Joint submission to the Task Force on the Legalization and Regulation of Marijuana

The Arthritis Society, Canadians for Fair Access to Medical Marijuana and the Canadian AIDS Society

August 29, 2016

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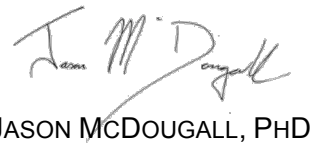

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EXECUTIVE SUMMARY

The needs of patients who use cannabis for medical purposes must remain at the heart of policy reform as the federal government moves ahead to legalize and regulate cannabis for personal use.

To this end, the Arthritis Society, Canadians for Fair Access to Medical Marijuana and the Canadian AIDS Society developed this submission to the Task Force on the Legalization and Regulation of Marijuana. We have also secured input and support from other organizations in the medical, scientific and patient communities who represent a range of health conditions and expertise.

Our submission outlines the unmet needs of patients under the current regulatory system for medical cannabis, drawing on the expertise of world-leading medical, scientific and policy leaders and the voice of patients who navigate the system.

A growing number of patients use cannabis as a therapy to manage their health conditions, including seizures, pain, insomnia, neurological issues, nausea and vomiting, and side effects from prescription medications. Despite having legal rights to access all forms of cannabis for medical purposes, patients currently experience a constellation of obstacles to accessing their medicine.

As for any therapeutic product, the Government of Canada has a responsibility to ensure access to a regulated and tested supply of medicine.

Our submission shines a light on the challenges as well as what is working in the current approach, and we provide specific recommendations on how the federal government can ensure that medically authorized cannabis is accessible, affordable, and supported by research.

In this context, we are confident that the Task Force will keep Canadian patients at the centre of its deliberations. The patient community thanks you and looks forward to working with the Task Force and the government in the coming months.

Summary of Recommendations

Accessible

1. Patients must have access to a supply of medical cannabis in all its forms and potencies that is regulated for safety, potency and quality.
2. Patients must have access to a reliable supply of medical cannabis through a variety of distribution options.
3. Patients must be informed about how to access medical cannabis as well as safe and effective use of different forms of medical cannabis (e.g., concentrates, dried flowers, edibles, etc.).

Affordable

4. Medical cannabis must not be subject to sales tax.
5. The regulatory approach to medical cannabis must enable health insurance plans to include medical cannabis.

Supported by research

6. The federal government must actively expand the evidence base on the medical use of cannabis through enhanced support and promotion of medical cannabis research.
7. The federal government must use additional policy levers at its disposal to help support and promote research into medical cannabis.

The patient-centred recommendations put forth in this document must be embedded in the legalization and regulation framework governing access to cannabis. The patient community welcomes the opportunity to work with the federal government as it develops its new regulatory approach to ensure that it supports patients as they access cannabis for medical purposes.

INTRODUCTION

On behalf of the patient community, The Arthritis Society, Canadians for Fair Access to Medical Marijuana and the Canadian AIDS Society commend the federal government and the Task Force on the Legalization and Regulation of Marijuana for exploring options as Canada moves to legalize and regulate access to cannabis for personal use.

As the fifth theme of the Task Force's Discussion Paper, appropriate access to cannabis for medical purposes should include a clear distinction in the regulatory approaches between medical cannabis and cannabis for personal use so that the currently unmet needs of patients with regard to access, information, affordability and research are prioritized and addressed.

Discussing elements of a new system presents an unprecedented opportunity to responsibly help the thousands of patients who access medical cannabis to manage their symptoms and support their health. As of today, there are more than 67,000 critically and chronically ill patients accessing cannabis through the *Marihuana for Medical Purposes Regulations* (MMPR) and every day, more patients are turning to cannabis as a therapeutic modality. Both the MMPR, which were enacted in 2014, and the *Marihuana Medical Access Regulations* that preceded them (2001-2014) have been found by the courts to need improvement to appropriately address patients' needs. The *Access to Cannabis for Medical Purposes Regulations*, which came into force on August 24, 2016, serve as an interim measure to address patients' rights to self-produce cannabis for medical purposes prior to the implementation of a new approach to regulating cannabis by the federal government.

Patients should be supported by public policy that aims to ensure access to a regulated supply of medical cannabis in a variety of forms and potencies, through different distribution channels. Improving patients' appropriate access to – and information about – medical cannabis to manage the symptoms related to their diseases empowers them to work with their health care professionals to make an appropriate care plan.

In contrast with many other therapies that patients rely on, the current regulatory landscape for medical cannabis presents unique challenges, including barriers to accessing a regulated source of supply. The current landscape is the result of a patchwork of regulations governing access to cannabis for medical purposes. Many of the reforms to the medical cannabis regulatory system were in response to court decisions that recognize specific rights that patients have to access this therapy. As such, the medical cannabis regulatory regime would benefit from reforms that update the system of regulatory oversight to strengthen it and make it more coherent and easier for patients to understand and navigate.

The Arthritis Society, Canadians for Fair Access to Medical Marijuana and the Canadian AIDS Society have collaborated in preparing this submission to the Task Force on the Legalization and Regulation of Marijuana to describe the challenges currently faced by patients in accessing medical cannabis and our recommendations for a patient-centred approach to the regulation of medical cannabis. This submission draws on earlier work of the country's leading experts in medical cannabis, a complete list of whom can be found in Appendix A. The Medical Cannabis Research Roundtable, a complete list of whom can be found in Appendix B, developed recommendations about research priorities during a workshop in December 2015. In addition, we have reached out to a wide range of stakeholders to support our proposal. The diversity of stakeholders represented on the signatory page of these

recommendations underscores the importance of this issue to patients and the broad support for these recommendations.

In particular, medically authorized cannabis should be accessible, affordable, and supported by research:

- **Accessible**: ensuring patients have legal access to a regulated supply of medical cannabis in all forms, potencies, and through a range of distribution channels and are empowered to make decisions about their treatment through evidence-based information;
- **Affordable**: removing the sales tax on medical cannabis and regulating cannabis as a therapeutic product to facilitate reimbursement / funding by public and private health insurance programs; and
- **Supported by Research**: expanding the evidence base on the medical use of cannabis through increased funding from federal granting bodies, the creation of new funding programs and by modernizing research licensing policies.

These recommendations will help ensure that any framework for access to medical cannabis on a broader scale respects and supports patients. As such, the patient-centred recommendations we are putting forth must be embedded in the legalization and regulation framework governing access to cannabis for recreational purposes.

ACCESSIBLE

Access to cannabis for medical purposes is available to patients who have received a medical document (much like a prescription) from a physician that authorizes them to receive a legal source of cannabis and sets out the recommended dosage to treat their symptoms. However, even when a practicing physician has provided patients with a medical document, patients frequently encounter obstacles to accessing regulated and tested medical cannabis.

Patients must have reliable access to medical cannabis from regulated sources that have been tested for safety and potency. The principles underlying the regulation of health products in Canada should also apply to medical cannabis. Patients' sources of supply should be regulated for safety, potency and quality from the point of production, including any processing or preparation of the medical cannabis, through distribution to patients.

Barriers to patient access to medical cannabis arise as a result of the limited number of distribution options. There are currently two avenues for patients to legally access medical cannabis:

1. **Through a Licensed Producer** (LP), which is authorized by Health Canada through a licensing process that ensures that the LP meets a number of safety and quality assurance requirements under the *Marihuana for Medical Purposes Regulations* and sends patients medical cannabis directly through the mail; and

2. **Through self-production**, whereby patients grow their own supply of medical cannabis or designate someone to grow it for them under the *Access to Cannabis for Medical Purposes Regulations*.

While both of the current distribution options have their merits, patients' needs are not being fully met through legal channels. In particular, self-production by patients (or the person they designate) poses specific challenges in ensuring that patients' supply of medical cannabis is safe and quality-assured with reliable and known potency. However, as patients have a right to be able to self-produce (or to designate someone to do so for them), the legalization and regulation framework must include an approach to ensuring the safety, potency and quality of self-produced sources of medical cannabis. This need becomes more acute when looking ahead to a legalized recreational market for cannabis. Any legalization and regulation framework must incorporate options to support patients in safely and consistently producing their own supply of medical cannabis.

A regulated source of supply must include a variety of different forms and potencies of medical cannabis. Being able to access a variety of forms of medical cannabis is a fundamental right of patients, which was recognized by the Supreme Court of Canada in *R. v. Smith* (2015).[1] In this unanimous judgment, the Court found that the regulations governing access to medical cannabis violated patients' constitutional rights by foreclosing their "reasonable medical choices" and by forcing them to choose between a legally available but inadequate treatment and an illegal and more effective one.[2] Further, the Court found that the effects of the law that prohibited access to different forms of

[1] *R. v. Smith*, 2015 SCC 34.
[2] *Ibid.* at para. 18

medical cannabis "undermines the health and safety of medical marihuana users by diminishing the quality of their medical care".[3]

Despite patients having a legal right to make reasonable medical choices by accessing medical cannabis in a variety of forms, access barriers remain. Not only does this deny many patients the most effective therapeutic benefit but it also creates an incentive for the purchase of unregulated and inexpertly composed home-made product, creating health and safety concerns. Ensuring that patients have access to different forms of medical cannabis would bring federal policy in line with the Supreme Court of Canada's judgment affirming patients' rights.

Regulating all sources of supply to ensure safety, potency and quality enables patients to access medical cannabis through a variety of distribution options. Canada's geographical reality creates barriers for patients to access medical cannabis. For some patients, their diseases or symptoms significantly impair their mobility, which further hampers their ability to access medical cannabis. As well, amongst the community of patients who rely on medical cannabis, different patients prefer different options. Patient choice should be supported through a wide range of options to access a regulated supply.

In particular, many patients choose to access cannabis for medical purposes through currently unregulated dispensaries. Expanding access by authorizing more regulated channels to market, including dispensaries, must be a key priority. There is also a clear need for on-site education about proper use of medical cannabis.[4] In this respect, one model of on-site access to medical cannabis that bears close resemblance is the "compassion club", which was recommended by the Senate Special Committee on Illegal Drugs (2002) as well as in litigation challenging the constitutionality of the *Marijuana for Medical Purposes Regulations.* In that court case, Justice Phelan stated that "…dispensaries are at the heart of cannabis access." A compassion club is a not-for-profit, community-based organization that distributes medical cannabis and offers related services, including information for patients.

As part of a responsive and coherent regulatory approach, patients must be supported and empowered to understand whether they are accessing medical cannabis that has been regulated for safety, potency and quality. Patient education should be supported by an oversight framework that includes packaging, labeling, testing, storage and handling of medical cannabis as it makes its way from production to distribution to patients from all sources and through a variety of channels. As access expands through a legalized and regulated regime for access to cannabis for recreational purposes, it will be increasingly important for Canadians to understand more about cannabis in order to make informed decisions about its use. This objective can be supported through providing them with evidence-based information.

Patient education is key to supporting patients to develop an appropriate care plan in collaboration with their healthcare provider. Both Canadians and their healthcare providers need more information about medical cannabis including appropriate form and dosage, interaction with other elements of a patient's treatment plan as well as the benefits and risks of medical cannabis. Patient education plays a crucial role in empowering patients to make appropriate medical choices.

[3] *Ibid.* at para. 25
[4] See *Allard v. Canada*, 2016 FC 236 at para. 162, per Phelan J.

Access Recommendations

1. **Access to a regulated supply of all products.** Patients must have access to a regulated source of supply of medical cannabis in all its forms and potencies. The system of regulatory oversight should ensure legal access to medical cannabis products, including but not limited to: herbal cannabis, capsules, tinctures, topicals, edible extracts and finished products. This move would bring federal policy into conformity with the recent Supreme Court of Canada ruling, *R. v. Smith* (2015).

2. **Different distribution options.** Patients must be able to reliably access a regulated and tested supply of medical cannabis regardless of where or how they access their therapy. Regulations should ensure that patients have access to medical cannabis through a wide range of distribution options, including access through regulated on-site sources such as compassion clubs and pharmacies in addition to mail order and self-production. It is important to recognize that there is no one-size-fits-all distribution model and to support patient choice to a regulated source of supply of medical cannabis.

3. **Patient education.** Patients should be educated about how to access medical cannabis as well as safe have evidence-based information about the use of different forms of medical cannabis (e.g., oil, dried flowers, food, etc.). This information empowers patients to determine the most appropriate treatment plan in collaboration with their healthcare provider. Patient groups, such as The Arthritis Society, Canadians for Fair Access to Medical Marijuana and the Canadian AIDS Society, will be key partners in empowering patients by providing them with information on medical cannabis and new research developments.

AFFORDABLE

Costs associated with the use of medical cannabis can be very burdensome for patients. Unlike other therapeutic products, patients cannot make use of existing policies and programs that help to address the costs of their medical care, such as zero-rated sales tax and access to health insurance coverage. As the federal government develops a new regulated market for recreational cannabis, patients' affordability concerns must be addressed. Failure to do so may undermine incentives for patients to seek a regulated supply of medical cannabis.

Affordability of medical cannabis is a pressing concern for many patients. Patients are often using less than their daily allowed dose in order to stretch the time between renewals of their medical authorization for cannabis and, in some cases, choosing between medical cannabis and other necessities such as rent, food or other medicines. According to a study of 628 self-reported users of cannabis for therapeutic purposes (CTP) in Canada:

> More than half of respondents reported that they were sometimes or never able to afford to buy sufficient quantity of CTP to relieve their symptoms, and approximately one third reported that they often or always choose between cannabis and other necessities (e.g. food, rent, other medicines) because of lack of money.[5]

Based on the average current pricing and dosage, medical cannabis patients, many of whom are on fixed incomes, bear costs upwards of $500/month. These expenses are in addition, often, to the other health expenses borne by patients, even after taking into account medical expense deductions.

In particular, there are two federal policies that hinder affordability of medical cannabis: the application of sales tax to medical cannabis, and the current regulatory approach that hinders the availability of health insurance coverage.

Currently, medical cannabis is subject to sales tax, making access more costly and less affordable for patients. Patients who access medical cannabis to manage their health conditions should be treated consistently with other patients who access health products to support their health and manage their illnesses. With the publication of the proposed *Marihuana for Medical Purposes Regulations* in December 2012, Health Canada stated in the Regulatory Impact Analysis Statement that it was "moving to treat marihuana like a medication."[6] Health Canada further emphasized that "treat[ing] marihuana as much as possible like any other narcotic used for medical purposes" was one of the key objectives of reforming the regulations.[7]

The current policy is inconsistent with the taxation of other prescription drugs by the Canada Revenue Agency. This same tax does not apply to prescription drugs and medical necessities, which are specifically exempted under the *Excise Tax Act*. In particular, the *Excise Tax Act* proclaims that drugs

[5] Barriers to access for Canadians who use cannabis for therapeutic purposes, Belle-Isle, L et al., *International Journal of Drug Policy*, 25 (2014) 691–699.
[6] Marihuana for Medical Purposes Regulations, *Canada Gazette I*, Vol. 146, No. 50 (December 15, 2012).
[7] Marihuana for Medical Purposes Regulations, *Canada Gazette II*, Vol. 147, No. 13 (June 19, 2013).

that are authorized by a healthcare practitioner and which are not available "over the counter" are zero-rated.[8]

Recently, the Tax Court of Canada and the Federal Court of Appeal have observed that applying sales tax to medical cannabis creates "uncertainty and confusion"[9] and that "this area of legislation needs work".[10]

There is broad support for removing sales tax on medical cannabis among Canadians. The House of Commons certified e-petition 190, which calls for the removal of sales tax on medical cannabis, has received over 10,800 signatures.[11]

Removing sales tax on cannabis for medical purposes would not preclude the federal government from levying sales tax on cannabis for recreational purposes and would underscore a clear distinction between medical cannabis and cannabis used for recreational purposes. In his recommendations on cannabis legalization and regulation policy, University of Waterloo Professor of Economics and Director of the Master of Public Service Program Anindya Sen emphasized the importance of treating medical cannabis as a separate regulatory system "based on the distinct issues each system faces,"[12] including distinct approaches to taxation.

Removing sales tax on medical cannabis would significantly improve affordability for patients. However, for many patients, the inequitable treatment of medical cannabis by both public and private health insurance plans poses the greatest financial obstacle to affordable access. In fact, many patients use medical cannabis after all other insured options are exhausted. Like other prescribed medicines, medical cannabis should be approved as a drug in order to qualify for health insurance coverage.

There are systems in place to reimburse patients for the costs of their approved medicines. Since cannabis was made accessible through the courts, it is in a unique situation not shared by prescribed medication. Future regulation of cannabis must provide a regulatory pathway for medical cannabis to be approved as a drug, allowing it to be eligible for inclusion on existing public and private drug formularies.

Affordability Recommendations

4. **Remove sales tax on medical cannabis**. Medical cannabis is used for a variety of health purposes and is relied upon by patients to manage a variety of symptoms. It should be treated like other medical necessities.

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[8] *Excise Tax Act*, R.S.C., 1985, c. E-15, Schedule VI-I-2.
[9] *Hedges v. Canada*, 2016 FCA 19 at para. 17.
[10] *Hedges v. The Queen*, 2014 TCC 270 at para. 99
[11] Parliament of Canada, E-petitions, e-190 (Tax system), online: https://petitions.parl.gc.ca/en/Petition/Details?Petition=e-190.
[12] Anindya Sen, "Joint Venture: A Blueprint for Federal and Provincial Marijuana Policy", C.D. Howe Institute E-Brief 235 (April 20, 2016), online: https://www.cdhowe.org/sites/default/files/attachments/research_papers/mixed/e-brief_235.pdf

5. **Enable health insurance plans to include medical cannabis**. Creating a pathway for Health Canada to approve medical cannabis as a drug would facilitate reimbursement by public and private health insurance plans. Status as an authorized therapeutic product, through which medical cannabis would receive a drug identification number (DIN), would facilitate cost coverage by both public and private health insurance plans. As with prescription medicines, medical cannabis should be covered by health insurance plans.

SUPPORTED BY RESEARCH

As the federal government examines options for legalization of cannabis for recreational use, the need is growing to increase scientific, clinical and policy research with respect to medical cannabis.

Although Health Canada has permitted access to medical cannabis by physicians for a number of years, there remains an enormous deficit of properly funded research and Canadian clinical trials into its therapeutic use. This creates barriers to patient access as many physicians express reluctance to provide medical authorization for medical cannabis in the absence of robust, peer-reviewed research. Recently, the President of the Canadian Medical Association, Dr. Cindy Forbes, called on "Health Canada and research agencies to fund the scientific research needed" to provide evidence for medical cannabis.[13]

Further, the lack of scientific and clinical research on medical cannabis has been cited by Health Canada as a key reason why medical cannabis is not regulated as a therapeutic product.[14] The separate legal regime for medical cannabis contributes to barriers to patient access, including the application of sales tax on purchases of medical cannabis and an unclear pathway for reimbursement by public and private insurance programs. As mentioned above, this creates barriers to insurance coverage and improving the affordability of this therapeutic product.

Safety and improved care for people living with a variety of medical conditions are top priorities for patient groups. Given the current lack of information on medical cannabis, we have begun to address this issue and call on the federal government to invest in this emerging research area.

To that end, patient groups and research and clinical communities collaborated to align on medical cannabis research priorities. To gather opinions, summarize perspectives and establish priorities, The Medical Cannabis Research Roundtable was formed, leading to discussion among experts and stakeholders on the subject of medical cannabis. Over two days in December 2015 in Vancouver, researchers, clinicians, service providers, health charities and patients discussed how best to go about investing in medical cannabis research to help those living with a variety of medical conditions. A complete list of participants (Appendix B) and research priorities (Appendix C) can be found in at the end of this submission.

The roundtable discussion had three main goals:

1. To better understand the current cannabis research landscape in Canada, and to identify key researchers.
2. To identify research priorities for the therapeutic use of medical cannabis in the areas of basic clinical science, health services, and policy.
3. To ensure cannabis research is relevant to all stakeholders involved in, and affected by, cannabis policy and services.

[13] Carly Weeks, "Medical marijuana: Does research back up claims of therapeutic benefits?", *The Globe and Mail*, July 28, 2016
[14] Marihuana for Medical Purposes Regulations, *Canada Gazette I*, Vol. 146, No. 50 (December 15, 2012).

Medical Cannabis Research Roundtable - Research Priorities

Basic research
The roundtable revealed a broad and varied range of potential basic research priorities related to medical cannabis. Through discussion, we found considerable alignment around the need for greater study of the endocannabinoid system (ECS), and the opportunities further research could offer. This approach to the ECS should be established as the 'foundational floor' of medical cannabis research, with further research being built on its findings.

1. Understanding the role of the endocannabinoid system (ECS) in disease
2. Pathophysiology
3. Pharmacodynamics (PD) & Pharmacokinetics (PK)

Clinical research
The roundtable offered opportunity for deep discussion on clinical research priorities. Clinical science combines principles of medicine, chemistry, biology, and experimental science, and evaluates and investigates medical treatments, principles and methods. The roundtable discussed and outlined four key priorities in this area:

1. Safety
2. Efficacy
3. Dosing
4. Administration

Health services and policy
The roundtable held an in-depth discussion on health services and policy research. Policy research is designed to look for ways to improve how healthcare services are organized, regulated, managed, financed, used, and delivered, in the interest of improving health and quality of life for Canadians. With that in mind, we agreed on four priority areas and discussed the details of each.

1. Implications of medical cannabis use public, social and economic health
2. Tools and strategies to better inform patients, healthcare professionals and the public about evidence-based data
3. Impact of legalization on medical cannabis regulation, access, and quality
4. How best to ensure equitable and non-discriminatory access to medical cannabis

The federal government has expressed an intention to develop a tax regime for recreational cannabis. A recent analysis by Avery Shenfeld estimates that the federal and provincial governments may expect to receive up to $5 billion in revenue from the taxation of cannabis.[15] Investing in research to explore the impacts of medical cannabis supports patients and should be a priority for recreational cannabis tax revenues. As noted above, the taxation of medical cannabis creates barriers to affordability. Removing sales tax on cannabis for medical purposes would not preclude the federal government from levying sales tax on cannabis for recreational purposes.

[15] Avery Shenfeld, "Growing Their Own Revenue: The Fiscal Impacts of Cannabis Legalization", *Economic Insights, CIBC World Markets* (January 28, 2016), pp. 7-8, online: http://research.cibcwm.com/economic_public/download/eijan16.pdf

In particular, the federal government can use tax revenues from recreational cannabis to actively invest in medical cannabis research that will help improve the lives of patients. Promoting and supporting research in medical cannabis would help to address many of the access barriers that patients currently confront and support several of the specific recommendations in this submission. To that end, we recommend that the federal government actively support medical cannabis research through investing $25 million over five years.

The federal government can also take action to support medical cannabis research by reforming its research licensing policies. To catalyze Canada's role as a leader on the international stage in this emerging area of research, the federal government can also help improve collaboration and coordination of research efforts throughout the country by establishing a Centre of Excellence in Cannabis Research.

Federal investment in medical cannabis research will also help address three key health priorities while stimulating economic growth.

First, the research will help patients optimize the use of medical cannabis to manage their symptoms. Reducing symptoms improves patients' quality of life and removes barriers to participating more fully in the workforce.

Second, with Canada's strong research and production infrastructure, Canada is well positioned to be a leader in medical cannabis research and realize the economic benefits that accrue from increased investment in health research. Third, reducing patients' symptoms reduces the burden on the healthcare system.

Research Recommendations

6. **Increase funding.** Expand the evidence base on medical use of cannabis through enhanced federal support and promotion of medical cannabis research. The federal government should commit $25 million over five years to support scientific, clinical and health services and policy research and expand the clinical evidence base of benefits and risks of medical cannabis. In particular, the granting councils (CIHR, NSERC and SSHRC) should target research funding to close knowledge gaps related to medical cannabis.

7. **Reform research policies.** The federal government should use additional policy levers at its disposal to help support and promote research into medical cannabis. Health Canada should modernize research licensing policies to actively facilitate research on medical cannabis. To further Canada's role as a leader in the area, a Centre of Excellence in Cannabis Research should be formed at a Canadian university.

THE PATH FORWARD

It is crucial that any regulatory approach to the legalization and regulation of cannabis for recreational purpose support patient access to a regulated and tested supply of medical cannabis and addresses patients' needs that are currently unmet. In particular, this presents an opportunity to consider the current barriers patients face to accessing a reliable source of medical cannabis and improve the regulatory system to make it more coherent and in line with overarching patient-centred objectives.

The patient community is an invaluable resource for the federal government as it works to develop its regulatory approach to recreational cannabis.

We appreciate the opportunity to provide recommendations to the Task Force and see this as the beginning of a dialogue between patients and the federal government as it works to implement refine its approach to cannabis.

RECOMMENDATIONS

Accessibility

1. **Access to a regulated supply of all products.** Patients must have access to a regulated source of supply of medical cannabis in all its forms and potencies. The system of regulatory oversight should ensure legal access to medical cannabis products, including but not limited to: herbal cannabis, capsules, tinctures, topicals, edible extracts and finished products. This move would bring federal policy into conformity with the recent Supreme Court of Canada ruling, *R. v. Smith* (2015).

2. **Different distribution options.** Patients must be able to reliably access a regulated and tested supply of medical cannabis regardless of where or how they access their therapy. Regulations should ensure that patients have access to medical cannabis through a wide range of distribution options, including access through regulated on-site sources such as compassion clubs and pharmacies in addition to mail order and self-production. It is important to recognize that there is no one-size-fits-all distribution model and to support patient choice to a regulated source of supply of medical cannabis.

3. **Patient education.** Patients should be educated about how to access medical cannabis as well as safe have evidence-based information about the use of different forms of medical cannabis (e.g., oil, dried flowers, food, etc.). This information empowers patients to determine the most appropriate treatment plan in collaboration with their healthcare provider. Patient groups, such as The Arthritis Society, Canadians for Fair Access to Medical Marijuana and the Canadian AIDS Society, will be key partners in empowering patients by providing them with information on medical cannabis and new research developments.

Affordability

4. **Remove sales tax on medical cannabis**. Medical cannabis is used for a variety of health purposes and is relied upon by patients to manage a variety of symptoms. It should be treated like other medical necessities.

5. **Enable health insurance plans to include medical cannabis**. Creating a pathway for Health Canada to approve medical cannabis as a drug would facilitate reimbursement by public and private health insurance plans. Status as an authorized therapeutic product, through which medical cannabis would receive a drug identification number (DIN), would facilitate cost coverage by both public and private health insurance plans. As with prescription medicines, medical cannabis should be covered by health insurance plans.

Research

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7. **Reform research policies.** The federal government should use additional policy levers at its disposal to help support and promote research into medical cannabis. Health Canada should modernize research licensing policies to actively facilitate research on medical cannabis. To further Canada's role as a leader in the area, a Centre of Excellence in Cannabis Research should be formed at a Canadian university.

APPENDIX A – LIST OF EXPERT CONTRIBUTORS

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Mandy McKnight
Patient Advocate

Leslie Best
Patient Advocate

This submission also drew on the expertise of the Medical Cannabis Research Roundtable. A full list of participants in the roundtable can be found in Appendix B.

APPENDIX B - MEDICAL CANNABIS RESEARCH ROUNDTABLE LIST OF PARTICIPANTS

Held in Vancouver, BC in December 2015

Affiliation	Name
Anesthesiologist, Ottawa	Linda Robinson
BC Cancer Care	Pippa Hawley
BC Civil Liberties	Micheal Vonn
BC Ministry of Health	Brian Emerson
BC Ministry of Health	Kenneth Tupper
Canadian AIDS Society	Lynne Belle-Isle
Canadian Arthritis Patient Alliance	Dawn Richards
Canadian Arthritis Patient Alliance	Don Mohoruk
Canadian Association of Medical Cannabis Dispensaries	Dieter MacPherson
Canadian Centre for Substance Abuse	Amy Porath-Waller
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Canadian Medical Association	Joyce Douglas
Canadian Medical Association	Owen Adams
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Child & Family Research Institute	Natasha Ryz
Consultant	David Hutchinson
Dalhousie University	Jason McDougall

Dalhousie University	Mary Lynch
Keynote Speaker	Ethan Russo
Health Canada	Hanan Abramovici
McGill University and Canadian Consortium for the Investigation of Cannabinoids	Mark Ware
McGill University	Mary Anne Fitzcharles
Michael Smith Foundation for Health Research	Bev Holmes
Pain BC	Maria Hudspith
University of British Columbia	Jon Page
University of British Columbia	M-J Milloy
University of British Columbia	Rielle Capler
University of British Columbia	Zachary Walsh
University of Calgary	Keith Sharkey
University of Ottawa	Cory Harris
University of Toronto	Lynda Balneaves
University of Toronto	Ruth Ross

APPENDIX C - MEDICAL CANNABIS RESEARCH ROUNDTABLE RESEARCH PRIORITIES

A. Basic research

The roundtable revealed a broad and varied range of potential basic research priorities related to medical cannabis. Through discussion, we found considerable alignment around the need for greater study of the endocannabinoid system (ECS), and the opportunities further research could offer. This approach to the ECS should be established as the 'foundational floor' of medical cannabis research, with further research being built on its findings.

1. **Understanding the role of the endocannabinoid system (ECS) in disease**
   - Does herbal cannabis or synthetic cannabinoids increase or decrease the effectiveness of the ECS?
   - Can the ECS be harnessed therapeutically in disease?

2. **Pathophysiology**
   - What are the impacts of herbal cannabis and synthetic cannabinoids in pre-clinical disease models?
   - What are the impacts of the many components of cannabinoids on pain and inflammation?

3. **Pharmacodynamics (PD) & Pharmacokinetics (PK)**
   - Can cannabis or its ingredients be delivered effectively using topical, oral or others delivery strategies that do not require smoking?
   - PD – effect of cannabinoid dosing on physiological function
   - PK – cannabinoid absorption, distribution, metabolism, and excretion

Embedded within all of these priorities is the need for researchers to have increased access to the plant-derived materials in order to conduct studies. Participants believed there could be many advantages to further ECS research, such as an ability to harness its power for therapeutic potential, or the creation of alternative pain treatments.

B. Clinical research

The roundtable offered opportunity for deep discussion on clinical research priorities. Clinical science combines principles of medicine, chemistry, biology, and experimental science, and evaluates and investigates medical treatments, principles and methods. The roundtable discussed and outlined four key priorities in this area.

1. **Safety**
   - Adverse events
   - Clinical end points (response, disease management and quality of life)
   - Short and long-term risks
   - Comparative risk to other treatments (e.g., NSAIDS)

2. **Efficacy**
   - Comparison of cannabis to standard treatment options

- The interaction of cannabis with other medications and treatments (including changes in lifestyle and diet)?
- Measurement across the domains of pain, fatigue, mental health and functionality

3. **Dosing**
   - A guided framework to standardise the amounts of active ingredients
   - Dosing across different types of derivatives/strains
   - Validation of approaches to self-titration/individualized dosing research to optimise symptom management
   - 'Start low, go slow and keep going'

4. **Administration**
   - Study the best route of administration and its relationship to dosing
   - Inhaled/vaporization, topical and ingestions methods

C. Health services and policy

The roundtable held an in-depth discussion on health services and policy research. Policy research is designed to look for ways to improve how healthcare services are organized, regulated, managed, financed, used, and delivered, in the interest of improving health and quality of life for Canadians. With that in mind, we agreed on four priority areas and discussed the details of each.

1. Study the implications of medical cannabis use on Canadian society as it relates to public, social and economic health.
2. The use of knowledge translation and exchange to provide evidence-based data to inform physicians, nurse practitioners, patients and the public better.
3. The impact of legalization on medical cannabis regulation, access, and quality.
4. How best to ensure access to medical cannabis is equitable and evolves in a non-discriminatory environment.