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SUBMISSION TO THE SENATE STANDING COMMITTEE ON SOCIAL AFFAIRS, SCIENCE AND TECHNOLOGY: BILL C-45 (CANNABIS ACT)

EXECUTIVE SUMMARY

The therapeutic benefits and safety profile of cannabis and its derivatives are well recognized. There is substantial clinical evidence from primary research reports and systematic reviews in support of their efficacy in the treatment of numerous diseases and conditions.

Notwithstanding this evidence, the classes of cannabis proposed by Bill C-45 limit the forms of cannabis legally available for therapeutic purposes to dried cannabis and cannabis oils – both of which have significant limitations.

Adding to the classes of cannabis legally available for medical purposes to provide for additional dosage forms is critical to maximizing the therapeutic benefits available from appropriate use of cannabis. These dosage forms should include oral tablets, topical creams, transdermal patches, aerosolized or dry powder metered-dose inhalers and other forms commonly used for health products.

Emblem seeks amendments to the proposed *Cannabis Act* which will provide for the availability of additional dosage forms of cannabis for medical purposes, and enable regulation of these forms to ensure that they meet potency, purity and quality requirements set out by Health Canada.

Availability of cannabis in these additional dosage forms will also stimulate important additional research into cannabis therapeutics and help develop important new therapies to better meet the needs of Canadian patients.

Proposed amendments to Bill C-45 are provided in the Appendix of this submission.

ABOUT EMBLEM CORP.

Emblem is a fully integrated licensed producer and distributor of medical cannabis under the ACMPR (Access to Cannabis for Medical Purposes Regulations). Led by a team of cannabis cultivation experts and experienced health care and pharmaceutical executives, it operates three distinct verticals – cannabis production, patient education centers, and medical dosage form research and development.

Emblem seeks to introduce world-class product innovation to Canada. Under construction is a 30,000 sq. ft. integrated building that includes a 5,000 sq. ft. GMP formulation and analytical laboratory dedicated to the development and production of cannabis formulations and advanced dosage forms.

Emblem's cannabis cultivation operations are located in Paris, Ontario with a current capacity of 2,000 kg per year from an indoor facility with state-of-the-art environmental controls. Work is underway on a 170,000 sq. ft. purpose-built greenhouse for medicinal cannabis - with an annual production capacity of 15,000 kg per year.

RATIONALE FOR ADVANCED DOSAGE FORMS OF CANNABIS FOR MEDICAL PURPOSES

The currently available dosage forms of cannabis for medical purposes have significant limitations. Smoking or vapourizing of dried cannabis results in the inhalation of potentially toxic compounds. Most patients and their physicians do not view smoking as an acceptable means of medication dosing. In addition, dose control is extremely imprecise with any form of inhalation of dried cannabis. While cannabis oils are a preferable means of administration, they are difficult to measure-out precisely and consistently, and as such are prone to dosing errors. Despite the significant benefits that would arise from the availability of additional, precisely controlled dosage forms of cannabis, the Cannabis Act and Health Canada's proposed regulatory framework do not provide for the availability of such dosage forms. This leaves patients and prescribers with very limited choices and undercuts the government's efforts to improve access to cannabis for medical purposes.

CONSTITUTIONAL RIGHT TO ACCESS

The government has a responsibility to ensure Canadians have consistent access to various forms of cannabis for therapeutic purposes. Previous court cases have established that the prohibition on non-dried forms of cannabis unnecessarily diminishes the quality of medical care for those authorized to use the drug. This is especially relevant with respect to additional, more advanced dosage forms that will encourage medical users to avoid smoking - and at the same time contribute to improved safety and therapeutic efficacy of cannabis. It would be inconsistent to allow for some forms of cannabis while prohibiting others, especially when these other forms have both safety and therapeutic advantages over dried flower and cannabis oil.

THERAPEUTIC BENEFITS OF MEDICAL CANNABIS

Therapeutic efficacy of cannabis has been established through scientific abstracts and manuscripts, including published primary research and systematic reviews. One review of note is the U.S. National Academies of Science, Engineering and Medicine's report, *The Health Effects of Cannabis and Cannabinoids*, published in January 2017¹. This report provides a comprehensive review of scientific evidence related to the health effects and potential therapeutic benefits of cannabis, and states that there is conclusive or substantial evidence that cannabinoids are effective:

- For treatment of chronic pain in adults;
- As an antiemetic in the treatment of chemotherapy-induced nausea and vomiting; and,
- For improving symptoms of spasticity in patients with multiple sclerosis.

The report also concludes that there is moderate evidence that cannabis is effective for additional therapeutic purposes (e.g. sleep disturbances) and more limited evidence of efficacy for others (e.g. increasing appetite). Overall, the Report lists 10 conditions for which there is at least some evidence that cannabis is effective – including anxiety and post-traumatic stress disorder.

Chronic pain is the indication for which cannabis is most frequently prescribed, which is supported by the conclusions of the National Academies Report. A Consensus Statement² published by the Canadian Pain Society in 2014 on the treatment of chronic neuropathic pain recommended cannabinoids as third-line agents for the treatment of this debilitating condition - subsequent to gabapentinoids and opioid analgesics. More recently, the desire of both patients and physicians to use opioid analgesics only when absolutely necessary has amplified the need for additional, effective analgesic agents.

¹ National Academies of Sciences, Engineering, and Medicine. 2017. *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24625>.

² Moulin D, Boulanger A, Clark A, et al. *Pharmacological management of chronic neuropathic pain: Revised consensus statement from the Canadian Pain Society*. Pain Research & Management: The Journal of the Canadian Pain Society. 2014;19(6):328-335. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4273712/>.

APPENDIX: SUGGESTED AMENDMENTS

Amend Bill C-45 to Expand the List of Permitted Classes of Cannabis

Currently, the permitted classes of cannabis are stated in section 33 and Schedule 4 of the proposed Cannabis Act are as follows:

33 Unless authorized under this Act, it is prohibited for a person that is authorized to sell cannabis to sell cannabis of any class that is not referred to in Schedule 4.

Schedule 4

Classes of Cannabis That an Authorized Person May Sell

<i>Item</i>	<i>Class of Cannabis</i>
1	dried cannabis
2	cannabis oil
3	fresh cannabis
4	cannabis plants
5	cannabis plant seeds

Based on medical evidence of the therapeutic benefits of cannabis and legislative intent to provide for the availability of additional dosage forms of cannabis for medical purposes, we propose amending Schedule 4 as follows:

Schedule 4

Classes of Cannabis That an Authorized Person May Sell

<i>Item</i>	<i>Class of Cannabis</i>
1	dried cannabis
2	cannabis oil
3	fresh cannabis
4	cannabis plants
5	cannabis plant seeds
<u>6</u>	<u>cannabis preparations, derivatives and formulations for medical purposes</u>

[Emphasis Added]

This amendment would allow Licensed Producers to sell, and manufacturers to produce, additional dosage forms of cannabis for medical purposes including oral tablets, topical formulations, metered-dose inhalers and other forms commonly used for health products.

Subsequent Additions to the Regulations Under Bill C-45

To ensure the availability of additional therapeutically superior dosage forms of cannabis, the legislative framework should be based upon a regulatory pathway that recognizes the body of safety evidence for the existing classes of cannabis that an authorized person may sell. The government has an opportunity to meaningfully improve the national framework by providing patients in need of medical cannabis with access to the best and most effective dosage forms.

We understand that regulations would be required to support such an amendment, and propose the following regulatory language to this effect:

Proposed Regulatory Provision Regarding Authorized Activities

X A licensed producer may possess, produce, sell, provide, ship, deliver, transport and destroy cannabis of any class that is referred to in Schedule 4.

Y Where a licensed producer intends to sell or provide cannabis derivatives, preparations and formulations, the derivative and/or preparation and/or formulation must be produced in accordance with the standards published by the Department of Health and as amended from time to time.