With the recent legalization of marijuana in Canada, as outlined in the Cannabis Act (Bill C-45), the stage has been set for unprecedented growth in the consideration and enactment of legislation which would similarly decriminalize other scheduled substances. Of particular note is the growing movement supporting the usage of "psychedelic drugs" such as psilocybin mushrooms – notably decriminalized in Denver, Colorado just last year – or MDMA (3,4 – methylenedioxymethamphetamine) in the treatment of depressive disorders such as severe PTSD. Trials with these drugs have shown initial promise in the alleviation of treatment-resistant depression<sup>1</sup> and end-of-life anxiety<sup>2</sup>. The United States Food and Drug Administration determined that studies involving these two drugs were compelling enough to be given the designation of "breakthrough therapy" in two separate cases. COMPASS Pathways, a life-science company dedicated to trailblazing innovative therapies in mental health, and MAPS (the Multidisciplinary Association for Psychedelic Studies) both drew interest from the FDA over several small phase two clinical trials<sup>4</sup>. Both of these trials showed comparable efficacy in the usage of psilocybin and MDMA to traditional anti-depressants such as sertraline (Zoloft) and paroxetine (Paxil).

Medical marijuana as a concept is not overly new on the Canadian scene. As early as 1999 marijuana was being provided to patients for medical purposes through section 56 of the Controlled Drugs and Substances Act which outlines the provision of scheduled substances to patients in need. Seemingly a loophole in the system at the time (as section 56 was intended for scheduled prescription medications, not illicit recreational drugs), this precedent brought about major legislative reform in the shape of the 2001 Marihuana Medical Access Regulations (MMAR). These regulations were adapted in 2013 into the Marihuana for Medical Purposes Regulations (MMPR) which allowed the mass production and sale of marijuana for medical purposes<sup>5</sup>. The biggest development came in 2016 when the Federal Court of Canada ruled that "reasonable access" to medical marijuana was not provided to its users in the ground-breaking case of Allard v. Canada<sup>6</sup>. From here, the 2017 Liberal Party, headed by Prime Minister Justin Trudeau, introduced and passed Bill C-45 and legalized cannabis to all Canadian Citizens at the age of majority.

In a landmark legislative decision a previously illicit substance had been legalized to all Canadian citizens. The catalyst in this movement was the section 56 class exemption which opened avenues furthering the universality of Canadian access to marijuana. But what does this have to do with the legalization of psychedelic drugs? In making this decision, the Canadian government had set a dangerous precedent: If illicit drugs can be shown to have significant medical benefits they may end up fully legal in as little as two decades.

Dr. Bruce Tobin is one man who seems to be repeating history. As a psychotherapist and professor at the University of Victoria, he has conducted trials with palliative care patients suffering from end-of-life depression and anxiety. In his research with psilocybin Dr. Tobin has seen remarkable reductions in anxiety with lasting effects in this patient population. Naturally, Dr. Tobin and his psychedelic therapy research group TheroPsil are pushing for a section 56 exemption of their own citing the evidence they have collected in recent years on the usage of psilocybin in palliative care. Dr. Tobin estimates that as many as 3000 patients across Canada may benefit from the treatment as current therapies are ineffective in alleviating their anxiety<sup>7</sup>. In March of 2019 Dr. Tobin filed for the exemption, but as of October 2019 he had still not heard back from the Canadian Health Minister. He has stated that he will wait until the end of the year, at which point he plans to pursue the Federal and Supreme courts where he believes he will find much success, citing marijuana precedence as a strong point of leverage: "There have been several landmark cannabis cases in which the High Courts have delivered very explicit judgements that Canadian citizens have the right to autonomy in making healthcare decisions with regards to life and death medical conditions".<sup>7</sup> Should this appeal go through there could be substantial ramifications to Canadian pharmacy practice.

In 2017, following the proposition of Bill C-45, NAPRA made a position statement which declared that pharmacists should remain key in providing patient information and guidance on the usage of marijuana products<sup>8</sup>. At this time no requirements for pharmacist education were laid out. In June 2018, just three months prior to legalization, the Ontario College of Pharmacists released 'A Cannabis Strategy for Pharmacy' – guidelines outlining the competencies expected in the proper provision of safe, informed patient care<sup>9</sup>. Again, no education requirements were set by the OCP. It was not until March 2019 – 6 months beyond the legalization date – that the OCP implemented mandatory cannabis education programming to be completed prior to March 2020. As of October 2019, the OCP remains the only provincial pharmacy body to have established mandatory cannabis competency education.

This reactive, half-hearted approach has left many Canadian pharmacists wholly unprepared for dealing with patient concerns, often ending up with more questions than answers. How can pharmacists be expected to provide optimal patient care without having strong foundational knowledge on the topic at hand?

Although history seems to be repeating itself from a legislative perspective, it does not and should not also occur from a patient-care standpoint. National and provincial governing bodies should take careful note of the precedence that cannabis has set and use it as a springboard to develop programming which demystifies psychedelic therapy. The College of Pharmacists of BC have already begun to identify potential issues regarding patient education and safety for both MDMA and psilocybin<sup>10</sup>. By taking this proactive approach, NAPRA and the CPhA could prepare Canadian pharmacists for what seems like an inevitability – legalization of psychedelic drugs. We have a decision to make as a profession: to act boldly and progressively with optimal patient care at the forefront of our minds or to stand by until a decision is made and hope we can keep up.

## **Works Referenced**

<sup>1</sup>Carhart-Harris, R., & Bolstridge, M. et al.(2016, May 17). Psilocybin with psychological support for treatment-resistant depression: an open-label feasibility study. Retrieved from <u>https://www.sciencedirect.com/science/article/pii/S2215036616300657</u>.

<sup>2</sup>Ross, S., Bossis, A., Guss, J., Agin-Liebes, G., Malone, T., Cohen, B., ... Schmidt, B. L. (n.d.). Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial - Stephen Ross, Anthony Bossis, Jeffrey Guss, Gabrielle Agin-Liebes, Tara Malone, Barry Cohen, Sarah E Mennenga, Alexander Belser, Krystallia Kalliontzi, James Babb, Zhe Su, Patricia Corby, Brian L Schmidt, 2016. Retrieved from https://journals.sagepub.com/doi/full/10.1177/0269881116675512.

<sup>3</sup>https://compasspathways.com/compass-pathways-receives-fda-breakthrough-therapy-designation-for-psilocybin-therapy-for-treatment-resistant-depression/

<sup>4</sup>ClinicalTrials.Gov Reference Numbers for the MAPS Phase Two Trials: <u>NCT00090064</u>, <u>NCT00353938</u>, <u>NCT01958593</u>, <u>NCT01211405</u>, <u>NCT01689740</u>, <u>NCT01793610</u>

<sup>5</sup><u>https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/understanding-new-access-to-cannabis-for-medical-purposes-regulations.html</u>

<sup>6</sup>Canadian Federal Court Citation Number 2016 FC 236

<sup>7</sup><u>https://psychedelicreview.com/therapsil-seeks-permission-for-psilocybin-treatments-for-dying-patients/</u>

<sup>8</sup><u>https://napra.ca/sites/default/files/2017-</u> 08/Position Statement Cannabis for medical and nonmedical purposes July2017.pdf

<sup>9</sup><u>https://www.ocpinfo.com/library/practice-related/download/cannabis-strategy-for-pharmacy.pdf</u>

<sup>10</sup><u>http://library.bcpharmacists.org/2\_About\_Us/2-1\_Board/Board\_Meeting\_Minutes-</u> 20180420.pdf