field trip

Special Access Program Submission

Submitted to the Hon. Patty Hajdu – February 10, 2021

TABLE OF CONTENTS

Hon. Patty Hajdu
Minister of Health
House of Commons
Ottawa, ON K1A 0A6

February 10, 2021

Dear Minister Hajdu,

On behalf of Field Trip Health Ltd.'s. (Field Trip) executive management and operational team members, please accept our submission in support of restoring potential access to restricted drugs through Health Canada's Special Access Program (SAP).

Summary of Submissions

As described in these submissions, Field Trip is supportive of the department's objective of reversing the regulatory changes made to the Food and Drug Regulations (Parts C and J) and the Narcotic Control Regulations of 2013 to permit access to restricted drugs through the SAP (the Amendments). However, we believe that certain matters must be clarified and/or considered as part of the Amendments.

In particular, we submit the following for your consideration:

- **MDMA and Psilocybin to Be Included**. While we consider the objective of the Amendments to be a sensible policy proposal, we believe that the Amendments should specifically enumerate that psilocybin and MDMA, as well as other well-studied psychedelic compounds such as LSD and DMT, will be made available through the SAP.

- **The Amendments Pertaining to Psychedelics are Medically Supported**. We believe that given the available safety and efficacy data in respect of psychedelic-assisted therapies, access to such treatments through SAP is medically justifiable and supportable.

- **Definition of "Serious or Life-Threatening" Must be Broad**. In order for the Amendments to achieve their intended stated policy objective, the definition of "serious or life-threatening conditions", particularly as it pertains to access to psilocybin and MDMA-assisted therapies, should be given a broad, robust and fulsome interpretation and not be read narrowly. As it pertains to access to psychedelic compounds, the definition of "serious or life-threatening conditions" should be read to include mental health conditions such as depression, anxiety, post-traumatic stress disorder, eating disorders, dysthymia and adjustment disorders, as well as disorders affecting the central nervous systems such as cluster headaches and migraines. Further, any mental health condition considered to be "treatment resistant" should be deemed to qualify as "serious or life-threatening". If such conditions are not included in the Amendments, the policy

objectives of the Amendments may not be achieved, and as discussed below, may further violate constitutionally protected rights of Canadians.

- **The Amendments Pertaining to Psychedelics are Legally Supported.** The Amendments are legally justifiable and supportable. We believe that access to psychedelic therapies may (and likely will) be recognized as a constitutionally protected right of Canadians, particularly if such a matter were to be litigated. As such, we believe that the Amendments move the Government of Canada closer to protection of such rights and is sensible in the context.

- **The Need for a Complete Regulatory Framework for Psychedelics.** While the Amendments are legally justifiable, we believe that they may be insufficient to protect the rights of Canadians. In particular, Section 7 of the Charter of Rights and Freedoms protects the right to liberty and security of the person and not to be deprived thereof except in accordance with the principles of fundamental justice. Liberty, it has been held, protects every Canadian's right to make fundamental personal choices free from state interference. We believe that, if a constitutional challenge pertaining to access to psychedelic therapies were pursued, it would be found that access to psychedelic therapies for medical purposes would be found to be protected under Section 7 of the Charter, similar to cannabis. Accordingly, we encourage the government to swiftly work toward legislating a regulatory framework that provides broad, consistent access to psilocybin, MDMA and other psychedelic therapies outside of SAP and Section 56 requests. Precedents exist for reclassification of Schedule 3 drugs in Canada. Previous regulations allowing medical access to cannabis offer a regulatory model to expand access to psychedelic therapies. More than 2,800 Canadians with terminal illness per year could potentially benefit from expanded access, not to mention the thousands of Canadians suffering with treatment-resistant mental illnesses. We recommend Health Canada consider the regulations detailed in the Cannabis Act (S.C. 2018, c. 16) as a potential model for the legalization of therapeutic psilocybin-assisted psychotherapy.

- **The Establishment of a Ministerial Advisory Council**. Appointed by the Minister, a council of industry leaders, including medical and business experts, patient advocates and community members, would provide vital, real-time data and recommendations on current clinical operations, progress made through the SAP, and the development of safety protocols and quality assurance for the approval of a legislated regulatory framework. We encourage the Government of Canada to work quickly toward the establishment of such a council.

- **COVID Must Be Considered**. In furtherance of the foregoing, we submit that it is vitally important that the Amendments and path to a complete regulatory framework for access to psychedelic therapies be viewed within the context of the COVID-19 pandemic and mental health crisis facing Canadians.

Backed by our own treatment experience and volumes of clinical data, which we have provided below, we consider it a matter of life and death.

- **MAiD Regulations**. In the coming months, Parliament is scheduled to perform a mandatory Statutory Review of Bill C-7: Medical Assistance in Dying (MAiD) regulations and their impact on Canadians over the past five years, including a review of palliative care. Based on research (see appendices) indicating that expanded regulatory access is justifiable given the established safety of psilocybin, its putative therapeutic benefits, Canada's aging population and the prevalence of end-of-life-distress (EOLD), we submit that Health Canada engage this meaningful process to formally introduce amendments to MAiD allowing for full legal, therapeutic access to proven psychedelic therapies.

In summary, as Health Canada begins to modernize specific drug policy regulations, we see the Amendments being a critical first step in recognizing the extreme mental and physical health challenges faced by thousands of Canadians each year. But it is only a first step.

As clinical and science-based evidence continues to demonstrate low-risk, life-changing outcomes of psychedelic-assisted therapies for patients with mental health conditions, we believe the appetite and demand for psychedelic therapies will continue to grow, especially when factoring comorbid suicidality in vulnerable Canadian populations and professions.

Field Trip will continue to make itself available to work with and support Health Canada on this important endeavour and we would welcome the opportunity to meet and discuss next steps at your earliest convenience.

Sincerely,

Dr. Ryan Yermus	**Dr. Michael Verbora**	**Ronan Levy**
Chief Clinical Officer	**Medical Director**	**Executive Chairman**

1. About Field Trip

Field Trip Health Ltd. (Field Trip) is a new kind of mental health and wellness company, focusing on legal psychedelic-assisted therapies for hard-to-treat mental health conditions like depression, anxiety and traumatic stress disorders.

Field Trip Health's outpatient mental health centers offer a deeply human experience, combining the science of modern medicine with the wisdom of the psychedelic approach along with technology- enabled personalized psychotherapy and wellness practices.

The patient journey begins with thoughtful assessment and preparation, continues through meaningful exploratory sessions with licensed medical and mental health professionals, and culminates with the integration of therapeutic insights into daily life. Each clinic has been purpose-built to provide a welcoming, safe and engaging environment for every client's treatment program.

Field Trip currently has operational clinics – offering ketamine-assisted psychotherapy – in Toronto, New York, Los Angeles, Chicago, and Atlanta with significant expansion plans across North America continuing through 2023.

2. Unmet needs in mental health

What defines a "serious or life-threatening condition" is arguably the most important question in this process, and the longer Canadians are exposed to events like COVID-19, the more urgent it becomes."

- *Ronan Levy*

There is a massive unmet mental health need in Canada, specifically when factoring major depressive disorder (MDD), treatment-resistant depression (TRD) and suicide. If left unremedied in the aftermath of COVID-19, these diseases will affect generations of Canadians on a social, physical and economic scale unlike anything ever witnessed in a developed country. Vulnerable Canadians experiencing pre-existing mental conditions, job loss, geographic isolation, cultural and racial divides, and peer isolation will suffer the most, putting unprecedented economic pressure on current and future governments – federal, provincial and territorial – in the years to come.

A recent U.S study found that the "prevalence of depression symptoms was more than 3-fold higher during COVID-19 compared with before the COVID-19 pandemic. Individuals with lower social resources, lower economic resources, and greater exposure to stressors (eg, job loss) reported a greater burden of depression symptoms" (Ettman et al, 2020). Researchers recommended that post–COVID-19 plans should account for the probable increase in mental illness to come, particularly among at-risk populations.

To further illustrate the benefits of psychedelic therapies and the potential impact they may have on Canadians with growing mental health problems, we have provided recent statistics and studies correlating the causality, burden and socioeconomic impact of MDD, TRD, and suicide with vulnerable populations living with the COVID-19 pandemic.

2.1. Major depressive disorder and treatment-resistant depression

Major Depressive Disorder (MDD), the complex mood disorder also known as clinical depression, is one of the most common psychiatric disorders seen in specialist and general medical practice. It is characterized by a sad, despairing mood that is present most of the day, nearly every day, for at least two weeks. MDD often impairs an individual's ability to perform or function at work, at school and in social relationships. Additional symptoms might include trouble sleeping, loss of interest in activities or hobbies, changes in appetite and weight, feelings of hopelessness, trouble concentrating, physical discomfort (including chronic pain), and thoughts of suicide.

As a multi-factorial disorder, there is no single cause of depression. Risk factors and potential triggers include a genetic predisposition or family history of depression, biological factors such as brain chemistry or endocrinological imbalances, psychological stressors such as chronic stress or trauma, or the onset of physical illness such as cancer and heart disease.

While a standardized definition is not widely established, *treatment-resistant depression (TRD)* is generally classified as depression that has not responded to multiple antidepressant medications – usually two or more. Approximately 30% of depression cases qualify as treatment-resistant (Mazrec et al., 2014; Warden et al., 2007).

The 12-month and lifetime prevalence of MDD in American adults has been estimated at 10.4% and 20.6%, respectively (Hasin et al., 2018). In Canadian adults, the 12-month and lifetime prevalence of MDD has been estimated at 4.7% and 11.2%, respectively (Knoll & MacLennan, 2017). In an ongoing survey (April-October 2020) conducted by Mental Health Research Canada (MHRC), findings revealed about four per cent of those surveyed said they experienced severe depression before the pandemic. As COVID unfolded, that number more than doubled to around 10 to 13 per cent (MHRC, 2021). Other surveys show even higher numbers, particularly with a younger cohort: The Centre for Addiction and Mental Health (CAMH) survey revealed around 24 per cent of people between the ages of 18 and 39 reported feeling depressed as of November (Yousif, 2021).

With rising sociopolitical unrest and economic uncertainty, as well as the impact of the COVID-19 pandemic on daily living and human interaction, these numbers are expected to continue rising.

Generalized Anxiety Disorder (GAD) was already one of the most reported mental illnesses in Canada before the pandemic, and it affects about three per cent of the population in any given year. In the same MHRC survey, participants were asked about their pre-pandemic anxiety levels, and five per cent surveyed in April 2020 said they experienced high levels of anxiety before COVID-19 (Yousif, 2021).

As the pandemic unfolded, the number of people who characterized their anxiety levels as moderate to severe jumped to around 20 per cent, quadrupling pre-pandemic rates. Those with pre-existing mental health conditions reported even higher levels of anxiety at 38 per cent. These results remained fairly consistent from April to October (Yousif, 2021).

2.2. Burden of disease

Yearly costs for depression and anxiety in Canada alone have reached $32 billion and $17 billion respectively, and disability claims due to mental health are a top employer concern. Higher workforce productivity would contribute an additional $32.3 billion annually to Canada's economy (Conference Board of Canada, 2019).

In 2017, Chiu et al published a study on the direct healthcare costs associated with psychological distress and major depression in Ontario. The objective of the study was to estimate direct healthcare costs incurred by a population-based sample of people with psychological distress or depression. The study found substantial healthcare costs associated with psychological distress and depression, suggesting that psychological distress and MDD have a high-cost burden and there may be public health intervention opportunities to relieve distress (Chiu et al, 2017). A legalized psychedelic framework is the kind of opportunity the Canadian government should be investing in.

The cost burden of mental health on Canada's healthcare system is unsustainable. In its 2019 Chartbook study, the Canadian Institute for Health Information (CIHI) predicated that mental health and addictions (MHA) spending would outstrip total health expenditure by four per cent annually (CIHI, 2019). Emergency Departments (ED) are overwhelmed with substance-use visits; the cost per day in designated mental health beds is higher in general hospitals, however, longer hospital stays increased the cost per stay in psychiatric hospitals (CIHI, 2019).

In a peer-reviewed study on severe mental illness (SMI) and health service utilization in the UK, SMI was associated with increased use of ED in 18 out of 20 of the analyses (Ronaldson et al). The same study revealed SMI was associated with increased inpatient hospital admissions over the study period (12 months to 15.5 years) in 35 of the 44 cases studied (Ronaldson et al, 2020).

In fact, when the impact of psychiatric comorbidity is analyzed between SMI and the use of inpatient, emergency, and primary care services for nonpsychiatric medical disorders, the findings reveal a case for system-wide integration of mental and physical healthcare. This only strengthens the case for an informed, regulated policy that supports therapeutic innovation on a national scale.

The fact is, increased ED visits, poor mental health days, and longer hospital stays are costing Canadian and U.S economies billions every year.

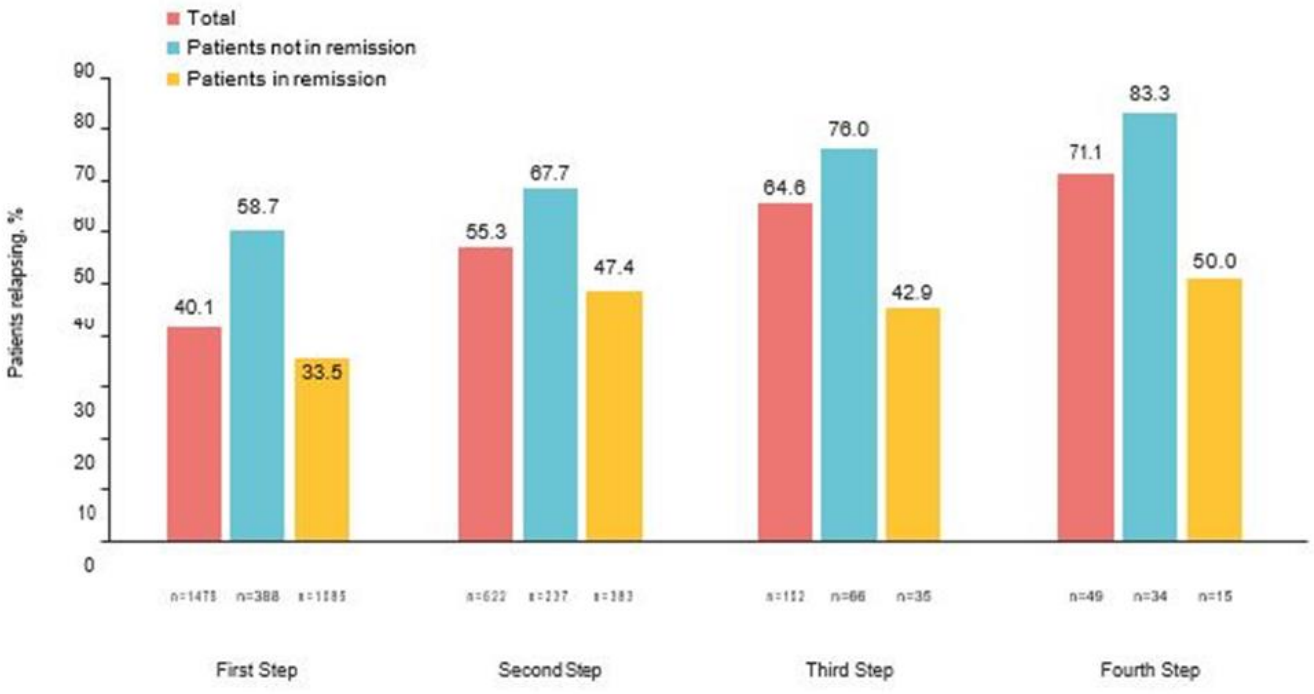
2.3. Lack of treatment options for depression

Existing treatment options do not currently meet the needs of the millions of people suffering from TRD, nor the millions more with MDD who will eventually stop responding to their current medication regimen. Relapse rates when switching or progressing an additional medication step are high, at 65% and 71% for the third and fourth steps, respectively *(Figure 3)*.

Those who do respond to treatment must wait an average of six weeks before any response is observed. Further, once a patient has responded to their second antidepressant medication, before their depression is considered treatment-resistant, the average time to relapse is only four months. A trial and error, "wait and see approach" is not serving the best interests of these patient populations (Warden et al., 2007).

While the treatment of mental health conditions – like depression – should be holistic in order to be successful in the long term, a lack of access to holistic treatment (e.g. a combination of psychotherapy, medication and other socio-behavioural interventions) remains a problem (Phelps, 2017). Of the estimated 17.3 million US adults who experienced a major depressive episode in 2017, including the 64% of whom who experienced severe impairment due to the episode, only 44% received care by a health professional and medication treatment (NIMH, 2018).

Figure 3. Depression relapse rates increase with each treatment step (switching or augmenting medication).



3. Vulnerable Populations and Professions

"It's a recipe for mental health issues…We know that social isolation and loneliness are strong predictors of mortality — they predict life expectancy better than smoking, obesity and diabetes. So being lonelier and socially isolated has a huge impact on us physically."

- Dr. David Dozois, professor of psychology at Western University and a member of MHRC's board of directors, on the impact of COVID-19.

The COVID-19 pandemic has exposed Canada's lack of mental health infrastructure and reinforced the need for innovative solutions that address mental and physical well-being. Tackling the mental health crisis in the immediate future is paramount to the short and long-term mental health of all Canadians, particularly young Canadians between 15 – 24 (CAMH, 2021) who are more likely to experience mental illness and/or substance use disorders than any other age group.

The pandemic, economy/jobs, and healthcare are the top three front-of-mind concerns for Canadians right now, yet if the status quo in mental health strategy is maintained, Canada (and the world) will face long-lasting, irreversible consequences. Vulnerable populations will be the first to suffer.

3.1. Military veterans, law enforcement & corrections, first responders, physicians

Perhaps the most alarming trend seen during the pandemic is the increase in those having suicidal thoughts. CMHA's survey asked participants in May and October whether they've had thoughts of suicide. In the May survey, 6.4 per cent answered yes. That increased to 10 per cent in October. Further data from Statistics Canada indicates that 2.5 per cent of the population reported having suicidal thoughts in pre-pandemic 2019 (Yousif, 2021).

Suicide among Canadian Veterans continues to be a top public health concern…Both male and female Canadian Veterans have a significantly higher risk of death by suicide compared to Canadians in the general population (Simkus et al, 2019). Despite the federal government having introduced a suicide-prevention strategy for military members and veterans in 2017, a June 2020 study revealed that 20 service members took their own lives in 2019, the largest number of military suicides since 2014 (Canadian Armed Forces, 2020). Further, a total of 175 Canadian military personnel have died by suicide since 2010. That is more than the 158 killed while serving in Afghanistan from 2001 to 2014 (Canadian Armed Forces, 2020).

Corrections officers are also suffering. There have been eight documented correctional officer deaths by suicide since January 2018 (Feyginberg, 2019).
Recent studies show that mental illness is relatively widespread amongst Canadian police officers, and that a number of police also engage in suicidal behaviours (Carelton et al, 2017). Furthermore, Canadian police officers are

disproportionately affected by mental illness, and a substantial number of municipal/provincial police (36.7%) and Royal Canadian Mounted Police (RCMP) (50.2%) report current symptoms of mental illness compared to the general population (~10%) (Carelton et al, 2017). While unconfirmed, some major police forces across Canada have claimed that more resources are being spent on disability instead of frontline police officers because of the mental health crisis (Private Communication, 2021).

In 2019, the Canadian Medical Association Journal (CMAJ) report published findings showing that suicide is an occupational hazard for physicians. Suicide is the only cause of mortality that is higher in physicians than nonphysicians. Compared with nonphysicians, male physicians are 40% more likely to die by suicide (rate ratio 1.41, 95% confidence interval [CI] 1.21–1.65), and the risk to female physicians is more than doubled (rate ratio 2.27, 95% CI 1.90–2.73) (Schernhammer et al, 2004). The report showed that suicidal physicians face unique barriers to care, develop suicidal ideation beginning in medical school, and that past or current regulatory complaints are associated with increased rates of suicidal ideation (Bourne et al, 2015).

What we know is that psychedelics and psychedelic-assisted therapy provide relief to individuals who respond poorly to classical treatments and may be able to replace long-term pharmaceutical interventions that have not shown significant symptom relief for patients. In fact, epidemiological studies show lower rates of mental health disorders and suicide among people who have used psychedelics like psilocybin compared to the overall population (Drug Policy Alliance, 2017).

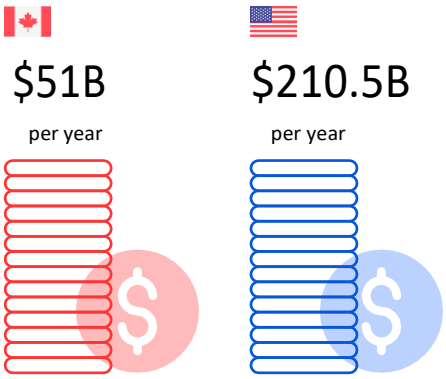
3.2. Public health gap in palliative care

Up to 80% of patients with advanced cancer are likely to suffer distressing thoughts around death (Grossman et al, 2017) and up to 50% of patients with generally incurable conditions are likely to have psychiatric diagnoses (Asghar-Ali et al, 2013). Symptoms include depression, anger, hopelessness, fear of suffering and loneliness (Swift et al, 2017, Grossman et al, 2017). Death anxiety may be a normal part of the human life cycle, but the current medicalized model (Dyck, 2019) can make it difficult for palliative patients to focus on their holistic and spiritual well-being, which palliative nurses consider to be of top concern (Rosa, 2019). The literature suggests a gap between current palliative care offerings and the current and expected future demand; the literature suggests this gap is driven by a lack of reliable pharmacological interventions for palliative dread (Bernstein, 2020, Rosenbaum et al, 2019) and an ageing population (Dyck, 2019). If left unaddressed, death anxiety may lead to more palliative patients seeking medical assistance in dying (MAID) (Grossman, 2017).

Psychedelics may be effective supportive agents for patients experiencing end-of-life distress and considering medical assistance in dying. While medical assistance in dying is a protected right in Canada, patients approaching death may be underserved if promising therapies are withheld. Psychedelic-assisted therapy can promote patients to safely surface concerns about mortality and face death, our “primordial fear” (Dutta, 2012) while simultaneously enabling resolution of those these concerns (Moreton et al, 2019). They can also help patients find meaning in death, embrace mortality, and appreciate their lives (James, 2020, Swift, 2017, Ross, 2016, Grob, 2013).

3.3. Socioeconomic Impact and Disability

Mental health conditions, specifically depression, are among the leading causes of productivity loss and disability in Canada and the United States.



In Canada, depression carries an estimated economic burden of at least CA$51 billion per year, including health care costs, lost productivity and reductions in health-related quality of life (Lim et al., 2008). It is estimated that, in any given week, at least 500,000 employed Canadians are unable to work due to mental health problems (Dewa, Chau, and Dermer,2010).

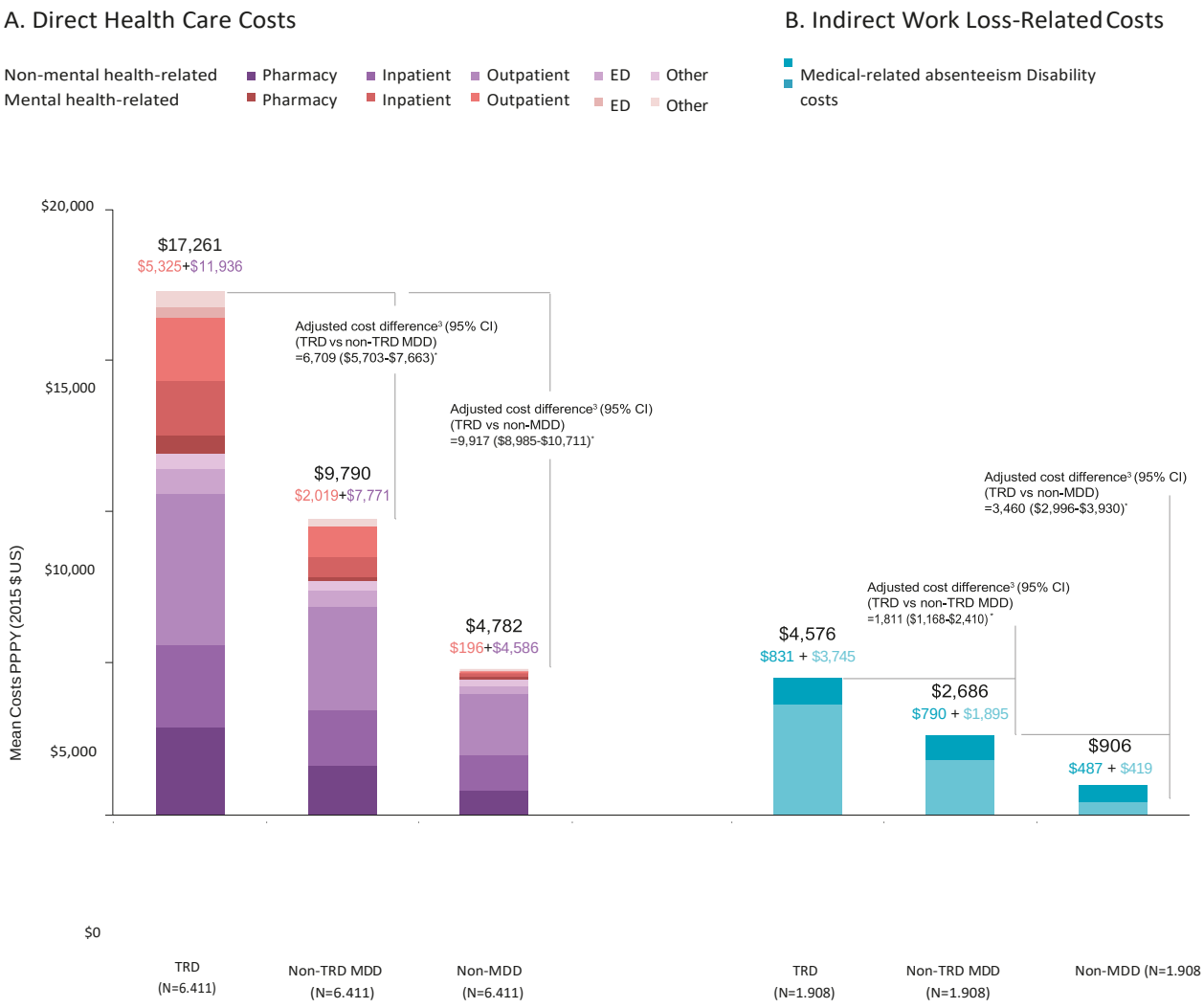
A 2011-2012 Canadian study of non-TRD MDD and TRD revealed stark contrasts in both short and long-term disability claims. In 2012, employees with TRD filed proportionally more short-term disability (STD) claims than those with non-TRD MDD (5.0% vs 1.0%) and more long-term disability (LTD) claims (4.1% vs. 0.3%). Of those with TRD filing STD and LTD claims, mean costs per claim were CA$7,832 and CA$13,928, respectively (Kellar et al., 2014).

In a July 2020 report produced by the Conservative Drug Policy Reform Group (CDPRG) and the Adam Smith Institute (ASI), evidence reveals the social and economic burden depression puts on the UK economy, resulting in an estimated £10 billion per year in reduced productivity, missed work, and treatment costs, with mental illness as a whole costing up to £94 billion. The report argues that with almost no depression drugs having been approved in decades, the "untapped" potential of psilocybin-assisted therapy is arguably an opportunity missed (CDPRG, 2020).

In the United States, MDD carries an estimated economic burden of $210.5 billion, annually. Accounting for a significant share of the MDD burden, the burden of treatment-resistant depression is estimated at $29-48 billion, annually, through direct health care costs and indirect work loss-related costs (Amos et al., 2018).

In a study of US claims databases, Amos et al. (2018) identified a mean adjusted direct health care cost difference, per patient per year, of US$6,709 between the TRD and non-TRD MDD groups, and US$9,917 between the TRD and non-MDD group *(Figure 1)*. Mean adjusted indirect work loss-related costs were also greater in the TRD group than in the non-TRD MDD and non-MDD groups, by US$1,811 and US$3,460, respectively *(Figure 1).*

.Figure 1. Comparison of direct and indirect costs per patient per year in TRD, non-TRD MDD, and patients without depression (non-MDD) over a 2-year time horizon.



Adjusted for baseline total health care costs and Quan-CCI.

P values and confidence intervals were obtained using a nonparametric bootstrap procedure (N=499)

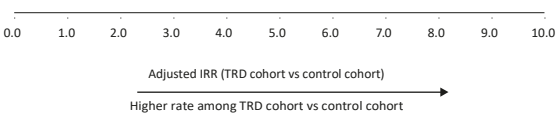
* Significant at the 5% level.

CI = confidence interval, MDD = major depressive disorder, PPPY = per patient per year, Quan-CCI = Quan-Charlson Comorbidity Index, TRD = treatment-resistant depression

Employees suffering from TRD were also more likely to utilize disability days than those with non-TRD MDD or those without MDD at an adjusted ratio of 1.87 and 6.92, respectively *(Figure 2).*

Figure 2. Comparison of health care resource utilization and indirect resource utilization in TRD, non-TRD MDD, and patients without depression (non-MDD) over a 2-year time horizon.

TRD cohort vs non-TRD MDD cohort	Adjusted IRR (95%CI)[3]	Pvalue*
Health care resource utilization		
Inpatient visits	1.96 (1.79-2.14)	<.001
No. of days		
ED visits Outpatient	2.34 (2.08-2.64)	<.001
visits Other visits	1.47 (1.39-1.56)	<.001
Indirect resource utilization	1.44 (1.41-1.48)	<.001
Total work loss days	1.52 (1.44-1.62)	<.001
Medical-related absenteeism days		
Disability days	1.74 (1.57-1.93)	<.001
TRD cohort vs non-MDD cohort	1.47 (1.34-1.62)	<.001
Health care resource utilization	1.87 (1.43-2.44)	<.001
Inpatient visits		
No. of days		
ED visits Outpatient		
visits Other visits	4.71 (5.24-5.22)	<.001
Indirect resource utilization	5.80 (5.10-6.60)	<.001
Total work loss days	2.94 (2.76-3.14)	<.001
Medical-related absenteeism days	3.57 (3.46-3.68)	<.001
Disability days	2.74 (2.57-2.91)	<.001
	6.16 (5.38-7.04)	<.001
	4.74 (4.19-5.36)	<.001
	6.92 (5.13-9.35)	<.001



Adjusted IRR (TRD cohort vs control cohort)

Higher rate among TRD cohort vs control cohort

Adjusted for baseline total health care costs and Quan-CCI. P values and confidence intervals were obtained using a Nonparametric bootstrap procedure (N=499)

* Significant at the 5% level.

CI = confidence interval, MDD = major depressive disorder, PPPY = per patient per year, Quan-CCI = Quan-Charlson Comorbidity Index

TRD = treatment-resistant depression

The impact of psilocybin and psychedelic-assisted therapy on the Canadian healthcare system would be transformative. On October 14, 2020, Dr. Eliott Marseilles, an expert in the economic evaluation of global health programs, and his colleagues released a ground-breaking study designed to help patients with treatment resistant PTSD. The study, entitled *The cost-effectiveness of MDMA-assisted psychotherapy for the treatment of chronic, treatment-resistant PTSD*, concluded that 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy (MAP) provided to patients with severe or extreme, chronic PTSD "appears to be cost-saving while delivering substantial clinical benefit. Third-party payers are likely to save money within three years by covering this form of therapy."

The study also reported substantial social benefits, which according to the authors was unplanned. They include:

- patients unable to work due to PTSD were able to return to work post-study.
- Reduction of PTSD symptoms, which could therefore lower disability payments and raise productivity.

For every 1,000 patients treated, the study estimated 30-year savings to the medical care system of $103 million, while generating 5,553 QALYs and averting 42.9 deaths (Marseilles et al, 2020). When factoring the cost to third-party payers, the study found payers were likely to save money by including MAP as a covered benefit for patients with chronic PTSD, even after adjusting for plan migration and upfront costs (Marseilles et al, 2020).

Smoking:

Psychedelics are also showing significant results in smoking cessation. Smoking causes a massive $6.5 billion in direct health care costs and $16.2 billion in total economic costs, including healthcare costs (Lung Association of Canada, 2021). Roughly 45,000 Canadians die each year as a result of smoking, contributing to three of the top five leading causes of death in Canada (Lung Association of Canada, 2021). In 2018, the Canadian government invested $330 million in a five-year tobacco and vaping strategy, predicting it will save millions of lives and billions by 2035. In its *Overview of Canada's Tobacco Strategy*, a commitment to provide "Access to More Choice" and "Strengthening our Foundations in Science, Research and Surveillance" we believe the integration of psilocybin and psychedelic therapies fall well within the parameters of "choice, science and research" for smoking cessation.

In one 2014 Johns Hopkins study (Nelson, 2014), 80 per cent of the smokers who participated in psilocybin-assisted therapy remained fully abstinent 12 months after the trial. By way of comparison, smoking cessation trials using varenicline (a prescription medication for smoking addiction) has success rates around 35 percent.

3.4. Trauma and stress-related indicators

Trauma, whether in the form of chronic stress exposure or a singular event, can lead to a number of psychiatric disorders, including depression, anxiety, acute stress disorder, and post-traumatic stress disorder (PTSD). The lifetime prevalence of PTSD, specifically, is estimated to be 9.2% and 7.8% in Canada and the United States, respectively. More acutely, past-month prevalence of PTSD is estimated to be 2.4% and 3.5% in Canada in the United States, respectively (Van Ameringen et al., 2008; Kessler et al., 2005). Lifetime prevalence is higher among certain professions, including military, police, firefighters and paramedics (Van Ameringen et al., 2008).

PTSD is highly comorbid with depression and substance use disorders *(Table 1)* and can cause stress- mediated health conditions such as obesity, cardiovascular disease and type-2 diabetes (Ahmadi et al., 2011; Dedert et al., 2010; Van Ameringen et al., 2008). While common treatment options include medication and psychological support, analyses have found that most people suffering from PTSD experience symptoms for well over one year, despite ongoing treatment, and at least 50% remain resistant to treatment, facing recurrent or chronic symptoms (Steinert et al., 2015).

A lack of direct data has limited the estimates of the economic impact of PTSD. However, the traumagenic nature of other mood and substance use disorders undoubtedly renders the economic impact of PTSD as intertwined with that of said conditions.

Table 1. Lifetime PTSD and comorbid disorders (n=645, weighted analysis).

	Men			Women			Total		
	With PTSD, %	No PTSD, %	O/R (95% CI)	With PTSD, %	No PTSD, %	O/R (95% CI)	With PTSD, %	No PTSD, %	O/R (95% CI)
MDD	63.0	22.6	5.8 (3.13-10.93)[a]	78.1	36.6	6.16 (3.94-9.64)[a]	74.0	30.9	6.36 (4.44-9.11)[c]
Alcohol abuse/ dependence	44.7	25.0	2.42 (1.34-4.01)[b]	21.3	12.1	1.97 (1.14-3.39)[b]	27.8	14.4	1.93 (1.25-2.71)[c]
Substance abuse/ dependence	41.3	10.3	6.14 (2.99-12.60)[a]	19.3	5.1	4.49 (2.17-9.30)[a]	25.5	7.2	4.43 (2.69-7.28)[c]

[a] $p < 0.001$, [b] $p < 0.01$: Men vs women and comorbidity for those with and without lifetime PTSD using Pearson chi-square and risk estimates.
c $p < 0.001$: Men and women combined, with and without PTSD and with comorbidity using Pearson chi-square and risk elements.

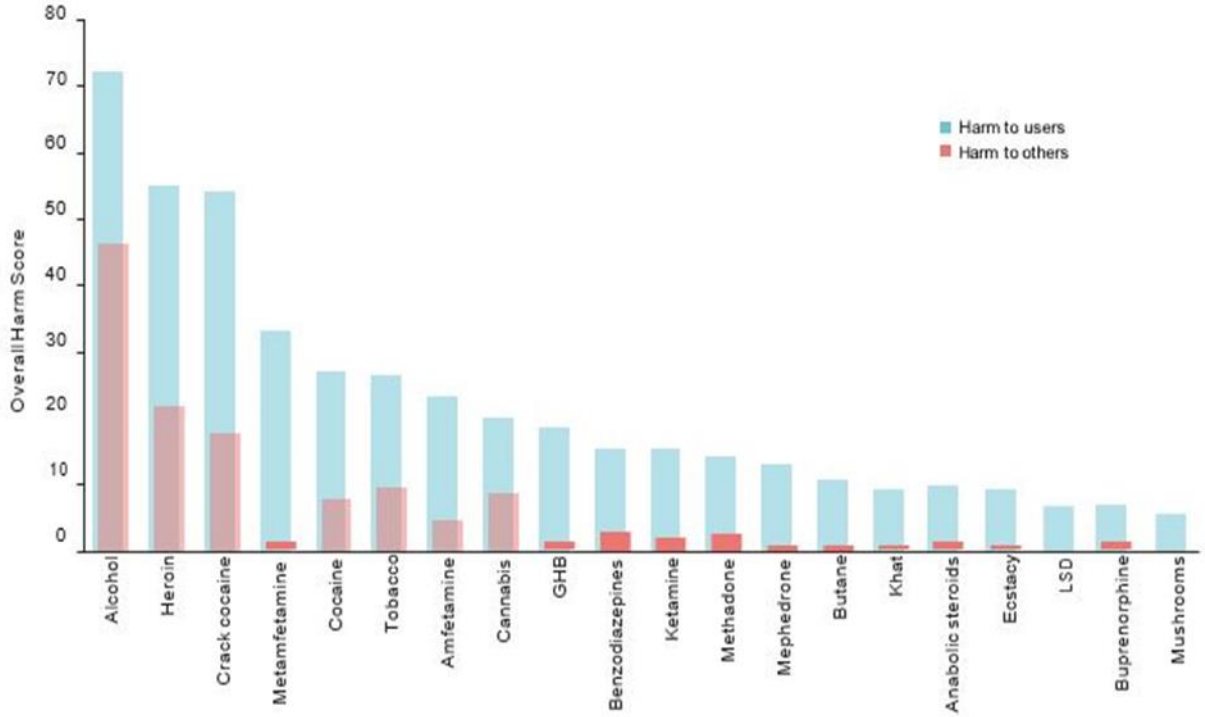
PTSD is the beast that continues to rear its ugly head in the minds of Canadian combat veterans and first responders, costing the Canadian government $20.7 billion annually (Wilson et al, 2018). Estimates suggest that as many as 2.5 million adult Canadians and 70,000 Canadian first responders have suffered from PTSD in their lifetimes (Wilson et al, 2018).

Between 2014 (the year Canada's Afghanistan mission ended) and 2017-18, the federal government had to top up the military's disability insurance plan several times to a total of more than $1.2 billion. Federal Supplementary Estimates for 2017-18 said that year's increase was due to "a significantly higher number of claims, largely owing to increased awareness and recognition of PTSD and mental health" (Adams, 2019). Mental and physical-health disability awards and benefits are not tracked or isolated by Veterans Affairs Canada (VAC), although the department agrees "many of its programs have a mental health component" (Adams, 2019).

4. Psychedelic Medicines

While psychedelics have been used for millennia via traditional medicine and some indigenous spiritual-cultural practices, their incorporation into modern medical practices has been met with legislative and social hurdles (Vollenweider & Preller, 2020). The unmet and increasing need for treatments for neuropsychiatric disorders such as depression, coupled with the growing body of evidence supporting the efficacy of psychedelics, has renewed public and medical interest in psychedelic medicine. Scientists widely agree that psychedelics present promising health benefits and favorable safety profiles compared to most consumed substances (Figure 7 below).

Figure 7; Nutt et al., 2010.



Psychedelics have shown the great promise in treating psychiatric and substance use disorders when used in a controlled environment with one or more skilled facilitators (Phelps, 2017). The various nuances of psychedelic medicine, from preparation for and integration of the experiences to the consideration of aesthetic features of the surrounding environment, are being studied at many world- renowned institutions such as Johns Hopkins University, Harvard, Imperial College London, Yale University, and the University of Toronto.

Evidence is mounting such that governments are beginning to acknowledge the benefits of these substances and permitting their use in a medical context. In 2020, Health Canada has approved the use of psilocybin-containing mushrooms to relieve depression and anxiety in patients facing terminal illnesses, and one patient without a terminal diagnosis.

Commercially, various companies are developing psychedelic molecules through the traditional clinical drug development pathway. Psilocybin and MDMA are in late-stage clinical trials for the treatment of treatment-resistant depression and post-traumatic stress disorder, respectively. Both molecules have been granted Breakthrough Therapy Designation by the US Food & Drug Administration (FDA) – a designation saved for drugs that treat serious conditions and demonstrate a substantial improvement over available therapies.

While potential tax revenue is key, secondary benefits could come as more people find effective therapy for what ails them. People with access to effective mental health treatment are more productive members of society, take fewer sick days and require fewer long-term hospitalizations. Potential cost savings for mental health care are astronomical, especially in states like Oregon, who recently passed Measure 109, essentially legalizing psilocybin-assisted therapy, where rates of mental health issues run high. Every year, billions of dollars are spent on disability coverage and general mental health care. Psychedelic treatments have the additional potential of costing much less to produce than their pharmaceutical counterparts.

4.1. Ketamine and safety

Ketamine is generally considered safe when administered in a clinical environment by medical professionals. As with other psychedelics, ketamine is contraindicated for individuals with diagnosed or suspected psychiatrically unstable conditions. Increases in blood pressure and heart rate can occur but rarely require any medical intervention at sub-anesthetic doses. Also rare at subanesthetic doses are slowed breathing and hypercapnia (elevated carbon dioxide levels in the blood) (Tyler et al., 2017).

While dissociative, or “psychedelic”, properties may be present even at low doses, a number of studies point to these experiential components as positive mediators of the molecule’s antidepressant effects. Indeed, research on psychedelics such as ketamine and psilocybin suggests that the experiential components of the treatment may be integral to enhancing and sustaining clinical outcomes (Luckenbaugh et al., 2014).

4.2. Clinical research

A review of seven systematic reviews of classical psychedelics demonstrates significant positive results in reducing end-of-life depression and anxiety in the following cases: ayahuasca for major depressive disorder, psilocybin for treatment-resistant depression, psilocybin for anxiety and depression associated with life-threatening cancer, and LSD for anxiety associated with life-threatening disease (Muttoni, 2019).

Psilocybin-assisted therapy has been documented in several clinical trials over the past ten years, indicating strong suggestions of efficacy for reducing anxiety and depression for patients facing cancer or terminal illness (Carhart-Harris et al, 2018, Griffiths et al. 2016, Ross et al, 2016, Grob et al, 2011). Psilocybin-assisted therapy may also be of support through its other psychiatric purposes (Shore 2020a). Encouraging results suggest its efficacy towards supporting patients with symptoms of treatment-resistant depression (Carhart-Harris et al, 2016) and depression (Carhart-Harris et al, 2016, Carhart-Harris et al, 2018, Ross et al, 2016), anxiety (Griffiths et al, 2016, Grob et al, 2011), substance use (Bogenschutz et al, 2015, Johnson et al, 2014), and obsessive-compulsive disorder (Moreno et al, 2006). Fifty-four (54) additional clinical trials using psilocybin are registered, a stage 3 randomized controlled trial, psilocybin for major depression, is currently underway.

In a 2018 study released by the Journal Frontiers of Pharmacology, author Eduardo Ekman Schenberg found that clinical results [from psychedelic-assisted therapy] so far have shown safety and efficacy, even for 'treatment resistant' conditions, and thus deserve increasing attention from medical, psychological and psychiatric professionals.

The safety and tolerability of these substances have been established in these studies, and promising results in the effectiveness in treating and lowering rates of remission have been reported. Notably, the Multidisciplinary Association for Psychedelic Studies (MAPS), has demonstrated substantial cost effectiveness of MDMA-assisted psychotherapy (MAP) in a population with PTSD. The peer-reviewed study estimated that, when used instead of traditional care, costs for MAP break even at 3.1 years post-treatment. Over a 30-year time horizon, a population of 1,000 individuals receiving the treatment would lead to a discounted net savings of $103.2 million, the avoidance of 43 premature deaths, and an additional 5.5 quality-adjusted life years (QALYs) gained per patient, on average (Marseille et al., 2020).

5. Conclusion

5.1. Develop a legalized regulatory framework that addresses therapeutic access for all palliative and non-palliative Canadians; and,

5.2. Provide a broad, robust and fulsome interpretation to include mental health conditions.

Canada needs a new legal framework to enable access, in prescribed circumstances, to psychedelic treatments and therapies. The beneficial health outcomes from such access are now supported by a considerable body of scientific study and research. With COVID-19 uncovering an emerging national crisis in mental health, our current supports for Canadians are becoming overwhelmed. Demand for new treatment regimens is mounting and deserves a full policy and regulatory response.

The Canadian government has been responding to this new and growing demand using existing regulatory tools, starting with *section 56* exemptions under the *Controlled Drugs and Substances Act.* This is an application-based Ministerial exemption that enables access to one applicant at a time. This process is already becoming overwhelmed by applications. Recently, Health Canada enabled application, under the Special Access Program, for certain psychedelic treatments. This is also an exemption-based application process. Although it is more efficient than a *section 56* Ministerial exemption, it still requires Canadians, through their physicians, to apply under SAP on a case-by-case basis. This system will likely soon be overwhelmed as well. Canadians are driving demand for a new legal framework, and the SAP is the perfect mechanism to develop it.

It is, therefore, our recommendation that Health Canada revise the SAP to allow for consideration of applications for access to MDMA and psilocybin-assisted psychotherapies. As one of the first and only Canadian companies offering therapeutic treatment through ketamine-assisted therapy, our safety protocols and quality assurance measures are a top priority. Based on that experience, we are providing a draft legal framework (Appendices 1) that proposes safety and mitigation protocols within the scope of ethical, confidential, and safe psilocybin-assisted psychotherapy. We believe this approach further enables increasing Canadian access to these potentially lifesaving therapies in a context of growing morbidity and mortality from serious mental illness in Canada.

Concurrently with the SAP review, Parliament is scheduled to perform a Statutory Review of the Medical Assistance in Dying (MAiD) Act and regulations, and their impact on Canadians over the past five years. This review is set for the winter of 2021 and will include a review of palliative care more generally. The fact that the SAP review and this Parliamentary Review are occurring at the same time provides an excellent opportunity to enact a new framework for legal use of psychedelics in prescribed circumstances.

The MAiD debate has been contentious, both within government and among Canadians generally. However, one area of general agreement across all interested parties is that we need to improve the quality of palliative care and

provide Canadians more treatment options at end-of-life. Psychedelic therapy is a proven treatment option at end-of-life that provides comfort, dignity, and peace of mind at this stressful time. Accordingly, we recommend that end-of-life treatment based on quality of life be a prescribed treatment option under a new legal framework for the use of psychedelics.

Outside of palliative care, there are a number of non-palliative circumstances where psychedelic therapy has been shown to have a beneficial health effect on patients. Beyond palliative care, we recommend prescribing the use of psychedelic therapy for any serious or life-threatening ailment. We further recommend that the definition of "serious and life-threatening" provide as "broad, robust and fulsome interpretation" as possible, to enable Canadian doctors to prescribe this treatment, where warranted, to as many Canadians as possible.

We believe it is imperative that non-palliative options include mental illness. Post-COVID, Canada will be dealing with record levels of mental illness, including depression, anxiety, eating disorders, and PTSD. The "negative mental health impacts of COVID-19 can be expected to last for some time and will place added burden on Canada's already overwhelmed mental health system" (CAMH, 2020). In many cases these mental illnesses are life threatening. In all cases they should be considered serious. As a result, we recommend that treatment of mental illness also be a legal prescribed use of psychedelic therapy.

In conclusion, we are recommending the adoption of a legal framework that not only meets the growing demand for treatment options by Canadians and their physicians, but also is backed by current science. We also believe that this new legal framework would be consistent with section 7 of the *Canadian Charter of Rights and Freedoms*, which states as follows:

> **7**. Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

A new legal framework enabling access to psychedelic therapies, in prescribed circumstances, for all Canadians in need would fulfill their Charter right to "security of the person" and be justified morally, scientifically, and constitutionally.

References

Adams, S. (2019). At what price?. Legion Magazine. https://legionmagazine.com/en/2019/07/at-what-price/

Ahmadi, N., Hajsadeghi, F., Mirshkarlo, H. B., Budoff, M., Yehuda, R., & Ebrahimi, R. (2011). Post-traumatic Stress Disorder, Coronary Atherosclerosis, and Mortality. The American Journal of Cardiology, 108(1), 29–33. https://doi.org/10.1016/j.amjcard.2011.02.340

Albuquerque, J. and Tulk, S. Canadian Medical Association Journal. Physician suicide. May 06, 2019 191 (18) E505; DOI: https://doi.org/10.1503/cmaj.181687

Amos TB, Tandon N, Lefebvre P, Pilon D, Kamstra RL, Pivneva I, Greenberg PE. Direct and Indirect Cost Burden and Change of Employment Status in Treatment-Resistant Depression:A Matched-Cohort Study Using a US Commercial Claims Database. J Clin Psychiatry. 2018 Mar/Apr;79(2):17m11725. doi: 10.4088/JCP.17m11725. PMID: 29474009.

Bernstein, I. (2020). At the Intersection of Palliative Care, Psychedelic Medicine, and Healthcare Reform: A Call for a New Hospice and Palliative Care Movement. Journal of Palliative Care, 1(15). https://doi.org/10.1177/0825859720946898

Bourne T, Wynants L, Peters M, et al. The impact of complaints procedures on the welfare, health and clinical practise of 7926 doctors in the UK: a cross-sectional survey. BMJ Open 2015;5:e006687.

Canadian Armed Forces. (2020). 2019 Veteran Suicide Mortality https://www.veterans.gc.ca/eng/about-vac/research/research-directorate/publications/reports/veteran-suicide-mortality-study-2019

Canadian Institute for Health Information. Chartbook 2019: Health System Resources for Mental Health and Addictions Care in Canada. https://www.cihi.ca/sites/default/files/document/mental-health-chartbook-report-2019-en-web.pdf

Carhart-Harris, R. L., Bolstridge, M., Day, C., Rucker, J., Watts, R., Erritzoe, D. E., Kaelen, M., Giribaldi, B., Bloomfield, M., Pilling, S., Rickard, J. A., Forbes, B., Feilding, A., Taylor, D., Curran, H. V., & Nutt, D. J. (2018). Psilocybin with psychological support for treatment-resistant depression: six-month follow- up. Psychopharmacology, 235(2), 399–408. https://doi. org/10.1007/s00213-017-4771-x

Carleton, R.N., Afifi, T.O., Turner, S., Taillieu, T., LeBouthillier, D.M., Duranceau, S., Asmundson, G.J.G. (2018). Suicidal ideation, plans and attempts among public safety personnel in Canada. Canadian Psychology, Advance online publication. http://dx.doi.org/10.1037/cap0000136.

Centre for Addictions and Mental Health. (2021). https://www.camh.ca/en/driving-change/the-crisis-is-real/mental-health-statistics

Chiu, M., Lebenbaum, M., Cheng, J., de Oliveira, C., and Kurdyak, P. (2017). PLOS ONE. The direct healthcare costs associated with psychological distress and major depression: A population-based cohort study in Ontario, Canada. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5584795/

Conference Board of Canada (2019). Canada's mental health agenda should address mental health in the workplace?. https://www.conferenceboard.ca/insights/blogs/canada-s-mental-health-agenda-should-address-mental-health-in-the-workplace

Conservative Drug Policy Reform Group. (2020). Home Office imply there's no need to reschedule psilocybin: Crispin Blunt MP launches economic investigation in response. https://www.cdprg.co.uk/press-releases/2020/8/5/home-office-imply-theres-no-need-to-reschedule-psilocybin-crispin-blunt-mp-responds-launching-investigation-into-the-direct-costs-of-pointlessly-blocking-promising-mental-health-treatment

Davis, Alan & Barrett, Frederick & May, Darrick & Cosimano, Mary & Sepeda, Nathan & Johnson, Matthew & Finan, Patrick & Griffiths, Roland. (2020). Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder: A Randomized Clinical Trial. JAMA Psychiatry. 10.1001/ jamapsychiatry.2020.3285

Dedert, E. A., Calhoun, P. S., Watkins, L. L., Sherwood, A., & Beckham, J. C. (2010). Posttraumatic Stress Disorder, Cardiovascular, and Metabolic Disease: A Review of the Evidence. Annals of Behavioral Medicine, 39(1), 61–78. https://doi.org/10.1007/s12160-010-9165-9

Dewa, Chau, and Dermer (2010). Examining the comparative incidence and costs of physical and mental health- related disabilities in an employed population. Journal of Occupational and Environmental Medicine, 52: 758-62. Number of disability cases calculated using Statistics Canada employment data, retrieved from http://www40.statcan.ca/ l01/cst01/labor21a-eng.htm

Dore, J., Turnipseed, B., Dwyer, S., Turnipseed, A., Andries,J., Ascani, G., Monnette, C., Huidekoper, A., Strauss, N., &Wolfson, P. (2019). Ketamine Assisted Psychotherapy (KAP): Patient Demographics, Clinical Data and Outcomes in Three Large Practices Administering Ketamine with Psychotherapy. Journal of psychoactive drugs, 51(2), 189–198. https://doi.org/10.1080/02791072.2019.1587556

Drug Policy Alliance. (January 2017). https://www.drugpolicy.org/sites/default/files/Psilocybin_Mushrooms_Fact_Sheet.pdf

Dyck, E. (2019). Psychedelics and Dying Care: A Historical Look at the Relationship between Psychedelics and Palliative Care. Journal of Psychoactive Drugs, 51(2), 102–107. https://doi.org/10.1080/02791072.2019.1581308

Dutta, V. (2012). Repression of death consciousness and the psychedelic trip. Journal of Cancer Research and Therapeutics, 8(3), 336–342. https://doi.org/10.4103/0973-1482.103509

Ettman, C.K, Abdalla, S.M, Cohen, G.H, Sampson, L, Vivier, P.M, Galea, S. (2020). Prevalence of Depression Symptoms in US Adults Before and During the COVID-19 Pandemic. JAMA Network Open. 2020;3(9):e2019686. doi:10.1001/jamanetworkopen.2020.19686

Feyginberg, E. (2019). Compiling the data on correctional officer suicide rates in Canada. Tema Counter Memorial Trust (via Blue Line). https://www.blueline.ca/compiling-the-data-on-correctional-officer-suicide-rates-in-canada/

Grossman, C., Brooker, J., Michael, N., & Kissane, D. (2017). Death anxiety interventions in patients with advanced cancer: A systematic review. Palliative Medicine, 32(1), 172–184. https://doi.org/10.1177/0269216317722123

Hashimoto, K. (2019), Rapid-acting antidepressant ketamine, its metabolites and other candidates: A historical overview and future perspective. Psychiatry Clin. Neurosci., 73: 613-627. doi:10.1111/pcn.12902.

Hasin DS, Sarvet AL, Meyers JL, et al. Epidemiology of Adult DSM-5 Major Depressive Disorder and Its Specifiers in the United States. JAMA Psychiatry. 2018;75(4):336–346. doi:10.1001/jamapsychiatry.2017.4602.

Haijen, E. C. H. M., Kaelen, M., Roseman, L., Timmermann, c, Kettner, H., Russ, S., Nutt, D., Daws, R. E., Hampshire, A.G., Lorenz, R., & Carhart-Harris, R. L. (2018). Predicting Responses to Psychedelics: A Prospective Study. Frontiers in Pharmacology, 9, 1. https://doi.org/10.3389/fphar.2018.00897

ICER. (2018). Esketamine for the Treatment of Treatment- Resistant Depression: Effectiveness and Value. Available at: https://icer-review.org/material/trd-final-evidence-report- and-meeting-summary/

James, E., Robertshaw, T. L., Hoskins, M., & Sessa, B. (2020). Psilocybin occasioned mystical-type experiences. Human Psychopharmacology, 35(5), e2742–n/a. https://doi.org/10.1002/hup.2742

Kellar, J., Mittmann, N., von Heymann, C., Zingaro, J., Kuriakose, B., & Li, A. (2014). Costs of Employees with Treatment-Resistant Depression Based on a Canadian Private Claims Database. Value in Health, 17(7), A456–A457. https://doi.org/10.1016/j.jval.2014.08.1252

Kessler, R. C., Chiu, W. T., Demler, O., Merikangas, K. R., & Walters, E. E. (2005). Prevalence, severity, and comorbidity of 12-month DSM-IV disorders in the National Comorbidity Survey Replication. Archives of general psychiatry, 62(6), 617–627. https://doi.org/10.1001/archpsyc.62.6.617

Knoll, A. D., & MacLennan, R. N. 2017. Prevalence and correlates of depression in Canada: Findings from the Canadian Community Health Survey. Canadian Psychology/ Psychologie canadienne, 58(2), 116–123. https://doi.org/10.1037/cap0000103

Lim et al. (2008). A new population-based measure of the burden of mental illness in Canada. Chronic Diseases in Canada, 28: 92-8.

Luckenbaugh, D. A., Niciu, M. J., Ionescu, D. F., Nolan, N. M., Richards, E. M., Brutsche, N. E., Guevara, S., & Zarate, C. A. (2014). Do the dissociative side effects of ketamine mediate its antidepressant effects?. Journal of affective disorders, 159, 56–61. https://doi.org/10.1016/j.jad.2014.02.017

Lung Association of Canada, (2021). Smoking & Tobacco Statistics. https://www.lung.ca/lung-health/lung-info/lung-statistics/smoking-and-tobacco-statistics#:~:text=Tobacco%20continues%20to%20be%20the,cent%20of%20Canadians%20currently%20smoke

Marseille E, Kahn JG, Yazar-Klosinski B, Doblin R (2020) The cost-effectiveness of MDMA-assisted psychotherapy for the treatment of chronic, treatment-resistant PTSD. PLOS ONE 15(10): e0239997. https://doi.org/10.1371/journal.pone.0239997

Mental Health Research Canada. National poll on impact of COVID-19: Four studies in 13-poll series https://www.mhrc.ca/national-data-on-covid

Moreno, F., Wiegand, C., Taitano, E., & Delgado, P. (2006). Safety, Tolerability, and Efficacy of Psilocybin in 9 Patients with Obsessive-Compulsive Disorder. The Journal of Clinical Psychiatry, 67(11), 1735–1740. https://doi.org/10.4088/jcp.v67n1110

Muttoni, S., Ardissino, M., & John, C. (2019). Classical Psychedelics for the Treatment of Depression and Anxiety: A Systematic Review. Journal of affective disorders, 258(2019), 11–24. https://doi.org/10.1016/j.jad.2019.07.076

Nelson, L. (2014). Hallucinogen in 'magic mushrooms' helps longtime smokers quit in Hopkins trial. HUB, Johns Hopkins University. https://hub.jhu.edu/2014/09/11/magic-mushrooms-smoking/

NIMH. 2018. Major Depression. https://www.nimh.nih.gov/ health/statistics/major-depression.shtml#part_155033

Nutt, D. J., King, L. A., & Phillips, L. D. (2010). Drug harms in the UK: a multicriteria decision analysis. The Lancet, 376(9752), 1558–1565. https://doi.org/10.1016/s0140-6736(10)61462-6

Phelps, J. (2017). Developing Guidelines and Competencies for the Training of Psychedelic Therapists. Journal of Humanistic Psychology, 57(5), 450–487. https://doi. org/10.1177/0022167817711304

Ronaldson, A., Lotte, E., Jayakumar, S., Jieman, A., Halvorsrud, K., Bhui, B.. (2020). Plos Medicine. Severe mental illness and health service utilisation for nonpsychiatric medical disorders: A systematic review and meta-analysis. Published: September 14, 2020https://doi.org/10.1371/journal.pmed.100328

Rosa, W., Hope, S., & Matzo, M. (2019). Palliative Nursing and Sacred Medicine: A Holistic Stance on Entheogens, Healing, and Spiritual Care. Journal of Holistic Nursing, 37(1), 100–106. https://doi.org/10.1177/0898010118770302

Rosenbaum, D., Boyle, A., Rosenblum, A., Ziai, S., & Chasen, M. (2019). Psychedelics for psychological and existential distress in palliative and cancer care. Current Oncology, 26(4), 225–226. https://doi.org/10.3747/co.26.5009

Ross, S., Bossis, A., Guss, J., Agin-Liebes, G., Malone, T., Cohen, B., Mennenga, S., Belser, A., Kalliontzi, K., Babb, J., Su, Z., Corby, P., & Schmidt, B. (2016). Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial. Journal of Psychopharmacology, 30(12), 1165–1180. https://doi.org/10.1177/0269881116675512

Schernhammer ES, Colditz GA. Suicide rates among physicians: a quantitative and gender assessment (meta-analysis). Am J Psychiatry 2004;161:2295–302.

Schenberg, E. (2018). Frontiers in Pharmacology. Psychedelic-Assisted Psychotherapy: A Paradigm Shift in Psychiatric Research and Development. Front Pharmacol. 2018; 9: 733. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6041963/

Shore, R., Gottfried, K. (2020. Psilocybin for End-of-Life Distress: Literature Review & Canadian Regulatory Context.

Steinert, C., Hofmann, M., Leichsenring, F., & Kruse, J. (2015). The course of PTSD in naturalistic long-term studies: High variability of outcomes. A systematic review. Nordic Journal of Psychiatry, 69(7), 483–496. https://doi.org/10.3109/08039488 2015.1005023

Swift, T., Belser, A., Agin-Liebes, G., Devenot, N., Terrana, S., Friedman, H., Guss, J., Bossis, A., & Ross, S. (2017). Cancer at the Dinner Table: Experiences of Psilocybin-Assisted Psychotherapy for the Treatment of Cancer-Related Distress. The Journal of Humanistic Psychology, 57(5), 488–519. https://doi.org/10.1177/0022167817715966

Tyler, M. W., Yourish, H. B., Ionescu, D. F., & Haggarty, S. J. (2017). Classics in Chemical Neuroscience: Ketamine. ACS chemical neuroscience, 8(6), 1122–1134. https://doi.org/10.1021/acschemneuro.7b00074

Van Ameringen, M., Mancini, C., Patterson, B. and Boyle, M.H. (2008), Post-Traumatic Stress Disorder in Canada. CNS Neuroscience & Therapeutics, 14: 171-181. doi:10.1111/j.1755- 5949.2008.00049.x.

Vollenweider, F.X., Preller, K.H. Psychedelic drugs: neurobiology and potential for treatment of psychiatric disorders. Nat Rev Neurosci 21, 611–624 (2020). https://doi.org/10.1038/s41583-020-0367-2

Warden D, Trivedi MH, Wisniewski SR, et al. Predictors of attrition during initial (citalopram) treatment for depression: a STAR*D report. Am J Psychiatry. 2007;164:1189–1197.

Wilson, S., Guliani, H., Boichev, G. (2020). On the economics of post-traumatic stress disorder among first responders in Canada. https://journalcswb.ca/index.php/cswb/article/view/6/30

Yousif, N. (Toronto Star, Jan. 4, 2021). The pandemic has taken a toll on mental health in Canada. Will it also change mental health care? https://www.thestar.com/news/gta/2021/01/04/the-pandemic-has-taken-a-toll-on-mental-health-in-canada-will-it-also-change-mental-health-care.html

Zarate, C. A., Jr, Singh, J. B., Carlson, P. J., Brutsche, N. E., Ameli, R., Luckenbaugh, D. A., Charney, D. S., & Manji, H. K. (2006). A randomized trial of an N-methyl-D-aspartate antagonist in treatment-resistant major depression. Archives of general psychiatry, 63(8), 856–864. https://doi.org/10.1001/archpsyc.63.8.856

field trip