



THE ME

Granting equitable access to psychedelic-assisted therapies



Report of the Subcommittee on Veterans Affairs

Standing Senate Committee on National Security and Defence

The Honourable David Richards, Chair The Honourable Pierre-Hugues Boisvenu, Deputy Chair

The Time is Now: Granting equitable access to psychedelic-assisted therapies



For more information, please contact us:

by email: veac@sen.parl.gc.ca

by mail: The Subcommittee on Veterans Affairs

Senate, Ottawa, Ontario, Canada, K1A 0A4

This report can be downloaded at :

https://sencanada.ca/en/committees/VEAC/Reports/44-1#?filterSession=44-1

The Senate is on X: @SenateCA,

Follow the subcommittee using the hashtag #VEAC

Ce rapport est également offert en français

Table of Contents

Order of Reference	4
The Subcommittee Membership	6
Members of the Standing Senate Committee on National Security, Defence and Veterans A	Affairs 6
Executive Summary	8
Introduction	9
Psychedelic substances bolster traditional treatments	12
What is known about psychedelics	17
MDMA (3,4-methylenedioxymethamphetamine), "ecstasy" or "molly"	18
Ketamine	19
Classical psychedelics	20
LSD (lysergic acid diethylamide)	21
Psilocybin (magic mushrooms)	21
Advantages and risks	22
Positions of the Government of Canada	27
Health Canada	27
Veterans Affairs Canada	29
Should access to psychedelic substances be expanded or restricted?	30
Conclusion	39
APPENDIX A – Witnesses	41
APPENDIX B – Briefs	43

Order of Reference

Excerpt from the Journals of the Senate of Thursday, February 10, 2022:

The Honourable Senator Dean moved, seconded by the Honourable Senator Dasko:

That the Standing Senate Committee on National Security and Defence be authorized to examine and report on:

- (a) services and benefits provided to members of the Canadian Forces; to veterans who have served honourably in the Canadian Armed Forces in the past; to members and former members of the Royal Canadian Mounted Police and its antecedents; and all of their families;
- (b) commemorative activities undertaken by the Department of Veterans Affairs Canada, to keep alive for all Canadians the memory of Canadian veterans' achievements and sacrifices;
 - (c) continuing implementation of the Veterans Well-being Act; and

That the committee report to the Senate no later than June 30, 2023, and that the committee retain all powers necessary to publicize its findings until 180 days after the tabling of the final report.

The question being put on the motion, it was adopted.

The Interim Clerk of the Senate,

Gérald Lafrenière

Excerpt from the Journals of the Senate of Thursday, April 27, 2023:

The Honourable Senator Dean moved, seconded by the Honourable Senator Omidvar:

That, notwithstanding the order of the Senate adopted on Thursday, February 10, 2022, the date for the final report of the Standing Senate Committee on National Security, Defence and Veterans Affairs in relation to its study on:

(a)services and benefits provided to members of the Canadian Forces; to veterans who have served honourably in the Canadian Armed Forces in the past; to members and former members of the Royal Canadian Mounted Police and its antecedents; and all of their families;

(b)commemorative activities undertaken by the Department of Veterans Affairs Canada, to keep alive for all Canadians the memory of Canadian veterans' achievements and sacrifices; and

(c)continuing implementation of the Veterans Well-being Act;

be extended from June 30, 2023, to December 31, 2025.

The question being put on the motion, it was adopted.

The Interim Clerk of the Senate,

Gérald Lafrenière

Excerpt from the *Journals of the Senate* of Thursday, November 2, 2023:

The Honourable Senator Dean moved, seconded by the Honourable Senator Ravalia:

That the Standing Senate Committee on National Security, Defence and Veterans Affairs be permitted, notwithstanding usual practices, to deposit with the Clerk of the Senate reports related to its study on issues relating to Veterans Affairs, including services and benefits provided, commemorative activities, and the continuing implementation of the Veteran's Well-being Act, if the Senate is not then sitting, and that the reports be deemed to have been tabled in the Senate.

The question being put on the motion, it was adopted.

The Interim Clerk of the Senate,

Gérald Lafrenière

The Subcommittee Membership



The Honourable David Richards

Chair



The Honourable
Pierre-Hugues Boisvenu
Deputy Chair

The Honourable Senators



Margaret Dawn Anderson



Marty Deacon (Ontario)



Hassan Yussuff

Members of the Standing Senate Committee on National Security, Defence and Veterans Affairs

The Honourable Senator Tony Dean, Chair

The Honourable Senator Jean-Guy Dagenais, Deputy Chair

The Honourable Senator Margaret Dawn Anderson

The Honourable Senator Peter M. Boehm

The Honourable Senator Pierre-Hugues Boisvenu

The Honourable Senator Andrew Cardozo

The Honourable Senator Donna Dasko

The Honourable Senator Marty Deacon

The Honourable Senator Stan Kutcher

The Honourable Senator Victor Oh

The Honourable Senator David Richards

The Honourable Senator Hassan Yussuff

Other Senators who have participated in the study:

The Honourable Senator Peter M. Boehm
The Honourable Senator Gwen Boniface
The Honourable Senator Bev Busson
The Honourable Senator Andrew Cardozo
The Honourable Senator Pat Duncan
The Honourable Senator Rebecca Patterson (Ontario)

Parliamentary Information and Research Services, Library of Parliament:

Jean-Rodrigue Paré, Analyst Diana Ambrozas, Analyst

Senate Committees Directorate:

Ericka Dupont, Procedural Clerk Catlin Seibel-Kamél, Legislative Clerk Natacha Umugwaneza, Administrative Assistant Marc-André Lanthier, Administrative Assistant

Senate Communications Directorate:

Ben Silverman, Communication Officer

Executive Summary

It is estimated that approximately 10% to 15% of Canadian veterans have been diagnosed with posttraumatic stress disorder (PTSD), as well as other physical and mental health issues that can accompany PTSD. These operational stress injuries (OSIs) should be treated as "moral injuries," as if the person's very spirit has been broken, making it impossible for them to make sense of their actions. Canadian veterans commit suicide more, much more, than other Canadians. This fact alone should be enough to mobilize the public authorities responsible, beginning with Veterans Affairs Canada, to engage in relentless, ongoing and urgent research that examines every possibility of alleviating the suffering of veterans who are suffering because they did their duty on our behalf and in our place.

Over the last decade, one such opportunity has emerged with psychedelic-assisted psychotherapies, particularly those using psilocybin and MDMA. Preliminary studies yielded promising results, and the U.S. Department of Veterans Affairs conducted clinical studies that sought to determine whether this type of psychotherapy should be made available to veterans experiencing severe, treatment-resistant symptoms. In July 2023, Australia has authorised psilocybin-assisted therapy in the treatment of cases of depression that are resistant to other treatments, and MDMA-assisted psychotherapy for the treatment of PTSD.¹

In Canada, Veterans Affairs Canada (VAC) adopted a wait-and-see approach when it was given this rare opportunity to explore new treatment options. The Subcommittee believes that the Department's position is ill-suited to the leadership role it should be taking on, wherein it should be doing everything in its power to improve the health of veterans, particularly those who have exhausted all the treatment options available to them.

For this reason, the Subcommittee is recommending the immediate implementation of a robust research program funded by VAC and the Department of National Defence (DND) in partnership with Health Canada, the Canadian Institutes of Health Research, and all other relevant partners. This approach would ensure, first of all, that those veterans most likely to benefit from it are given access to treatment with the best scientific support available, and second of all, that the initial findings on the effectiveness of this treatment for veterans are either proven or qualified.

Research on these subjects is constantly evolving and will continue to do so. No one can predict whether progress will be spectacular or whether there will be setbacks. What we know today is that there is no reason to wait for results from other countries, because the results would still need to be confirmed for our veterans. It is the Government of Canada's duty to assure veterans that it is doing everything in its power, immediately, to respect its solemn commitment to support, at any cost, those who chose to defend us with honour.

8

¹ Australian Government, "<u>Update on MDMA and psilocybin access and safeguards from 1 July 2023"</u>

"There is a scientific and moral imperative to discover and deploy newer treatments that we can offer our veterans."

Colonel (Ret'd) Rakesh Jetly, Former Chief Psychiatrist, Canadian Armed Forces,
 VEAC, November 2, 2022

Introduction

Over the last 50 years, Western nations have become more aware of how mental health issues can be devastating for individuals and families, regardless of socio-economic status. Research on members of the military who were deployed in combat zones was one of the key drivers of this growing awareness.

During the First World War, the severe symptoms of what we call PTSD today were understood to be the brain's physiological reaction to artillery barrages, which affected the skull, termed "shell shock." When it was discovered that similar symptoms could be found in military personnel who were not exposed to artillery shelling, the medical establishment began exploring the possibility that it was a psychiatric condition, which was known as "war neurosis."

After the Second World War, about 10% of American troops deployed in Europe were declared "psychiatric casualties," and in 1952 the American Psychiatric Association (APA), in the first edition of its *Diagnostic and Statistical Manual of Mental Disorders* (DSM), renamed war neurosis "gross stress reaction."

During the early years of the Vietnam War (1965–1967), the considerable efforts made by the American army to prevent the appearance of mental health problems were so successful that it appeared as though the condition had disappeared altogether. The diagnosis of "acute stress reaction" was even withdrawn from the second edition of the DSM in 1968.

A cold dose of reality proved that this optimism was misplaced when, in 1971, Dwight Johnson was shot and killed while attempting to hold up a liquor store at gunpoint. An American war hero, Johnson had been awarded the U.S. Medal of Honor the previous year. After hearing about this event, Dr. C. F. Shatan, who had studied psychiatry at McGill University in Montreal, coined the term "post-Vietnam syndrome." At the APA's 1977 annual general meeting, held in Toronto that year, members considered the proposed diagnoses of "catastrophic stress disorder" and "post-combat stress reaction." The term retained for the third edition of the DSM in 1980 was "post-traumatic stress disorder."

² For a historical overview of PTSD since WWI, see Wilbur J. Scott, "PTSD in DSM-II: A Case in the Politics of Diagnosis and Disease," *Social Problems*, 37-3, August 1990.

In Canada, during the 40 relatively peaceful years following the Korean War, mental health issues were not at the forefront of public consciousness. It was General Roméo Dallaire's book that sparked a shift.³ He described the tragedy he witnessed when he was the head of the United Nations mission in Rwanda in 1994, and also gave his personal account of the depression and suicide attempts that led him to leave the Canadian Armed Forces (CAF) in 2000. He went on to participate in the work headed by Dr. Peter Neary, who was overseeing a reorganization of all services for Canadian veterans. Passed in 2005, when Canadian participation in the war in Afghanistan was at its peak, this reform included for the first time a rehabilitation program with a psychiatric and psychosocial component for veterans suffering from the aftereffects of their involvement in the horror of war.

According to various studies reviewed in the <u>Federal Framework on Posttraumatic Stress Disorder:</u> <u>Recognition, collaboration and support</u>, of the 460,000 veterans still living in Canada, between 7.5% and 16.4% self-reported having PTSD. Many of these veterans also suffer from physical health issues and other mental health issues, such as depression, general anxiety disorder or substance abuse. When these mental health issues are associated with military service, they are referred to as "operational stress injuries," or OSIs.⁴

These OSIs can have a devastating impact on the well-being of veterans. For example, according to data from Veterans Affairs Canada, the suicide rate is 50% higher for male veterans than for the general population, 200% higher for female veterans, consistently across age groups, and 250% higher for male veterans under the age of 25.

These statistics alone should be enough to spur the Government of Canada to research treatments that can alleviate the suffering of those who risked their lives for all Canadians.

While it has gotten easier to make a clear diagnosis over the last 40 years, few treatment options are available, and they are largely ineffective. This should redouble the efforts of anyone responsible for improving the well-being of veterans.

The most common treatment for OSIs is individual or group psychotherapy. The Subcommittee's report examines a number of innovative approaches that have been developed to adapt psychotherapy sessions to the lived experiences of veterans, such as those delivered by Veterans Affairs Canada clinics and the <u>Veterans Transition Network</u>. Despite the progress achieved through these psychotherapeutic approaches, the OSI and PTSD remission rate is estimated to be 30% to 40%. That means that 60% to 70% of those suffering from PTSD will experience symptoms

_

³ Roméo A. Dallaire, *Shake Hands with the Devil*, Random House Canada, 2003.

⁴ For more information on OSIs, see the statement by Dr. J. Don Richardson, Co-Chair, Section on Military and Veterans, Canadian Psychiatric Association, Senate Subcommittee on Veterans Affairs, *Evidence*, 22 March 2023.

throughout their lives, to varying degrees of severity. How can Canada settle for such a high rate of failure?

From a pharmacological perspective, paroxetine and sertraline are the only two medications approved for the treatment of PTSD, and their efficacy has proven to be limited. They also come with side effects, such as headaches and nausea, as well as more serious side effects, such as cognitive impairment, sexual dysfunction and sudden weight loss or gain. Accordingly, it is worth considering any new treatment likely to improve the quality of life for veterans.

In the last 20 years, preliminary studies have suggested that some psychedelic drugs could help address the symptoms veterans experience when taken in a supervised, clinical psychotherapeutic setting:

The rationale behind this approach is that these drugs can catalyze the psychotherapeutic process, for example, by increasing the capacity for emotional and cognitive processing through pharmacologically diminishing fear and arousal, by strengthening therapeutic alliance through increased trust and rapport, or by targeting processes of fear extinction and memory consolidation.⁷

These new developments are being welcomed with enthusiasm by many veterans, researchers and health care professionals, but are viewed with some trepidation by medical authorities, drug regulatory agencies, governments and the general public. In the fall of 2022, Alberta was the first province to issue guidelines on the use of psychedelics. A number of clinical studies have already been launched by the U.S. Department of Veterans Affairs. Given that these promising findings may lead to new treatments with better results than traditional approaches, governments have a duty to explore them rigorously, to determine when it is appropriate to use them and to make them accessible as soon as possible. However, since research on this subject is limited, caution is in order. The system must clearly identify which veterans could benefit from psychedelic-assisted therapy and which veterans could be at higher risk, recognizing that some stakeholders may be eager to move forward based on the preliminary findings.

Furthermore, none of the studies that have produced promising results have been conducted among veterans specifically, regardless of their country of origin. As this report will demonstrate, the particularities of veterans' experiences are such that they tend to respond to treatments

⁵ See, for example, studies by Jonas, D.E., Cusack, K., Forneris, C.A., Wilkins, T.M., Sonis, J., Middleton, Gaynes, B.N. (2013) "Psychological and Pharmacological Treatments for Adults With Posttraumatic Stress Disorder (PTSD)," Rockville MD; and Difede J., Olden, M., & Cukor, J. (2014), "Evidence-based treatment of post-traumatic stress disorder," *Annual Review of Medicine*, 65:319–332.

⁶ Krediet, Erwin *et al.*, "Reviewing the Potential of Psychedelics for the Treatment of PTSD," <u>International Journal of Neuropsychopharmacology</u>, Volume 23, Issue 6, June 2020, pp. 385–400.

⁷Krediet, Erwin *et al.*, *op. cit.*, p. 386.

differently than the general population. As such, results applicable to the general population cannot simply be extrapolated to the veteran population.

This report is divided into three sections. The first section outlines the ineffectiveness of traditional approaches for treating mental health issues among veterans, as well as the findings of the key studies on psychedelic-assisted therapies. The second section considers the position of Health Canada and VAC on the effectiveness of these treatments, the need to expand access to them and the need for more in-depth research. The third and final section addresses challenges involving the capacity of the public health care system to offer these treatments in a coordinated and efficient manner.

The Subcommittee heard from approximately 20 witnesses over the course of seven meetings. The Senators would like to thank the witnesses for their contributions. It is the Senators' hope that this report accurately reflects witnesses' views and is in the best interests of Canadian veterans.

Psychedelic substances bolster traditional treatments

Traditional psychotherapeutic approaches used to treat posttraumatic stress disorder (PTSD) are based on the assumption that the fear associated with remembering the traumatic event leads to behavioural avoidance, which prevents the person from confronting and resolving their inner conflict. Retired Colonel Rakesh Jetly, former Chief Psychiatrist of the Canadian Armed Forces (CAF), explained the situation as follows:

You ... relive [the traumatic event] in the therapy room. It's a very difficult therapy. You talk about it again and again and again until you desensitize and habituate. That's the traditional exposure therapy. There are a few other therapies. The problem with that is the dropout rate is extremely high. Maybe if we're lucky, it helps half the people, but about half the people drop out. It's extremely difficult and hard. Psychologically, soldiers, men and women, are very defended and very tough, so it's very hard to access the true feelings. They will go through the motions and they will attend the appointments, but they often don't get better because things like shame, guilt and fear and a lot of these emotions are hard to express.⁸

According to Colonel Jetly, the traditional approach for treating PTSD uses a fear-based paradigm, for example, a person's experience when a loved one dies. While trauma-based mental health issues are classified in a separate category today, the treatments deemed appropriate for these issues are the same as for a fear of heights or other common phobias. The main treatments are prolonged exposure therapy and cognitive behavioural therapy. Although these approaches have

12

⁸Colonel (Ret'd) Rakesh Jetly, Former Chief Psychiatrist, Canadian Armed Forces, As an individual, VEAC, *Evidence*, 2 November 2022.

been refined in recent decades, Colonel Jetly believes that they do not address the fact that "there is grief, there is horror, there is shame and there is guilt" tied up in what the veterans are experiencing. "If you're [feeling] guilty, talking about it again and again and again isn't going to help; it actually might make it worse."

These differences in what veterans experience could be linked to what Lieutenant-General Roméo Dallaire has described as a "moral injury."

I was treated for nearly 20 years for PTSD, only to realize during that time that what I had seen, the decisions I had taken, the ethical dilemmas I had found myself in — of nearly playing God about who would live and who would not — facing child soldiers and making decisions — those scenarios and dilemmas attack the core of what we are. They attack our fundamental premises of our life, societies, values, religious beliefs and the nature of what we believe humanity is. ¹⁰

General Dallaire shared a veteran's difficult memory to illustrate how these moral injuries affect the very core of who they are:

... I had a sergeant who met with me a few years back in a shopping centre and introduced himself. He had been in for 12 years, served in an infantry regiment and had experience overseas. I asked him if he had deployed. He said that he had: five times between Yugoslavia and Afghanistan. I asked him what his job was in the regiment. At that moment, he instantaneously broke down — tears, unable to speak and trembling. I had to take him aside to the hallway, and we spoke, and it took about five or six minutes to get him back. He said that he had been back for over five years, and he still had not hugged his children because he was a sniper, and he had to take out the children — girls, some of them pregnant — who were used as suicide bombers.

That's the depth of what this injury is. ... But in moral injuries, we have not fully grasped the extraordinary breakdown of the individual's capability of coming back to normalcy—to the normal life—because everything that they live by has been attacked. ¹¹

Both conventional therapy and medication are unable to address the depth of these injuries. From a pharmacology perspective, paroxetine and sertraline, which are types of selective serotonin

⁹ Colonel (Ret'd) Rakesh Jetly, Former Chief Psychiatrist, As an individual, VEAC, Evidence, 2 November 2022.

¹⁰ Lieutenant-General (Ret'd) Hon. Roméo A. Dallaire, former senator, As an individual, VEAC, *Evidence*, 15 February 2023.

¹¹ Lieutenant-General (Ret'd) Hon. Roméo A. Dallaire, former senator, As an individual, VEAC, *Evidence*, 15 February 2023.

reuptake inhibitors (SSRIs), are the only two medications approved for the treatment of PTSD, and their efficacy has proven to be limited. According to Dr. Lynette Averill, of the Baylor College of Medicine, the situation is the same in the United States:

While these are critical interventions, they are simply not enough. [SSRIs] are slow-acting anti-depressants with a latency period of weeks to months before a therapeutic benefit, a period which is dangerous and puts people at risk for self-harm and other self-destructive behaviours and has a very distressing side-effect profile.

Further, even when optimally delivered, approximately 40% of patients don't respond. Rates of non-response are even higher among patients with chronic and complex presentations like so many of our military veterans. Even among those who do respond, many remain symptomatic and lead restricted lives.¹²

Given the limitations in treating these issues, which have a serious impact on the well-being of veterans and their families, every single promising new treatment must be considered.

As Dr. Averill said so eloquently:

It is imperative that there is governmental support for exploring novel therapeutics with potential to offer relief and healing to individuals who have been failed by our current treatments, especially those interventions which have the potential to offer rapid and robust improvements. Our veterans deserve and demand a leave-no-stone-unturned approach to explore potential means of prevention and treatment. ¹³

One such opportunity is available today. In the last 20 years, the search for better mental health treatments has led to a renewed interest in the use of psychedelic drugs whose therapeutic effects had originally been documented in the 1950s and 1960s, before most Western governments banned them in the late 1960s. At that point, research on psychedelic substances was halted.

In the mid-2000s, small clinical trials yielded encouraging data when certain psychedelics were used in conjunction with psychological support. According to Dr. Muhammad Ishrat Husain, of the Centre for Addiction and Mental Health, 2016 marked a turning point, with the publication of a study "showing that in 19 patients with treatment-resistant depression, a dose of psilocybin, when combined with psychological support, led to large and sustained improvements in depressive

¹³ Lynnette A. Averill, Associate Professor, Menninger Department of Psychiatry and Behavioral Sciences, Baylor College of Medicine, As an individual, VEAC, *Evidence*, 23 November 2022.

¹² Lynnette A. Averill, Associate Professor, Menninger Department of Psychiatry and Behavioral Sciences, Baylor College of Medicine, As an individual, VEAC, *Evidence*, 23 November 2022.

symptoms in this complex group of patients."¹⁴ Psilocybin is the chemical constituent of magic mushrooms, and psilocybin-assisted psychotherapy has since become one of the most promising treatments for depression and alcohol abuse. MDMA-assisted psychotherapy for treating PTSD has also yielded encouraging results. The therapeutic approach for these interventions is generally "cognitive processing," which is a variant of the "cognitive-behavioral approach" when applied to trauma-based issues. ¹⁵

It is still not fully understood why some of these substances yield these results, but a number of hypotheses are being proposed. According to Dr. Husain, "The classic psychedelic drugs are thought to induce quite complex behavioural, psychological and physiological effects through their actions on the serotonin 2A receptor." According to Colonel Jetly:

These medicines, for example MDMA, which is ecstasy, creates something called increased empathy. If you think about it, that empathy towards others also applies to yourself, so it allows people to drop some of their defences, their guards, and really talk about what's bothering them. That's one thing. The therapy doesn't necessitate having to relive the trauma. It's more access to the deeper memories.

With psychedelics, on the other hand, like the LSD or psilocybin, it's a much harsher experience. It's a true experience. It causes brain changes that, again, allow new ideas or new thoughts to emerge. 17

Kelsie Sheren was deployed to Afghanistan in April 2009 as an artillery gunner with the 5e Régiment d'artillerie légère du Canada (5 RALC) and participated in the operations of the British armed forces. After being exposed to intense fighting and experiencing the death of a friend, she was diagnosed with PTSD. The medications she was prescribed while she was still serving did not alleviate her symptoms, and she was medically released in 2011. Her experience from that point on, which she described to the Subcommittee, helps explain why many veterans turn to psychedelic substances:

¹⁴ Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health, As an individual, VEAC, *Evidence*, 26 October 2022.

¹⁵ See the <u>manual developed in the United States</u> by the Department of Veterans' Affairs for the use of cognitive processing therapies to treat PTSD in veterans.

¹⁶ Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health, As an individual, VEAC, *Evidence*, 26 October 2022.

¹⁷ Colonel (Ret'd) Rakesh Jetly, Former Chief Psychiatrist, As an individual, VEAC, *Evidence*, 2 November 2022.

Once back in Canada, I was doing everything I could to heal and even get better. I spent the next decade of my life receiving the treatment that Veterans Affairs Canada, or VAC, and the operational stress injury, or OSI, clinic made available to me: talk therapy, eye movement desensitization and reprocessing, or EMDR, therapy, cognitive behavioural therapy, or CBT, and exposure therapy. ... At the height of my treatment, I was ... on 11 different pharmaceutical drugs. Nothing was working. I was suicidal, angry, hurting and lost, and I was completely helpless. I didn't think I could ever become a healthy person or a productive part of society again. The words that VAC said rang in my ears for years: "You'll never work again." My life was over at 21. Psychedelic-assisted therapy is the only reason I am alive, and that is because I was lucky enough to gain access.¹⁸

Initially, Ms. Sheren had to travel internationally to receive psychedelic-assisted therapy. Subsequently, she was able to access treatment through Health Canada's Special Access Program as part of the clinical trials carried out by Apex Labs. As the present report will show, as long as studies cannot conclusively show whether access to these substances can be expanded, the only way for veterans with treatment-resistant symptoms to access psychedelics is to participate in clinical trials. This is why the members of the Sub-Committee insist on the need to fund such clinical trials generously and immediately, so that the veterans who would benefit most can have access to these treatments as quickly as possible.

Nigel McCourry served two years in the United States Marine Corps. He was deployed in Iraq for eight months in 2004, and when he appeared before the Subcommittee he described some of the horrible experiences he lived through. When he was discharged in 2005, no mention was made of what he went through in Iraq. It took until 2011 before he was diagnosed with severe PTSD:

16

¹⁸ Kelsie Sheren, Artillery Gunner (Medical Ret'd), Canadian Armed Forces, As an individual, VEAC, *Evidence*, 19 April 2023.

I would spend all day stuck inside of memories of Iraq, and looking at pictures of Iraq. ... It was the worst part of my life that I ever had. I went to the VA [United States Department of Veterans Affairs], and, for treatment, they offered me talk therapy and a long list of psychopharmaceuticals: different types of antidepressants, medications to help me relax and medications to help me fall asleep. I tried it all. I did the talk therapy; I really wanted it to work, but I felt so guarded during the therapy that I could never really reach a point where it was useful. ... Then, by chance, I came across the MDMA-assisted psychotherapy research that was going on. ... After the first treatment, my sleep issues went away, and I haven't had the issues following sleeping at night ever since. ... I was able to mentally move on from the experiences in Iraq. ¹⁹

Mr. McCourry told the Subcommittee that he had one treatment a month for five months in 2012, and then after that did not use any psychedelics or traditional psychopharmaceuticals at all.²⁰

What is known about psychedelics

To better understand what is meant by the term "psychedelic substances" in the context of assisted psychotherapy, it is important to outline what is currently known about each type. A recent study reviewed the various drugs that have been clinically tested. They are grouped into four categories: MDMA (ecstasy or molly), ketamine, classical psychedelics such as LSD and psilocybin (magic mushrooms), and cannabinoids. In the last five years in Canada, MDMA and psilocybin have received exemptions from the *Controlled Drugs and Substances Act* so that pharmaceutical companies can begin clinical trials. In the United States, MDMA and psilocybin were designated as "breakthrough therapies" by the US Food and Drug Administration (FDA), while ketamine was approved for treatment-resistant depression. ²¹ The topic of cannabinoids will not be addressed in this report because it was recently the subject of two studies, one by the <u>Senate Subcommittee</u> (VEAC) and one by the <u>House of Commons Standing Committee on Veterans Affairs</u> (ACVA).

¹⁹ Nigel McCourry, Lance Corporal (Medical Ret'd), United States Marine Corps, As an individual, VEAC, *Evidence*, 19 April 2023.

²⁰ Nigel McCourry, Lance Corporal (Medical Ret'd), United States Marine Corps, As an individual, VEAC, *Evidence*, 19 April 2023.

²¹ Krediet, Erwin et al., op. cit., p. 386.

MDMA (3,4-methylenedioxymethamphetamine), "ecstasy" or "molly"

MDMA was first synthesized in 1912 while developing another medication that could stop bleeding. Its psychoactive effects were not discovered until the 1970s, and some therapists used it until it became a controlled substance in the mid-1980s.

According to Health Canada, MDMA is a stimulant made and sold illegally that can cause hallucinations. It triggers feelings of pleasure and increased physical energy. A <u>study published in 2010</u> that followed 20 patients showed the therapeutic potential of MDMA. In the study, 12 patients received MDMA during their psychotherapy sessions, while the remaining 8 received a placebo. In the first group of patients, 10 of the 12 (83%) noted a decrease in symptoms, no longer meeting the criteria for a PTSD diagnosis, while in the second group, only two patients experienced similar results. The experiment was replicated several times with less momentous but still positive results, and in 2017, MDMA-assisted psychotherapy was designated as a "breakthrough therapy" to treat PTSD in the United States. ²² Many clinical trials are currently underway around the world. It has been possible to moderate the negative effects of MDMA when the drug is administered in a controlled clinical environment.

Dr. Walsh explained that:

The most promising development for PTSD is likely MDMA-assisted psychotherapy. It has been fast-tracked in the U.S., and we're already looking at special access. It seems to really accelerate the reprocessing of trauma and facilitate a strong bond between the therapist and the client in a rapid way. That's important for veterans who are trying to go through the re-experiencing and reprocessing that's so important in the cure for PTSD.

So MDMA is the most prominent and promising of new treatments, but there are people who are working tirelessly to find other alternatives. MDMA is the leading one.²³

Dr. Walsh is associated with Numinus Wellness, which <u>announced</u> in January 2022 that it had completed all necessary steps to begin enrolling participants in its clinical trial. It was granted a section 56 exemption from the <u>Controlled Drugs and Substances Act</u> to allow the use of MDMA to test its safety and efficacy in treating patients with severe PTSD throughout the duration of the clinical trial.

²² Krediet, Erwin, et al., op. cit., p. 386.

²³ Zachary Walsh, Professor, Department of Psychology, University of British Columbia, As an individual, VEAC, *Evidence*, 26 October 2022.

A clinical trial is underway in the United States and its final results are much anticipated. According to Sabrina Ramkellawan of the Multidisciplinary Association for Psychedelic Studies (MAPS), an organization that is funding these clinical trials and promoting psychedelics for treating mental health issues:

MDMA Phase 3 clinical trial results show 67% of participants who received three MDMAassisted therapy sessions no longer qualified for a PTSD diagnosis, and 88% experienced a clinically meaningful reduction in symptoms. Second Phase 3 data has been completed just two weeks ago, and we are awaiting results and will be excited to share them in the near future.²⁴

Colonel Jetly explained that, once these results have been published in peer-reviewed scientific journals, the US Food and Drug Administration (FDA) is expected to approve the use of MDMA as a treatment for PTSD within a year or two.²⁵ In Canada, a study led by Dr. Anne Wagner is underway in Toronto, sponsored by the Canadian branch of MAPS. 26 In July 2023, Australia has authorised psilocybin-assisted therapy in the treatment of cases of depression that are resistant to other treatments, and MDMA-assisted psychotherapy for the treatment of PTSD.²⁷

Ketamine

Ketamine is a fast-acting anesthetic that is legal for use in medical surgery. According to Health Canada, it is a dissociative drug, "producing a sense of mind from body separation (dissociation)." It has also been known to be used as a date-rape drug.

Ketamine has been used in a psychotherapy context since the 1990s to treat alcoholism and heroin addiction, and more recently as an antidepressant. Study findings suggest that it has a beneficial effect on suicidal ideation, which led the US FDA to approve ketamine for the treatment of patients with severe symptoms of treatment-resistant depression in March 2019. To date, only a few studies have been published on treating PTSD with ketamine. ²⁸ According to Professor Walsh, the effects of ketamine on depression and suicidality are not as long-lived as the effects of psilocybin.²⁹ In Canada, the Chronic Pain Centre of Excellence, funded by Veterans Affairs Canada, launched an

²⁴ Sabrina Ramkellawan, Co-Chair, Board of Directors, Multidisciplinary Association for Psychedelic Studies (MAPS), VEAC, Evidence, 23 November 2022.

²⁵ Colonel (Ret'd) Rakesh Jetly, Former Chief Psychiatrist, As an individual, VEAC, *Evidence*, 2 November 2022.

²⁶ Sabrina Ramkellawan, Co-Chair, Board of Directors, Multidisciplinary Association for Psychedelic Studies (MAPS), VEAC, Evidence, 23 November 2022.

²⁷ Australian Government, "Update on MDMA and psilocybin access and safeguards from 1 July 2023"

²⁸ Krediet, Erwin et al., op. cit., p. 389.

²⁹ Zachary Walsh, Professor, Department of Psychology, University of British Columbia, As an individual, VEAC, Evidence, 26 October 2022.

<u>expression of interest</u> in 2021 on the effectiveness of ketamine for veterans managing chronic pain and mental health conditions.

Toronto company Field Trip Health started trading on the <u>NASDAQ</u> exchange in July 2021. It specializes in psychedelic medical treatment and offers ketamine therapy in its clinics. Meanwhile, Braxia Scientific, in Vancouver, published a <u>study</u> in October 2021 suggesting that ketamine could have contributed to suicide reduction during the COVID-19 pandemic.

Health Canada's position on ketamine is that:

Ketamine is the only psychedelic drug that has been authorized for sale in Canada. One form of ketamine, esketamine, has been authorized by Health Canada for use in the treatment of serious forms of depression. Ketamine is most often used as an intravenous anesthetic for surgical purposes, but it is also being used off-label for the treatment of mental health conditions.

Health Canada is aware of clinics offering ketamine-assisted psychotherapy for the treatment of mental health disorders, including PTSD. A health practitioner's decision to prescribe a drug off-label is a practice of medicine that falls under provincial and territorial jurisdiction. The use of ketamine as a potential treatment option for PTSD continues to be studied.³⁰

Health Canada is taking a cautious approach. Ketamine for any purpose other than treating severe depression is contraindicated.

Classical psychedelics

Psychedelic drugs such as LSD, DMT (ayahuasca) and magic mushrooms were used in the 1950s and 1960s for psychedelic-assisted psychotherapy. Hundreds of scientific articles were published on their use until these drugs were banned in the mid-1960s. However, they continued to be used in the Netherlands in a therapeutic context to treat PTSD. Since the early 2000s, there has been renewed interest in psilocybin, the active ingredient in magic mushrooms. Psilocybin has received a designation of "breakthrough therapy" in the United States for treating depression. No study results have been published on the use of psychedelics for the treatment of PTSD, but many clinical trials are underway.³¹

³⁰ Shannon Nix, Associate Assistant Deputy Minister, Controlled Substances and Cannabis Branch, Health Canada, VEAC, *Evidence*, 30 November 2022.

³¹ Krediet, Erwin et al., op. cit., p. 391.

LSD (lysergic acid diethylamide)

According to <u>Health Canada</u>, LSD is a hallucinogenic drug made from a fungus that grows on rye and other grains. Its long-term mental health risks are well-documented. At this time, it is not an option for treating mental health issues.

Psilocybin (magic mushrooms)

According to <u>Health Canada</u>, "at this time, there are no approved therapeutic products containing psilocybin in Canada or elsewhere. ... While some initial clinical trials have shown promising results, the evidence is currently limited." This assertion now needs to be qualified since, since this testimony, Australia has authorised psilocybin-assisted therapy in the treatment of cases of depression that are resistant to other treatments.³²

Despite this caution, according to Dr. Walsh, psilocybin appears to be the substance with the most promising results for treating depression.³³ Various Canadian companies are carrying out research and development projects in this area.

In August 2020, Canadian pharmaceutical company NeuroPharm Inc., in partnership with the Leiden University Medical Centre in the Netherlands, announced the launch of a <u>clinical study</u> on psilocybin to treat PTSD in veterans. NeuroPharm is a subsidiary of Mydecine Inc., a pharmaceutical company founded in 2020 and headquartered in Vancouver. According to its <u>website</u>, Mydecine's goal is to ensure that psychedelic medicine is seen as an accepted and adopted form of treatment within the health care system. <u>Mydecine's chief medical officer</u> and the person in charge of this clinical study is Colonel (Ret'd) <u>Rakesh Jetly</u>, who served as the senior advisor in psychiatry for the Canadian Armed Forces from 2011 to 2021 and the Chair for Military Mental Health at The Royal's Institute of Mental Health Research in Ottawa. In January 2022, Mydecine announced <u>another clinical study on psilocybin</u> in partnership with <u>Combat Stress</u>, a non-profit organization helping veterans in the United Kingdom affected by PTSD.

<u>Apex Labs Inc.</u> is another company in Vancouver involved in treating veterans' PTSD with psilocybin. It began a clinical study similar to Mydecine's in 2022.

According to Ms. Ramkellawan, of the Canadian subsidiary of MAPS, which has funded studies in the United States, "[p]silocybin Phase 2b clinical trial results show 30% of patients in the 25-milligram group were in remission at week three." These results are promising, but nothing is known of the long-term effects. Dr. Husain made the following statement:

³² Australian Government, "Update on MDMA and psilocybin access and safeguards from 1 July 2023"

³³ Zachary Walsh, Professor, Department of Psychology, University of British Columbia, As an individual, VEAC, *Evidence*, 26 October 2022.

³⁴ Sabrina Ramkellawan, Co-Chair, Board of Directors, Multidisciplinary Association for Psychedelic Studies (MAPS), VEAC, *Evidence*, 23 November 2022.

The Canadian Institutes of Health Research put out a funding call specific to psilocybin-assisted therapy that is looking at three different clinical populations — depression, alcohol use disorder and end-of-life distress — to look at the effectiveness and safety in Canadian populations. Again, that will be giving us more safety and efficacy data. It's a two-year study period, and they are expecting quick results from those funding opportunities.³⁵

These initiatives will provide conclusive evidence about whether these treatments are safe and effective.

Advantages and risks

According to Dr. Husain, what sets certain types of psychedelic-assisted therapies apart is that any beneficial effects seem to be stronger and longer-lasting than those of other types of treatments.³⁶ That is the case for MDMA-assisted treatment for PTSD. In these patients, the advantages are very clear.

Zachary Walsh is a psychology professor at the University of British Columbia, a paid advisor for Numinus Wellness and Entheotec BioMedical, and an unpaid member of the MAPS advisory board and MycoMedica Life Sciences. According to him, the subjective experience of psychodelic substances allows to reach the existential dimensions of the mental health problem. Their advantages are therefore irreplaceable:

These altered experiences, sometimes called 'the trip,' play a key role in their therapeutic effects.

³⁵ Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health, As an individual, VEAC, *Evidence*, 26 October 2022.

³⁶ Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health, As an individual, VEAC, *Evidence*, 26 October 2022.

It is the changes emanating from the experiences, rather than direct physiological changes associated with the medicine, that are primary. The reliance on acute subjective effects is promising in that it suggests that a few administrations may be sufficient rather than prolonged use, as is the case with most sedatives and antidepressants that are used to treat these conditions.

In this way, psychedelic therapies may be compared to surgeries. They require brief periods of intense clinical attention that produce long-lasting health changes when they work. It seems that patients take something away from their psychedelic experiences that translates into enhanced meaning in life and reductions in the hopelessness and low mood that characterize depression, PTSD and other mental health disorders.³⁷

However, according to Dr. Husain, the methodology used in clinical trials has come under criticism:

As you can imagine, it's very difficult to conduct a truly blinded, randomized clinical trial because when you are administering a psychedelic, a patient knows that they're receiving it because the drugs are so potent in their psychoactive effects. So getting an adequate control group has been a challenge. Over 90% of people who have been allocated to receive the psychedelic know that they are receiving the psychedelic, and that's not what we're used to in our traditional appraisal of evidence.³⁸

While the study findings are not always as clear-cut as hoped for, the beneficial effects still appear to be significant and the risks seem to be minor for the vast majority of patients.

In fact, the concerns about psychedelic substances are primarily associated with the irrational actions that patients may take. That is why therapeutic support must be very structured while the substance is active. It is also why there are no plans to expand access to these substances outside of a therapeutic setting, as recommended by David Fascinato, Executive Director of the Heroic Hearts Project Canada, who said, "Access and evidence-based approaches can go hand in hand with access and healing." As regards unrestricted access to these treatments, the approach supported by the Subcommittee is in line with the views expressed by Oliver Thorne, of the Veterans Transition Network, who said that "psychedelics should only be made available in a monitored psychotherapeutic setting, not as a self-administered, stand-alone treatment." He added, "We still

³⁷ Zachary Walsh, Professor, Department of Psychology, University of British Columbia, As an individual, VEAC, *Evidence*, 26 October 2022.

³⁸ Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health, As an individual, VEAC, *Evidence*, 26 October 2022.

³⁹ David Fascinato, Executive Director, Heroic Hearts Project Canada, VEAC, *Evidence*, 2 November 2022.

do not understand the long-term effect of taking these substances. We still do not understand fully when they should not be used, what the contraindications are."40

Once the immediate effects have dissipated, there does not appear to be any statistically significant adverse events, such as a decline in mood that may occur in the hours or days following the use of these substances. According to Dr. Husain:

If you look at the data and the participants who received MDMA or psilocybin and then compare it to the control groups, there is no statistically significant difference in any adverse events. Generally, there were no serious adverse events in any of the trials.

That is encouraging. It shows that some of the preconceived notions that you have, this sort of decline in mood after taking MDMA may not be, in fact, correct. I think that comes with street ecstasy use, and often people are using that in combination with other substances like alcohol and so on, which may be contributing.⁴¹

In the longer term, the risk of addiction also appears to be minor, but it has not been confirmed scientifically. Professor Walsh explained as follows: "Although these drugs are used illicitly, the risk of addiction is low and frequent use is rare, even in illegal contexts. Psilocybin is not used compulsively, even in uncontrolled settings, and work in animal models confirms this." A review of existing studies on psychedelic-assisted psychotherapy did not identify any specific risks associated with the abuse of these substances or dependency when they are used in a supervised clinical setting. Setting.

According to Dr. Husain, despite these advantages, it is still too early to consider expanding clinical access to these substances. A number of small clinical trials have yielded promising data on the potential of psilocybin and MDMA to treat depression and PTSD, but he gave the following explanation:

⁴⁰ Oliver Thorne, Executive Director, Veterans Transition Network, VEAC, *Evidence*, 15 February 2023.

⁴¹ Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health, As an individual, VEAC, *Evidence*, 26 October 2022.

⁴² Zachary Walsh, Professor, Department of Psychology, University of British Columbia, As an individual, VEAC, *Evidence*, 26 October 2022.

⁴³ Krediet, Erwin *et al.*, "Reviewing the Potential of Psychedelics for the Treatment of PTSD," *International Journal of Neuropsychopharmacology*, Volume 23, Issue 6, June 2020, pp. 388-389.

It is not data that is generalizable at this point. I do not think these drugs are yet ready for clinical translation because of the issues in the clinical trials that have been currently published, including issues with their design and the small sample sizes, which make it very hard to confirm their safety and effectiveness. 44

Furthermore, the medium- and long-term effects of these treatments are unknown. According to Dr. Averill, "[o]ne area of research that we do not have a lot of answers for yet is the durability of effect, which is how often people may need to re-engage in those interventions." ⁴⁵

Very little is known about the beneficial effects of these substances among veterans. We know that veterans tend to respond differently to treatment than the general population. In the United States, veteran-centric research is only just beginning. Dr. Averill described a research project in Texas on psilocybin and PTSD among veterans:

As you may or may not know, research specifically with veteran cohorts is relatively limited, so that will mostly be a research review of what psychedelic medicine findings have been thus far for stress- and trauma-related concerns broadly speaking.

... We have not formally started the study. We are in that process.

Baylor College of Medicine is currently finalizing contracting with Texas Health and Human Services and in tandem to that we are working on our drug supply contract with Usona Institute, one of the two companies that currently has the FDA breakthrough therapy indication. They will be the ones to supply psilocybin and then working on the IRB — the Institutional Review Board — regulatory piece as well.⁴⁶

According to Professor Walsh, in Canada "we do not have reliable data from Canadian veterans on the effects of these medicines." The advantages and risks of these substances for veterans are still largely unknown.

⁴⁴ Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health, As an individual, VEAC, *Evidence*, 26 October 2022.

⁴⁵ Lynnette A. Averill, Associate Professor, Menninger Department of Psychiatry and Behavioral Sciences, Baylor College of Medicine, As an individual, VEAC, *Evidence*, 23 November 2022.

⁴⁶ Lynnette A. Averill, Associate Professor, Menninger Department of Psychiatry and Behavioral Sciences, Baylor College of Medicine, As an individual, VEAC, *Evidence*, 23 November 2022.

⁴⁷ Zachary Walsh, Professor, Department of Psychology, University of British Columbia, As an individual, VEAC, *Evidence*, 26 October 2022.

The Time is Now: Granting equitable access to psychedelic-assisted therapies

The most significant risk that has emerged to date relates to the quality of the therapeutic support patients receive. Last July, <u>CBC</u> reported that two clinical trials on MDMA-assisted psychotherapy were suspended by Health Canada due to concerns about patient safety and that the department would review all other similar trials taking place recently.⁴⁸

Therefore, it is paramount to find an appropriate balance between providing timely access to these new treatments for those who are the most likely to benefit from them and doing so in a safe and professional context governed by the strictest ethical and professional rules.

the sponsor did not implement systems and procedures to ensure the tasks were appropriately delegated to study staff.

These concerns associated with the use of MDMA in a therapeutic context were raised after a complaint was filed against MAPS about therapists engaging in inappropriate practices during clinical trials in 2015. The <u>video of a session</u> taking place in Vancouver in 2015 was released in the United States before being <u>published by CBC in March 2022</u>.

⁴⁸ The first of the clinical trials underway, sponsored by Remedy Institute, was issued a non-compliant rating from Health Canada in June 2022. After the necessary corrections to the study protocol had been made, the clinical trial was reinstated on 29 September 2022.

An inspection report was prepared for the second clinical trial underway, sponsored by the Multidisciplinary Association for Psychedelic Studies Canada (MAPS Canada). It was rated as being compliant, but a number of deficiencies were identified. Health Canada called for corrective action to be taken regarding the following observations:

⁻ the sponsor, in this case MAPS, did not implement systems and procedures to ensure the quality of the clinical trial for five separate observations;

⁻ the sponsor did not implement systems and procedures to train study staff;

⁻ the clinical trial records had errors and/or missing information that did not allow for complete and accurate reporting, interpretation, and verification;

⁻ the sponsor did not implement systems and procedures to ensure equipment was maintained and calibrated;

Positions of the Government of Canada

Health Canada

According to Shannon Nix, Associate Assistant Deputy Minister at Health Canada, the primary psychedelics being studied for their potential in treating certain mental health issues are "controlled substances" under the <u>Controlled Drugs and Substances Act</u>, and exemptions are necessary in order to legally undertake activities with these substances.

Psychedelic-assisted psychotherapy has shown promise in clinical trials as an emerging treatment for patients with mental health conditions. In particular, the use of MDMA in combination with psychotherapy is showing promise as a treatment option for PTSD.

However, with the exception of ketamine, no psychedelic drugs have been authorized for clinical use in Canada or elsewhere. Evidence related to the effectiveness of psychedelic drugs in the treatment of PTSD is still very much under development.⁴⁹

As mentioned earlier, this assertion now needs to be qualified since, since this testimony, Australia has authorised psilocybin-assisted therapy in the treatment of cases of depression that are resistant to other treatments, and MDMA-assisted psychotherapy for the treatment of PTSD.⁵⁰

In November 2022, Ms. Nix explained that, in Canada, "there are nine clinical trials studying MDMA, three studying psilocybin — these have been authorized by Health Canada — and there's also one clinical trial authorized for ketamine in the treatment of PTSD." ⁵¹

Patients participating in these trials had access to psychedelic substances under Health Canada's Special Access Program. Health care practitioners can apply to use unauthorized drugs on behalf of their patients. According to Ms. Nix, "[t]o access a drug through this program, health care professionals need to demonstrate that the requested drugs are for the treatment of a serious or life-threatening health condition, and that conventional therapies have failed, are unsuitable or are unavailable in Canada."

⁴⁹ Shannon Nix, Associate Assistant Deputy Minister, Controlled Substances and Cannabis Branch, Health Canada, VEAC, *Evidence*, 30 November 2022.

⁵⁰ Australian Government, "Update on MDMA and psilocybin access and safeguards from 1 July 2023"

⁵¹ Shannon Nix, Associate Assistant Deputy Minister, Controlled Substances and Cannabis Branch, Health Canada, VEAC, *Evidence*, 30 November 2022.

In instances where there is a medical need and it can be demonstrated that access to psychedelic controlled substances is not possible or suitable through either clinical trials or the Special Access Program, individuals can also apply for what is known as a subsection 56(1) exemption under the Controlled Drugs and Substances Act.⁵²

This subsection 56(1) exemption is a discretionary power that permits the Minister to create exemptions "for scientific or medical purposes, or for a purpose that is otherwise in the public interest." When she appeared before the Subcommittee, Ms. Nix stated as follows:

The Special Access Program and the subsection 56(1) exemptions are not meant to be mechanisms to encourage the early use of unauthorized drugs or as means of circumventing clinical development or the established drug review and authorization process. However, Health Canada recognizes that there are times when access to unauthorized drugs might be appropriate.⁵³

After hearing from witnesses, certain points about clinical trials and exemptions as part of the Special Access Program remained unclear. Ms. Nix confirmed that nine clinical trials in Canada were using MDMA and three were using psilocybin. However, Karen Reynolds, Director General of Health Canada's Pharmaceutical Drugs Directorate, stated that, as part of the Special Access Program, there were "44 approvals for 58 patients," but none of the 11 applications for MDMA were approved. According to Ms. Reynolds, they were denied "because we do not have a source of pharmaceutical-grade MDMA that is available. Under the Special Access Program, we look to provide patients with what we call pharmaceutical-grade or good manufacturing practice-compliant product so that we know that it's a pure product and doesn't contain any other substances or whatnot." It remains unclear how patients participating in the nine MDMA clinical trials were able to procure it.

The fact that there is no source of safe product is also a barrier for those calling for accessibility to be expanded immediately. Professor Walsh, for instance, suggested increasing access to better understand the risks associated with these substances:

⁵² Shannon Nix, Associate Assistant Deputy Minister, Controlled Substances and Cannabis Branch, Health Canada, VEAC, *Evidence*, 30 November 2022.

⁵³ Shannon Nix, Associate Assistant Deputy Minister, Controlled Substances and Cannabis Branch, Health Canada, VEAC, *Evidence*, 30 November 2022.

⁵⁴ Karen Reynolds, Director General, Pharmaceutical Drugs Directorate, Health Products and Food Branch, Health Canada, VEAC, *Evidence*, 30 November 2022.

⁵⁵ Karen Reynolds, Director General, Pharmaceutical Drugs Directorate, Health Products and Food Branch, Health Canada, VEAC, *Evidence*, 30 November 2022.

I agree that we need more trials. I don't know if that is going to meaningfully impact access in the short term. I think I might take a slightly different approach, which is to make sure we increase access and then monitor it carefully. I'm kind of saying the same thing, but instead of saying let's have trials and people can get access through the trials, I think we should be providing access.⁵⁶

The advantages and risks associated with these substances are known only when taken in a very regulated psychotherapeutic context, usually involving two psychotherapists for an extended period. Subcommittee members believe that expanding access without being able to guarantee a safe environment is too risky, given our current limited knowledge.

Veterans Affairs Canada

Veterans Affairs Canada (VAC) does not provide health care to veterans. Its role is to complement services provided by provincial health insurance plans by paying authorized suppliers to provide these services. Since many mental health services are not covered by provincial health plans when they are not provided by doctors, a significant part of VAC's health care spending is to provide mental health treatment.

The department's guiding principles for approving a mental health treatment include:

that the treatment is evidence-based, supported by published peer-reviewed literature and focused, when possible, on veteran health, and that the treatment is approved by Health Canada, is not experimental, has an acceptable safety profile, is cost-effective, aligned with treatments used in the Canadian Armed Forces and the RCMP and, to the extent possible, is gender and culturally sensitive.⁵⁷

Based on these guidelines, in September 2021 VAC assessed the scientific data available regarding the effectiveness of psychedelic-assisted psychotherapy for the treatment of PTSD and other mental health issues. According to Dr. Alexandra Heber, VAC's Chief Psychiatrist, "[b]ased on our review of the literature and deliberations, the Mental Health Treatment Review Committee did not recommend the use of psychedelics or psychedelic-assisted psychotherapy at this time." ⁵⁸

⁵⁶ Zachary Walsh, Professor, Department of Psychology, University of British Columbia, As an individual, VEAC, *Evidence*, 26 October 2022.

⁵⁷ Dr. Alexandra Heber, Chief of Psychiatry, Veterans Affairs Canada, VEAC, *Evidence*, 27 April 2022, 3:3.

⁵⁸ Dr. Alexandra Heber, Chief of Psychiatry, Veterans Affairs Canada, VEAC, *Evidence*, 27 April 2022, 3:16.

According to the Mental Health Treatment Review Committee, the studies did not clearly demonstrate that the benefits outweighed the risks for these substances and had insufficient data on risks to certain at-risk populations (people with psychotic or dissociative disorders, severe PTSD or suicidal ideations).

VAC's position is to wait for the preliminary findings of existing studies to be confirmed by other studies that may address veterans specifically.⁵⁹ However, the department does not appear to have proactively engaged in funding or carrying out such studies.

The Subcommittee believes that VAC'S wait-and-see approach does not fit with the leadership role it should be taking on in addressing the suffering experienced by veterans. It is clear that, while it is important to minimize risks, psychedelic-assisted psychotherapy could be a solution for some veterans. There is no reason not to immediately explore how to take advantage of this rare opportunity for a new treatment.

Should access to psychedelic substances be expanded or restricted?

Even the most cautious recognize the tremendous potential of psychedelics in conjunction with a structured psychotherapeutic approach. However, scientific evidence confirming these results is not strong enough to overcome the real and perceived risks associated with these substances. There is also insufficient evidence of the beneficial effects of these substances among veterans, who tend to respond differently to treatments than the general public, and yet all studies to date have only involved the general public. As Dr. Richardson explained, "military-related or combatrelated PTSD does not respond as well to treatments ... when compared to civilian-related PTSD." He added, "PTSD in the military context tends to be more severe and tends to be related to repeated traumatic events." 60

Lastly, veterans interested in participating in these treatments must be assured that the therapeutic support they are receiving is safe and the people administering the treatment are competent.

However, research efforts clearly must be ramped up in the short term to address these grey areas. According to Dr. Jetly, that would require providing funding for clinical trials:

⁵⁹ Dr. Alexandra Heber, Chief of Psychiatry, Veterans Affairs Canada, VEAC, *Evidence*, 27 April 2022, 3:16. ⁶⁰ Dr. J. Don Richardson, Co-Chair, Section on Military and Veterans, Canadian Psychiatric Association, VEAC, *Evidence*

⁶⁰ Dr. J. Don Richardson, Co-Chair, Section on Military and Veterans, Canadian Psychiatric Association, VEAC, *Evidence*, 22 March 2023.

Right now, these medicines — make no mistake — they're in the experimental phase, and it's very compelling evidence. What someone like me is advocating for is we need to do it within the guise of trials. There are people who are ill who aren't getting better. Under the auspices of Health Canada, let's fund some trials. We're not in a position now where legally you will have psychedelic treatment for everybody who wants it. There's special access. I would say Veterans Affairs is conservative by design, but while you're waiting for the approval, you could be part of the solution by having people voluntarily sign up for trials if the conventional treatments haven't worked, and then we could contribute to the literature internationally and do the work necessary. ⁶¹

Dr. Averill expressed a similar desire in the American context:

Supporting research funding, reducing regulatory barriers to expedite research and the advancement of science, supporting expanded access programs and supporting thoughtful legislation that really looks at safe, ethical, accessible and equitable use are critical.⁶²

MAPS Canada gave the same recommendation:

Conducting clinical trials with MDMA and psilocybin specifically in the Canadian veteran population that will help provide access to veterans, train practitioners and assess safety and efficacy, including health economics and cost-benefit analysis of psychedelic-assisted psychotherapy in comparison to the standard of care. Clinical trials are already happening in VA — Veterans Affairs — hospitals across the U.S. 63

Oliver Thorne, of the Veterans Transition Network, said that studies should not be funded by organizations with commercial interests, an observation that was echoed by Lieutenant-General (Ret'd) Roméo Dallaire.⁶⁴

In Canada, research funding is allocated through the Canadian Institutes of Health Research (CIHR). They already fund research on psychedelics for treating substance use dependence, major

⁶¹ Colonel (Ret'd) Rakesh Jetly, Former Chief Psychiatrist, As an individual, VEAC, Evidence, 2 November 2022.

⁶² Lynnette A. Averill, Associate Professor, Menninger Department of Psychiatry and Behavioral Sciences, Baylor College of Medicine, As an individual, VEAC, *Evidence*, 23 November 2022.

⁶³ Sabrina Ramkellawan, Co-Chair, Board of Directors, Multidisciplinary Association for Psychedelic Studies (MAPS), VEAC, *Evidence*, 23 November 2022.

⁶⁴ Oliver Thorne, Executive Director, Veterans Transition Network, VEAC, *Evidence*, 15 February 2023; and Lieutenant-General (Ret'd) Hon. Roméo A. Dallaire, former senator, As an individual, VEAC, *Evidence*, 15 February 2023.

depressive disorder or end-of-life psychological distress. They do not have any categories for treating PTSD or veterans in particular. The CIHR could receive funding from VAC, the Department of National Defence, Health Canada and other government organizations to carry out research, possibly in collaboration with the Canadian Institute of Military and Veteran Health Research (CIMVHR). According to Dr. Jetly, "[i]f there was a call for psychedelic assisted psychotherapy in veterans, ten universities will answer that call and will do the highest quality work possible." ⁶⁵

Dr. Weiss, CIHR Scientific Director, confirmed that this approach is feasible:

Since we are the health research agency that funds clinical trials through peer-reviewed assessment of these trials, we can definitely collaborate with Veterans Affairs at any point should there be an interest in expanding the scope and breadth of the clinical trials that look at psychedelic-assisted psychotherapy. That is definitely a possibility.⁶⁶

Accelerating research in this way would have the additional advantage of ensuring that veterans who are the most likely to benefit from these treatments can access them more quickly. According to Dr. Husain, "we aren't going to be able to generate more data on safety and effectiveness until we have easier access to this treatment for our Canadian veterans who are suffering from intractable PTSD symptoms." Dr. Richardson expressed a similar view: "More research is needed, and should be reserved for treatment resistance, meaning they have tried other treatments and have not responded."

Furthermore, people interested in providing these treatments would have an incentive to obtain the training they need, at a rate that would support the demand created by the clinical trials. If access were to be expanded immediately, there would not be enough trained therapists to meet the demand, which would create an additional risk. General Dallaire explained: "This cannot be a commercial exercise. It has to be an intellectually rigorous one and one with ethical standards. We cannot reduce it or stall it. We have to move forward. That is a difficult scenario to meet." 69

These studies could also help find a solution to the methodological problem relating to psychedelic substances. As Professor Walsh explained:

⁶⁵ Colonel (Ret'd) Rakesh Jetly, Former Chief Psychiatrist, As an individual, VEAC, Evidence, 2 November 2022.

⁶⁶ Samuel Weiss, Scientific Director, CIHR Institute of Neurosciences, Mental Health and Addiction, Canadian Institute of Health Research, VEAC, *Evidence*, 30 November 2022.

⁶⁷ Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health, As an individual, VEAC, *Evidence*, 26 October 2022.

⁶⁸ Dr. J. Don Richardson, Co-Chair, Section on Military and Veterans, Canadian Psychiatric Association, VEAC, *Evidence*, 22 March 2023.

⁶⁹ Lieutenant-General (Ret'd) Hon. Roméo A. Dallaire, former senator, As an individual, VEAC, *Evidence*, 15 February 2023.

The classic placebo control is a real problem. In the control condition, the placebo condition, someone is lying down, wearing an eye mask and headphones, feeling nothing for eight hours. So it's not only that people guess when they are in the active condition; for the people in the control condition, it can be quite unpleasant.

We need to find other ways to assess these treatments. 70

The approach supported by the Subcommittee will surely come as a disappointment to those witnesses who would have preferred granting much wider access to psychedelic substances. Mr. Fascinato, for example, criticized the slow scientific process that forces certain veterans to make an impossible choice between limiting themselves to traditional treatments that have proven to be ineffective or to using psychedelics either illegally or by travelling to another country where access is easier.

[T]he clinical trials are fairly narrow in their criteria and what they are looking for by way of individuals and numbers. When we are talking about how many people could stand to benefit and how many people are exploring this potentially, it's like a waterfall into a funnel. There is no way to capture it all.

It is the same thing with section 56 exemptions. As I understand it, you have to receive sign-off from the minister of health, and then there are still issues with regard to access. You might have access to a controlled substance but not be able to carry it. Immediately, you are in contradiction to federal regulations.

With the SAP, again, it is a high bar in terms of qualifying for the special access program. Individuals, as I understand it, have been turned away because they haven't explored every single option available to them, and that includes sometimes going to other parts of the province or out of province, and that might be beyond the financial resources of individuals who are already having a bad time."⁷¹

⁷⁰ Zachary Walsh, Professor, Department of Psychology, University of British Columbia, As an individual, VEAC, *Evidence*, 26 October 2022.

⁷¹ David Fascinato, Executive Director, Heroic Hearts Project Canada, VEAC, *Evidence*, 2 November 2022.

Professor Walsh echoed this call for greater access:

We need to treat people as they are living right now. The hunger for these treatments is huge among people who are suffering. I'm worried that people will turn to illicit providers; they already are. We need to provide safe access to the many veterans who want to use these treatments because otherwise they will go to the grey market or remain untreated. The consequences are quite negative if we don't allow access.⁷²

Subcommittee members wish to help expand this access, but in a way that takes into account both the limited scientific knowledge and the current capacity of health care professionals to offer therapeutic support safely. Dr. Husain explained as follows:

I do have a concern about how this type of treatment would be scaled up in terms of the numbers of veterans and other people who are suffering because it is a very resource-intensive treatment. As providers, we need to think about how we could scale it up because, at the moment, it requires two trained therapists for a minimum of 12, sometimes up to 20, hours of psychological support around the treatment. Where I am in Ontario, access to OHIP-covered psychotherapy is almost impossible.⁷³

In general, Canadian veterans have better access to mental health treatment than the general Canadian population:

- All veterans and members of their families can call a toll-free number, and VAC will provide
 up to 20 hours of psychological support by certified professionals. The caller does not need
 to be a VAC client or provide any proof of diagnosis or of a link between their needs and
 their military service. The first session usually takes place within two to three weeks of the
 initial call.
- All veterans receiving Mental Health Benefits through VAC have access to hundreds of health care professionals through Medavie Blue Cross, and they receive these services at no cost.

⁷² Zachary Walsh, Professor, Department of Psychology, University of British Columbia, As an individual, VEAC, *Evidence*, 26 October 2022.

⁷³ Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health, As an individual, VEAC, *Evidence*, 26 October 2022.

- All veterans participating in the VAC Rehabilitation Program can obtain services from mental health professionals through the "Partners in Canadian Veterans Rehabilitation Services," the subcontractor that delivers the department's Rehabilitation Program.
- All veterans who are VAC clients and have mental health problems associated with their military service can access services provided by the 10 <u>operational stress injury clinics</u> overseen by VAC or by the <u>Operational Trauma and Stress Support Centres (OTSSCs)</u> overseen by the <u>Department of National Defence</u>.

Basic services are available, but to obtain specialized services, such as the psychiatric assessments needed to begin treatment, wait times can be long.⁷⁴ The additional challenge of psychedelic-assisted psychotherapy is that very few health care professionals are trained to offer the treatment safely. Launching a robust research program leading to clinical trials would encourage mental health care professionals to acquire this training and clarify the parameters. Dr. Husain provided the following explanation:

There have been concerns with monitoring the person when they're having a six-to-eight-hour hallucinogenic experience because a lot of individuals with mental health conditions, like depression and post-traumatic stress disorder, may be quite distressed by that hallucinogenic experience. It's thought that the continuous monitoring is needed to, in a way, guide people through those distressing or difficult experiences. It's also important, in the run-up to that treatment experience, to educate the patient on what's involved and to set intentions for that session. Following the therapy itself, they debrief about what happened during the treatment session and how they can use the learnings moving forward and integrate them into their lives. So there is a lot of psychological support around it.

No studies, to my knowledge, have used psilocybin or MDMA or LSD in clinical populations without the use of psychological support. We can't reliably say at this point whether we know it's safe to deliver without that key component.

The need for that is unknown, but as I mentioned earlier, 12 to 20 hours of psychotherapy around each session is a hell of a lot of psychotherapy, and I do worry about how we will increase access to prevent it from becoming something that's only available to a select few.⁷⁵

⁷⁴ Dr. J. Don Richardson, Co-Chair, Section on Military and Veterans, Canadian Psychiatric Association, VEAC, *Evidence*, 22 March 2023

⁷⁵ Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health, As an individual, VEAC, *Evidence*, 26 October 2022.

The requirements for this type of psychotherapy mean that access is restricted to those who are the most likely to benefit from it. Veterans and first responders are the most likely to suffer from mental health issues. Therefore, it is reasonable to plan to offer innovative treatments to members of this group who, after an in-depth assessment, are deemed to be the most likely to benefit from it.

Finding the balance between providing these treatments and having the capacity to provide them is an issue in the United States as well. As Dr. Averill explained:

Initial clinical trials have been promising to the point that the U.S. Food and Drug Administration, or FDA, has granted breakthrough therapy designations to both MDMA-and psilocybin-assisted therapies for PTSD and depression respectively, meaning that these interventions are thought to demonstrate improvement over our currently available interventions, that these are safe and that these have limited potential for abuse.

Yet, because these drugs are classified as Schedule I, it is nearly impossible to legally access these breakthrough therapies, including for patients who have already exhausted all available interventions and are at serious risk for suicide or, at the very least, serious risk for loss of day-to-day quality of life.⁷⁶

Although the encouraging findings of the preliminary studies have made some people eager to proceed right away, if these results are confirmed, it would still take several years before this type of psychotherapy could be provided on a larger scale. According to Dr. Husain, "the timeline from when the phase III study is completed to actual use in the clinic could still be two to three years at minimum, with regard to the approvals required from any given jurisdiction to be able to then access the controlled substance for use. I would stay that it is still a way off in terms of regulated clinical usage."⁷⁷

In the fall of 2022, Alberta introduced guidelines on the use of psychedelics. According to Dr. Jetly, these guidelines include steps to legalization once the results of phase III clinical trials for MDMA are known in 2023: "That's the first province that has had discussions, and I have been on boards advising. Ontario is considering it, and there has been some discussion, and there is also some, I believe, in Nova Scotia. There is some crosstalk, but in terms of the funding and the research being done, it's still piecemeal." ⁷⁸

36

⁷⁶ Lynnette A. Averill, Associate Professor, Menninger Department of Psychiatry and Behavioral Sciences, Baylor College of Medicine, As an individual, VEAC, *Evidence*, 23 November 2022.

⁷⁷ Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health, As an individual, VEAC, *Evidence*, 26 October 2022.

⁷⁸ Colonel (Ret'd) Rakesh Jetly, Former Chief Psychiatrist, As an individual, VEAC, *Evidence*, 2 November 2022.

Ms. Ramkellawan, of MAPS Canada, criticized the fact that these guidelines do not provide for access to substances except through psychiatrists.

They would go through the Special Access Program, but if you are looking at getting access in Alberta, you would have to go through a psychiatrist only. There are bottlenecks with that, because there is already a waiting list to see a psychiatrist. If it is only limited to psychiatrists, there is another access issue and barrier there.

There are talks that there has to be specific training, but we do not know exactly where that training is coming from, which has to be done by those psychiatrists, and who would be allowed to access the SAP for patients in Alberta.⁷⁹

Given the uncertainty surrounding even the most liberal processes for using these substances, as is the case in Alberta, caution is warranted. Health Canada is for now withholding judgment on the scope of these new regulations. Ms. Nix noted the following:

Federal drug laws will continue to apply, including the requirements around the sale of any drug needing to be authorized by Health Canada before it can be marketed and prescribed in Canada. We are working closely with Alberta to understand the scope of these new regulations. To the best of my knowledge, they are the only province that has started work in this space.⁸⁰

Given:

- the need to support as energetically as possible all treatments likely to improve the well-being of veterans;
- the promising preliminary findings of studies on psychedelic-assisted psychotherapy;
- the limited knowledge about the risks associated with using psychedelic substances in a psychotherapeutic context;
- the limited capacity of health care professionals to provide these treatments in a safe manner;

⁷⁹ Sabrina Ramkellawan, Co-Chair, Board of Directors, Multidisciplinary Association for Psychedelic Studies (MAPS), VEAC, *Evidence*, 23 November 2022.

⁸⁰ Shannon Nix, Associate Assistant Deputy Minister, Controlled Substances and Cannabis Branch, Health Canada, VEAC, *Evidence*, 30 November 2022.

The Time is Now: Granting equitable access to psychedelic-assisted therapies

- the better access to these treatments that could be achieved through large-scale clinical trials;
- the normalization of the training needed to offer these treatments in a safe manner stemming from large-scale clinical trials; and
- the incentive to manufacture pharmaceutical-grade substances that these clinical trials would create,

the Subcommittee recommends:

Recommendation

That Veterans Affairs Canada and the Department of National Defence, in collaboration with Health Canada and the Canadian Institutes of Health Research, as well as the applicable provincial and territorial authorities, immediately launch and fund a large-scale research program on psychedelic-assisted psychotherapy for treating those mental disorders and other conditions that have been identified as potentially being therapeutic targets for these types of interventions.

The Subcommittee does not want to downplay VAC's efforts to support veterans, but Subcommittee members would like to emphasize that the Department must recognize the urgency of addressing the outstanding questions about the therapeutic value of psychedelics, and that it must take the lead on implementing this recommendation quickly.

Conclusion

Armed conflicts in the last 50 years have demonstrated that the horror that members of the military experience in combat zones can destroy their ability to distinguish right from wrong, and can disturb their conscience to the point that they cannot find meaning in their own actions. The savage violence of war destroys all ideals and causes moral wounds so deep that they can choke all hope of giving meaning and purpose to one's own actions. Military members' source of motivation, that noble desire to rally together to accomplish a mission, to contribute to a cause, becomes the bottomless pit where their humanity is lost when they become veterans.

Using the term mental health issues in this context is a euphemism that glosses over moral injuries. Posttraumatic stress disorder, depression, anxiety, and the abuse of alcohol, drugs or medication are the labels we use to try to make sense of what has been lost and to convince ourselves that there is something to be learned, we who are witnesses, whether sympathetic or condescending, to their suffering.

Our country's veterans die by suicide more, much more, than any other Canadians. And yet suicide is only the tip of the iceberg. It is the ultimate solution, burying in icy silence the suffering of those who still hope to live. Each of them chose to give themselves, body and soul, to protect us and what we hold dear, on our behalf and in our place. Thanks to their sacrifice, we all can try to find our own happiness. Who is more deserving of our dedication and our efforts to prevent and heal whatever could affect their will to live than they are?

Psychedelic-assisted psychotherapy is a developing field of study that may hold therapeutic promise in a variety of mental disorders and other conditions in veterans. Currently available research findings suggest that a robust program of study, that includes efficacy and effectiveness research, be undertaken to determine the safety, therapeutic impacts, efficiency, and applicability/implementation of the various types of this modality. As veteran Kelsie Sheren asked, "Why wouldn't we, at least, put a little more funding into it to find out?" We know enough to take action. The American government launched clinical studies in 2022. No matter what their findings show, these studies will have to be replicated in Canada to ensure that the results can be applied to our own veterans. So why wait? The veterans that will benefit the most are those who have no hope left. Do we have anything else to offer them? Is the possibility that one, two, five suicides could be prevented not reason enough? Do we really need more justification if there is a possibility that we can reunite veterans with their parents, partners, friends, and children and re-establish those ties of love and purpose that war destroyed?

We owe it to our veterans to explore every possibility. They should not be left to explore these options on their own. The entire hierarchy of the Canadian Armed Forces, of the Royal Canadian Mounted Police, every employee at Veterans Affairs Canada and the entire Government of Canada, plus whatever researchers and health care professionals that the government can mobilize, should tackle this issue without hesitation. These veterans are suffering because they rose to the highest calling of our nation. In return, Canadian decision-makers should do everything in their power, explore every avenue, leave no stone unturned, in case even one is hiding a wisp of a solution that

The Time is Now: Granting equitable access to psychedelic-assisted therapies

could help them improve their daily lives. Let's tackle this problem with all available resources, motivated by their despair. What could be more important than that?

APPENDIX A – Witnesses

Wednesday, April 27, 2022

- Dr. Alexandra Heber, Chief of Psychiatry, Veterans Affairs Canada
- Dr. Barbara O. Rothbaum, Executive Director, Emory Healthcare Veterans Program and Associate Vice Chair of Clinical Research, Department of Psychiatry, Emory School of Medicine

Wednesday, May 4, 2022

- The Honourable Lawrence MacAulay, P.C., M.P., Minister of Veterans Affairs
- Paul Ledwell, Deputy Minister, Veterans Affairs Canada
- Steven Harris, Assistant Deputy Minister, Service Delivery Branch, Veterans Affairs Canada

Wednesday, May 11, 2022

- Colonel (Ret'd) Nishika Jardine, Veterans Ombud, Office of the Veterans' Ombudsman
- Duane Schippers, Deputy Veterans Ombud, Office of the Veterans' Ombudsman

Wednesday, October 26, 2022

- Dr. Muhammad Ishrat Husain, Lead of the Mood Disorders Service and Clinician Scientist, General Adult Psychiatry and Health Systems Division, Centre for Addiction and Mental Health
- Zachary Walsh, Professor, Department of Psychology, University of British Columbia

Wednesday, November 2, 2022

- Colonel (Ret'd) Rakesh Jetly, Former Chief Psychiatrist, Canadian Armed Forces
- David Fascinato, Executive Director, Heroic Hearts Project Canada

Wednesday, November 23, 2022

- Dr. Lynnette A. Averill, Associate Professor, Menninger Department of Psychiatry and Behavioral Sciences, Baylor College of Medicine
- Sabrina Ramkellawan, Co-Chair, Board of Directors, Multidisciplinary Association for Psychedelic Studies

Wednesday, November 30, 2022

- Shannon Nix, Associate Assistant Deputy Minister, Controlled Substances and Cannabis Branch, Health Canada
- Karen Reynolds, Director General, Pharmaceutical Drugs Directorate, Health Products and Food Branch, Health Canada
- Samuel Weiss, Scientific Director, CIHR Institute of Neurosciences, Mental Health and Addiction, Canadian Institute of Health Research

The Time is Now: Granting equitable access to psychedelic-assisted therapies

 Stephanie Priest, Acting Director General, Centre for Mental Health and Wellbeing, Public Health Agency of Canada

Wednesday, February 15, 2023

- Lieutenant-General (Ret'd) the Honourable Roméo A. Dallaire, former senator
- Oliver Thorne, Executive Director, Veterans Transition Network

Wednesday, March 8, 2023

• Dr. Andrea Lee, Policy Associate, Canadian Psychological Association

Wednesday, March 22, 2023

• Dr. J. Don Richardson, Co-Chair, Section on Military and Veterans, Canadian Psychiatric Association

Wednesday, April 19, 2023

- Kelsie Sheren, Artillery Gunner (Medical Ret'd), Canadian Armed Forces
- Nigel McCourry, Lance Corporal (Medical Ret'd), United States Marine Corps

APPENDIX B – Briefs

- <u>Brief</u> from Spencer Hawkswell, Chief Executive Officer, Therapsil
- Brief from Dr. J. Don Richardson
- Submission by Tony Macie
- <u>Brief</u> from Corey Pettipas
- Follow up by Health Canada



Printed by Senate Printing Service / Imprimé par le service des impressions du Sénat

sencanada.ca 😝 🎔







