with HIV/AIDS and to its member organizations. As part of the fact sheets developed on the medicinal use of cannabis, we have included a fact sheet on 'Tips for Growing Cannabis Safely'. This fact sheet provides information on how to avoid the growth of microbiological contaminants, as well as where to find resources on how to cultivate cannabis for medicinal purposes.

Recommendation

We recommend that Health Canada, under the Controlled Drugs and Substances Act, license some Canadian laboratories to test cannabis that is grown for medical purposes by persons who hold an Authorization to Possess and/or a License to Produce through the MMAR, regardless of where the authorized person obtained the cannabis.

d. Issues Regarding Home Insurance

During our consultations, some people reported that they faced difficulties in obtaining home insurance when they are cultivating cannabis for their medical purposes. The Canadian AIDS Society spoke with the Insurance Bureau of Canada to find out how best to advise people on this issue.[36] The Insurance Bureau of Canada provides policy texts for Canada's insurance companies to consider including in their insurance policies.

Home insurance policies have an exclusion clause with regard to the production of drugs, such as: "This policy does not insure against loss or damages directly or indirectly caused, in whole or in part, by an illegal drug operation." The key word to look for in an insurance policy is 'illegal'. If a person is producing cannabis legally, with a license to produce issued by Health Canada, then their insurance policy should be valid in the case of an insurance claim. If, however, the exclusion clause does not specify the 'illegal' production of drugs, then it is best to search for a policy that does in order to be covered in the event that a claim should be sought. The Insurance Bureau of Canada does not officially have a policy with regard to the legal production of cannabis for medical purposes. They are aware of this situation and are considering establishing a working group to address it.

Action by the Canadian AIDS Society

The Canadian AIDS Society has prepared fact sheets on the use of cannabis for medicinal purposes for people living with HIV/AIDS. One of the fact sheets on 'Tips for Growing Cannabis Safely' includes information about what people should look for in their insurance policy.

Recommendation

We recommend that the Insurance Bureau of Canada develop an official policy regarding insurance coverage when a person is legally licensed to produce cannabis for medical purposes, and that the Bureau disseminate this information to insurance companies across Canada.

e. MMAR Calculations for the Limit on the Number of Plants

The MMAR include an equation to calculate the number of plants a person can be licensed to produce. The equation accounts for an authorized person's daily dose of cannabis, in grams, whether the plants will be grown inside or outside, the number of growth cycles per year, and the expected yield of dried cannabis per plant. It also accounts for some loss of crop.

> *"I grow my own. The biggest downfalls about that are first of all having the space to do it. I do have a space but concealing it from your neighbourhood, especially when the police are broadcasting alerts to be on the lookout for so called grow houses. So that's a problem."*
>
> *—Focus group participant*

There are many variables that influence how much cannabis a garden will yield. It is known that there is great variability in the average amount of dried cannabis that a plant will yield, which is dependent on the strain, the growing conditions and the grower's experience. It is also common practice, when one grows indoors, to 'clone' the plant to continue the cycle of growth. This simply involves taking clippings from a mother plant and rooting them to create more plants. Cloning is a skill and clones often do not take root. As a result, licensed people sometimes find themselves with the appearance of having more plants than is indicated on their license to compensate for the clones they will likely loose. Adhering to the number of plants allowed can be a challenge for people who produce cannabis, and it may result in criminal prosecution if a person is found to be exceeding the number of allowed plants.

The challenge is to find a method that can best estimate if a cannabis garden is meeting the medicinal needs of an authorized person. One method, based on the canopy size[37] one grows, is said to offer a more accurate calculation of how much cannabis a garden yields while providing authorized persons with a variety of options on how they can set up their garden. Basically 100 square feet of outdoor mature garden canopy typically yields three pounds (or 1,361 grams) of processed bud per year.[38] Currently under the MMAR, about 60% of authorized persons have an authorization for 5 grams per day, or 1,825 grams per year.[39] The canopy size method makes it easier for police to monitor and to visually assess whether or not a garden is in compliance with the law, as they would simply need to measure the area.

Recommendation

We recommend that Health Canada study the proposed model offered in the document "Cannabis Yields and Dosage", available at <http://www.safeaccessnow.net/pdf/sanhandbook04.pdf>, and consider integrating these calculations into the MMAR, to replace the equation that is currently used to calculate the number of plants a person with a license to produce is allowed to grow.

f. Local Efforts to Crack Down on Grow-Ops

As reported in the media and by people we consulted, some municipalities have established programs to crack down on the number of cannabis grow-ops in their jurisdiction. While we feel that these communities have the best interest of their residents at heart, these efforts have a negative impact on the lives of people who are licensed to grow cannabis for medical purposes. These programs encourage neighbours to come forward and report suspicious activity in their area. They advertise what to look for and who to call if you suspect a neighbour is growing cannabis.

This causes people with licenses to be stressed about their neighbours finding out. Growers should take extra measures to camouflage their garden. While we think that a licensed person would most likely not be subjected to criminal prosecution should they be

> *"I got worse things to worry about then the cops coming, anyhow. I got to worry about staying alive with my pills and growing the right amount of plants. That's another thing. I mean it's hard to do. I'm doing clones and stuff or whatever and it's hard to keep track. What happens if they come in one day and I have 21 plants and I'm only allowed to have 19. Do they yank them all out or what? Who knows what happens."*
>
> *—Focus group participant*

investigated by the police, we fear the safety repercussions and the unwanted attention that authorized persons would experience if the word got out in their neighbourhood that they are producing cannabis for their medicinal purposes.

Action by the Canadian AIDS Society

While the Canadian AIDS Society cannot control what goes on throughout Canada's municipalities and how they choose to address the proliferation of cannabis grow-ops, we can provide advice to people who have licenses to produce cannabis for medical purposes. We have included, as part of the fact sheets, some tips on discretion with regard to their home garden, as well as information on what Authorizations to Possess and Licenses to Produce allow and do not allow according to the MMAR.

iii. Designated Person License to Produce

Making provisions within the MMAR to enable people to designate someone to grow for them facilitates access to cannabis for medical purposes for seriously ill Canadians who may not be in a situation where they can grow for themselves.

The MMAR state that a designated grower may only grow for one authorized person, and may only collectively grow with a maximum of two other growers. According to Health Canada, these limits were put in place so as to avoid diversion of cannabis into the community.

It is no secret that cannabis is widely available in Canada on the 'black market', except for some remote areas where it is difficult to obtain. The Fraser Institute estimates that Canadians spend anywhere from $1.8 billion to $4.4 billion for cannabis in 2000 (compared to $2.3 billion for tobacco). This said, arguments for imposing restrictions on the production and distribution of medicinal cannabis for fear of diversion into the general population are unjustified.

Furthermore, these limitations on designated growers were found to be in violation of section 7 of the Charter in the *Hitzig* case, in which the Court invalidated the provisions which prevented designated growers from receiving compensation, from growing for more than one authorized person, and from growing in combination with more than two other designated growers (see section 4D).[40]

For there to be more legal options for authorized persons, the restrictions imposed on designated growers must be lifted to allow designated growers to produce cannabis for multiple authorized persons, and to do so collectively with more than two other growers. This would enable pharmacies and compassion clubs to obtain a legal source of cannabis and offer a variety of strains and products. This would also logically result in fewer licenses to produce to be issued, making it easier to monitor for quality control, and easier for law enforcement purposes, as there would be fewer sites.

"Along the way we got asked by a lot more patients across Canada to provide for them. . . .we're now up to almost 100 patients in the Health Canada/MMAR program who have requested our product and who have provided us with all their license information and wanting us to provide to them. Of course, we have submitted a lot of those designated grower forms to Health Canada for processing and we get rejection letters back. . . . From a grower perspective, wanting to provide to these people, it is very frustrating knowing that we can only legally provide to two patients. . . I think that is the most frustrating part, knowing that these people are really ill and knowing that we are producing a product that we certainly feel very content and happy about providing, yet very limited in terms of who we can supply to and access to that product for patients. Certainly I think the government program is going the wrong direction in terms of limiting access further to multiple choices for the patient."

—Eric Nash and Wendy Little, Designated Growers

Recommendation

We recommend that Health Canada lift the restrictions imposed on designated growers, to allow them to produce medical cannabis for multiple authorized persons, and to do so collectively with more than two other growers. The cannabis production facilities could be regulated and monitored to ensure quality control.

iv. The Government's Plan to Phase Out Licenses to Produce

As mentioned earlier, Health Canada's vision is to eventually distribute medicinal cannabis through Canadian pharmacies, and phase out Licenses to Produce medicinal cannabis (both personal and designated persons licenses). While we support the development of pharmacy distribution of medical cannabis, we do not support eliminating legal options for authorized persons to supply themselves. Whatever the reasons are for someone to produce their own cannabis, we support a person's choice in how they obtain cannabis for their medicinal needs, in accordance to what best suits their needs.

For many, the decision to grow their own cannabis is purely economical, and may be the only way they can afford to supply themselves with cannabis for their medicinal needs, until such a time as other provisions can be made to assist them with the costs. Some people tell us that they will simply continue to produce cannabis for themselves regardless of whether they can obtain a license or not, which alarms us. Seriously ill Canadians should not be forced to hide and 'go underground' to be able to have access to the therapy of their choice. It seems that further limiting legal options for seriously ill Canadians without financial compensation is a step backward in ensuring legal access to the treatment of their choice without fear of prosecution, and we question the constitutionality of doing so.

Once again, we point out how novel our federal medical cannabis program is on the world scene. Canada has found an innovative way of providing compassionate access to cannabis for seriously ill Canadians who need it for medical purposes. The government's cannabis is thoroughly tested to ensure its safety, and labelled to provide the maximum amount of information to its users.

Nonetheless, we question this vision that would lead to the government's monopoly on the legal supply of medical cannabis for authorized persons. Health Canada has made a policy choice to focus upon the cannabis produced for them under contract as the exclusive legal source of supply for authorized Canadians. Originally, this cannabis was to be produced strictly for research purposes, but Health Canada was compelled to make provisions for a lawful supply by the ruling in the *Hitzig* case (see section 4D).[41] In that case, the Court of Appeal recognized that a lawful supply could be facilitated by the authorization of compassion clubs, the loosening of restrictions upon designated producers, or the distribution of cannabis produced under government contract. The June 2005 amendments to the MMAR did not contemplate the authorization of compassion centres nor the lifting of restrictions on designated producers that currently limits them to grow for one authorized person only.

Compelling authorized persons to choose the government's cannabis will not satisfy the constitutional requirements of section 7 of the Charter if the government product proves to be unsatisfactory to seriously ill Canadians. As previously mentioned, the

> *"When I was working on my plants, I found that to be very therapeutic and very nature oriented. I was doing something, I was producing my own medicine, it was very positive. . . . And if they were to take that away as well, I still think that I would choose to do it illegally.*
>
> *"My biggest problem with this whole idea is that they want to stop us from producing it on our own and they are not providing any means for us to pay for this. That's the biggest problem. It's all about the dollar. For me, I cannot afford to buy the amount of marijuana that I smoke. I can't."*
>
> —*Focus group participants*

government's cannabis has been highly criticized, and whether these claims are well founded or not, the public's perception has been negatively affected. This is reflected in the low number of people who choose the government's cannabis to supply themselves. The low uptake of the government's product by authorized persons (about 14%) is of concern to us in light of the government's stated vision of phasing out licenses to produce. This will leave authorized persons with only one legal option to supply themselves with medical cannabis, the government's supply.

In light of the significant impact that phasing out licenses to produce would have on many authorized persons, it is critical to examine Health Canada's primary reason for choosing its contractor as the only lawful source. Health Canada has asserted on many occasions that this is due to the 1961 United Nations *Single Convention on Narcotic Drugs*. It claims that this treaty requires the government to assert a monopoly over the production and distribution of cannabis. If Health Canada is correct in this assessment of its international obligations, then the only available course of action would involve making improvements to its product and providing a variety of products to better meet the needs of authorized persons. However, the UN treaty is fraught with ambiguity. A careful examination of its terms shows that Health Canada is not legally required to maintain a monopoly over production. As the UN treaty is purportedly the barrier to constructing distribution options, it warrants a detailed discussion.

Although Health Canada does not need to own the cannabis, it may be required to become the sole purchaser of the product. Article 23 of the Single Convention refers to obligations such as the requirement for all cultivators of cannabis to deliver their total crops of cannabis to the agency for distribution.[42] In other words, even if Article 23 applies to medical cannabis, the thrust of the Article solely involves monitoring and control. To prevent diversion of medical cannabis into black markets, the Convention requires the government to purchase the cannabis from its licensed producers, and then allows the government to control wholesale, export, and import (but not retail). As noted in the Commentary of the Single Convention, it was anticipated that having the government offer "prompt payment, a good price and other favourable conditions to purchase"[43] would assist in preventing diversion into illicit markets. Therefore, Article 23 simply contemplates that the government control wholesale and international trade after offering its producers fair market value for the harvest. Article 23 cannot extinguish the producer's proprietary rights in the product. Our courts would require the Convention to have much clearer and explicit language before it would allow the Convention to extinguish vested property rights.

This said, we are concerned that Health Canada's vision of phasing out licenses to produce and of solely distributing the government's cannabis through Canadian pharmacies will result in even fewer authorized persons having legal access to a supply of medicinal cannabis. While we support the proposed distribution of medical cannabis through Canadian pharmacies, we call on the government to put seriously ill Canadians first and provide several legal options for authorized persons to obtain medicinal cannabis.

We fear that limiting legal access to one source will result in more people seeking illegal sources, despite having authorizations to possess. We already see, from our consultations, that very few people obtain their cannabis from the government's source. Limiting legal options even further will exacerbate this situation.

Action by the Canadian AIDS Society

The Canadian AIDS Society will continue to provide accurate and up-to-date information about the MMAR and about the legal options available for people to supply themselves with medical cannabis. We will also continue to advocate for changes to the MMAR to provide more legal options for sources of medical cannabis for authorized persons.

Recommendation

We strongly oppose Health Canada's vision to phase out licenses to produce. We recommend that Health Canada lift restrictions imposed on designated producers and allow them to grow for multiple authorized persons, and collectively with more than two

other designated producers. The cannabis production facilities could be regulated and monitored to ensure quality control.

v. Compassion Clubs

The "compassion club" or "cannabis club" concept developed in California in the 1990s. Various centres exist throughout Canada, although they remain an illegal source of cannabis. The existence of compassion clubs has largely depended upon the courage of dedicated individuals and the exercise of police discretion not to lay charges. Although there have been some raids, the prosecutions of clubs that follow certain guidelines have not succeeded to date. A few of the clubs have even managed to obtain a not-for-profit society status either in their province or with Industry Canada.

Compassion centres offer a range of strains and delivery systems, whereby patients discover the product which works best for them through a process of trial and error. Clubs in San Francisco, for example, offer various products and services such as a number of strains ranging from 5 to 60 varieties, vaporizers, peer counseling, edibles, tinctures, clones, hash and hash oil.[44]

For the purposes of this report, we conducted an informal survey of the practices of clubs across Canada to present a glimpse into the services they provide (see Table 3). Altogether, the clubs that responded to our questions served more than 6,450 people who use cannabis for medicinal purposes and offered a variety of services and options. In our consultation, 35.9% of respondents use compassion clubs as a source of medicinal cannabis. It is interesting to note that these centres serve the needs of more people than does the entire MMAR program, and the number only accounts for the centres that responded to our survey.

> *"Compassion club offers a safe environment and it provides medicinal marijuana which is not laced with some street drugs like, meth, speed, crack, etc. Buying from the streets. . . is very risky, personal safety wise, and product safety wise."*
>
> *"In Vancouver, they have tinctures, they have edible, they have non-alcoholic tinctures, alcoholic tinctures, they do sell vapourizers so there [are] alternatives there and that is part of the reason why I wanted to get a membership there because I want to quit smoking cigarettes and I want to quit smoking weed but I want to be able to have the THC."*
>
> *"I basically discovered there was a whole lot of money being made by someone, being sucked out of the community, with no accountability, no taxation and no thought for the people that he's affecting. So I am currently working with a number of groups to do a new cannabis club that will be member driven, not for profit, open, accountable, and responsive to the members it's suppose to serve."*
>
> —*Focus group participants*

Table 3. Summary of Services and Products Available in Canadian Compassion Clubs

Club	% of Members with HIV/AIDS	Allows Members to Smoke in Facility	Number of Strains	Vaporize Available	On-Site Peer Counseling	Edibles	Tinctures	Hash	Hash Oil	Clones for Sale
1	58	N	75	Y	N	Y	Y	Y	Y	Y
2	29	Y	50-70	Y	N	Y	Y	Y	Y	Y
3	15-20	N	3-11	N	Y	Y	Y	O	O	on order
4	3	O*	1-2	N	N	N	N	N	N	N
5	20-25	N	35 (5 daily)	Y	Y	Y	Y	Y	N	Y
6	60	N	25-30 (8-10 daily)	Y	Y	Y	Y	Y	O	O

*occasionally

This may reflect some of the barriers regarding access to the federal program, it may reflect an ideological preference for non-governmental agencies or community-based organizations, or it may reflect the fact that the centres provide an accessible, user-friendly and product-diverse environment.

In general, in order to become a member of a compassion club, an applicant must complete a registration form that includes their name, diagnosis and symptoms, as well as their physician's name, signature, and address. Clubs often contact doctors to verify the information prior to allowing membership. By signing the form, doctors declare that they have discussed the use of cannabis with their patient and that they will continue to monitor their condition. Membership is usually free. Some clubs have member orientation sessions to provide them with information about safe and effective use of cannabis, information on different strains, products and modes of ingestion, as well as to introduce them to the clubs' policies, procedures and its code of conduct. Members are usually required to sign an agreement to adhere to these policies.

As there are no standards for the operation of clubs, there are a variety of organizational structures, and some clubs are not accountable for their financial or other activities. The most established club in Canada, the British Columbia Compassion Club Society (BCCCS), has put forward a proposal for "Operational Standards for Distribution of Medicinal Cannabis".[45] Since then, the BCCCS and the Vancouver Island Compassion Society have broadened and expanded this document with the hope of setting basic voluntary standards for the safe operation of all compassion clubs in Canada: "Guidelines for the Community-Based Distribution of Medicinal Cannabis in Canada.[46] We would like to see operational standards for the clubs to ensure that the product they are providing is controlled for safety and quality, that the services they provide meet the needs of seriously ill Canadians, and that there is financial accountability so that they are not profiting at the expense of seriously ill Canadians.

Despite their existence and the good work they have done over the years, the legal status of compassion clubs remains unclear. Technically, they are illegal operations, although those who operate within certain guidelines have not yet been successfully prosecuted as they have been seen as providing a valuable service to the community. Some are also registered not-for-profit societies either within their province or federally. Philippe Lucas, Founder and Director of the Vancouver Island Compassion Society, speaks on compassion clubs and the role of community-based distribution of cannabis in Canada:

> **"**The community-based distribution of cannabis is a role that actually precedes the medical marijuana program. The Vancouver club just turned 8 this year, we are about to turn 6 this year. We were founded in 1999 as a non-profit society and I think that there is an incredible amount of unique knowledge, experience, and expertise that resides in the compassion clubs. Many of the problems that our federal program might have been better addressed by working more closely with these clubs… The elephant in the room is that these clubs exist, that they've got a good record of success, and that for the most part they have been an incredibly positive force in terms of allowing safer access to cannabis in Canada…. I believe that Canadians would be much better served by community-based distribution and production of cannabis, and community-based research as well."

Clubs operate within a harm reduction model by providing a safe environment, a safer source of cannabis than the black market, as well as alternatives to smoking. They also refer their members to other social services they may need. Many clubs work within the community they are located in. The Vancouver Island Compassion Society, for example, has a good relationship with their local police. After a community consultation, they established a policy of no smoking on the premises. They have done presentations at local AIDS and hepatitis C organizations, among others. They have done outreach and education to the local medical community and, over the last few years, nursing students from the local university have done practicum placements with them for credit.

The other aspect of this particular club has been their decision to produce their own cannabis, which allowed the club to gain control over the method of production and over the quality of the cannabis they

offered. Producing their own cannabis permitted them to offer the cannabis to their members at a lower cost. They established a production facility for a period of 18 months. In May 2004, however, despite their broad community consultations and open communications with police, the VICS production facility was raided by the RCMP. The court hearings are still taking place. Lifting restrictions on designated producers' licenses would enable clubs to follow this model and produce and control their own cannabis. Quality control of the product is essential. However, given the current legal limitations, most clubs deal with several underground growers.

Another person who is involved in a different compassion club accepted to be interviewed anonymously. When asked about how the club controlled the quality of the product produced by outsourced growers, this person had this to say:

> "Well the problem with … the climate that is created by the law as it is right now it makes it extremely difficult for these people to be open and transparent and even accountable to anyone and so it's only one person who is a volunteer of the club who actually has anything to do at all with our producers… We do have a few of them who are licensed with Health Canada but of course they are contravening their Health Canada license by also providing us with product. They are willing to do it because they understand the various barriers that people have and they are also limited in their ability to be able to produce and to make their product available. These are the limitations within the MMAR itself."

There is a lot of good will to provide seriously ill Canadians with a quality product, although the current prohibitory environment renders this difficult.

The model of methadone maintenance treatment delivery in Canada may serve as a potential model within which cannabis could be dispensed. In the methadone model, some physicians are allowed to prescribe methadone once they have received a Section 56 exemption under the Controlled Drugs and Substances Act. The actual dispensing of methadone is done in a variety of settings, including substance use treatment services, community-based health centres, private medical clinics, community pharmacies, hospital-based health clinics, HIV/AIDS services, mental health agencies and correctional facilities.[47] All staff involved in the dispensing of methadone through these various settings must be certified in a medication dispensing course offered through local pharmacies or community colleges. The methadone is ordered every few weeks by an exempted doctor and the prescriptions are sent to the pharmacy, which then delivers them to the centres where they are to be dispensed.[48] We see no reason why a similar model could not be adopted using compassion centres across Canada.

Unlike pharmacies, compassion clubs have the advantage of providing opportunities for social networking for its clients. Given that people with HIV/AIDS are often marginalized and isolated, the value of this type of support, known as "social capital", is immeasurable and contributes to greater health and quality of life. Compassion clubs often host social events and sometimes provide opportunities for volunteering. Governments can encourage social capital by facilitating the conditions that favour it.[49]

Action by the Canadian AIDS Society

The Canadian AIDS Society abides by community action principles of empowerment, community support, self-help, holistic approach, accountability, harm reduction and greater involvement of people living with HIV/AIDS[50]. As such, we favour a not-for-profit, community-based model of distribution of medicinal cannabis and of its related services. We have provided information to people living with HIV/AIDS about compassion clubs, both in terms of informing them of the fact that these clubs are not a legal source of medicinal cannabis, as well as where to find these clubs. We will continue to support such establishments and the work that they do and to advocate for their inclusion in a legal system of distribution of medicinal cannabis. We will continue to advocate for the establishments of operational standards of these centres, especially with regard to quality control of the cannabis they provide. We will also advocate for these clubs to adopt a model that holds them accountable for their activities. A not-for-profit charitable organization model would meet these needs. This said, we do not exclude other ways of distributing cannabis for medicinal purposes, for

example, the pharmacy distribution model proposed by Health Canada. We believe in providing options to people that best suit their needs. We will explore the possibility of supporting compassion centres through the process of obtaining the appropriate authorizations to be able to operate legally.

Recommendation

We recommend that the government authorize compassion clubs that meet operational standards and recognize them as legal dispensaries of medicinal cannabis.

vi. Safety and Quality of the Product

Safety of medicinal cannabis is an important consideration, especially for people living with HIV/AIDS who have compromised immune systems. Regardless of whether the cannabis is produced by the government or by the black market, it is essential that people living with HIV/AIDS not be exposed to contaminated cannabis. Health Canada has posted metal and biological testing results for their product on its web site, but without accompanying explanation for the raw data. It would be very helpful if Health Canada also provided a clear explanation for its conclusion that there are no outstanding safety issues relating to heavy metal and biological contamination in their cannabis.

According to Richard Viau, Director of Drug Analysis Service at Health Canada,

> "When buying from the black market, you do not know what you are getting… The situation with black market marihuana is in direct contrast to the legal pharmaceutical industry where there is government inspection, verification of testing and control is the norm and the product end user can have assurance that they are getting what they believe they are getting… The marihuana grown by [our licensed dealer] is produced under well defined conditions, in a controlled environment and in a very specific and well documented manner which is verified by Health Canada. Before it is distributed, the marihuana is tested for the presence of 28 metals, the presence of mould/fungus and aflotoxins and micotoxins (carcinogenic substances) which can be produced by mould or fungus. Last but not least, the marihuana is irradiated to ensure that it does not contain any viable mould spores. In addition to the above testing, the marihuana is tested to ensure that its THC content is within the range stated on the package. This ensures that recipients will receive a product with a consistent THC content. Some recipients have advised us that this is a very positive feature as compared to product bought from the black market where they had to readjust their dose with every purchase. For people who are living with a disease and whose immune system may be compromised, I would think they would prefer to receive a product which is grown under controlled conditions and which is fully tested rather than taking a chance with the unknown."

For a medical user, the operative concept is the product's effectiveness in relieving symptoms. The most significant problem presented by reliance upon the government's cannabis is the fact that the government only offers one strain of cannabis for diverse medical applications. There is a growing body of evidence suggesting that different cannabinoid ratios may have different therapeutic applications, which coheres with the subjective experience of many patients. However, there is a clear need to conduct clinical research into the question of strain-specific response and the interplay of the cannabinoids. Until this research is conducted, Health Canada's decision to release only one strain for distribution to authorized Canadians may not be a constitutionally adequate alternative to the diverse supply currently available to them through licenses to produce, or available to many patients through the vehicle of unauthorized compassion centres and within the black market. Some people who use cannabis for medicinal purposes also seek an organic product. Organic agriculture involves cultivating plants without the use of chemical fertilizers, pesticides or food additives. It prohibits the use of mineral fertilizers, synthetically compounded pesticides, growth regulators, antibiotics, hormones and genetic manipulation of plants.[51] The term 'organic' refers to products produced under a system that meets the organic agriculture standards as set by the Standards Council of Canada. For a product is certified organic, it must conform to specified requirements.[52] Gamma irradiation is prohibited under all organic standards internationally.

Many people who grow their own cannabis, or growers that supply compassion clubs, report that they grow organic cannabis. Of course, as these products are not inspected or regulated, there is no way to determine whether or not they meet the standards for organic certification. Two designated growers, Eric Nash and Wendy Little, who operate Island Harvest in British Columbia, did manage to get their medicinal cannabis certified as organic by the province of British Columbia. However, since they are restricted to grow for only one authorized person each under the MMAR, this certified organic cannabis is currently not available to other authorized persons.

While the cannabis grown under contract for the government reportedly meets the Good Agricultural Practices and Good Manufacturing Practices standards, it is not certified organic according to the standards established by the Standards Council of Canada. Since the cannabis produced for the government is gamma-irradiated, it does not meet the organic standards, as stated above. There is much public dispute over whether irradiating products poses any health risks or alters products in some way. Public concerns about food irradiation have been expressed in various settings. Whether food irradiation poses a problem or not, we feel that people should have a choice as to the products they ingest. An organic option is requested and needed for seriously ill Canadians who choose to use organic products. While we do not doubt that the cannabis produced for the government is safe, given that it is rigorously tested to ensure its safety, we do know that some medicinal cannabis users want an organic product. They also seek a variety of strains to meet their individual needs.

Recommendation

Once again, we recommend that Health Canada lift restrictions imposed on designated producers and allow them to grow for multiple authorized persons, and collectively with more than two other designated producers. The cannabis production facilities could be regulated and monitored to ensure quality control.

We recommend that Health Canada, under the Controlled Drugs and Substances Act, license Canadian laboratories to test medicinal cannabis that is grown by persons who hold an Authorization to Possess and/or a License to Produce through the MMAR.

vii. Cost of Cannabis for Medical Purposes

Cost is a significant barrier to access to medical cannabis for people living with HIV/AIDS. Some people report that their doctor has charged them to complete the medical declaration for their application to the federal medical cannabis program. Costs of any sort are a barrier for many people living with HIV/AIDS. There are currently no provisions for reimbursement, neither for the physician to complete the form nor for the patient who has to pay a doctor to do so.

As for the cost of cannabis, our consultations revealed that the average amount that medicinal users spent on cannabis per month was $242.69, ranging from $0.00 to $1500.00. When asked whether they can usually afford to buy enough cannabis to relieve their symptoms, 39.8% stated that they can sometimes afford enough cannabis, whereas 23% stated that they can never afford enough cannabis. This means that almost 70% of respondents are not able to afford enough cannabis for their medicinal needs.

In addition, 39% of respondents were not using cannabis for medicinal purposes. We wanted to hear from non-users so that we could determine whether they wanted to use cannabis for medicinal purposes but were experiencing barriers, or whether it was simply their choice not to use cannabis. Thirteen percent of non users mentioned that they cannot afford cannabis. The cost of cannabis is a barrier both for people who

> *"I run a debt. Thank god for my parents, really. Because I basically run in the hole every month. I'm just playing catch up so now when I run out of the Prairie Plant stuff, and I have a month to pay my bill, I'm not going to be able to. And they said I could not order any more until I paid that bill. So in probably 15 days I'm going to be back in my wheelchair."*
>
> —Focus group participant

currently use cannabis for medicinal purposes and for some people who want to use cannabis to manage their symptoms but cannot afford to.

Prohibition on cannabis has inflated its price. In 1964, Herbert Packer coined the term "crime tariff" to refer to the overly-inflated cost of illicit contraband.[53] In particular, the price of illicit drugs is grossly inflated to reflect the risk that suppliers assume in conducting an illegal business. The cultivation of plants is not a costly enterprise but the crime tariff has set the cost of black market cannabis at $200-$250/oz and $2,500-$3,000/lb, depending upon the location in Canada. Given this reality within the environment of cannabis prohibition, it is probably more cost-effective for medical users to produce their own cannabis, despite the initial capital expenditure for indoor grow equipment that could be in excess of $1000. For some people, self-sufficiency is an ideal situation. For many, cultivation is beyond their physical and financial means.

People who cannot produce their own cannabis have two choices under the MMAR: they can either designate a producer or purchase cannabis from the government. There are no data on the costs incurred by designating a producer, but the price of the government's cannabis has been set by Health Canada at $5/g and $150/oz, plus applicable taxes. The government has made its product more affordable than the black market. Compassion club prices vary somewhat. For example, some clubs charge $10/g and $196-$252/oz. The largest club in British Columbia is able to offer a wider range of products and prices with the cost ranging from $3-$9/ g ($84-$252/oz), with an average of $8/g. On occasion, clubs offer discounts and donations to their members. Since the supply network for compassion clubs is not integrated into a legal distribution system, their prices largely track the crime tariff prices.

Although the government product is generally less expensive than cannabis available on the black market, it is still priced at $150/oz. According to Richard Viau, Director, Drug Analysis Service at Health Canada and manager of the contract with the only current licensed dealer,

> "the cost of the marihuana obtained from Health Canada is made up of two components: production costs which include the growing and preparation, etc. of the product and the packaging and distribution costs. At $5/g, the Health Canada product is selling at about 1/2 to 1/3 of the black market price for marihuana (based on published police and other data)". [54]

According to Health Canada, about half of these costs are incurred to ship the product to authorized persons.[55]

If the restrictions on designated producers were lifted and experienced growers could grow on an economy of scale, the cost of medical cannabis would become considerably more affordable than it currently is. Affordability is a major issue for any person suffering from a debilitating illness. Among people with HIV/AIDS for whom unemployment or underemployment is a significant problem, the question of cost is even more important.[56]

There is no reason to believe that the development of cannabis as a pharmaceutical product will reduce the costs of this treatment option. Marinol®, a synthetic THC, was approved in 1985 and its cost still proves to be a problem for most patients (the majority of which are people living with HIV/AIDS). Currently, in the US, the cost of a single dose of Marinol® ranges between $4.00 and $8.00. The average cost ranges from $12.00 to $32.00 per day. The price of Marinol® for its most commonly used indication, anorexia in AIDS, is estimated at $200 per month. The person's out-of pocket expenses tend to be much less, however, due to reimbursement through public or private health insurance.[57]

The recent conditional approval of Sativex®, an oromucosal spray derived from extracts of the whole cannabis plant indicated for neuropathic pain in people with multiple sclerosis, confirms that including cannabis in the conventional pharmacopeia will not significantly reduce its costs. One vial of Sativex® costs $158 for 51 sprays. It is estimated that the average user will use 5 sprays/day at a cost of approximately $15.00/day or approximately $450/month. This monthly amount is significantly more than the average amount of about $250/month spent by the

people living with HIV/AIDS. There is no reason to believe that the current and future development of cannabis-based medicines by pharmaceutical companies will reduce the current costs of cannabis as therapy.

The only cost advantage of conventional pharmaceuticals is that many of these drugs have their costs covered by provincial and other drug plans. Currently, the costs of cannabis produced by the government, by authorized persons or by designated producers are not covered. However, as mentioned earlier, a recent decision of the government in the 2005 budget has made the costs of the government's cannabis, and the designated producers' cannabis, an eligible expense under the Medical Expense Tax Credit. This will assist in partially defraying the costs of this therapy.[58]

Although the federal government dictates the basic parameters of universal health care through the *Canada Health Act*, the provincial governments are responsible for determining which drugs and services will be funded. Every province has a formulary which lists drugs which qualify for reimbursement. Medical cannabis is not currently found on any provincial formulary. To establish some uniformity and constituency in provincial drug formularies, the Common Drug Review (CDR) was established. All publicly-funded federal/provincial/territorial drug plans are participating in this venture, with the exception of Quebec. The CDR process can only begin once Health Canada approves a new drug for sale in Canada, through the granting of a Notice of Compliance (NOC) or a Notice of Compliance with Conditions (NOC/c). Upon receiving Health Canada approval, the official submission of a drug to the CDR can be made either by the drug manufacturer, a particular drug plan, or by the Advisory Committee on Pharmaceuticals (ACP), which is an independent body of experts that provides advice to the CDR.

The review considers many factors, primarily grouped into two areas: (1) the recorded safety and efficacy of the drug; and (2) the pharma-economic impact of adding the drug to the formularies. The CDR, however, simply makes recommendations. Because of the financial burdens that are involved in drug funding, the final decision to add a drug to a formulary rests with each individual drug plan Thus, even if medical cannabis was recommended by the CDR, there would still be need for the individual drug plans to accept the recommendation.

The Common Drug Review would be the most efficient vehicle for getting medical cannabis reimbursed for all medical users who are eligible for drug coverage. However, the process would have to be initiated by the manufacturer, in this case the government's licensed dealer, and would first require that Health Canada grant cannabis a NOC or NOC/c. It is not clear how effective a CDR review would be, considering that last year the Canadian Treatment Action Council (CTAC) made a public complaint that the CDR has moved too slowly in considering requests to add new HIV medications to Canadian formularies.[59]

Some provincial drug plans consider reimbursement for drugs that are not listed on their formularies. These independent request mechanisms are initiated by individuals and their physician. In particular, there are some provincial programs which are specifically targeted towards facilitating access to non-formulary drugs for HIV/AIDS patients. For example, in Ontario the Facilitated Access Program provides patients and physicians with an expedited process for obtaining reimbursement for non-formulary drugs. The list of drugs eligible for reimbursement through the Facilitated Access Program includes "nutrition products". If funding is available for nutritional products, it's conceivable that a drug targeted at appetite stimulation, such as cannabis, would be eligible for similar coverage.

The current obstacle for extending both formulary and special access funding to medical cannabis is that these provincial programs require that the drug be approved and that it have a Notice of Compliance (NOC), a Notice of Compliance with Conditions (NOC/C) or a Drug Identification Number (DIN).

Meanwhile, one community organization, Toronto People With AIDS Foundation (TPWAF), has been pro-active in establishing a system whereby people can be reimbursed for their medical cannabis. As Laurie Edmiston, formerly Executive Director of Toronto PWA Foundation, states: "It really took a

few years to establish this program. It started with a position statement supporting people living with HIV/AIDS' treatment choices, including medicinal marijuana. Part of our long-standing Financial Assistance Fund covered expenses related to treatment choices that are not covered in other health plans, such as vitamins. Medicinal marijuana obviously fit there."

In this model, the Board of Directors of TPWAF is responsible for policies and for the organization's budget, which includes approving how much money goes into the financial assistance fund. The staff determines the criteria for the various Financial Assistance Funds and administers its implementation. This included requiring a receipt from a compassion club and a note from a health care practitioner indicating that their patient is using medical cannabis with their knowledge. At first physicians were reluctant to provide letters and compassion clubs were reluctant to provide receipts. They did work it out and the program was established.

The Canadian AIDS Society would like to see such programs be established by more of its member organizations and realizes that AIDS service organizations have limited resources. It is clear that costs are a significant barrier to access to cannabis for many people living with HIV/AIDS, and unless progress is made toward getting cannabis approved as a drug, with a Notice of Compliance, reimbursement options will remain severely limited.

Action by the Canadian AIDS Society

The Canadian AIDS Society, in collaboration with CTAC and other national partners, will explore the option of initiating the process for formulary consideration for medicinal cannabis by addressing the Advisory Committee on Pharmaceuticals and advocating for them to initiate Common Drug Review proceedings. The Canadian AIDS Society will encourage its member organization that do not already do so to explore the possibility of offering a financial assistance program for medicinal cannabis, within the confines of their limited resources, at least until such a time as other reimbursement options are available to people living with HIV/AIDS.

Recommendation

Once again, we call on the government and the medical and scientific communities to take the necessary measures to see to it that cannabis is considered for drug approval, so that it can eventually be considered for reimbursement from available drug plans. Until such a time, consideration must be given to other mechanisms for reimbursement of the costs of medical cannabis for seriously ill Canadians.

1 This information was obtained through an Access to Information request #A-2004-00516 for the total yearly cost of the Office of Cannabis Medical Access since 1999, broken down by year: 1999-2000: $118,808.28; 2000-2001: $580,540.34; 2001-2002: $4,200,240.58; 2002-2003: $3,515,091.93; 2003-2004: $2,403,739.00; 2004-2005: $264,014.65 (up until 09/20/05); for a total of $11,082,434, plus $5.7 million for the contract with Prairie Plant Systems to produce cannabis, plus $7.5 million for the Medical Marihuana Research Strategy. These costs add up to $24,282,434.

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7 See section 4B – The Birth of the *Marihuana Medical Access Regulations* – for more details.

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11 Libby Davies MP and Senator Pierre Claude Nolin. Letters to Sheila Fraser, Auditor General of Canada, and to the Hon. Ujjal Dosanjh, Minister of Health, December 2, 2004.

12 Key stakeholders include seriously ill Canadians and the organizations that represent them, law enforcers, medical professionals (physicians, pharmacists, nurses), researchers, and compassion clubs.

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17 Spilker B. Guide to Clinical Trials. New York: Raven Press; 1991, 14.

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21 Information Sheet of Canadian Medical Protective Association (CMPA) dated October 2001 - This letter was part of the court record in *R. v. Hitzig* – Letter on file with legal consultant.

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25 Ibid, p.9.

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Future of Medical Cannabis in Canada

A. Herbal Cannabis and the Development of Cannabis-Based Pharmaceuticals

Cannabis is a plant that would normally be considered a natural health product were it not for its designation as a controlled substance. It remains to be seen how access to cannabis for medical purposes will continue to develop in Canada and around the world. The renewed interest in cannabis as a therapy comes at a time when the public's confidence in synthetic medicines produced by large pharmaceutical companies has been shaken by recalls and warnings issued about a few popular medications, upon discovering adverse side effects either not disclosed by drug sponsors, or not discovered during the course of the clinical trial process. Although the reputation of cannabis has been tarnished by officials in the past, many people welcome the reintroduction of a plant medicine used for centuries by different cultures.

Pharmaceutical companies have shown an interest in developing cannabis-based medicine. As expected, the focus of research and development has been on synthetic derivatives, and in the next decade one should expect to see a variety of synthetic cannabis-based medicines on the market. In 2005, a report was issued assessing the market potential of cannabis-based medicines which concluded that cannaniboid medicines will achieve "blockbuster" status in the pharmaceutical markets in the next five years.[1] Within the coming year, it is expected that a number of new cannabinoid medicines will receive drug approval. In the near future, there will be flood of new cannabinoid medicines; however, this process is just beginning.

The flooding of the market with cannabis-based medicines will take a considerable amount of time. Regardless of the availability of pharmaceutical products derived from cannabis, some seriously ill Canadians will continue to opt for herbal cannabis. Improvements must be made to the MMAR program and research should be commenced to better our understanding of herbal cannabis and its medicinal properties, and to address the critical question of whether or not herbal cannabis, in a smoked or vaporized form, would be a superior medicine to those being feverishly developed by the industry.

B. The Proposed Pharmacy Distribution

The government's plan to distribute medical cannabis through Canadian pharmacies was presented to the focus group participants for their reaction. For the most part, they were quite receptive to the possibility of obtaining medical cannabis through a pharmacy, like their other medications. The convenience of a one-stop shop appealed to many participants, as they already have to go to a pharmacy to pick up their other medications. Costs were a concern. Some mentioned that they would support pharmacy distribution if the cost of the product was reasonable, or if the costs were covered. The concern over the quality and variety of the product was also clear. People wanted a variety of strains and a fresh product, preferably in whole buds. Some resisted the idea of pharmacy distribution if it meant that only the government product would be available. Finally, there were those who were not receptive to a pharmacy distribution of medical cannabis at all. Some wanted to continue growing their own cannabis, especially if there was no financial compensation for the product that would be available in pharmacies. Many prefered the compassion club distribution model and had concerns about the knowledge of cannabis use being lost if left in the hands of pharmacists. Some questioned the quality of the government product and the lack of choice in strains, and stated that they would continue to access cannabis through other sources. The most resistance to the pharmacy distribution model was heard from participants in British Columbia. One group suggested a triad of health professionals

"As far as the pharmacy issue goes, . . . my biggest problem with this whole idea is that they want to stop us from producing it on our own and they are not providing any means for us to pay for this. It's all about the dollar. For me, I cannot afford to buy the amount of marijuana that I smoke. . . The thought of going into the pharmacy, the idea of phasing out growing our own and strictly distribution through pharmacy without providing anyway to pay for that, it's ridiculous!"

"Ideally, for one-stop shopping, what you want to do, is have a pharmacist, a cannabinist, and a nutritionist so you get your supplements, and you get it all in one stop. They're all in one file and all three people, all three specialists can look at your file, see how everything interacts. It also minimizes disclosure."

"The pharmacy access is definitely a great idea and have it covered under the exceptional drug status, the same as the cocktails or narcotics or what not. If they feel the need to control it that way, well they need to make sure that it's accessible as well. Right now it's not accessible. . . It would be nice it I could just walk in there with a prescription, like my nabilone. . . [It would be] nice to know that there's a regular supply there. It would make life so much easier and stress free because it is such a necessity, especially for my life."

"I don't like that idea. I like getting it from compassion clubs only. . . I think that compassion clubs should be allowed to be licensed for the purpose of cultivation and distribution of cannabis. I feel very strongly about that."

—Focus group participants

would be useful in assisting them with the medications and health issues: a pharmacist, a "cannabist", and a nutritionist.

i. Interview with Health Canada

Health Canada provided their insight about the proposed pharmacy distribution. Beth Pieterson, Director General of the Drug Strategy and Controlled Substances Program, said "hopefully that is what we are going to be focusing our efforts on, just look at distribution in general, not just pharmacies but other better ways to distribute the marijuana." Health Canada's plan is to have licensed dealers deliver directly to the pharmacies. When asked about the price, Ms. Pieterson mentioned that this will be up to the provinces to determine: "The pharmacist …would be responsible to order the amount and keep it and they would make the decision of how much they keep on site".

Regarding the information that pharmacists would provide to medical cannabis users, Ms. Pieterson stated that Health Canada was creating a training program for pharmacists to educate patients directly on how to use cannabis. She also mentioned that organizations such as the Canadian AIDS Society can assist Health Canada in informing medical cannabis users about the pharmacy distribution pilot project.

ii. Interview with a Pharmacist

According to Dr. Glenda MacDonald, a doctor of pharmacy, pharmacists are in a good position to provide information regarding the medical use of cannabis to people who come to them:

> "Pharmacists are far more comfortable [than physicians] with [providing information] because our primary concern is to make sure it works and it doesn't cause any problems. Safety and efficacy are the issues. In terms of safety, the substance has been around for thousands of years as you well know, and there is an increasing amount of evidence from well conducted trials that it is a safe product… people do need help for things like this and to have a health care professional that

> is accessible, pharmacists are very accessible to people."

Another advantage that is seen with the pharmacy distribution is the pharmacist's access to information about other medications that people are taking. They could therefore counsel people on potential drug interactions. "And in terms of drug interactions, there are no major ones that would be a concern with antiretrovirals." added Dr. MacDonald.

She also added the importance of monitoring people to ensure their medications are working properly. She compared it to other medications and had concerns about the fact that cannabis is not yet treated like any other medication. Perhaps this will be built into the pharmacy distribution pilot project Health Canada plans on launching.

> "Say with the other medications, if somebody goes in and they have high blood pressure, they get treatment, their medication gets paid for, all the tests that are associated with determining whether it is being effective or not are all covered by our health care system. They get information on side effects from a pharmacist when they're getting their prescription filled, they're going back to make sure that the disposition for a follow up visit to make sure that it's effective, all those things. That doesn't apply here… nobody is saying so how is it working, how much are you using, what route are you using, how long until you get your peak effect, does it last long enough, how about trying this. That is what my approach to medication is, as a pharmacist, to make sure that someone is using it appropriately and that it's working and that it's not causing problems. That whole part of it is left out of it."

She also commented on costs: "I think that it's really important that there be some mechanism for reimbursement. I think that's a huge barrier."

iii. Will pharmacy distribution work?

During our consultations, we heard support for the distribution of medical cannabis through pharmacies, on the condition that there would be a selection of fresh products, with various strains of different potencies, and reimbursement for the costs, like other medications. The convenience of one-stop shopping is enticing to people. Pharmacists are also receptive to dispensing medicinal cannabis and providing information on the use of cannabis for medical purposes, as well as its potential interactions with their other medications. We welcome the decentralization of the distribution of medical cannabis and believe that providing cannabis in pharmacies would facilitate access for seriously ill Canadians, especially in smaller communities.

For the pharmacy distribution model to work, there will need to be a selection of strains and potencies of cannabis to suit the different medical needs of authorized persons. To achieve this, the government must lift restrictions on the production of cannabis for medical purposes.

As mentioned earlier in the report, cannabis in its herbal form must be considered for a NOC/c, approved as a drug and be eligible for coverage under medical insurance plans for people to buy into a pharmacy distribution model.

We have seen from the Netherlands' experience that making medical cannabis available in pharmacies may not be an answer for people. The Netherlands made two strains of medical cannabis available in their pharmacies a few years ago, and the uptake has not been as was expected. Their pharmacies reported sitting on stock piles of medical cannabis and their Minister of Health reported significant financial losses for the program. The price of the products available in pharmacies was greater than the price of cannabis available in coffee shops. Coffee shops also offer a wide variety of products.[2]

The Canadian government's plan to distribute medical cannabis through pharmacies has yet to manifest and has been progressing slowly. It will be interesting to see how this vision will be implemented and how authorized persons will respond to it. The Canadian AIDS Society will support this effort and inform its membership and stakeholders of its developments. We will also continue to advocate for alternative models of distribution for medical cannabis in Canada.

C. Exploring Other Models of Distribution

i. Proposed Community Garden

During our consultations, people proposed an interesting model for the production and distribution of medicinal cannabis. They suggested a community garden where medicinal cannabis would be cultivated 'by the people, for the people', in a co-operative structure where the money made would be used to operate the garden and employ staff. We favour the community-based production of cannabis for medicinal purposes, especially if the model includes the participation of people living with HIV/AIDS.

When asked about the government's proposed pharmacy distribution model, Beth Pieterson, Director General of the Drug Strategy and Controlled Substances Program, said "hopefully that is what we are going to be focusing our efforts on, just look at distribution in general, not just pharmacies but other better ways to distribute the marijuana." If Health Canada is receptive to considering other models, it is then important to provide them with community-based input into the next developments. The Canadian AIDS Society will continue to put the community's suggestions forward for consideration.

"Our dream is to have people with HIV and AIDS supply their own medicine."

"Yeah, a nice community farm where we all pitch in."

"My dream would be for Health Canada to help us along, to get us some funding so that we can get these little co-ops going for ourselves... But everybody comes together and contributes."

"That's it. Exactly. A collective."

"If it's a non-profit society. That's my vision."

"Sell our own pot and half of that money goes to the workload of the people to be employed... give them a job... they could all be there and work together and whatever money is being put back in, it goes to the board to decide how to distribute that money."

—Focus group participants

D. Cannabis as a Complementary Therapy

Since cannabis is a plant, which would normally be considered a natural health product and a complementary therapy were it not for its classification as a controlled substance, we present the following information to explore all aspects of the complexities associated with cannabis as a therapy.

i. Use of Complementary Therapies by People Living with HIV/AIDS

The use of cannabis as part of their therapy is consistent with the increasing trend for people living with HIV/AIDS to make use of complementary/alternative medicines. A 2001 report by the Canadian HIV/AIDS Legal Network outlined the increased reliance upon, and increasing costs of, complementary/alternative medicines[3] On the related issue of the cost of alternative and complementary health care for persons living with HIV/AIDS, the following statements were made:

- A 1995 study by CRIT/Canadian AIDS Society surveyed 200 people with HIV/AIDS in Toronto, and found that, on average, they spent 10-20% of their incomes on complementary therapies.[4]
- The crucial question is the extent to which public health insurance schemes should cover complementary/alternative therapies.[5]

Medicinal cannabis use by persons living with HIV/AIDS bears much in common with this community's use of complementary medicine. Beyond serving the interests of autonomy and choice in turning to complementary medicines, patients who use cannabis have been shown to have achieved better adherence to their conventional drug regimen. Although for many patients the use of cannabis is an integral part of their treatment regimen, the cost of this complementary medicine is not covered by any provincial drug plan.

There are many reasons for patients to turn to non-conventional treatment options and for people living with HIV/AIDS, the most common reasons for reliance upon these alternative options are:

- to take active control over one's own health care;
- to boost immune function;
- to lower viral load and prevent, delay, or treat symptoms of HIV disease progression or opportunistic infections;
- to help with side effects of conventional therapy (antiretroviral drugs and treatments for opportunistic infections), which facilitates adherence to a prescribed drug regimen;
- to help relieve stress, depression and fatigue, and improve general well-being.[6]

In addition, patients turn to complementary/alternative medicines with great regularity as an exercise in autonomy and self-determination. Most medical interventions are dictated by physicians and patients have little control over the process. With alternative medicines, there may be no need for physician intervention and this freedom to choose can be empowering for patients.

Many people with HIV/AIDS who use complementary and/or alternative therapies express the view that when they take an active role in their treatment regime, by educating themselves and seeking out alternative therapies, they are empowered and reclaim the control in their lives they feel they have lost as a result of acquiring HIV and of the social and other barriers that people with HIV/AIDS often experience. The following personal narratives are examples of the proactive attitude current among many people with HIV/AIDS:

- "With this disease, you have to do it for yourself. You have to be your own doctor. There is so much information out there. You can't count on somebody to get it all for you. Especially when it doesn't matter to them. And with alternatives, so many people don't even bother to learn about them. So that's one thing. You really have to become your own doctor with AIDS."
- "I see truth in alternative therapies. They're everything with AIDS. They're an alternative to giving in and a way to fight back. The best defence we have is to stay alive."[7]

The use of cannabis fits comfortably within this empowering paradigm of complementary/alternative medicine. Despite the pulmonary complications associated with smoking, people living with HIV/AIDS welcome delivery systems that do not involve pills, which are often difficult to "keep down" during waves of nausea. As one commentator notes, "no one could explain how someone with nausea and vomiting was supposed to hold down a pill the size of a bath oil bead."[8] People appreciated the opportunity to try an alternative, herbal product and they also appreciate the self-titration (i.e. dose control) aspects of smoking. Such a quest for self-determination and autonomy is consistent with the nature of the section 7 rights under the Charter of Rights, which has been characterized as the right to make fundamental personal decisions (i.e. the choice of medical treatment) without undue state interference.

ii. The Status of Naturopathic Doctors

Allopathic doctors do not normally deal with herbal medicines. Their training consists mainly of prescribing pharmaceutical products that have gone through the regulatory drug review process. They know and understand this system and trust its scientific rigor. Naturopathic doctors, on the other hand, have experience in dealing with complementary and alternative therapies, including herbal remedies, and

> *"When Canadians are telling Commissioner Romanow that they want to take charge of their health care, let them take charge of their health care. Let's provide them with the resources to ensure safety and low risk products, and the information to make an informed choice. . . we're for informed choice, which means you have to provide the public with all the information on both sides and let them make a decision. If they have chosen to make that decision, you have to support them."*
>
> *—Sean O'Reilly, Executive Director of the Canadian Association of Naturopathic Doctors*

may be in a better position to assist people who use cannabis for medicinal purposes. This discipline is gaining recognition across Canada.

Naturopathic doctors are not yet recognized in all provinces. According to Sean O'Reilly, Executive Director of the Canadian Association of Naturopathic Doctors, there are currently regulations in four provinces: Ontario, BC, Manitoba and Saskatchewan. Alberta's regulations are in the final process stage and should be ready for the spring of March 2006. "We are moving forward in all the other provinces and territories toward regulations because we feel that it's very important for public safety. There are actually about 1030 licensed naturopathic doctors across the country." she states. Naturopathic doctors have a minimum training of three years of pre-med sciences, and then attend a four year full time program at an accredited school for naturopathic medicine. There are five schools in North America. They cover all the sciences and particular naturopathic modalities which include botanicals, nutrition, lifestyle counselling, acupuncture, Asian or traditional Chinese medicine and homeopathy. They are the general practitioners of the complimentary and alternative medicines field. The term 'complimentary' is favoured over the term 'alternative', as naturopathic doctors work in compliment with other disciplines.

Naturopathic doctors have been very involved in the development of the natural health products (NHP) regulations. They do not, however, have access to natural health products under Schedule F of the regulations, which lists controlled substances. Cannabis is currently included in Schedule F. Ms. O'Reilly adds:

> "[Naturopathic doctors] want access to those NHPs that they have the education, training and experience to work with that are presently on controlled schedules. One of the things that we have suggested is perhaps a separate schedule of those substances, available only to regulated health care professionals such as NDs. Medicinal marijuana would come into that. They would like to be able to refer their patients to compassion clubs or to other areas or to whatever the government designates as an acceptable distribution centre. There is a concern of the quality of the product."

Naturopathic doctors would like to be able to sign the application forms for the federal medical cannabis program: however, they are not yet regulated across the country. Once that has been accomplished, there may be a change. According to Ms. O'Reilly, it comes down to access for the patient. If their practitioner of choice is denied the authority to sign the applications, then people are being denied access to what they have chosen as their health care option. The Romanow Commission[9] made it very clear that Canadians want to take responsibility for their own health care. They want access to the practitioner of their choice.

Naturopathic doctors were very supportive of the development of the natural health products regulations. They are in favour of labelling products to include information regarding dosage, contraindications, and other relevant information about the product. They also want quality control to meet Good Manufacturing Practices. We trust that Health Canada will revisit the MMAR to provide authority to naturopathic doctors to sign application forms to the federal medical cannabis program once they have achieved official recognition across Canada.

iii. Cannabis as a Natural Health Product

Herbal cannabis appears to have far more in common with a natural health product than a conventional pharmaceutical. As of 2004, with the enactment of the *Natural Health Products Regulations (NHPR)*[10] under the *Food and Drug Act*, a new regulatory regime was established for natural health products. Many activists have claimed that access to medicinal cannabis would be enhanced by moving cannabis into this product directory. There is no doubt that a whole-plant medicine is commonly considered a natural health product and not a pharmaceutical medicine. There is also little doubt that the classification of cannabis as a natural health product would facilitate easier access to the drug, considering that natural health products are available over-the-counter without prescription. The drug approval process for NHP classification is also less rigorous than the NOC approval process for pharmaceuticals, which is gov-

erned by the *Food and Drug Regulations*. On the other hand, given that eligibility for drug formularies is contingent upon NOC status, there is less likelihood of a natural health product being considered for drug coverage. Indeed, presently, natural health products are not currently listed on any drug formularies, and there is great debate as to whether they will appear on these lists in the future.

Overall, there would be both practical and symbolic value in reclassifying cannabis as a NHP; however, the fact that NHPs do not require a prescription for use undercuts the possibility of the government considering such a reclassification. Due to the illicit nature of cannabis and its psychoactive potential, there is little chance that the government would deem it appropriate to reclassify cannabis as a drug subject to less rigorous control with over-the-counter access. In this vein, it is not surprising that the NHPR explicitly excludes controlled substances from NHP eligibility, a fact which poses significant legislative obstacles to any efforts at reclassification.

Essentially, before the NHPR, natural health products were either classified as "drugs" (with a NOC) or were wholly unregulated. Unregulated substances present the perception of risk to consumers, and the goal of regulation involved mitigating this uncertainty in an attempt to boost consumer confidence. As for those substances that were formally NOC "drugs" (with drug identification numbers or DIN), the prospect of NHP classification was an enticing possibility for manufacturers, given the easier access to over-the-counter sales. In both circumstances, these regulations were drafted to respond to a booming industry, as reflected by the acknowledgment in the NHRP Regulatory Impact Statement that: "recent surveys have shown that more than one-half of Canadian consumers regularly take vitamins and minerals, herbal products, homeopathic medicines and the like, products that have come to be known as natural health products (NHPs)."

Thus, the mandate of the NHPR involves the regulation of products that consumers can select and use themselves without the need to consult a health care provider and obtain a prescription. In fact, the NHPR is filled with references to this notion of "self-care," and section 2(2) clearly precludes any substance listed in Schedule F of the *Food and Drug Regulations* (i.e. prescription drugs) from being considered as a natural health product. Therefore, medical cannabis would not appear to be an ideal candidate for NHP status, since the hesitation concerning its safety and efficacy ensures the inevitability of its designation as a prescription drug. However, the use of medical cannabis by people living with HIV/AIDS fits perfectly within the "self-care" paradigm of the NHPR.

Although it may be possible, and desirable, to pursue a NHP classification for cannabis, it is essential to note that the NHPR explicitly excludes illicit substances under Schedules I to V of the *Controlled Drugs and Substances Act* from its regime (cannabis is in Schedule II). That being said, the NHPR does allow some particular substances that are listed in Schedule VI of the CDSA to be considered as natural health products (whereupon they are regulated by both the NHPR and the CDSA). This list includes: benzylmethylketone, ephedrine, ergometrine, ergotamine, lysergic acid, and pseudoephedrine. It is unclear what criteria were employed to include these illicit drugs in the NHPR, but at first glance, it seems arbitrary, or at least confusing, to exclude cannabis and include lysergic acid and ephedrine, in view of concerns over consumer safety.[11] If the NHPD criteria for the inclusion and exclusion are arbitrary, it may be vulnerable to constitutional challenge, and a claim that medical cannabis should be considered for NHP designation may be successful.

Despite the benefits of reclassifying cannabis as a natural health product, it would require extensive advocacy with an uncertain result. The government would likely be resistant to these efforts, as such reclassification would undermine the criminal prohibition of cannabis by suggesting that it is a harmless substance, and it would surely cite security and diversion concerns of over-the-counter accessibility.

Although the reclassification of cannabis as a natural health product does leave the impression that the product is relatively harmless, it must be recognized that NHPs can have adverse health consequences in certain circumstances, especially for people living with HIV/AIDS. The Canadian HIV/AIDS Legal Network noted some problems with the use of some

natural health products by people living with HIV/AIDS, such as unknown adverse interactions between NHPs and other medications or NHPs.[12]

Whether cannabis is governed by the *Natural Health Product Regulations* or the *Food and Drug Regulations*, the need to conduct clinical research remains. Cannabis may be a relatively harmless substance, but the unique context of treating a disease of the immune system demands careful study to ensure that adverse effects are not generated by the interaction of this plant with antiretroviral drug regimens.

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2 DW-World.de. Dutch Prefer Cannabis Cafes to Pharmacies, February 7, 2005. Available from: <www.dw-world.de/dw/article/0,1564,1480510,00.html>.

3 Canadian HIV/AIDS Legal Network. Complementary/Alternative Health Care and HIV/AIDS: Legal, Ethical & Policy Issues in Regulation. Ottawa: Canadian HIV/AIDS Legal Network; 2001, 35.

4 Canadian HIV/AIDS Legal Network. Complementary/Alternative Health Care and HIV/AIDS: Legal, Ethical & Policy Issues in Regulation. Ottawa: Canadian HIV/AIDS Legal Network; 2001.

5 *Ibid.* at 59.

6 *Ibid*., 16.

7 *Ibid*., 16-7.

8 Werner C. Medical Marijuana and the AIDS crisis. In Russo E, editor. Cannabis Therapeutics in HIV/AIDS. New York: Haworth Press Inc; 2001, 26.

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12 Canadian HIV/AIDS Legal Network. Complementary/Alternative Health Care and HIV/AIDS: Legal, Ethical & Policy Issues in Regulation. Ottawa: Canadian HIV/AIDS Legal Network; 2001, 32-33.

Conclusion and Recommendations

Canada has been a frontrunner in enabling legal access to herbal cannabis for medical purposes. As such, the *Marihuana Medical Access Regulations* are a work in progress and there are still many challenges to address within the federal medical cannabis program. The Canadian AIDS Society believes that medical cannabis should be readily available to all seriously ill Canadians upon a doctor's prescription, and that people should be able to choose among a variety of high-quality, standardized products through different modes of delivery, including in herbal form, and get reimbursed for the costs. Regrettably, we doubt this ideal will ever be achieved so long as the government maintains the criminal prohibition of cannabis use. The Canadian AIDS Society will continue to push for changes to improve access to cannabis for medicinal purposes for seriously ill Canadians who choose to use it as part of their therapy. Canadians should not have to break the law to access the therapy of their choice.

It must be remembered that the creation and amendment of the MMAR, which provide the framework for legal access to cannabis for medical purposes, would not have occurred but for the looming presence of judicial review. The creation of the federal medical cannabis program was imposed on Health Canada by the courts, and it may be challenging to secure necessary reform of the MMAR without the fear of litigation. It is not suggested that litigation is the only vehicle to achieve necessary law reform. Litigation is a very crude instrument for the formulation of public policy. It may be that the piecemeal and fragmented nature of litigation makes the process unsuitable for achieving effective and meaningful health policy. Another shortcoming of using litigation as the tool to remodel the MMAR is the reluctance of Canadian courts to develop wide-ranging structural injunctions and related remedies to ensure that the affected government bodies will take the necessary steps to abide by a ruling under the constitution. Constitutional demands from a court can be thwarted by poor or limited implementation. Negotiation and discussion with the government may be a more effective vehicle for proposed reforms to the MMAR. This dialogue could take place in a forum such as a Stakeholder Advisory Committee on Medical Cannabis. The Canadian AIDS Society remains committed to participating in this process. In this document, we offer some of our future actions as well as recommendations to be considered. This is our call to action to all key stakeholders. We must, as a collective, find a way to address the barriers that prevent seriously ill Canadians from having access to medicinal cannabis without fear of criminal prosecution, as is their right, and if it is their informed choice.

A. Summary of Recommendations

"Our Right"

1. **Need for Evaluation and Accountability of Federal Medical Cannabis Program**

   - We, the Canadian AIDS Society, recommend that the Auditor General conduct a performance audit of all aspects of the current federal medical cannabis program, including the Health Canada's Marihuana Medical Access Division and the contract with the current licensed dealer which produces cannabis for the government, to ensure that resources are adequately allocated to address the needs of seriously ill Canadians.

2. **Need to Be Included in the Policy Dialogue**

   - We recommend that the government re-establish a Stakeholder Advisory Committee on Medical Cannabis to provide a forum for key stakeholders to exchange information and provide ongoing input into the federal medical cannabis program and the policies, regulations and legislation that govern it.

3. Need to Be Protected from Criminal Prosecution

a. Lack of Awareness and Misinformation about the Federal Medical Cannabis Program

- We will continue to raise awareness about the federal medical cannabis program so that seriously ill Canadians who use or want to use cannabis for medical purposes can apply and be protected from criminal prosecution. We remain committed to disseminating accurate and up-to-date information about the federal medical cannabis program and the *Marihuana Medical Access Regulations* to people living with HIV/AIDS across Canada, and to building the capacity of our member organizations to respond to information request and assist people living with HIV/AIDS with the application process.

- We recommend that Health Canada and organizations such as the Multiple Sclerosis Society, the Arthritis Society, the Canadian Cancer Society and others disseminate accurate and up-to-date information about the federal medical cannabis program and the *Marihuana Medical Access Regulations* to the people they serve, and that they build the capacity of their member organizations, if this applies, to respond to information requests and to assist them with the application process. We are open to collaborating on these efforts, within the confines of available resources.

b. Federal Medical Cannabis Program's Application and Renewal Process

- We recommend that Health Canada evaluate its resource needs to ensure that applications and renewals are processed in a timely manner to avoid gaps in a person's legal authority to possess and produce cannabis.

- We recommend that Health Canada address delays in the renewal of Authorizations to Possess and Licenses to Produce by providing an acknowledgement of receipt of the renewal application, which could temporarily extend the authorization period until such a time as a new authorization and license are issued.

c. Reluctance of Physicians to Participate in the Program

- We have prepared a series of fact sheets[1] on the medicinal use of cannabis, which includes an information sheet that patients can bring to their physicians. It includes information about the amendments to the MMAR, and practical information about cannabis use, which may make physicians more comfortable supporting a patient's application. It also includes information about the Release Form for Medical Practitioners from the Canadian Medical Protective Association.

- We recommend that researchers conduct a survey of physicians to obtain information about their attitudes toward the use of cannabis for medical purposes, as well as to assess their knowledge of the medical applications of cannabis in the treatment and symptom management of HIV/AIDS. This type of research should be solicited through the CIHR Medical Marijuana Research Program or other funding agencies. Once this information is available, a continuing education module can be developed to provide proper training to physicians about the use of cannabis for medical purposes.

- We recommend that, as part of a survey of physicians about their attitudes and knowledge related to the medical use of cannabis, physicians be asked about their willingness to be included on a referral list for patients seeking physicians who support applications to the federal medical cannabis program.

- We will explore the possibility of developing and managing for a referral list for people living with HIV/AIDS seeking physicians who, in the appropriate clinical circumstances, are willing to sign applications to the federal medical cannabis program, within the confines of our resources.

- If they have not already done so, we recommend that the Canadian Medical Association and other medical associations communicate the changes made to the MMAR to their member physicians to ensure that they have the latest

information and are aware that family physicians can now sign their patients' application forms, and that there has been a shift of responsibility from the physician to the patient in accepting the potential risks and benefits of using cannabis for medical purposes.

- If they have not already done so, we recommend that the Canadian Medical Protective Association communicate with their member physicians to inform them of the Release Form for Medical Practitioners and its purpose with regard to liability.

4. Need to Address Stigma and Discrimination

- To address stigma and discrimination directed at people who use cannabis for medicinal purposes, we will disseminate information about the use of cannabis for medicinal purposes, bring forward the voices of people living with HIV/AIDS and the realities they face when choosing cannabis as part of their therapy, and encourage dialogue among stakeholders on these issues, within the confines of the resources available to us. We will provide information about where people can obtain information about legal remedies if they have suffered discrimination because of their medicinal use of cannabis.

- We recommend that all key stakeholders, including the government, join our efforts in disseminating information about the medicinal use of cannabis and the federal medical cannabis program. We must also find opportunities to engage others in dialogue about the use of cannabis for medicinal purposes.

- We call on all levels of government and on the medical and scientific communities to take measures to ensure that there is adequate research, information dissemination, and related services so that seriously ill Canadians are provided with standards of care around their treatment of choice, without discrimination.

"Our Choice"

Seriously ill Canadians need to have access to the proper information regarding the medicinal use of cannabis to empower them to make informed choices. They also need choices with regard to legal, safe and affordable sources of cannabis.

5. Need to Generate and Disseminate Information Regarding the Medicinal Use of Cannabis

- To address many of the information needs expressed by the people living with HIV/AIDS we consulted, we prepared a series of fact sheets to provide information about the various aspects of the medicinal use of cannabis, as well as listing resources where they can find more information. These sheets will be disseminated widely to our membership and at various events relevant to people living with HIV/AIDS, within the confines of available resources.

- We call on our member organizations to assist us in disseminating the fact sheets on Cannabis and HIV/AIDS, to develop position statements on the use of cannabis as therapy for people living with HIV/AIDS and to support our advocacy efforts with regard to the use of cannabis for medicinal purposes by people living with HIV/AIDS.

- To address the need for more research on the medicinal use of cannabis, we will continue to provide letters of support to researchers for the research priorities we have identified, and we will sit on community advisory committees as requested. We are also willing to collaborate in the development of research protocols and with the recruitment of participants, within the confines of available resources.

- We recommend that all key stakeholders, including Health Canada, engage in the gathering and dissemination of information on medicinal cannabis to people living with HIV/AIDS and other seriously ill Canadians.

- We recommend that the Canadian Institutes for Health Research, through the Medical Mari-

juana Research Program, issue a Request for Proposals for a Marijuana Open Label Safety Initiative for a trial to assess the safety and efficacy of smoked cannabis on appetite stimulation, nausea and vomiting, pain and other HIV/AIDS related symptoms.

- If researcher interest is still low or non-existent, we recommend that Health Canada actively solicit research in this area through targeted contracts. In particular, we recommend that funding bodies such as the Canadian Institutes for Health Research, or Health Canada directly, solicit research proposals in the following areas:

  Randomized controlled trials comparing smoked and vaporized cannabis to pharmaceutical products currently available for stimulating appetite, managing nausea and vomiting, and managing pain

  Long-term effects of cannabis on the immune system and on antiretroviral medications

  Therapeutic effects of various strains of cannabis and cannabinoid profiles on specific symptoms

  Research into the direct effects of cannabinoids on CD4 cell counts and viral load

  Research into alternative modes of delivery such as vaporizers

  Community-based research

6. Need to Access to Legal, Safe, Reliable and Affordable Sources of Cannabis

a. Information Regarding Sources of Cannabis

- With regard to access to a source of cannabis, we will continue to provide accurate and up-to-date information about the MMAR, and about the legal options available for people to supply themselves with medical cannabis. We will also continue to advocate for changes to the MMAR to provide more legal options for authorized persons.

b. Access to Testing

- We recommend that Health Canada, under the Controlled Drugs and Substances Act, license Canadian laboratories to test medicinal cannabis that is grown by persons who hold an Authorization to Possess and/or a License to Produce through the MMAR, regardless of where the authorized person obtained the cannabis.

c. The Government's Cannabis

- Given the low uptake of the government's cannabis by authorized persons, we recommend that Health Canada provide 5g samples of cannabis to newly authorized persons to encourage more authorized persons to try the government's product and subsequently order it, to minimize the number of authorized persons that depend on an illegal source of cannabis.

d. Licenses to Produce

- We strongly oppose the government's vision to phase out Personal Licenses to Produce and we recommend that they continue to issue licenses to produce cannabis for medical purposes to authorized persons. We suggest that the government review the distribution of cannabis for medical purposes overall and evaluate how it can best suit the needs of authorized persons.

- We recommend that Health Canada lift restrictions imposed on designated producers and allow them to grow for multiple authorized persons, and collectively with more than two other designated producers. The cannabis production facilities could be regulated and monitored to ensure quality control.

- We recommend that Health Canada establish a mechanism through which holders of a Personal License to Produce may report a loss of crop and obtain immediate authorization to have access to the government's supply until such a time as they are able to supply themselves adequately again through their home garden.

- We recommend that Health Canada study the proposed model offered in the document "Can-

nabis Yields and Dosage", available at <www.safeaccessnow.net/pdf/sanhandbook04.pdf>, and consider integrating these calculations into the MMAR, to replace the equation that is currently used to calculate the number of plants a person with a License to Produce is allowed to grow.

- We recommend that the Insurance Bureau of Canada develop an official policy regarding home insurance coverage when a person is legally licensed to produce cannabis for medical purposes, and that the Bureau disseminate this information to insurance companies across Canada.

e. Community Based Distribution of Cannabis

- We abide by community action principles of empowerment, community support, self-help, holistic approach, accountability, harm reduction and greater involvement of people living with HIV/AIDS[2]. As such, we favour a not-for-profit, community-based model of distribution of medicinal cannabis and of its related services. We support organizations such as some compassion clubs that operate on the basis of these principles. We will continue to support such establishments and the work that they do, and to advocate for their inclusion in a legal system of distribution of cannabis for medicinal purposes. We will continue to advocate for operational standards of these centres, especially with regard to quality control of the cannabis they provide. We will also advocate for these clubs to adopt a model that would hold them accountable for their activities. A not-for-profit charitable organization model would meet these needs. This said, we do not exclude other ways of distributing cannabis for medicinal purposes, for example the pharmacy distribution model proposed by Health Canada. We believe in providing options to people that best suit their needs. We will explore the possibility of supporting compassion centres that meet our principles through the process of obtaining the appropriate authorizations to operate legally.

- We recommend that the government authorize compassion clubs that meet defined operational standards and recognize them as legal dispensaries of medicinal cannabis.

f. Approval of Cannabis as a Drug

- We call on the government and the medical and scientific communities to take the necessary steps to facilitate the process of obtaining drug approval, or conditional drug approval, for medicinal cannabis so that physicians may prescribe it, and that consideration can be given to having the costs of the product covered under provincial drug plans.

g. Reimbursement for Medical Cannabis

- The Canadian AIDS Society, in collaboration with CTAC and other national partners, will explore the option of initiating the process for formulary consideration for medicinal cannabis by addressing the Advisory Committee on Pharmaceuticals and advocating for them to initiate Common Drug Review proceedings.

- We will encourage our member organization that do not already do so to explore the possibility of offering a financial assistance program for medicinal cannabis, within the confines of their limited resources, at least until such a time as other reimbursement options are available to people living with HIV/AIDS.

- We recommend that the Minister of Finance revise the medical expense tax credit to allow authorized persons who have a License to Produce cannabis for medical purposes to claim expenses incurred in producing cannabis for their medical purposes. These costs include a portion of their electricity bills, based on the square footage of their cultivation area, costs for equipment and supplies purchased to start up and maintain their production of medical cannabis and the costs of seeds required to start their home garden. All of these costs should be allowed under the medical expense tax credit.

- We call on the government and the medical and scientific communities to take the necessary measures to see to it that cannabis is considered for drug approval, so that it may eventually be

considered for reimbursement from available drug plans. Until such a time, consideration must be given to other mechanisms of reimbursement for the costs of medical cannabis for seriously ill Canadians.

B. Concluding Remarks

In Canada, Canadians have a constitutional right to use cannabis as part of their therapy. This right is established and will remain as long as prohibition on cannabis is upheld. Securing this right through the federal medical cannabis program is one step. We must work together to make this right a reality and to facilitate access to the federal medical cannabis program by addressing the barriers to ensure that seriously ill Canadians are protected from criminal prosecution for using the therapy of their choice. Since the government has a constitutional obligation to facilitate access to cannabis, we must also work collectively to find creative solutions to provide safe, legal and affordable sources of cannabis for seriously ill Canadians to end their reliance on the black market. We must address the information needs regarding the use of cannabis as a therapy to ensure that people have adequate information to make informed choices about their health and well-being.

As long as prohibition on cannabis remains, the current regulatory environment will continue to affect the everyday life of seriously ill Canadians who use cannabis as part of their therapy. In addition to advocating for policy changes with regard to medical cannabis, the Canadian AIDS Society will continue to advocate for drug policy and law reform. The Canadian AIDS Society will also work with the Canadian government in the development of a national framework for action to reduce the harms associated with alcohol, other drugs and substances in Canada. The national framework sets the stage for the "systematic, ongoing review of the benefits and potential adverse consequences associated with Canadian and international policies and frameworks… to strengthen Canada's ability to both establish its own effective responses and influence the modernization of international policies and legal frameworks." [3]

We hope that providing the voice of people living with HIV/AIDS and sharing their experiences about their daily realities of obtaining legal access to cannabis for medicinal purposes will contribute to a better understanding of existing policies. Further policy changes must be developed to better suit the needs of people living with HIV/AIDS and other seriously ill Canadians.

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1 The series of fact sheets is available on our web site at <www.cdnaids.ca/cannabis>.

2 Canadian AIDS Society. The Community Action Principles of the Canadian AIDS Society. Adopted by the CAS Board of Directors, May 1991. Amended December 2005. Available from: <www.cdnaids.ca/web/casmisc.nsf/cl/cas-gen-0051>.

3 Health Canada and the Canadian Centre on Substance Abuse. National Framework for Action to Reduce the Harms Associated with Alcohol and Other Drugs and Substances in Canada: Answering the Call. First Edition, Fall 2005.

APPENDICES

Appendix A — List of Key Stakeholder Interviews

Key Stakeholders Interviewed

1.	Beth Pieterson	Director General, Drug Strategy and Controlled Substances Programme, Health Canada
2.	Dr. Richard Viau	Director, Drug Analysis Service, Health Canada
3.	Michael McCulloch	Senior Policy Advisor, HIV/AIDS Policy, Coordination and Programs Division, Public Health Agency of Canada
4.	Dr. Mark Ware	Pain Physician and Researcher, Montreal General Hospital Pain Clinic
5.	Dr. Isra Levy	Director, Office of Public Health, Canadian Medical Association
6.	Sharon Baxter	Executive Director, Canadian Hospice Palliative Care Association
7.	Sean O'Reilly	Executive Director, Canadian Association of Naturopathic Doctors
8.	Philippe Lucas	Founder and Director, Vancouver Island Compassion Society; Founder, Canadians for Safe Access; Director of Communications, Drug Sense; Authorized medical cannabis user
9.	Denis Pelletier	National Marijuana Grow-Ops Coordinator, Royal Canadian Mounted Police
10.	Christopher McNeil	Deputy Chief of Operations, Halifax; Chair, Drug Abuse Committee, Canadian Association of Chiefs of Police
11.	Eric Nash	Licensed Designated Producer
12.	Dr. Glenda MacDonald	Doctor of Pharmacy
13.	Richard Neron	Newfoundland and Labrador Provincial Representative, Canadian Treatment Action
14.	Laurie Edmiston	Executive Director, Canadian AIDS Treatment Information Exchange
15.	Glenn Betteridge	Senior Policy Analyst, Canadian HIV/AIDS Legal Network
16.	Trevor Stratton	Consultant, Canadian Aboriginal AIDS Network
17.	Dr. Virgina Salares	Housing Researcher, Research Division, Canada Mortgage and Housing Corporation
18.	Anonymous	Unlicensed medical cannabis producer
19.	Kate Brown	Therapist, Youth Addiction Service, Child, Youth and Family Program, Centre for Addiction and Mental Health
20.	John Church	Insurance Bureau of Canada

Appendix B — Key Passages from the Decision in *R. v. Parker* (2000)

i. R. v. Parker (2000), 49 O.R. (3d) 481– Key Passages

(a) The (Liberty Interest

Liberty includes the right to make decisions of fundamental personal importance. Deprivation of this right must also accord with the principles of fundamental justice. It can be concluded that **the choice of medication to alleviate the effects of an illness with life-threatening consequences is such a decision** ... [This decision] is a right that Robins J.A. ranked as "fundamental and deserving of the highest order of protection .... **To intrude into that decision-making process through the threat of criminal prosecution is a serious deprivation of liberty** (pp. 513, 517).

(b) The Security Interest

[Section 7] protects the right to make choices concerning one's own body and control over one's physical and psychological integrity free from interference by criminal prohibition. **Preventing Parker from using marijuana to treat his condition by threat of criminal prosecution constitutes an interference with his physical and psychological integrity** (pg. 519).

(c) The Principles of Fundamental Justice

To summarize, a brief review of the case law where the criminal law intersects with medical treatment discloses at least these principles of fundamental justice:

i. The principles of fundamental justice are breached where the deprivation of the right in question does little or nothing to enhance the state's interest.

ii. A blanket prohibition will be considered arbitrary or unfair and thus in breach of the principles of fundamental justice if it is unrelated to the state's interest in enacting the prohibition, and if it lacks a foundation in the legal tradition and societal beliefs that are said to be represented by the prohibition.

iii. The absence of a clear legal standard may contribute to a violation of fundamental justice.

iv. If a statutory defence contains so many potential barriers to its own operation that the defence it creates will in many circumstances be practically unavailable to persons who would *prima facie* qualify for the defence, it will be found to violate the principles of fundamental justice.

v. An administrative structure made up of unnecessary rules, which result in an additional risk to the health of the person, is manifestly unfair and does not conform to the principles of fundamental justice (pp. 521-522).

(d) Common Law Right of Access to Treatment

While there is obviously a difference between a right to refuse treatment and a right to demand treatment, they can also be seen as two points on a continuum rooted in the common-law right to self-determination with respect to medical care. This includes the right to choose to select among alternative forms of treatment .... Some common-law support for access to drugs with a therapeutic value can also be found in the defence of necessity .... Not permitting access to medicine that may relieve debilitating symptoms of illness is inconsistent with the common understanding about the purpose of proper medical care (pp. 527-528).

(e) Blanket Prohibitions on Medical Use

The blanket prohibition on possession and cultivation, without an exception for medical use, does little or nothing to enhance the state interest. To the extent that the state's interest in prohibiting marijuana is to prevent the harms associated with marijuana use including protecting the health of users, it

is irrational to deprive a person of the drug when he or she requires it to maintain their health. As in *Morgentaler*, the court must consider the actual effect of the legislation. While the exemption for therapeutic abortions was designed to preserve the pregnant woman's health, it had the opposite effect in some cases by imposing unreasonable procedural requirements and delays. **If the purpose of the marijuana prohibition is to protect the health of users and thereby eliminate the related costs to society, the overbroad prohibition preventing access to the drug to persons like Parker, who require it to preserve their health, defeats that objective** (pg. 530).

(f) The Harms Associated with Marijuana

The parties placed a considerable body of evidence before Sheppard J. about the medicinal use of and claims about marijuana ....Consumption of marijuana is relatively harmless compared to the so-called hard drugs and including tobacco and alcohol and there is no "hard evidence" that even long-term use can lead to irreversible physical or psychological damage. Marijuana use is not criminogenic (i.e., there is no causal relationship between marijuana use and criminality) and it does not make people more aggressive or violent. There have been no recorded deaths from consumption of marijuana. Marijuana does have an intoxicating effect and it would not be prudent to drive while intoxicated. As with tobacco smoking, marijuana smoking can cause bronchial pulmonary damage, especially in heavy users. There may be other side effects from the use of marijuana and its effects are probably not as benign as was thought some years ago. However, these other effects are not acute except in very narrow circumstances, for example, people with schizophrenia. (pp. 495-496).

(g) Restricting Access to New Drugs

There may be circumstances in which the state interest in regulating the use of new drugs prevails over the individual's interest in access. This, however, is not one of those circumstances. **The evidence establishes that the danger from the use of the drug by a person such as Parker for medical purposes is minimal compared to the benefit to Parker and the danger to Parker's life and health without it.** It may be that the state is entitled to require the approval of the patient's choice by a physician in much the same way that in *Morgentaler*, Beetz J. contemplated that even if there was a right of access to abortion founded upon the right to liberty, a second medical opinion as to the mother's health could be justified in some circumstances because of the state interest in the protection of the foetus. However, the current legal and administrative structure completely deprives Parker of any choice, even with the approval of his physician (pp. 536-537).

(h) The Constitutional Failure of the s. 56 Exemption Process (Interim Guidance Document)

If this is wrong and, as a result, the deprivation of Parker's right to security of the person is in accord with the principles of fundamental justice because of the availability of the s.56 process, in my view, s. 56 is no answer to the deprivation of Parker's right to liberty. The right to make decisions that are of fundamental personal importance includes the choice of medication to alleviate the effects of an illness with life-threatening consequences. It does not comport with the principles of fundamental justice to subject that decision to unfettered ministerial discretion. **It might well be consistent with the principles of fundamental justice to require the patient to obtain the approval of a physician, the traditional way in which such decisions are made. It might also be consistent with the principles of fundamental justice to legislate certain safeguards to ensure that the marijuana does not enter the illicit market.** However, we need not finally determine those issues, which, as will be explained in considering the appropriate remedy, are a matter for Parliament (pg. 545).

Appendix C — Key Passages from the Decision in *Hitzig et. al v. Canada* (2003)

i) *Hitzig et. al. v. Canada* (2003) 177 C.C.C.(3d) 449 (Ont.C.A.) – Key Passages:

(a) Violation of Liberty and Security

The right to liberty can also be properly viewed more broadly, to include the right to make decisions of fundamental personal importance. See *R. v. Parker*, *supra*, at 228-29. Viewed in this way, s. 7 requires that if the state seeks to interfere with these decisions, it must comply with the principles of fundamental justice in doing so. Like the other rights encompassed by s. 7 this aspect of the right to liberty is protected not just in the context of the criminal law, but against any deprivation that occurs as a result of an individual's interaction with the justice system and its administration (p. 483).

Here, as in *Parker*, there is no doubt that the decision by those with the medical need to do so to take marihuana to treat the symptoms of their serious medical conditions is one of fundamental personal importance. While this scheme of medical exemption accords them a medical exemption, it does so only if they undertake an onerous application process and can comply with its stringent conditions. Thus, the scheme itself stands between these individuals and their right to make this fundamentally important personal decision unimpeded by state action. Hence the right to liberty in this broader sense is also implicated by the MMAR (p. 484).

It is equally clear that the right to security of the person of those with the medical need to use marihuana is implicated in the circumstances of this case. In *Parker*, *supra*, this court reviewed the jurisprudence and concluded that this right encompasses the right to access medication reasonably required for the treatment of serious medical conditions, at least, when that access is interfered with by the state by means of a criminal sanction (p. 484).

(b) Principles of Fundamental Justice - Failure to Provide a Lawful Supply

The state's obligation to obey the law is fundamental to our system of justice. No one would argue that it does not have general acceptance among reasonable people: *Rodriguez, supra*, at 607. The state's obligation to obey the law is well established at common law through the process of judicial review, is implicitly recognized in the preamble to the *Constitution Act*, 1867, (U.K.), 30 and 31 Vict., c. 3, is expressly recognized in the preamble to the *Constitution Act*, 1982, and is further recognized in s. 52 of the *Constitution Act*, 1982. We have no hesitation in concluding that the state's obligation to obey the law is a principle of fundamental justice (p. 490).

The MMAR do not require the state to violate the law. They do, however, create an alliance between the Government and the black market whereby the Government authorizes possession of marihuana for medical purposes and the black market supplies the necessary product. The MMAR provide a viable medical exemption to the prohibition against possession of marihuana only as long as there are individuals who are prepared to commit a crime by supplying the necessary medical marihuana to the individuals that the Government has determined are entitled to use the drug. At the same time, the MMAR force seriously ill individuals who have been found to be in need of medical marihuana to consort with criminals to fill that medical need. Forcing sick people to go to the black market to get their medicine can only discourage respect for the law and at the same time signal that the medical needs of these people are somehow not worthy of the same kind of consideration as other medical needs (p. 490).

A Government scheme that depends on the criminal element to deliver the medically necessary product, and that drives those in need of that product to the black market strikes at the same values that underlie the state's obligation to obey the law. The MMAR, far from placing the Government in the position of a positive role model or on the moral high ground, are calculated to bring the law into disrepute and de-

value the worth and dignity of those individuals to whom the MMAR are applied. The Government's obligation to obey the law must include an obligation to promote compliance with and respect for the law (p. 491).

The inevitable consequences of the absence of a legal source of marihuana for those who have been determined to be in medical need of the drug are inconsistent with the fundamental principle that the state must obey and promote compliance with the law. In our view, the absence of a legal source of supply renders the MMAR inconsistent with the principles of fundamental justice (p. 491).

(c) Principles of Fundamental Justice - Restrictions on Eligibility to Enter the Program

Expressed in the language of s. 7, the notion of balancing individual rights against collective interests itself reflects what may rightfully be termed a "principle of fundamental justice" which, if respected, can serve as the basis for justifying the state's infringement of an otherwise sacrosanct constitutional right. Related to this principle is the concept described by Sopinka J. in *Rodriguez*, *supra*, where he said that if the state action which causes the deprivation does little or nothing to enhance the state's interest, it can properly be seen as arbitrary and not in accordance with fundamental justice. In such circumstances there cannot possibly be a fair balance between the individual's rights and the collective interests. Sopinka J. put it this way, at 594: "Where the deprivation of the right in question does little or nothing to enhance the state's interest (whatever it may be), it seems to me that a breach of fundamental justice will be made out, as the individual's rights will have been deprived for no valid purpose." (pp. 495-496)

The Hitzig applicants simply say that the requirement to have a second specialist support the application for an individual in category 3 does little or nothing to enhance the state's interest and in that sense represents an arbitrary restriction. We agree. The second specialist requirement is clearly an additional restriction on the acquisition of a medical exemption by those in category 3. Yet it is hard to see that the second specialist adds anything that could be said to advance the state interest. The second specialist is no differently qualified than the first. Ironically, the second specialist is not asked at all to opine about the availability of other possible treatments, which is the principal justification advanced by the state for any specialist involvement. Rather, the second specialist is required only to agree with the first specialist that marihuana would mitigate the symptom and that the benefits outweigh the risks. And in doing so the second specialist does not see the individual but merely reviews the medical file. In these circumstances the requirement for a second opinion adds so little if any value to the assessment of medical need that it is no more than an arbitrary barrier standing between an individual in category 3 and a medical exemption. In this particular respect only, the eligibility conditions of the MMAR do not accord with the principles of fundamental justice (pp. 498-499).

(d) Remedy

We have earlier described the ineffectiveness of the DPL [Designated Producer License] provisions of the MMAR to ensure a licit supply to ATP holders. That ineffectiveness appears to stem very largely from two prohibitions in the MMAR. First, a DPL holder cannot be remunerated for growing marihuana and supplying it to the ATP holder (s. 34(2)). Second, a DPL holder cannot grow marihuana for more than one ATP holder (s. 41(b)) nor combine his or her growing with more than two other DPL holders (s. 54). These barriers effectively prevent the emergence of lawfully sanctioned "compassion clubs" or any other efficient form of supply to ATP holders. Indeed, when asked in argument which specific barriers had to be removed to provide for a lawful source of supply, counsel for the Hitzig applicants immediately cited these provisions (p. 502).

As the record makes clear, there are a number of people who already have a source of marihuana and wish to engage in compassionate supply of it to those in medical need. Indeed the Government's case rested in large part on their existence. It argued that they effectively serve as "unlicensed suppliers" for ATP holders. It may be that not all of these people would satisfy the requirements to become DPL holders set out in the MMAR. However, we are satisfied that, on

this record, enough would do so that taken together with existing DPL holders, the DPL mechanism as modified could then provide a licit source of supply to ATP holders. Once this modification is implemented, ATP holders would therefore no longer need to access the black market to get the marihuana they need (p. 502).

Nor for DPL holders drawn from "unlicensed suppliers" is there a "first seed" problem requiring that they enter the black market. They already have their first seed. For future DPL holders who do not have their first seed, the constitutional problem presented by their need to access the black market once in order to get that first seed is far less than the problem under the MMAR, where ATP holders themselves are mostly unable to obtain designated producers and, not being healthy enough to grow their own marihuana, must regularly and repeatedly access the black market (pp. 502-503).

However, even this limited first seed difficulty would be eliminated if future DPL holders who did not already have their first seed could access the Government supply to obtain it. The regulation that was brought into force on July 8, 2003 would appear to provide for just that solution (p. 503).

Taking these considerations together, we conclude that the remedy which most directly addresses the constitutional deficiency presented by the absence of a licit supply of marihuana is to declare invalid sections 34(2), 41(b) and 54 of the MMAR. This will allow all DPL holders to be compensated, to grow for more than one ATP holder, and to combine their growing with more than two other DPL holders. Provided that the regulation of July 8, 2003 remains in place and is acted upon, there is no need to declare that the Government has a constitutional obligation to provide the first seed to those DPL holders who do not have one (p. 503).

....

...we acknowledge that the Government could choose to address the constitutional difficulty by adopting an approach fundamentally different from that contemplated in the MMAR. The alternatives range from the Government acting as the sole provider, to the decriminalization of all transactions that provide marihuana to an ATP holder. Indeed, even if the Government is content with the solution contained in the MMAR as modified by our order, it may seek to impose reasonable limits, provided they do not impede an effective licit supply, for example on the amount of compensation that a DPL holder can claim or on the size of the operation that a DPL holder can undertake.

...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 (pp. 505-506).