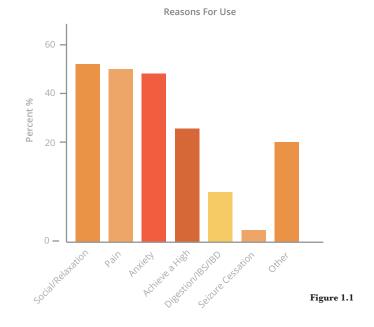


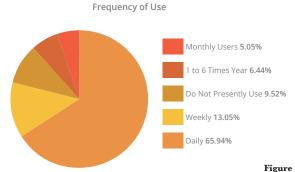
Andrew Charrette, MSc.; Najla Guthrie, CEO, KGK Science; Mal Evans PhD; CSO

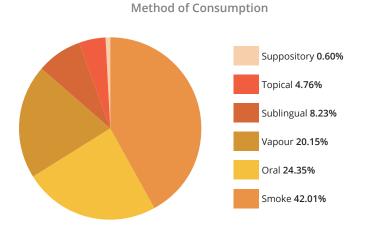
total of 147 million people, 2.5% of the world population, consume cannabis (annual prevalence) compared with 0.2% consuming cocaine and 0.2% consuming opiates [1]. The geographical spread of cannabis cultivation and use almost covers every country of the world. As of April 2018, approximately 4.2 million or 14% of Canadians aged 15 and above reported having used cannabis products in the past three months [2]. Cannabis regulations have historically followed the prohibitionist model, but as continuing research sheds light on its potential benefits, the cannabis regulatory landscape is becoming less restrictive.

### **A Snapshot of the Average Canadian Consumer**

A total of 3156 participants completed the survey conducted by KGK Science on cannabis use in Canada between March 1 – Oct 16, 2018. 49% of the participants identified themselves as male, 50% identified as female with the average age and BMI of the population to be 40 years old and 28 kg/m2, respectively. Figure 1.1: Most participants reported using cannabis for recreational purposes, followed by pain and anxiety.







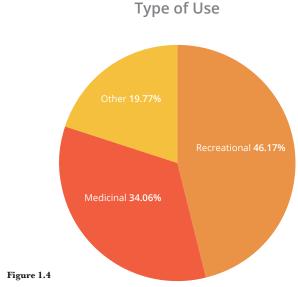


Figure 1.3

# **Canada's First Mover Advantage**

In October 2018, Canada became the first G7 nation to legalize the use of recreational cannabis, while cannabis for medical use has been legal since 2001. The past two decades have seen rapid changes in the regulatory framework. The possession, production and distribution of medical cannabis was regulated by the Medical Marijuana Purposes Regulations (MMPR) which was formed in 2013 and overseen by Health Canada. Under the MMPR, doctors could prescribe medical cannabis to their patients, who then purchased it from commercial growers licensed by Health Canada. However, under the MMPR, patients did not have the option to grow their own cannabis. Due to this, the patients' inability to grow their own medicine under the MMPR, it was struck down in 2015 by the federal court as unconstitutional and was replaced by the 'Access to Cannabis for Medical Purposes Regulation (ACMPR)' in 2016. Under the ACMPR, patients can continue to purchase cannabis from licensed producers but can now register with Health Canada to produce limited amounts for their own medical purposes, or designate licenced producers to produce it for them. The loosening of regulatory hurdles to medical marijuana had a tremendous effect on the number of patients using cannabis - the number of registered medicinal marijuana patients increased from 174,503 in April 2017 to 269,502 patients in December 2017.

In 2015, the government approved licensed producers to produce and sell cannabis buds and oils in addition dried marijuana and allowed authorized users to possess these forms of cannabis [3]. This opened doors to further research in the production and development of cannabis-based medicines. Interest in research and production gained momentum after the government's proposal to legalize cannabis

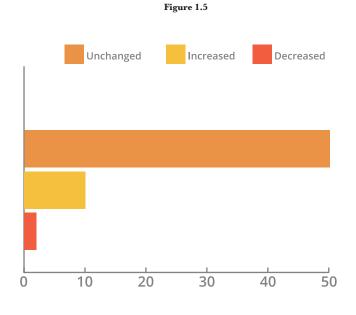
for recreational use in 2015. In June 2016, a nine-member Task Force on Cannabis Legalization and Regulation was formed to jointly discuss and put forth proposals on the regulations surrounding possession and use of recreational cannabis post-legalization [4]. Recognizing the incomplete knowledge base, the Task Force proposed multiple precautionary approaches to minimize risks associated with consumption, patterns of use and susceptibility of vulnerable populations. These included setting the minimum age to 18 years to purchase products, restricting advertisement of cannabis and cannabis-based products to the public to protect youth and requiring any therapeutic claims promoted by companies to conform to applicable legislations.

**Bill C-45** (the Cannabis Act) was introduced on April 13, 2017 and passed into Senate on June 20, 2018 [5]. The bill received Royal Assent and following a few months that allowed for governments and regulatory bodies to prepare for legalization, cannabis for recreational purposes was legalized

## Canada's Legalization of Marijuana Offers a Test Case for Other Countries.

-Wall Street Journal

on October 17, 2018. The Bill was in accordance with the final report published by the Task Force. The act restricts



the promotion of cannabis and outlines penalties ranging from tickets to 14 years in jail for exceeding possession limits, illegal distribution, surpassing cultivation and production limits, carrying cannabis across international borders and involving youth in cannabis-related activities. Regulatory processes for medical cannabis continue to remain unchanged. Companies focused on research and development, and laboratories interested in conducting activities with cannabis are required to apply for a Dealer's License under the Narcotic Control Regulations, which falls under the authority of the Controlled Drugs and Substances Act (CDSA). Forty-two laboratories in Canada currently hold this license [6].

Anticipated Change of Use After Legalization %

As Bill C-45 worked its way through the Canadian Parliament, the cannabis sector experienced remarkable changes. The 2018 Federal Financial Budget [7], stated that low-THC containing products (<0.3%) which are commonly used for medical marijuana and prescription medicines will be exempt from excise duties. The federal government also proposed that the total of federal and provincial taxes on cannabis products should not exceed C\$1.00 per gram, or 10 % of the producer's sale price of a product [7]. The budget also announced that the government has allocated approximately C\$46 million for education and awareness initiatives addressing the risks of cannabis use, including those implemented by community-based and indigenous organizations. Cannabis research is currently a priority for the Canadian Institute of Health Research (CIHR), the Institute of Neurosciences Mental Health and Addiction (INMHA) and Government of Canada for the development of a solid framework for cannabis use, education and regulation [8]. In 2017, CIHR awarded C\$1.4 million in grants to 14 different projects to study the effects of marijuana on public health including second-hand marijuana smoke and its effects on pregnancy. Banks however have taken a cautious approach while sanctioning loans to companies in the cannabis industry. In December 2017, CIBC became the first major bank to approve a loan to a cannabis-related business. In March 2018, the CEO of TD bank expressed that TD would consider financing the cannabis sector after recreational marijuana became legal.

Canada's openness concerning cannabis encourages economic growth and scientific innovation and legalization is expected to loosen the barriers to access and research of cannabis and cannabis-related products. A Deloitte report published in 2018 revealed that the recreational cannabis market will generate up to \$4.34 billion in sales in 2019, with an additional \$510 million to \$1.04 billion to be generated by the illegal cannabis market. The report also mentioned a paradigm shift in cannabis consumer demographics, suggesting an older population – aged 35 to 54 years versus the typical consumer age of 18 to 34 years - will now enter the market to access the safe and standardized product sold by the Canadian government. This shift could signal a business and scientific opportunity, as standardized products with substantiated claims would be attractive to a mature and more educated population. The legal Cannabis market in Canada is expected to become a \$6 billion industry with some of that money funneled toward research.

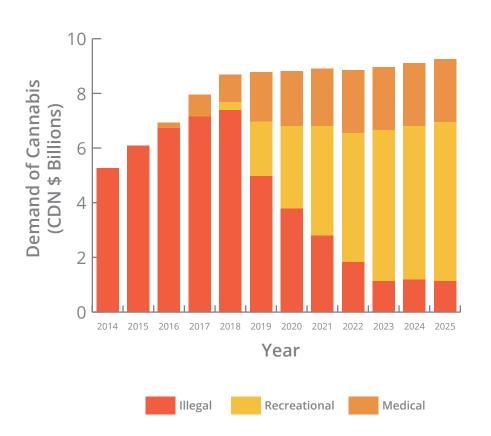
See: figure 1.6 below.

Figure 1.6

iigate 1.0
Federal
Provincial
Municipal

Figure 1.7

Canadian Cannabis Market



The relationship between consumption patterns and product preferences in ethnic and indigenous groups have not been extensively researched. Canada has a multi-ethnic - multi-racial population, and that provides opportunities for subgroup analyses when conducting clinical trials for the supplement industry. Understanding prevalence and patterns of use along with genetic variations present due to differences in race and ethnicity – can help companies to narrow the scope of their products to a target population. Tuck et al. (2017) found that in Ontario, East Asians and South Asians had lower cannabis use rates whereas Caribbean groups had higher cannabis use rates compared with Canadians. Further identification of groups interested in the cannabis market can help focus efforts towards the development of targeted health products and supplements. Legalization is also expected to attract increased foreign attention and establish Canada as a leading innovator and distributor of cannabis.

Legalization is expected to flood the Canadian market with medicinal and recreational cannabis products. Currently, two cannabis-based drugs Sativex and Cesamet are sold in Canada. While Sativex is indicated to treat symptoms of multiple sclerosis, Cesamet is used to treat severe nausea and vomiting caused by chemotherapy. As of March 2018, there are more than 200 cannabinoid-based natural health products authorized for sale containing only the stalk and non-viable seeds and contain less than 10 parts per million of THC. There are 96 companies that are either licensed producers themselves, or own licensed producers (partially or wholly) in Canada with a public listing on the Toronto Stock Exchange, Toronto Stock Exchange Ventures or the Canadian Securities Exchange. Although Canadian companies are getting creative with ideas for cannabis products ranging from oldfashioned cookies to beer brewed with marijuana to cater to the recreational market, the sale of edible products to recreational users is not yet legally permitted. The Cannabis Act currently allows the sale of cannabis oil, fresh cannabis, dried cannabis, cannabis plant seeds and cannabis plants. The sale of edible cannabis products is expected to be permitted within 1-year after the Cannabis Act came into legislation. With Canada's recreational cannabis sales expected to reach \$6 billion by 2021, surpassing the \$1.3-billion estimate for the mature medical-marijuana market, legalization is considered to have created Canada's proverbial 'pot of gold'.

#### CANADA'S THE FIRST MOVER ADVANTAGE

- 171 firms have applied for producer or distributor status under the new Canadian market scheme
- C\$10 projected average price per gram as market matures
- 24 publicly-traded Canadian marijuana companies with \$24 billion market capital
- Cannabis stocks have grown tenfold in past two years
- \$9.21 billion total projected cannabis demand in 2025
- \$2.1 to \$2.3 billion Parliamentary Budget Officer's projections for retail sales in Ontario



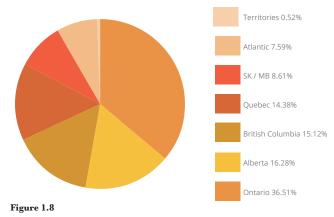
### Lessons from Other Countries

In 2013, Uruguay became the first country to legalize the growth, sale and use of cannabis. This legalization allowed the purchase of up to 40 grams per month at pharmacies or the cultivation of up to 6 plants in homes. However, due to the government's strict regulations around legal cultivation and purchase and due to the lack of incentives for pharmacies to sell cannabis, most citizens have preferred to buy cannabis illegally even after legalization. Five years later, the Uruguayan newspaper El Pais, reported that black market sales cannabis have tripled incentives for pharmacies [9].

The United States federal government classifies herbal cannabis as a Schedule I drug under the Controlled Substances Act, and states 'no currently accepted medical use and a high potential for abuse' [10]. However, at the state level, as of September 2018, 31 states along with Washington D.C. have legalized medical marijuana, and 9 states along with Washington D.C. have legalized marijuana for recreational purposes [11]. Despite the federal classification of herbal cannabis as a Schedule I drug, individual pharmaceutical-grade products are scheduled separately, such as the Schedule III classification of Marinol®, which is a THCbased prescription product. Therefore, the regulatory landscape in the USA has been muddled with conflicting federal and state laws. Although state laws in some states allow for the regulated use of cannabis for medicinal as well as recreational purposes, the federal illegality imposes barriers not only to obtaining and using marijuana products for medical use, but also preventing conducting primary research evaluating its pharmacological effects. Moreover, the implementation of restrictive regulatory policies has resulted in greater resistance from users. For example, Colorado tried to ban smoking in public in an attempt to regulate cannabis users, which instead led to an increase in edibles in the forms of cookies and pies resulting in a concurrent growth in calls

to poison control as children accidentally consumed them. Legislations outlining reforms of cannabis laws have been proposed in several European countries [12]. The Dutch government has allowed sales in coffee shops since 2017, but black market products have continued to grow. Spain has introduced cannabis social clubs (CSCs) for the distribution of cannabis to members, some that have been shut down while others tolerated. These clubs have spread throughout Spain and have been observed opening in other European areas. The Spanish law does not allow sale of cannabis stating that public cultivation by clubs is a crime, implying that private cultivation faces no charges [12]. Multiple other countries in Europe are starting to relax their laws, and it has been demonstrated that decriminalization as opposed to prohibition results in a preference for milder cannabis [13] which may have a significant impact on health outcomes.







## The Next Steps ...

As the first G7 nation to fully legalize cannabis, Canada has the first mover advantage to establish itself as leader in this field. As new research highlights the benefits of cannabis, there is a potential birth of a multi-billion-dollar industry, Nations across the globe are looking up to Canada as it attempts to stamp out illegal sales and turn this billion-dollar black market into a legal enterprise able to generate stable taxes and create thousands of jobs. Scientists and medical practitioners advocate that federal and provincial governments must promote scientific evidence informed policy making. Information from controlled trials is required to establish cannabis as a potential therapeutic for several conditions such as chronic pain, epilepsy and anxiety as well as a health and wellness supplement. Currently, there is a knowledge gap in the understanding of the appropriate strains, dosages, proportions of the two cannabinoids, THC and CBD, routes of administration, product formulations and the effects of use in the presence of other conditions. There are currently over 20

ongoing clinical trials in Canada involving cannabis that are listed on clinicaltrials.gov, with most of these studies focussing on the use of cannabis in pain management and treatment of mental health conditions. The government has encouraged innovative research and development in the cannabis sector to prove its potential as a medicinal therapeutic as well as a health supplement.

## References

- 1. World Health Organization. (n.d.). Cannabis Substance Abuse Facts and Figures. Retrieved from http://www.who.int/substance\_abuse/facts/cannabis/en/
- 2. National Cannabis Survey. (2018, april 18). Retrieved from Statistics Canada: Canada's national statistical agency: https://www150.statcan.gc.ca/n1/pub/11-627-m/11-627-m2018009-eng.htm
- 3. Health Canada. (2016a, August). Understanding the New Access to Cannabis for Medical Purposes Regulations. Retrieved from Government of Canada: https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/understanding-new-access-to-cannabis-for-medical-purposes-regulations.html
- **4.** Health Canada. (2016b). A Framework for the Legalization and Regulation of Canadis in Canada. The Final Report of the Task Force on Canadis Legalization and Regulation. Government of Canada.
- **5.** Health Canada. (2018a, June 20). Bill C-45, the Cannabis Act, passed in Senate. Retrieved from Government of Canada: https://www.canada.ca/en/health-canada/news/2018/06/bill-c-45-the-cannabis-act-passed-in-senate.html
- **6.** Health Canada. (2018b, July 12). Laboratories licensed to conduct activities with cannabis.Retrieved from Govern ment of Canada: https://www.canada.ca/en/health-canada/services/list-licensed-dealers.html
- 7. Department of Finance Canada. (2018). Equality Growth A Strong Middle Class. Her Majesty the Queen in Right of Canada.
- **8.** Canadian Institudes of Health Research. (2017). Health Research Needs and Priorities Related to Cannabis Legaliza tion and Regulation Workshop. Montréal, QC: Government of Canada.
- **9.** Hudak, J., Ramsey, G., & Walsh, J. (2018). Uruguay's cannabis law: Pioneering a new paradigm. Washington: WOLA: Center for Effective Public Management at The Brookings Institution.
- **10.** Drug Enforcement Administration. (n.d.). Drug Scheduling. Retrieved from U.S. Department of Justice: https://www.dea.gov/druginfo/ds.shtml
- 11. 31 Legal Medical Marijuana States and DC Medical Marijuana. (2018, Spetember 25). Retrieved from ProCon: https://medicalmarijuana.procon.org/view.resource.php?resourceID=000881&print=true
- **12.** Hughes, B., Quigley, E., Ballotta, D., & Griffiths, P. (2017). European observations on cannabis legalization. Addiction, 112(7):1136-1137.
- 13. Reinarman, C. (2009). Cannabis policies and user practices: market separation, price, potency, and accessibility in Amsterdam and San Francisco. Int J Drug Policy, 20(1):28-37

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