SUBMISSION TO HEALTH CANADA
IN RESPONSE TO NOTICES OF INTENT TO REFUSE
***CDSA* S. 56(1) EXEMPTIONS**

APPLICANTS' WRITTEN REPRESENTATIONS

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PART I – OVERVIEW

1. These are written representations in response to the November 1, 2022, notices of intent to refuse healthcare practitioners' requests for exemptions under s. 56(1) of the *Controlled Drugs and Substances Act*[1] to possess, transport, consume, and destroy psilocybin as part of TheraPsil's experiential training program in psilocybin-assisted psychotherapy.

2. The Minister of Health must grant the exemptions because the Minister's discretion is limited by s. 7 of the *Charter*.[2] Section 7 requires that the Minister grant exemptions when evidence indicates the exemption will decrease illness and there is little or no evidence that it will have a negative impact on public safety. There is considerable scientific research demonstrating that psilocybin-assisted psychotherapy is safe and effective at treating a variety of serious medical conditions and has no negative impact on public safety.

3. The Minister's decision engages healthcare practitioners' right to liberty because s. 4 of the *CDSA* prohibits possession of psilocybin and threatens imprisonment. Practitioners need to train with psilocybin to provide optimal care to patients. The expert consensus, which is derived from more than half a century of experience and

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[1] *Controlled Drugs and Substances Act*, SC 1996, c 19 [*CDSA*].
[2] *Canadian Charter of Rights and Freedoms*, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11 [*Charter*].

peer-reviewed studies, is that healthcare practitioners need experiential training to provide the safest and most effective treatment.

4. The Minister's decision also engages patients' s. 7 rights to life, liberty, and security of the person. A refusal would infringe liberty since it limits a decision of fundamental personal importance by inhibiting patients' ability to make a reasonable medical choice. It would infringe on security of the person since it prevents access to the safest and most effective version of psilocybin-assisted psychotherapy – therapy done by an experientially trained practitioner. And it would infringe on life since it increases the risk of death by suicide or medical assistance in dying for patients with depression or end-of-life distress. There are thousands of patients needing assessment and support to obtain psilocybin-assisted psychotherapy and needing treatment with the therapy, but there are currently very few qualified healthcare practitioners able to support and treat them. Most of these qualified practitioners are clustered in just a few areas of the country, effectively inaccessible to most patients seeking treatment.

5. The theoretical possibility of access through a clinical trial does not justify this infringement. No psilocybin trials are currently enrolling healthy healthcare practitioners. The upcoming Phase II ATMA trial will not be accessible to many TheraPsil trainees, nor is it compatible with TheraPsil's training program. TheraPsil is unable to sponsor its own trial, and it would be unethical for TheraPsil to sponsor such a trial or require its trainees to participate in one. Regardless, the delay in treatment that would result from waiting for a trial to be set up, itself, infringes s. 7.

6. If the Minister refuses the exemption requests, the decision will be arbitrary, overbroad, and grossly disproportionate. A refusal does not further the *CDSA*'s twin goals of health and public safety since no benefit will come from refusing the exemptions. There is no evidence of harm from the consumption or obtaining of non-GMP psilocybin mushrooms from previous s. 56(1) exemptions, and any risk can be mitigated by using easily accessible drug testing services, which are verified and approved by Health Canada.

7. Rather, a refusal will hinder the *CDSA*'s twin goals. It will delay treatment or force patients to receive less safe and efficacious treatment from non-experientially trained practitioners. A refusal will cause suffering and unnecessary loss of life since, without treatment, some patients with depression may commit suicide and some with end-of-life distress may access medical assistance in dying earlier than they otherwise would have. A refusal will therefore violate s. 7 of the *Charter*.

8. We respectfully submit that the Minister must grant the exemptions for all the healthcare practitioners in TheraPsil's training program.

PART II – STATEMENT OF FACT

1) Psilocybin-Assisted Psychotherapy

9. Psilocybin-assisted psychotherapy is the professionally guided use of psilocybin in combination with psychotherapy.[3] The therapy starts with at least three preparatory sessions in which the patient and therapist develop trust and rapport and discuss topics critical to a safe and effective therapy. This is followed by a medicinal session, in which the patient consumes a therapeutic dose (5 g) of dried psilocybin mushrooms under the continual supervision and guidance of a team of at least two trained, qualified, and regulated healthcare practitioners. After the medicinal session, the patient meets with a therapist for at least three therapy sessions to integrate the experience.[4]

10. Psilocybin-assisted psychotherapy is safe and effective medical treatment for end-of-life distress, treatment resistant depression, and major depression.[5] Studies indicate it may also be a safe and effective treatment for substance use disorders and other medical conditions.[6]

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[3] Affidavit of Vanathy Paranthaman, Nov 11, 2022 ("**Paranthaman Affidavit**"), para 2.
[4] Paranthaman Affidavit, paras 9-11. Terminal patients may die before completing all integration sessions.
[5] Affidavit of James Bunn ("**Bunn Affidavit**"), para 6.
[6] Bunn Affidavit, paras 30-40.

A. Is Effective Medical Treatment

11. Clinical trials have proven that psilocybin-assisted psychotherapy is effective at treating end-of-life distress. Specifically, clinical trials have concluded that

    a. A single moderate dose of psilocybin in conjunction with psychotherapy produces rapid, robust, and enduring anti-anxiety and anti-depressant effects in patients with cancer-related psychological distress;[7] and

    b. A single dose of psilocybin administered under psychologically supportive conditions produces substantial and enduring decreases in depressed mood and anxiety along with increases in quality of life and decreases in death-anxiety in patients with a life-threatening cancer diagnosis.[8]

12. Clinical trials have proven that psilocybin-assisted psychotherapy is effective at treating treatment-resistant depression and major depression. Specifically, clinical trials have concluded that

    a. Psilocybin administered with psychological support is safe and effective for treating depression and anxiety symptoms in patients with treatment-resistant major depression;[9]

    b. Psilocybin-assisted therapy is efficacious in producing large, rapid, and sustained antidepressant effects in patients with major depressive disorder;[10] and

    c. Psilocybin administered with psychological support produces a substantial decrease in depression scores, similar in amount to the antidepressant drug Escitalopram when measured on one depression symptom scale;

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[7] Bunn Affidavit, para 8 & Exhibit “A”.
[8] Bunn Affidavit, para 13 & Exhibit “B”.
[9] Bunn Affidavit, para 19 & Exhibit “C”.
[10] Bunn Affidavit, para 23 & Exhibit “D”.

psilocybin is more effective on 12 other metrics, and it has fewer adverse side effects than Escitalopram.[11]

13. Studies indicate that psilocybin-assisted psychotherapy may be effective at treating substance use disorders. Specifically, studies have concluded that

    a. Experience with psychedelic drugs is associated with a decreased risk of opioid abuse and dependence, suggesting efficacy in the treatment of substance use disorders;[12] and

    b. Psilocybin may be a potentially efficacious adjunct to current smoking cessation treatment models, and in the context of a structured treatment program, psilocybin holds considerable promise in promoting long-term smoking abstinence.[13]

B. Is Safe

14. Clinical trials have proven, and expert studies have concluded, that psilocybin-assisted psychotherapy is safe, both in the short- and long-term. Specifically, studies have concluded that

    a. Psilocybin administered with psychological support is safe for treating depression and anxiety symptoms in patients with treatment-resistant major depression;[14]

    b. Psilocybin produces the least harm to individuals out of 20 drugs assessed (including ketamine, alcohol, tobacco, and cannabis);[15]

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[11] Bunn Affidavit, para 27 & Exhibit “E”.
[12] Bunn Affidavit, para 31 & Exhibit “F”.
[13] Bunn Affidavit, para 36 & Exhibit “G”.
[14] Bunn Affidavit, para 19 & Exhibit “C”.
[15] Bunn Affidavit, para 43 & Exhibit “I”.

c. 10 mg and 25 mg doses of psilocybin[16] are generally well tolerated and do not have any detrimental short- or long-term effects on cognitive functioning or emotional processing;[17]

d. A psilocybin dose of 0.6 mg/kg (eg. 51 mg in an 85 kg adult)[18] causes no serious physical or psychological events within 30 days;[19]

e. There are no long-term adverse effects from psilocybin administered in a responsible clinical setting; short-term adverse reactions are extremely uncommon, are resolved by strong interpersonal support, and are all positively integrated at long-term follow-up;[20]

f. Use of psilocybin is relatively safe as only few and relatively mild adverse effects have been reported.[21]

C. No Public Safety Risk

15. Studies demonstrate that psilocybin-assisted psychotherapy has no negative impact on public safety. Specifically, studies have concluded that

    a. Use of classic psychedelic substances (including psilocybin) is associated with lowered odds of crime arrest;[22]

    b. The public perception in Canada, the US, the UK, and the EU of psilocybin's harm is in line with data on actual harm, which indicates psilocybin is safe, but is at odds with current legal classifications in those countries;[23]

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[16] Equivalent to 1 g or more and 2.5 g or more of dried psilocybin mushrooms respectively. *See* Bunn Affidavit, Exhibit "O", para 3.
[17] Bunn Affidavit, para 47 & Exhibit "J".
[18] Equivalent to 5.1 g or more of dried psilocybin mushrooms. *See* Bunn Affidavit, Exhibit "O", para 3.
[19] Bunn Affidavit, para 53 & Exhibit "K".
[20] Bunn Affidavit, para 58 & 61, Exhibit "L".
[21] Bunn Affidavit, para 63 & Exhibit "M".
[22] Bunn Affidavit, para 68 & Exhibit "N".
[23] Bunn Affidavit, para 72 & Exhibit "O".

c. The harms of psilocybin are low compared to prototypical abused drugs, and these concerns are addressed with dose control, patient screening, preparation and follow-up, and session supervision in a medical facility;[24]

d. The public health risks and criminal aspects of psilocybin use are negligible;[25] and

e. Psilocybin produces the least harm to society out of 20 drugs assessed (including ketamine, alcohol, tobacco, and cannabis).[26]

16. Between August 4, 2020, and February 1, 2022, the Minister of Health approved 58 exemptions for patients supported by TheraPsil, allowing them to possess and consume psilocybin for psilocybin-assisted psychotherapy, and 19 exemptions for healthcare practitioners, allowing them to possess and consume psilocybin for experiential training.[27] There is no evidence of any negative health or public safety impacts resulting from these exemptions. To the contrary, patients have reported that the therapy substantially improved their health,[28] and healthcare practitioners have reported that the experiential training enabled them to provide better care to patients.[29]

17. None of these exemptions provided a legal source of psilocybin, so all grantees used psilocybin that was either illegally sourced or they grew their own. None of the psilocybin complied with good manufacturing practices. Even with this being the case, none of the users experienced any negative health effects.[30]

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[24] Bunn Affidavit, para 76 & Exhibit “P”.
[25] Bunn Affidavit, para 79 & Exhibit “M”.
[26] Bunn Affidavit, para 82 & Exhibit “I”.
[27] Affidavit of Yasmeen Sadain, Nov 11, 2022 (“**Sadain Affidavit**”), para 13 & Exhibit “C”.
[28] Affidavit of Thomas Hartle, Nov 11, 2022 (“**Hartle Affidavit**”), paras 46-58 & Exhibits “F”-“K”.
[29] Affidavit of Valorie Masuda, Nov 7, 2022 (“**Masuda Affidavit**”), paras 7-8.
[30] Sadain Affidavit, paras 15-16 & Exhibit “D”.

2) Canada Needs More Experientially Trained Practitioners

A. There is a Large Medical Need

18. There is currently a large medical need for psilocybin-assisted psychotherapy that far outstrips what can be met by the very few healthcare practitioners qualified to assess, support, and treat patients.[31]

19. In less than 22 months, from May 2020 to February 7, 2022, TheraPsil[32] received more than 900 requests for assistance accessing psilocybin-assisted psychotherapy. TheraPsil had to turn away or waitlist more than 800 of these patients due to the lack of qualified healthcare practitioners.[33] Now, nine months later, the waitlist is even longer.[34] These patients requesting assistance have identified as being in every province and territory in Canada except for Nunavut.[35]

20. The 13 affidavits of waitlisted patients included in these submissions[36] demonstrate that many patients whom TheraPsil has had to turn away are suffering from serious medical conditions for which psilocybin-assisted psychotherapy is a safe and effective treatment. The vast majority suffer from treatment-resistant depression, major depression, and stress and anxiety disorders.

21. These individuals suffer immensely every day. The effects from which they suffer include overwhelming negative emotion, a lack of hope and joy, an inability to regulate emotions, self-hatred, low concentration, low motivation, and constant

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[31] Paranthaman Affidavit, para 18.
[32] TheraPsil is a non-profit patient advocacy organization dedicated to helping Canadians in medical need access legal psilocybin-assisted psychotherapy.
[33] Paranthaman Affidavit, paras 19-20 & Exhibit “C”.
[34] Paranthaman Affidavit, para 21.
[35] Paranthaman Affidavit, para 23 & Exhibit “C”.
[36] Affidavit of Kristine Porter, Nov 10, 2022; Affidavit of Katherine Leda Marykuca, Feb 24, 2022; Affidavit of Kathleen Phyllis Westlake, Feb 26, 2022; Affidavit of Jessica Marie Pietryszyn, Feb 23, 2022; Affidavit of Melissa Slade, Feb 23, 2022; Affidavit of William Alves, Feb 25, 2022; Affidavit of Jeremy Isaac Moore, Feb 24, 2022; Affidavit of Thaddeus Conrad, Feb 25, 2022; Affidavit of Matthew Douglas Hunter, Feb 25, 2022; Affidavit of Shawn Dustin McLaren, Feb 25, 2022; Affidavit of Luc-Alexandre Parenteau, Nov 8, 2022; Affidavit of Shannon Elizabeth McKenney, Nov 7, 2022; Affidavit of Solange Martin, Feb 24, 2022 (collectively “**Waitlisted Patient Affidavits**”).

fatigue. Many are impaired in their daily functioning, finding it challenging to complete daily tasks like grocery shopping. Many are unable to work and are forced to rely on long-term disability for decades. Many are prevented from having children, a career, or academic success. Many have described with great sadness how their mental health conditions have stopped them from having close, nurturing relationships, or from holding onto any relationships at all. Some have panic attacks, nightmares, flashbacks, dissociation, and memory problems. Some feel like they are unable to experience a life worth living or to even be a worthwhile human being.[37]

22. Many have had suicidal thoughts. Some have attempted suicide.[38]

23. These individuals have tried many conventional treatments, but none have relieved them of their suffering. They have tried meditation, counselling, cognitive behavioural therapy, talk therapy, acceptance and commitment therapy, dialectical behaviour therapy, Healing Touch therapy, group therapy workshops, retreat seminars, hospital programs, exercise, yoga, neuroscience psychoeducation, repetitive transcranial magnetic stimulation, homeopathy, acupuncture, ‘energy medicine’, and Buddhist psychology.[39]

24. They have tried dozens of different types of medications and combinations of medications, including selective serotonin reuptake inhibitors, vitamins, CBD/THC, herbals, and homeopathic medicine.[40]

25. Some have tried electroconvulsive therapy. Some who did found their concentration and memory deteriorating.[41] Others declined due to the high risk of serious side effects.[42]

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[37] Waitlisted Patient Affidavits.
[38] Alves Affidavit, para 3; McLaren Affidavit, para 2; Pietryszyn Affidavit, para 5; Marykuca Affidavit, para 9; Westlake Affidavit, para 3; Moore Affidavit, para 3.
[39] Waitlisted Patient Affidavits.
[40] Waitlisted Patient Affidavits.
[41] Marykuca Affidavit, para 8; Westlake Affidavit, para 4.
[42] Slade Affidavit, para 4.

26. A few have tried microdosing psilocybin and experienced some health benefits, which provides concrete evidence that psilocybin-assisted psychotherapy may be an effective treatment for them personally.[43]

27. The 13 waitlisted patients have turned to doctors, therapists, clinical trials, wellness corporations, non-profit organizations, friends, family, and internet searches seeking to find someone to help them undergo legal psilocybin-assisted psychotherapy, but they have had no success because there is a severe shortage of doctors, therapists, and other healthcare practitioners adequately trained to assist them.[44]

B. It is Time-Intensive

28. Psilocybin-assisted psychotherapy requires many hours from multiple healthcare practitioners who are knowledgeable and properly trained to assess, support, and treat a patient.

29. First, the patient must be assessed by a physician (either a nurse practitioner or medical doctor). This physician will determine whether psilocybin-assisted psychotherapy is an appropriate treatment for the patient.[45]

30. Next, the patient must be supported by the physician in obtaining legal access to psilocybin. This support can currently happen in one of two ways. Either the physician can provide the patient with their written recommendation for a s. 56 exemption, or the physician can make a Special Access Program ("**SAP**") request.[46]

31. The SAP request form is eight pages long and requires a large amount of time and effort. The physician must comprehensively detail the patient's current condition, medical history, comorbidities, and all treatment options tried and failed. The physician must also provide data and references supporting the safety and efficacy of the requested drug.[47] In addition, the physician must commit to mandatory

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[43] Porter Affidavit, paras 18-21; McKenney Affidavit, paras 13-14.
[44] Waitlisted Patient Affidavits.
[45] Paranthaman Affidavit, para 6.
[46] Paranthaman Affidavit, para 7; *Food and Drug Regulations*, CRC, c 870, s C.08.010(1).
[47] Masuda Affidavit, para 56 & Exhibit "D".

reporting requirements, including completing a follow-up form after each administration of the drug.[48]

32. The physician who fills out the SAP form must administer the drug themself. Because of this, only physicians who have experiential training, and are thus qualified to administer psilocybin-assisted psychotherapy, can prepare these forms. This duty cannot be off-loaded to anyone else.[49]

33. After the patient has received an exemption or access through SAP, the patient needs two experientially trained healthcare practitioners to conduct the therapy. One practitioner is the primary therapist, and the other is the secondary, also known as a co-sitter.[50] At least one of these two practitioners must be a therapist since physicians are not trained in psychotherapy, and they, therefore, cannot conduct the preparatory and integration sessions alone.[51]

34. The patient must meet with the healthcare practitioners for at least three preparatory sessions, totalling five to eight hours, to develop trust and discuss topics critical to a safe and effective therapy. The primary therapist must attend all three sessions, and the secondary therapist must attend at least the final session.[52]

35. The medicinal session lasts approximately eight hours[53] and takes place in a warm, quiet, private, and aesthetic living-room-like environment.[54] It often takes place in the patient's home.[55]

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[48] Masuda Affidavit, para 59.
[49] Masuda Affidavit, para 60.
[50] Paranthaman Affidavit, para 8; Bunn Affidavit, paras 88-89 & 98 & Exhibits "Q" & "S".
[51] Masuda Affidavit, paras 40-41.
[52] Paranthaman Affidavit, para 9; Masuda Affidavit, para 44; Bunn Affidavit, para 97; Hartle Affidavit, para 34.
[53] Masuda Affidavit, para 44.
[54] Paranthaman Affidavit, para 10.
[55] Masuda Affidavit, para 44.

36. The next day, the primary and secondary therapists meet with the patient for an integration session. The primary therapist meets with the patient for at least two more integration sessions in the following weeks.[56]

37. Patients needing more than one treatment must gain approval through a medical consult to repeat the treatment protocol.[57]

C. Experiential Training Improves Safety and Efficacy

38. Therapists administering psilocybin-assisted psychotherapy need experiential training, in which they undergo the therapy as a patient, to deliver the safest and most effective treatment to their patients. The expert scientific community unanimously agrees on this point, and this consensus is supported by both the scientific literature and the personal experiences of practitioners and patients.

39. Therapists and physicians who deal with an altered state of consciousness need to familiarize themselves with the altered state. If they do not, they will not properly understand patients' emotional and psychological vulnerability and be fully present and available to the patient. Much like a conventional psychiatrist or psychotherapist must undergo therapy to conduct it, so too must those who conduct psilocybin-assisted psychotherapy.[58]

40. Scholarship in psychedelic therapy frequently reiterates that psychedelic therapists must have first-hand experience in psychedelic therapy. Therapists who have had psychedelic reactions can then understand similar reactions in their patients. The Czech model in the 1950s, for example, required five experiential sessions for therapists' training.[59] As such, a literature review, published in the peer-reviewed *Journal of Humanistic Psychology*, has identified personal experience with

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[56] Paranthaman Affidavit, para 11; Masuda Affidavit, para 44, Hartle Affidavit, para 45.
[57] Paranthaman Affidavit, para 13.
[58] Masuda Affidavit, paras 7-8.
[59] Bunn Affidavit, para 93.

psychedelics as one of twelve domains of necessary training for psychedelic therapists.[60]

41. Similarly, a multidisciplinary committee of Canadian experts listed personal experience as a core competency for credentialing psychedelic therapists in an article published in 2021 in the peer-reviewed journal *Canadian Psychology*. The six-person committee was comprised of experts in psychiatry, clinical psychology, palliative care, anthropology, ethics, and legal studies, with decades of experience surrounding the use of psychedelics.[61] The committee made its recommendations based on, *inter alia*, a literature review, review of training programs outside Canada, and consultations with a broad range of scholars, researchers, practitioners, and therapists in the Canadian psychedelic community.[62]

42. The committee recommended that both primary and secondary facilitators have personal experience with the psychedelic drug used in psychotherapy in a licensed or sanctioned setting since psychedelic substances usually shift one's perception of self and one's sense of reality. The committee warns that it may be difficult to guide patients skillfully without direct personal experience with the substance.[63]

43. Many more of the foremost experts in the world have expressed the same conclusion. The following table notes some of the statements by experts, which are in letters included in these submissions.

Expert	**Qualifications**	**Expert Opinion**
Drug Science Advisory Committee	Leading scientific body on drugs in the UK, founded by Dr. David Nutt	"[T]raining therapists through a personal psychedelic experience is essential to allow therapists to understand this unparalleled modality and to improve the overall safety for future patients".[64]
Dr. James Fadiman	Senior Research Fellow, Sofia University	"[T]raining in this area is a necessity before working with patients".[65]

[60] Bunn Affidavit, para 94 & Exhibit "R", p 475.
[61] Bunn Affidavit, Exhibit "Q", p 4.
[62] Bunn Affidavit, Exhibit "Q", p 11.
[63] Bunn Affidavit, para 89 & Exhibit "Q", p 13, bullet 2.
[64] Letters from Experts, Tab B.
[65] Letters from Experts, Tab C.

Dr. Roland R Griffiths	Professor, Departments of Psychiatry and Neurosciences, Johns Hopkins University School of Medicine; Director, Johns Hopkins Center on Psychedelic and Consciousness Research	"While in a state of non-ordinary consciousness, it is imperative that the patient is expertly supported and guided by someone who is familiar with these states to ensure safety and promote lasting healing. Due to the numerous studies and reports involving psilocybin assisted psychotherapy over the past 60 years, it has been become clear that the best way for therapists gain sufficient familiarity with such altered states is through personal experience with the substance – at present, there is no other way of becoming intimately familiar with the nonordinary states of consciousness occasioned by psilocybin than by experiencing them."[66]
Dr. Erika Dyck	Tier 1 Canada Research Chair in the History of Health & Social Justice at the University of Saskatchewan	"One critical feature of this past research involved experiential knowledge. Indeed, the ethical protocols in place at that time insisted that researchers and clinical practitioners draw from their own personal experience with these psychoactive substances before engaging in therapeutic relationships."[67]
Mark Haden	Adjunct Professor, UBC School of Population and Public Health; Director of Clinical Research, Pysgen	"The therapist's own experience with these medicines is crucial in their skill development."[68]
Dr. Paul Grof	Professor of Psychiatry, University of Toronto; Director, Mood Disorders Center, Ottawa	"While the patients experience non-ordinary states of consciousness, they must be expertly guided and supported by someone intimately familiar with such states. Over the past 60 years, it has been learned and concluded that the therapists gain sufficient familiarity with such states only through personal experience with the substance. […] There really is no other way of becoming sufficiently familiar with nonordinary states of consciousness than experiencing them."[69]
Dr. Phil Wolfson	MD, former Assistant Clinical Professor of Psychiatry at UCSF; Founding Member of Heffter Research Institute	"It is a necessity for qualified practitioners administering psychedelic medicines to their patients to have their own experience with these medicines."[70]

44. These opinions are supported by the results of multiple studies published in peer-reviewed journals. For example, a study published in the *Journal of Psychoactive Drugs* concluded that a guide's personal experience with psilocybin is important to produce optimal outcomes for psilocybin-assisted psychotherapy patients.[71] This

[66] Letters from Experts, Tab E.
[67] Letters from Experts, Tab G.
[68] Letters from Experts, Tab H.
[69] Letters from Experts, Tab I.
[70] Letters from Experts, Tab J.
[71] Bunn Affidavit, para 101 & Exhibit "T", p 5, column 2, para 1.

study found a very strong patient preference for a guide with personal experience with psilocybin. Because prior research had found that therapies provide the most benefit when they align with patient preferences, the study concluded that aligning with patients' preference for an experiential trained therapist is important to achieve optimal outcomes.[72]

45. Another study, published in the journal *Addiction Research & Theory*, concluded that those undergoing a psychedelic experience preferred that those caring for them have extensive psychedelic experience and a pre-existing relationship.[73] It noted that "many early […] and contemporary researchers […] have emphasized the need for direct personal experience to successfully function as therapists."[74]

46. Another study, published in the *Journal of Humanistic Psychology*, concluded that it may be an ethical imperative for a therapist to have their own psychedelic experiences before practicing psychedelic-assisted psychotherapy.[75] In a survey of 23 psychedelic therapists, most emphasized the importance of having their own experiences with psychedelics and none spoke against the idea. Many noted the potential for harm that may arise when a practitioner does not have a personal, experiential sense of the vulnerability inherent in an altered state of consciousness.[76]

47. Health Canada's own consultations in review of s. 56(1) applications have come to the same conclusion. All the experts Health Canada consulted "have strongly indicated that personal experience with psilocybin is required in order to safely guide patients through treatment sessions."[77]

48. In December 2020 and January 2021, the Minister acknowledged the potential benefit of experiential training when the Minister approved 19 healthcare

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[72] Bunn Affidavit, para 104 & Exhibit "T", p 5, column 2, para 1.
[73] Bunn Affidavit, para 106 & Exhibit "U", p 388.
[74] Bunn Affidavit, Exhibit "U", p 388.
[75] Bunn Affidavit, para 111 & Exhibit "V", p 23.
[76] Bunn Affidavit, para 114 & Exhibit "V", p 17.
[77] Paranthaman Affidavit, para 17 & Exhibit "B".

practitioners' s. 56(1) exemptions for experiential training because of "in particular the potential benefits that would be derived by the patients you intend to guide through psilocybin-assisted psychotherapy following your experiential use of psilocybin".[78]

49. To be clear, although one article with expert recommendations contains the statement that knowledge of descriptions of altered states of consciousness is necessary, it does not say that knowledge of descriptions is alone sufficient for the safest and most effective treatment. In fact, the authors of that paper have made public written statements that personal experience is also necessary.[79] The consensus of the scientific community is that personal experience with the altered states of consciousness is necessary, not merely knowledge of descriptions.

50. There is such a broad consensus about the requirement for experiential training that there have not been, and could not be, any clinical trials comparing treatment by non-experientially trained practitioners to those fully trained. The Canadian scientific ethical policy guide ("**TCPS2**")[80] states that a "genuine uncertainty" (clinical equipoise) must exist in the relevant expert community about what interventions are most effective for a given condition, for a clinical trial to be ethical.[81] The TCPS2 reiterates, "[E]thical issues arise when one group may fare better or worse than another".[82] Simply put, it would be unethical for a researcher to conduct a clinical trial comparing the safety and efficacy of experientially- vs. non-experientially-trained practitioners because of how well established experiential training is as a best practice.

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[78] Sadain Affidavit, para 14 & Exhibit "D".
[79] See Bunn Affidavit, Exhibit "S", page 13 for statement that monitors must "be familiar with descriptions of altered states of consciousness". Two of the three authors of that paper, Dr. William Richards and Dr. Roland Griffiths, have written letters to the Minister as part of these submissions, stating that personal experience is also necessary. (*See* Letters from Experts, Tabs D & E.)
[80] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2018, Sadain Affidavit, Exhibit "T".
[81] Sadain Affidavit, para 71 & Exhibit "T", Ch 11, s A, "Clinical Equipoise", para 1.
[82] Sadain Affidavit, Exhibit "T", Ch 11, s A, "Clinical Equipoise", para 3.

D. There are Not Enough Trained Practitioners

51. There are currently not enough experientially trained healthcare practitioners to meet the large patient need. The trained practitioners are clustered in only a few areas of Canada making them practically inaccessible to patients outside the local vicinity.

52. Only 19 Canadian healthcare practitioners have been granted exemptions to possess and consume psilocybin as part of a training program. These exemptions were granted before TheraPsil had established its training program, and many of these 19 practitioners have since retired from practice or did not end up participating in the program.[83]

53. Because of this, there are very few qualified practitioners. There are only three practitioners on TheraPsil's roster of healthcare practitioners who are authorized to act as primary therapists and have received s. 56(1) exemptions for experiential training. All three are in southwest British Columbia (North Saanich, Abbotsford, and Duncan). One is a therapist, one is a Registered Clinical Counsellor, and one is a medical doctor.[84]

54. These three practitioners have limited time and resources to treat patients and cannot necessarily treat patients outside of their local area.[85] The sole physician, Dr. Valorie Masuda, has testified that she has no additional capacity to take on any more patients, and she does not know of anyone else to whom she could refer a patient for assessment, support, and treatment.[86]

55. TheraPsil has been forced to make the difficult decision to allow fifteen practitioners who have not received an exemption, and therefore not completed experiential treatment, to treat patients without supervision from a training program instructor.

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[83] Paranthaman Affidavit, para 24; Sadain Affidavit, para 13 & Exhibit "C".
[84] Paranthaman Affidavit, para 28 & Exhibit "D".
[85] Masuda Affidavit, para 45.
[86] Masuda Affidavit, para 46.

These decisions were made after going through an extensive assessment and screening process. Although TheraPsil is confident that this process ensures an acceptable level of safety and efficacy for the treatment, the lack of experiential training means that patients may be subject to suboptimal care. TheraPsil has only made this decision because the alternative in many instances is no care at all.[87] Two of these fifteen practitioners have received notices of intent to refuse their s. 56(1) exemption requests,[88] and ten others had their exemption requests refused in June 2022.[89]

56. None of the above-mentioned 18 practitioners are located outside of British Columbia, Ontario, and Quebec.[90]

57. There is a need not only for a greater number of trained practitioners, but for trained practitioners to be practicing in every part of the country. Psilocybin-assisted psychotherapy works best when a patient has an ongoing relationship with their therapist.[91] For this to happen, the therapist must be in the same local area as the patient. An ongoing relationship is not easily achieved by remote therapy. Thomas Hartle, the first psilocybin-assisted psychotherapy patient in Canada to receive a s. 56(1) exemption, did his preparatory and integration sessions via phone because he lives in Saskatoon, far from any qualified practitioners. He notes that it was inferior to an in-person meeting because of the inability to read body language or facial expressions.[92] The 2021 Canadian expert committee on psychedelic therapy noted that there is little research to guide practitioners on best practices for conducting psychedelic-assisted therapy remotely.[93]

58. The lack of qualified therapists in patients' local areas makes the treatment cost-prohibitive for many. Many people who need psilocybin-assisted psychotherapy are

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[87] Paranthaman Affidavit, para 29.
[88] Paranthaman Affidavit, para 31.
[89] Paranthaman Affidavit, para 30.
[90] Paranthaman Affidavit, paras 28 & 30.
[91] Masuda Affidavit, para 66; Bunn Affidavit, para 108 & Exhibit "U", p 388.
[92] Hartle Affidavit, para 35.
[93] Bunn Affidavit, para 90 & Exhibit "Q", p 14.

unable to work because of their medical condition[94] and cannot afford the cost of flights and accommodations.[95]

59. Three experientially trained healthcare practitioners located in the southwest corner of British Columbia are simply not sufficient to meet the need of more than 800 patients on TheraPsil's waitlist, nor the thousands more across Canada who would benefit from psilocybin-assisted psychotherapy.

60. The 13 affidavits of patients across Canada who have been unable to find a healthcare practitioner to assist them, are just a small sampling of the vast need that is not being met due to the severe shortage of trained doctors, therapists, and other healthcare practitioners.

3) Exemption Requests for Experiential Training

A. TheraPsil's Training Program Needs Exemptions

61. TheraPsil provides a training program in psilocybin-assisted psychotherapy to develop a pool of trained healthcare practitioners whom they can confidently include on their roster of practitioners able to support treatment. This list is made available to prospective patients seeking assessment and treatment.[96]

62. More than 350 healthcare practitioners have taken TheraPsil's training. One hundred and thirty-two more practitioners are scheduled for training in the next seven months, and more than 1,150 healthcare practitioners are on TheraPsil's waitlist to take the training.[97]

63. The training program is comprised of 12 Units.[98] Unit 11 is a 60-hour experiential training module, in which trainees experience the role of both a guide and a

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[94] *See* Alves Affidavit, para 3; Marykuca Affidavit, para 3; Westlake Affidavit, para 3; McKenney Affidavit, para 10.
[95] *See* Hartle Affidavit, paras 79, 86, 91 & 96-97.
[96] Sadain Affidavit, para 4.
[97] Sadain Affidavit, para 6.
[98] Sadain Affidavit, para 8.

patient.[99] In this Unit, trainees undergo 1-3 full-strength therapeutic psilocybin sessions at least one month apart, each conducted according to TheraPsil's Clinical Protocol,[100] which reflects best practices in psilocybin-assisted psychotherapy.[101]

64. Unit 12 is a clinical supervision module. During this Unit, trainees conduct a minimum of ten hours of casework while under the supervision of one of TheraPsil's head trainers.[102]

B. Exemption Requests

65. Because trainees need to consume psilocybin to complete experiential training, trainees are unable to complete it unless granted an exemption under s. 56(1) of the *CDSA*. TheraPsil supports its trainees in their applications for exemptions.[103]

66. In December 2020 and January 2021, the Minister of Health granted exemptions to 19 healthcare practitioners affiliated with TheraPsil.[104]

67. Throughout 2021 and 2022, TheraPsil assisted many more healthcare practitioners in its training program with submitting requests for s. 56(1) exemptions to complete experiential training.[105]

68. Many of these healthcare practitioners reside in areas of Canada that currently have no healthcare practitioners adequately trained to help the many patients seeking assistance.[106] For example, in Manitoba, there are currently no fully trained and qualified healthcare practitioners, but there are 10 patients on TheraPsil's waitlist.[107] One of these patients is Thaddeus Conrad, who suffers from post-traumatic stress disorder ("**PTSD**"). His affidavit is included in these submissions.[108] Two Manitoba

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[99] Sadain Affidavit, para 9.
[100] Attached at Sadain Affidavit, Exhibit "B".
[101] Sadain Affidavit, para 10.
[102] Sadain Affidavit, para 12.
[103] Sadain Affidavit, para 11.
[104] Sadain Affidavit, para 13 & Exhibit "C".
[105] Sadain Affidavit, para 24.
[106] Paranthaman Affidavit, para 37.
[107] Paranthaman Affidavit, Exhibit "C".
[108] Conrad Affidavit.

healthcare practitioners have requested exemptions.[109] If these two exemptions are approved, patients who otherwise have no qualified healthcare practitioners within thousands of kilometres could gain access to psilocybin-assisted psychotherapy.

69. As another example, there are currently no healthcare practitioners practicing in Ontario or Quebec who have been able to undergo legal experiential training,[110] but there are more than 120 patients on TheraPsil's waitlist from these two provinces. Twelve of these patients live in the Ottawa-Gatineau region.[111] One patient in Gatineau, Luc-Alexandre Parenteau, is a former member of the Canadian Forces who suffers from PTSD incurred during his military service. His affidavit is included in these submissions.[112] There are five healthcare practitioners party to these submissions who are in Ottawa and, if granted an exemption, could help treat Mr. Parenteau and the other eleven patients in need.[113]

70. If the healthcare practitioners party to these submissions are granted the requested exemptions, they will be able to complete the entire training program. This would significantly increase the number of qualified healthcare practitioners in Canada and allow more patients who need psilocybin-assisted psychotherapy to undergo this treatment and address their serious health problems.[114]

C. Notices of Intent to Refuse

71. In June 2020, Health Canada sent final refusals to more than 158 healthcare practitioners seeking experiential training.[115] The refusals of 96 of these healthcare practitioners who were in TheraPsil's training program are currently being judicially reviewed by the Federal Court.[116]

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[109] List of Healthcare Practitioners Represented, rows 56-60.
[110] Paranthaman Affidavit, Exhibit "D".
[111] Paranthaman Affidavit, Exhibit "C".
[112] Parenteau Affidavit.
[113] List of Healthcare Practitioners Represented, rows 49-50.
[114] Paranthaman Affidavit, para 38.
[115] Paranthaman Affidavit, para 35.
[116] Estwick Affidavit, paras 40-61.

72. On November 1, 2022, Health Canada sent identical notices of intent to refuse the exemption requests of each of the healthcare practitioners party to these submissions.

73. In these notices, Health Canada said that it intended to refuse the exemption requests because a clinical trial "may be available" to the healthcare practitioners and that a clinical trial "may help achieve [their] intended purpose".

74. It noted that a trial had recently been approved but admitted that the trial may not be available to all healthcare practitioners across Canada. From other communications with Health Canada, we are aware that Health Canada is referring to a trial by ATMA Journey Centers ("**ATMA**").[117] ATMA recently completed a Phase I trial and is planning a Phase II trial to test the efficacy of psilocybin for treating Covid-19 related mental health issues.[118] As will be discussed below, the ATMA trials are not accessible to all healthcare practitioners nor compatible with TheraPsil's training program.

75. Health Canada erroneously stated that a clinical trial would be a suitable mechanism to complete TheraPsil's training and would protect the best interests of the healthcare practitioners as participants. As will be outlined below, a clinical trial would do neither.

76. Health Canada erroneously claimed that because the psilocybin obtained in a clinical trial would comply with good manufacturing practices ("**GMP**") there were health and safety benefits to a clinical trial as opposed to a s. 56(1) exemption. As will be outlined below, a clinical trial provides no additional health and safety benefits over a s. 56(1) exemption.

77. Finally, Health Canada claimed that experiential training was unneeded to conduct psilocybin-assisted psychotherapy. As outlined above, the consensus of the expert scientific community is that experiential training is necessary for the safest and most

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[117] Sadain Affidavit, para 27 & Exhibit "H".
[118] Sadain Affidavit, paras 38-39 & Exhibit N.

effective treatment with psilocybin-assisted psychotherapy, and there is no evidence to the contrary. While it may be possible to perform some version of psilocybin-assisted psychotherapy without experiential training, it is less safe and effective. A refusal, therefore, hinders the twin goals of the *CDSA*, which are to promote health and safety.

4) Clinical Trials Are Not Available

78. Clinical trials might be a theoretical regulatory pathway for access, but they are not, in reality, available. There are currently no psilocybin clinical trials enrolling that will provide access to psilocybin for all the healthcare practitioners to complete TheraPsil's experiential training program. The upcoming Phase II ATMA trial has not started yet. Moreover, it is incompatible with TheraPsil's training program and will not be accessible to all the healthcare practitioners. TheraPsil cannot sponsor its own trial, and it would be unethical for TheraPsil to sponsor a trial or require its trainees to participate in a trial.

A. Currently No Trials Currently Enrolling Healthcare Practitioners

79. There are presently no psilocybin clinical trials enrolling healthcare practitioners.

80. ATMA's Phase I trial with 14 participants has already completed its experiential portion,[119] and there are no other psilocybin trials currently enrolling healthcare practitioners.[120]

B. Phase II ATMA Trial Will Be Inaccessible and Incompatible

81. The upcoming Phase II ATMA trial will not be accessible to all the healthcare practitioners, and it is incompatible with TheraPsil's training program.

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[119] Sadain Affidavit, para 38 & Exhibit "N".
[120] Sadain Affidavit, paras 48-51 & Exhibits "O" & "P".

i) Inaccessible

82. The Phase II ATMA trial will not be accessible to many of the healthcare practitioners. It will only be open to those suffering from Covid-19 related mental health challenges.[121] This along with other strict inclusion criteria will likely cause many trainees not to be eligible.[122]

83. Further, the trial is unlikely to provide sufficient access to the number and geographic spread of healthcare practitioners who were given notices.[123] There will certainly not be enough spots in this trial for all 350 healthcare practitioners who have taken TheraPsil's training program, the 132 set to take training in the next seven months, and the more than 1,150 who are on the waitlist.[124]

84. Furthermore, it is unclear when the Phase II trial will begin.[125] The delay from waiting for the start of this trial would cause many patients to suffer unnecessarily.[126]

ii) Incompatible with TheraPsil Training

85. Even if the trial were to start immediately and all the healthcare practitioners were both eligible for the trial and within physical proximity to trial locations to make participation practically viable, the Phase II ATMA trial is still not compatible with TheraPsil's training program.

86. TheraPsil's training program is carefully designed to reflect best practices in psilocybin-assisted psychotherapy training. Deviation from these best practices to fit within the parameters of a private corporation's clinical trial risks reducing the

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[121] Sadain Affidavit, para 39 & Exhibit "N".
[122] Sadain Affidavit, para 61 & Exhibit "I".
[123] Sadain Affidavit, para 54.
[124] Sadain Affidavit, para 53.
[125] Sadain Affidavit, para 40.
[126] Sadain Affidavit, para 52.

quality of the training, potentially decreasing the safety and efficacy of psilocybin-assisted psychotherapy for the patients who desperately need it.[127]

87. For example, in TheraPsil's training program, the trainees work in dyads (preferably of two different genders) and alternate between the roles of patient and therapist. It is extraordinarily unlikely that this model would be permitted in a clinical trial since having participants who also act as the therapist would introduce additional variables, making the experiment less tightly controlled.[128]

88. It is also crucial that TheraPsil trainees conduct their experiential session under the observation of one of TheraPsil's head trainers. This allows the head trainer to assess the trainee's abilities in the context of patient interaction, guide them, and determine whether the trainee is ready to support patients. Building this relationship with the head trainer is necessary to establish trust prior to engaging in Unit 12 of TheraPsil's training program, Clinical Supervision, in which one of TheraPsil's head trainers supervises the trainee for a minimum of ten hours while the trainee supports patients.[129]

89. Additionally, TheraPsil's Clinical Protocol requires that trainees ingest a therapeutic dose of psilocybin mushrooms, 5 grams, to ensure that the trainee understands firsthand the effects of a therapeutic dose prior to treating patients. If the amount of psilocybin mushrooms ingested as part of the clinical trial deviates even slightly from this dosage, the training experience will be significantly compromised.[130]

90. ATMA's trial will use synthetic psilocybin, not psilocybin mushrooms.[131] This difference alone makes ATMA's trial unsuitable as a mechanism for practitioner

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[127] Sadain Affidavit, para 42.
[128] Sadain Affidavit, para 43, *see also* Sadain Affidavit, para 78 & Exhibit "U" for the Office of Clinical Trials' statements to this effect.
[129] Sadain Affidavit, para 44.
[130] Sadain Affidavit, para 45.
[131] Sadain Affidavit, para 46 & Exhibits "J" & "N".

training to treat patients, who will consume psilocybin mushrooms, because the practitioner will have a significantly different experience from their patients.

91. Thomas Hartle, who has experienced treatment with both natural mushrooms and synthetic psilocybin has testified that natural mushrooms are more effective for him because natural mushrooms caused a more gradual onset of the trip and a slower decline at the end of the therapy. The gradual onset meant that he was eased into the experience and had time to meditate and center himself, thereby experiencing less anxiety. The slower decline was helpful for his integration of the experience.[132]

92. Another difference is that psilocybin mushrooms are known to cause an upset stomach. This is much less frequent with synthetic psilocybin,[133] so an experience with synthetic psilocybin likely will not familiarize healthcare practitioners with this aspect of the patient experience.

93. There is also a ceremonial aspect to consuming psilocybin as a mushroom, which grows naturally from the ground, rather than as a synthesized substance. Because the therapy is directed at a patient's mental health, the difference in mental state influenced by the different forms in which psilocybin is consumed can result in a different therapy experience.[134]

C. TheraPsil Cannot Sponsor a Clinical Trial

94. Since the ATMA trials are the only psilocybin trials that Health Canada has authorized for healthcare professionals,[135] Health Canada suggested that TheraPsil may wish to consider sponsoring its own trial.[136] This is not realistically possible.

95. TheraPsil is a small patient advocacy and support organization. TheraPsil is not a large scientific organization capable of conducting a clinical trial. It does not have

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[132] Hartle Affidavit, paras 92-94.
[133] Sadain Affidavit, para 46.
[134] Sadain Affidavit, para 46; *see also Allard v Canada*, 2016 FC 236 at para 93, [2016] 3 FCR 303.
[135] Sadain Affidavit, paras 48-51 & Exhibits "J", "O" & "P".
[136] Sadain Affidavit, Exhibit "J".

the necessary institutional resources and expertise to do so, even if it were provided funding.[137]

96. Health Canada has published a Notice to Stakeholders clarifying the requirements for conducting clinical research with psilocybin. This Notice sets out numerous strict regulatory requirements that must be followed and steps that must be taken to sponsor a trial.[138] TheraPsil does not have this capacity.[139]

97. Regardless, even if TheraPsil were to sponsor its own trial, the process involves many steps to reach the point at which all sites are initiated and ready to enroll participants. These steps are estimated to take at least 12 months. This time estimate does not include any possible amendments that may be required to the study design.[140] The timeline could not be reduced below 12 months by any efforts Health Canada might make to speed up the process, including by addressing all requests for meetings in an expedited manner or providing additional support to reduce barriers. There are many aspects of designing and conducting a clinical trial that simply take time.[141]

98. TheraPsil would need to plan the study, obtain approval from a research ethics board, and prepare a submission to Health Canada for approval. Health Canada would analyze the submission and render a decision. Then researchers and participants would need to be recruited and suitable venues obtained.[142]

99. Furthermore, because clinical trials must be controlled and focused on one primary outcome, the trial would likely have restrictive inclusion and exclusion criteria, which would exclude many individuals from being able to participate in a trial.[143]

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[137] Sadain Affidavit, para 57.
[138] Sadain Affidavit, Exhibit “Q”.
[139] Sadain Affidavit, para 56.
[140] Sadain Affidavit, para 58.
[141] Sadain Affidavit, para 60.
[142] Sadain Affidavit, para 59.
[143] Sadain Affidavit, para 61.

100. Patients need help now. Any delay will cause patients who qualify for treatment to suffer unnecessarily, and many patients will likely die before receiving treatment.[144]

D. Clinical Trial is Unethical

101. It would be unethical for TheraPsil to conduct a clinical trial for training purposes. And, even if the Phase II ATMA trial, or another similar trial, was made available to all healthcare practitioners and was compatible with TheraPsil's training program, it would be unethical for TheraPsil to require its trainees to participate in such a study.

i) Research Ethics Board Member Advises of Unethicality

102. A member of the University of British Columbia Research Ethics Board ("**UBC REB**") has advised that it would not be ethical to conduct a clinical trial for therapist training without a specific research question.[145] The effects of psilocybin in healthy human subjects (including therapist trainees) are known,[146] so the principle of clinical equipoise is not met, and there is no valid research question.[147]

103. The UBC REB member also pointed out that ethics boards have limited resources, and it is not ethical for research ethics boards to consider intensive research proposals geared towards meeting the expectations of policy makers or regulators rather than valid research needs.[148]

104. The UBC REB member's conclusion that such a clinical trial would be unethical is aligned with both Canadian and American ethical guidelines, as set out in the US National Institute of Health Clinical Centre's 7 Ethical Principles ("**NIH Principles**") and the Canadian Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans ("**TCPS2**").

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[144] Sadain Affidavit, para 62; Masuda Affidavit, para 69.
[145] Sadain Affidavit, para 64 & Exhibit "R".
[146] Bunn Affidavit, paras 46-61 & Exhibits "J", "K" & "L"; Sadain Affidavit, para 79 & Exhibit "U".
[147] Sadain Affidavit, para 64 & Exhibit "R".
[148] Sadain Affidavit, para 65.

ii) NIH Principles

105. The first NIH Principle says that the answer to a clinical trial's research question must be important or valuable enough to justify asking people to accept some risk or inconvenience for others. It clarifies, "In other words, answers to the research question should contribute to scientific understanding of health or improve our ways of preventing, treating, or caring for people with a given disease." The Principle states categorically, "Only if society will gain useful knowledge […] can exposing human subjects to the risk and burden of research be justified."[149]

106. The second NIH Principle says that a study should be designed in a way that will get an understandable answer to a valuable research question. The Principle again states categorically, "Invalid research is unethical because it is a waste of resources and exposes people to risk for no purpose."[150]

iii) TCPS2 Standards

107. The Canadian standard, TCPS2, instructs that "[c]linical trials should not be conducted unnecessarily on questions that have already been definitively answered".[151] There must be a genuine uncertainty on the part of the relevant expert community about the research question at issue.[152]

108. TCPS2 warns that clinical trials may interfere with therapeutic value. Because the purpose of a trial is to evaluate an intervention, "elements of a clinical trial design may interfere with [participants'] own health care objectives".[153] They can likewise interfere with training objectives.

109. TCPS2 prohibits conducting trials for any reason other than a bona fide scientific purpose. It specifically warns against trials that are conducted for commercial

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[149] Sadain Affidavit Exhibit "S".
[150] Sadain Affidavit Exhibit "S".
[151] Sadain Affidavit, para 70 & Exhibit "T", Ch 11, s A, "Systemic Review".
[152] Sadain Affidavit, para 71 & Exhibit "T", Ch 11, s A, "Clinical Equipoise".
[153] Sadain Affidavit, para 72 & Exhibit "T", Ch 11, s A, "Therapeutic Misconception".

reasons.[154] The ATMA trials are conducted by a for-profit corporation to facilitate paid participation in its training program.[155]

110. TCPS2 also warns against unnecessary duplication of studies. It states that unnecessary duplication should be avoided to "reduce the burden on participants."[156] If TheraPsil or any other organization were to sponsor a similar trial, it would undoubtedly be unnecessarily duplicative, contrary to TCPS2.[157]

111. Based on TCPS2 and the NIH Principles, it would be unethical to conduct a study that is duplicative, has no important and valuable research question to answer, and does not meet the standard of clinical equipoise. Therefore, it would not be ethical for TheraPsil to require its trainees to participate in a study merely to satisfy bureaucratic preference, nor would it be ethical for TheraPsil to sponsor such a study itself.

iv) Office of Clinical Trials Confirms Unethicality

112. The Office of Clinical Trials ("**OCT**") confirmed that it would be unethical for TheraPsil to conduct a clinical trial for training purposes when it told the Controlled Substances Directorate unequivocally, "A clinical trial is not possible for the situation TheraPsil is requesting." The OCT stated that "[a]long with ethical concerns and no clear benefit, the risks don't justify exposure."[158]

113. The OCT noted that there would be issues of conflict of interest and bias in the results if practitioners were the subjects of the trial. There could be a "potential bias in favour of treatment" since "practitioners may downplay discomfort or under report adverse events."[159]

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[154] Sadain Affidavit, para 73 & Exhibit "T", Ch 11, s B, "Pharmaceutical Trials, "Phase IV".
[155] Sadain Affidavit, Exhibit "I".
[156] Sadain Affidavit, para 75 & Exhibit "T", Ch 11, s D.
[157] *See* for example, those at Bunn Affidavit, paras 46-61 & Exhibits "J", "K" & "L".
[158] Sadain Affidavit, paras 76-77 & Exhibit "U".
[159] Sadain Affidavit, para 78 & Exhibit "U".

114. The OCT also stated that it would be unethical because the study "is not considered necessary." The OCT stated that trials in healthy volunteers are not common and are typically used to establish dosing. Since "there are already a number of studies globally on psilocybin dosing, this request is not feasible."[160]

5) Clinical Trials Provide No Safety Benefit

115. A clinical trial's assurance that only GMP psilocybin would be consumed provides no safety benefit over a s. 56(1) exemption since there is no evidence of harm to health or safety from non-GMP psilocybin, and any risk that might exist can be easily mitigated by getting the psilocybin tested.

A. No Evidence of Harm from Non-GMP Psilocybin

116. There is no evidence of harm to anyone from consuming or obtaining non-GMP psilocybin approved by a s. 56(1) exemption.

117. The Minister granted exemptions to 19 healthcare practitioners in December 2020 and January 2021. The Minister knew that psilocybin was not approved as a drug under the *Food and Drugs Act* or its regulations and knew that there were no products containing psilocybin approved as therapeutic drugs in Canada.[161] Nevertheless, the Minister did not view the risk to be significant enough to deny the exemptions nor even to require additional safety measures such as having the psilocybin tested before consuming.[162]

118. None of the 19 healthcare practitioners who were granted exemptions experienced any negative health or safety impacts from using non-GMP psilocybin for their experiential training.[163]

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[160] Sadain Affidavit, para 79 & Exhibit "U".
[161] Sadain Affidavit, para 15.
[162] Sadain Affidavit, Exhibit "D".
[163] Sadain Affidavit, para 16.

119. The Minister has also granted exemptions to more than 58 patients to consume non-GMP psilocybin,[164] and there is no evidence of any negative health or public safety impacts resulting from these exemptions.

120. Furthermore, expert scientific analysis of drugs used outside of a clinical or GMP setting found psilocybin mushrooms to be the safest of a list of 20 common drugs. Psilocybin is much safer than alcohol and cannabis, both of which are legal for recreational use.[165] On a scale of 0-100 with higher numbers indicating more harm, alcohol scored 72, cannabis scored 20, and psilocybin mushrooms scored 6.[166]

B. Drug Testing Available to Ensure Safety

121. Any risk that might exist from consuming non-GMP psilocybin, can be mitigated easily by using a drug testing service to determine the potency and whether there are any added substances.

122. There are various drug testing services throughout Canada where people can have their drugs tested. For example, the Vancouver Island Drug Checking Project uses multiple drug checking instruments to determine a sample's main active ingredients, fillers or cutting agents, and any unexpected drugs. It is free, and people can send in samples by mail.[167]

123. Another service, Pura Analytical Labs ("**Pura**"), offers a psychedelics potency analysis, which can quantify the amount of psilocybin, psilocyin, and baeocystin in whole dried mushrooms. Pura uses instrumentation and techniques verified and approved by Health Canada, and people can ship samples to Pura and receive their results online.[168]

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[164] Sadain Affidavit, Exhibit "C".
[165] Bunn Affidavit, para 43 & Exhibit "I".
[166] Bunn Affidavit, Exhibit "I", p 1561.
[167] Sadain Affidavit, paras 18-21 & Exhibit "E".
[168] Sadain Affidavit, paras 21-23 & Exhibit "F".

124. Accordingly, a clinical trial would provide no health or safety benefit over a s. 56(1) exemption.

PART III – POINTS IN ISSUE

125. The Applicants submit that the sole issue to be determined is whether denying the exemptions would unjustifiably infringe s. 7 of the *Charter*.

PART IV – SUBMISSIONS

126. Section 7 of the *Charter* requires the Minister to grant the exemption requests because a refusal would infringe on patients' rights to life, liberty, and security of the person and infringe on healthcare practitioners' liberty interests. This infringement would be arbitrary, overbroad, and grossly disproportionate because it would not further the *CDSA*'s twin goals of health and public safety. This infringement could not be saved by s. 1 because it is not rationally connected to the *CDSA*'s objectives, is not minimally impairing, and is not proportional.

1) Binding Jurisprudence

A. Medical Cannabis

127. The law relevant to this case has been well-established over the last two decades by a long string of medical cannabis cases. These cases have confirmed that the government cannot restrict access to a controlled substance that has the potential to provide a health benefit unless the restrictions protect health or safety in a real and practical way that is supported by evidence. All the following cases were about cannabis, a substance that presents a much higher risk to both users and the public than psilocybin,[169] yet courts repeatedly struck down restrictions on access.

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[169] Bunn Affidavit, paras 42-45 & Exhibit "I", pp 1561 & 1562.

i) R v Parker: Must Ensure Practical and Timely Access

128. In 2000, the Ontario Court of Appeal, in *R v Parker*,[170] held that the government cannot refuse access to medical treatment on the basis that another way of obtaining the treatment exists unless that other way is accessible in a practical and timely manner.

129. In *R v Parker*, the accused required cannabis to control his epilepsy. He was charged with possession under s. 4 of the *CDSA*. The Court struck down the marijuana prohibition in s. 4 because it violated Parker's s. 7 rights to liberty and security of the person.[171]

130. In doing so, the Court considered the impact of the possibility of access through the regulatory scheme or a s. 56 exemption, but it held that these defenses did not save the provision because their availability was "illusory",[172] and the delays involved in s. 56 applications endangered applicants' health.[173] The Court specifically noted that the "theoretical availability" of a certain program made no difference since there were practical barriers making it prohibitively difficult for the patient to access the program.[174]

ii) R v Krieger: No Need to Attempt All Alternative Treatments

131. In 2003, the Alberta Court of Appeal, in *R v Krieger*, held that the right to security of the person is infringed by the denial of treatment with medical cannabis, even if the person had not attempted all other alternative treatments.[175]

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[170] *R v Parker*, 49 OR (3d) 481, [2000] OJ No 2787 [*Parker*]
[171] *Ibid* at para 210.
[172] *Ibid* at paras 163 & 174.
[173] *Ibid* at para 189.
[174] *Ibid* at para 165.
[175] *R v Krieger*, 2003 ABCA 85 at para 3, 18 Alta LR (4th) 227, affirming *R v Krieger*, 2000 ABQB 1012 at para 28, 307 AR 349.

iii) R v Hitzig: Access Restrictions Must Add Additional Benefit

132. In 2003, the Ontario Court of Appeal, in *R v Hitzig*,[176] struck down portions of the *Marihuana Medical Access Regulations* ("**MMAR**")[177] which made access to cannabis more onerous, even though there were multiple alternative ways to access cannabis.

133. *Hitzig* consisted of three civil applications challenging the constitutionality of the MMAR. The MMAR provided access to medical cannabis through four different pathways: i) a personal-use production ("**PPL**") licence, ii) a designated-person production licence ("**DPL**"), iii) a licensed dealer, and vi) the ability of the Minister to import seeds.[178] The Court called the licensed dealer route "meaningless" since there were no dealers in operation at the time.[179] This "theoretical option" was thus given no weight in the s. 7 analysis.[180] There were also two clinical trials underway at the time, yet those were both not seen as a sufficient source of cannabis.[181]

134. The Court struck down the MMAR requirements that DPL holders could only grow for one person, could not be renumerated, and could not combine their growing with more than two other DPL holders. The Court held that any "regulatory constraints on access" implicate the right to security of the person, even without considering the criminal sanctions.[182] Citing the Supreme Court in *Rodriguez*,[183] it held that a criminal sanction on someone who would assist a medical cannabis user also violates the user's security of the person.[184]

135. The Court upheld the requirement that the user obtain a recommendation from a doctor or specialist but struck down the requirement for a second specialist's

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[176] *Hitzig v Canada*, [2003] OJ No 3873, 111 CRR (2d) 201.
[177] *Marihuana Medical Access Regulations*, SOR/2001-227.
[178] *Hitzig v Canada*, [2003] OJ No 3873 at paras 57-62, 111 CRR (2d) 201.
[179] *Ibid* at para 61.
[180] *Ibid* at para 88.
[181] *Ibid* at para 27.
[182] *Ibid* at para 95.
[183] *Rodriguez v British Columbia (Attorney General)*, [1993] 3 SCR 519, [1993] ACS no 94.
[184] *Hitzig v Canada*, [2003] OJ No 3873 at para 95, 111 CRR (2d) 201.

recommendation. It held that an "onerous application process" impeded the right to make fundamentally important personal decisions under s. 7.[185] The requirement for a second specialist opinion was arbitrary because it added "little if any value", despite the requirement for the first specialist's opinion contributing to public safety.[186] This demonstrates that a limit to access that does not add significant value because it is redundant with another means of protection is arbitrary even when, on its face, it appears to be rationally connected to protecting safety.

136. The Court recognized the urgent need for treatment by those with serious illnesses and refused to suspend the remedy. The Court said that delaying the remedy when some patients may die in the meantime is inconsistent with fundamental *Charter* values.[187]

iv) Sfetkopoulos v Canada: Future Access is No Answer

137. In 2008, the Federal Court of Appeal, in *Sfetkopoulos*, confirmed that neither the possibility of more access in the future nor the availability of an alternative supply in the present can justify restricting access to a controlled substance for medical treatment.[188]

138. *Sfetkopoulos* was a judicial review application of an application for one person to be the DPL for 18 medical cannabis users.[189] The Federal Court struck down the MMAR provision which restricted DPL holders to producing for only one user, and the Federal Court affirmed the decision on appeal.

139. The impugned provision had been struck down in *Hitzig*, but the government re-enacted it since there was now one licensed dealer in operation. The government sought to defend the re-enactment by this change in circumstance.[190] The

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[185] *Ibid* at para 93.
[186] *Ibid* at para 145.
[187] *Ibid* at para 175.
[188] *Sfetkopoulos v Canada (Attorney General)*, 2008 FC 33 at paras 18 & 19, [2008] FCJ No 6, ***aff'd*** *Canada (Attorney General) v Sfetkopoulos*, 2008 FCA 328 at para 3, [2008] FCJ No 1472.
[189] *Sfetkopoulos v Canada (Attorney General)*, 2008 FC 33 at para 3, [2008] FCJ No 6.
[190] *Ibid* at para 19.

government also attempted to justify the restriction by saying the restriction on DPLs was necessary to maintain an approach of moving towards a supply model where medical cannabis would be produced and made available like other prescription drugs.[191]

140. The applicants claimed that the quality of the product from the licensed dealer was inferior, and that it was inadequate because the licensed dealer only made one strain of cannabis available. Despite the applicants' evidence regarding quality being "hearsay and anecdotal" and the expert scientific evidence of the different therapeutic effects of various strains indicating "great uncertainty",[192] this weak evidentiary basis did not defeat their claim.

141. Even though the Court found that the licensed dealer "certainly does provide an alternative avenue of access", the Court said it was "not tenable for the government […] to force [users] either to buy from the government contractor, grow their own or be limited to the unnecessarily restrictive system of designated producers."[193] The restriction on DPLs was arbitrary because it caused individuals a major difficulty with access while providing no commensurate furtherance of state interests.[194]

142. The Court rejected the government's argument that the possibility of more access in the future justifies the restrictions in the present, saying, "It is no answer to say that someday there may be a better system. Nor does the hope for the future explain why a designated producer must be restricted to one customer."[195]

v) Allard v Canada Injunction: Irreparable Harm from Delayed Treatment

143. In 2014, the Federal Court of Appeal, in *Allard*, confirmed that the mere likelihood of negative effects on one's health from an inability to access medical treatment

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[191] *Ibid* at para 18.
[192] *Ibid* at para 19.
[193] *Ibid* at para 19.
[194] *Ibid* at para 20.
[195] *Ibid* at para 18.

results in irreparable harm.[196] It, thus, upheld an interlocutory injunction to provide multiple routes of access to cannabis, pending the hearing on the merits.

vi) R v Smith: Cannot Restrict Safer or More Effective Version of Treatment

144. In 2015, the Supreme Court of Canada, in *R v Smith*, held that the government could not restrict access to a safer or more effective version of a treatment simply because there was access to another version of the treatment.[197]

145. *Smith* challenged the prohibition on access to non-dried cannabis. Evidence indicated that in some circumstances the use of non-dried cannabis is more effective and less dangerous than using dried cannabis.[198] Accordingly, the Court found the decision to use non-dried cannabis for the treatment of some health conditions was "medically reasonable", so criminalizing access to this particular form of treatment infringes liberty and security of the person.[199] Liberty is infringed by the threat of incarceration, and security of the person is infringed "by forcing a person to choose between a legal but inadequate treatment and an illegal but more effective choice".[200]

vii) Allard v Canada: Anecdotal Evidence & Patient Perspective Suffice

146. In 2016, the Federal Court, in *Allard*, struck down the entire medical cannabis regulatory regime because it restricted users to a single supply of medical cannabis without guaranteeing sufficient quality, strains, and quantity would be available at an acceptable price.[201]

147. The *Marijuana for Medical Purposes Regulations* ("**MMPR**"),[202] which replaced the MMAR, eliminated patients' ability to grow their own cannabis, requiring them to

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[196] *Canada v Allard*, 2014 FCA 298 at para 13, [2014] FCJ No 1241.
[197] *R v Smith*, 2015 SCC 34 at para 18, [2015] 2 SCR 602.
[198] *Ibid* at para 19.
[199] *Ibid* at para 20.
[200] *Ibid* at para 18.
[201] *Allard v Canada*, 2016 FC 236 at para 15, [2016] 3 FCR 303.
[202] *Marihuana for Medical Purposes Regulations*, SOR/2013-119.

only obtain cannabis from a licensed producer, which would have to comply with various quality and security measures.[203]

148. The plaintiffs argued that patients needed access to a variety of strains because they had different effects,[204] but they only had anecdotal evidence of the therapeutic value of various strains.[205] Nevertheless, the Court held that in the absence of more and better studies, "anecdotal evidence is a reasonable substitute".[206] The Court also stated that since the use of medical cannabis has both physical and psychological effects, the relief given is influenced in part by the patient's perspective. If the choice of strain has some effect on a patient's perspective, it "cannot be callously dismissed as something akin to a placebo."[207]

149. The Court held that the access restrictions violated s. 7 and were arbitrary because there was not sufficient proof they reduced risk to health and safety or improved access to cannabis. In the alternative, even if a connection were found, the restriction was still overbroad and did not minimally impair s. 7 rights.[208]

B. Supreme Court of Canada

150. Some Supreme Court decisions from outside the medical cannabis jurisprudence are also directly relevant to the *Charter* analysis in this case. The following cases are binding precedent that instruct that the government cannot delay access to treatment, including by interfering with healthcare practitioners' ability to possess controlled substances, unless there is evidence that the access limitation will have a positive impact on health or safety.

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[203] *Allard v Canada*, 2016 FC 236 at paras 38-39, [2016] 3 FCR 303.
[204] *Ibid* at para 134.
[205] *Ibid* at para 85.
[206] *Ibid* at paras 87 & 211.
[207] *Ibid* at para 93.
[208] *Ibid* at para 16.

i) R v Morgentaler: Timely Treatment Required

151. In 1988, the Supreme Court, in *R v Morgentaler*, held that forcing someone to commit a crime to obtain timely, effective medical treatment violates their security of the person.[209] The Court struck down the requirement that a woman must obtain a certificate from a therapeutic abortion committee before having an abortion because delays caused by the mandatory procedures created risks to health.[210]

ii) Rodriguez v British Columbia: Bodily Choice Protected

152. In 1993, the Supreme Court, in *Rodriquez*, held that choices concerning one's own body are encompassed by security of the person.[211] If the infringement does "little or nothing" to enhance the state's interest, it will not be in accordance with the principles of fundamental justice.[212]

iii) Carter v Canada: Right to Decide One's Own Fate

153. In 2015, the Supreme Court, in *Carter*, confirmed that people have the right to make medical choices even if the choices are risky, and the government cannot interfere with their liberty to take these risks.[213]

154. The Court reiterated the "tenacious relevance" of the principle that competent individuals are free to make decisions about their bodily integrity. This right to "decide one's own fate" entitles adults to direct the course of their own medical care. The right to medical self-determination is not vitiated by the fact that serious risks or consequences (even risks that include death) may flow from the person's decision.[214]

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[209] *R v Morgentaler*, [1988] 1 SCR 30 at 90, 63 OR (2d) 281.
[210] *Ibid* at 33 & 92.
[211] *Rodriguez v British Columbia (Attorney General)*, [1993] 3 SCR 519 at 587, [1993] ACS no 94.
[212] *Ibid* at 594.
[213] *Carter v Canada (Attorney General)*, 2015 SCC 5 at para 67, [2015] 1 SCR 331.
[214] *Ibid* at para 67.

iv) Canada v PHS: Duty to Grant Healthcare Practitioner Exemptions

155. In 2011, the Supreme Court held, in *PHS*, that the Minister must grant s. 56 exemptions to healthcare practitioners to enable them to provide a certain medical treatment where evidence indicates the medical treatment is effective and there is little or no evidence that it will have a negative impact on public safety.[215]

156. In *PHS*, the Minister had denied the s. 56 exemption request of Insite, a safe injection site. The Supreme Court held that *CDSA*'s s. 4 prohibition on possession engaged the liberty interests of Insite staff since staff needed to illegally possess drugs to provide care to clients.[216] It also engaged the clients' life and security of the person interests since without an exemption, healthcare professionals would be unable to offer medical supervision and counselling to the clients. This deprives clients of medical care. In this way, the limits on the s. 7 rights of the healthcare providers also limit the s. 7 rights of clients.[217]

157. The Supreme Court held that s. 4, itself, was not arbitrary, overbroad, or grossly disproportionate solely because s. 56 acted as a "safety valve" excluding the cases that did not further the *CDSA*'s twin goals of health and public safety from s. 4's blanket prohibition.[218]

158. Consequently, the Court stated that "[i]f there is a *Charter* problem, it lies not in the statute but in the Minister's exercise of the power the statute gives him to grant appropriate exemptions."[219] The Minister's discretion, therefore, is not absolute. It must conform with the *Charter*.[220]

159. The Court overturned the Minister's refusal of the s. 56 exemption and ordered *mandamus* compelling the Minister to grant the exemption because the refusal was

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[215] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at para 152, [2011] 3 SCR 134 [*PHS*].
[216] *Ibid* at para 90.
[217] *Ibid* at para 91.
[218] *Ibid* at paras 113-114.
[219] *Ibid* at para 114.
[220] *Ibid* at para 117.

arbitrary and grossly disproportionate.[221] It was arbitrary because it undermined the *CDSA*'s purposes of health and safety, and it was grossly disproportionate because the potential denial of health services and the correlative increase in death and disease to drug users outweighed any benefit that might be derived from maintaining an absolute prohibition on Insite's premises.[222]

160. The Supreme Court set out a clear test for when the Minister must grant s. 56 exemptions. Exemptions must be granted when evidence indicates the exemption will decrease disease and there is little or no evidence that it will have a negative impact on public safety.[223]

2) Section 7 is Engaged

161. A refusal to grant healthcare practitioners exemptions would violate the s. 7 rights of both healthcare practitioners and patients. Thus, the Minister's discretion is constrained by the *Charter*. The exemptions must be granted.

A. Healthcare Practitioners' Liberty

162. Healthcare practitioners' liberty interests are engaged by the *CDSA*'s prohibition on possession of psilocybin and by the Minister's exemption decision since healthcare practitioners need to possess psilocybin to undergo experiential training and provide the safest and most effective care to patients. Healthcare practitioners risk imprisonment if they attempt to obtain crucial experiential training without an exemption.

B. Patients' Life, Liberty, and Security of the Person

163. Patients' rights to life, liberty, and security of the person are engaged by decisions about whether to grant healthcare practitioners access to psilocybin for training purposes.

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[221] *Ibid* at para 150.
[222] *Ibid* at para 136.
[223] *Ibid* at para 152, *see also* para 140.

i) Restricting Reasonable Medical Choices Engages Liberty

164. Liberty includes the right to make decisions of fundamental personal importance, including the right to choose, on medical advice, to use a controlled substance for treatment.[224] Decisions that foreclose a reasonable medical choice are a limit on liberty.[225]

165. Psilocybin-assisted psychotherapy is a safe and effective treatment for a variety of conditions.[226] The Minister has granted exemptions to many patients and has made regulatory changes to theoretically allow access through SAP, but this access is illusory because there are not enough trained practitioners in Canada to assess, support, and treat the patients in need.[227]

166. This lack of trained practitioners forecloses the reasonable medical choice of attempting psilocybin-assisted psychotherapy for a person with depression, anxiety, or end-of-life distress. TheraPsil's record of their 800+ person waitlist[228] and the affidavits of 13 of these waitlisted patients[229] evidence this foreclosure.

ii) Denying Timely, Safer, or More Effective Treatment Engages Security

167. Decisions that prevent access to health care deprive patients of their right to security of the person. [230] Allowing access to a certain medical treatment but not to a safer or more effective version of the treatment also infringes security of the person.[231]

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[224] *Sfetkopoulos v Canada (Attorney General)*, 2008 FC 33 at para 10, [2008] FCJ No 6, ***aff'd*** *Canada (Attorney General) v Sfetkopoulos*, 2008 FCA 328, [2008] FCJ No 1472.
[225] *R v Smith*, 2015 SCC 34 at para 18, [2015] 2 SCR 602.
[226] Bunn Affidavit, paras 6-65 & Exhibits "A"-"M"; Masuda Affidavit, paras 15-20; Hartle Affidavit, paras 46-58 & Exhibits "F"-"K".
[227] Paranthaman Affidavit, paras 18-34; Masuda Affidavit, paras 38-40, 61-68; Waitlisted Patient Affidavits.
[228] Paranthaman Affidavit, paras 19-21 & Exhibit "C".
[229] Waitlisted Patient Affidavits.
[230] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at para 93, [2011] 3 SCR 134.
[231] *R v Smith*, 2015 SCC 34 at para 18, [2015] 2 SCR 602.

168. While it may be possible for a person to conduct some form of psilocybin-assisted psychotherapy without undergoing experiential training, this treatment will be less safe and/or less effective than if the treating practitioner had undergone the training. Health Canada's own experts have strongly indicated this,[232] numerous other experts have opined this,[233] and multiple studies published in peer-reviewed journals have concluded this.[234] There is no evidence to the contrary.

169. Even if the only evidence that experiential training improves safety or efficacy were mere anecdote (which it is not), this evidence would be sufficient to prove a s.7 infringement. In *Allard*, the Federal Court held that "in the absence of more and better studies about the therapeutic value […], anecdotal evidence is a reasonable substitute".[235]

170. Additionally, patients have expressed their strong preference for a healthcare practitioner with experiential training, both in affidavits to this specific proceeding,[236] and in peer-reviewed studies surveying hundreds of people.[237] Because psilocybin-assisted psychotherapy is a psychological treatment, highly dependent upon the patient's mindset and setting,[238] the relief given is influenced in part by the patient's perspective. Peer-reviewed research has, in fact, found that patients benefit more from therapy when it aligns with their preferences.[239] The Federal Court in *Allard* held that any benefits resulting from aligning treatment with patient preference "cannot be callously dismissed as something akin to a placebo."[240] Restrictions that deprive patients of their preferred treatment thereby violate both the security of the person and the liberty to make a reasonable medical choice.

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[232] Paranthaman Affidavit, para 17 & Exhibit "B".
[233] Letters from Experts, Tabs B-K.
[234] Bunn Affidavit, paras 85-114 & Exhibits "Q"-"V".
[235] *Allard v Canada*, 2016 FC 236 at para 87, [2016] 3 FCR 303.
[236] Hartle Affidavit, paras 92-94.
[237] Bunn Affidavit, paras 102-103 & 106-108 & Exhibits "T" & "U".
[238] Bunn Affidavit, para 104 & Exhibit "T", p 5, column 2, para 1.
[239] Bunn Affidavit, para 104 & Exhibit "T", p 5, column 2, para 1.
[240] *Allard v Canada*, 2016 FC 236 at para 93, [2016] 3 FCR 303.

iii) Risk of Suicide or MAID Engages Life

171. Decisions that create an increased risk of death for a person, either directly or indirectly, violate the right to life.[241]

172. Many patients who suffer from depression commit suicide if they are left untreated. Seven of the waitlisted patients who have submitted affidavits have contemplated or attempted suicide.[242]

173. Kristine Porter, one of the waitlisted patients, has major depressive disorder and has attempted suicide many times. For a year, she kept a belt hanging in her closet, ready to hang herself. She put her head through the belt many times. Other times she wandered off into the forests of British Columbia, hoping to fall off a cliff and die. On one occasion, the police found her and sat with her in a ditch trying to convince her to go to the hospital. She did not see the point. She had already tried every legal treatment, and none had worked.[243]

174. In November 2020 her situation was dire. She was extremely suicidal. Her family doctor was calling her almost every day to check in on her. It was around this time that she began seeking access to psilocybin-assisted psychotherapy.[244] Two years later she still has no prospect of treatment in sight. We are lucky she is still alive today. Every day that treatment is delayed increases the risk that she will die.

175. Additionally, some people will choose medical assistance in dying ("**MAID**") who would not if they were treated with psilocybin-assisted psychotherapy.

176. Dr. Masuda, a palliative care physician and MAID assessor, has testified that many people with end-of-life distress choose MAID because they want to end their psychological pain and anxiety, but some may choose to live longer if their end-of-

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[241] *Carter v Canada (Attorney General)*, 2015 SCC 5 at para 62, [2015] 1 SCR 331.
[242] Alves Affidavit, para 3; McLaren Affidavit, para 2; Pietryszyn Affidavit, para 5; Marykuca Affidavit, para 9; Westlake Affidavit, para 3; Moore Affidavit, para 3; Porter Affidavit, paras 14-16.
[243] Porter Affidavit, paras 14-15.
[244] Porter Affidavit, paras 16 & 23.

life distress was treated with psilocybin-assisted psychotherapy.[245] In fact, one of her patients canceled their already-booked MAID date after receiving psilocybin-assisted psychotherapy.[246]

177. The barrier to treatment caused by the lack of experientially trained healthcare practitioners means a person can often obtain MAID more quickly than psilocybin-assisted psychotherapy. For patients whose natural death is reasonably foreseeable, there is no waiting period, and MAID can be conducted within days of a patient application.[247]

178. There is a particular urgency to increasing access to psilocybin-assisted psychotherapy right now because on March 17, 2023, the law will change so that people with mental illness as their sole underlying condition will have access to MAID.[248]

179. If the Minister grants exemptions to these healthcare practitioners, there will be more trained practitioners in Canada and in patients' local areas.[249] More patients will be treated. Fewer patients will die.

180. If the Minister does not grant these exemptions, there will continue to be a severe shortage of trained healthcare practitioners in Canada and patients' local areas. Patients will not be able to obtain timely treatment from a team of trained healthcare practitioners. Some will receive treatment only after waiting months or years. Some will never be treated. Many will unnecessarily suffer. Some will die.[250]

C. Theoretical Availability of a Clinical Trial Makes No Difference

181. Health Canada's assertion that an "existing regulatory pathway" (conducting a clinical trial) "may be available" to the healthcare practitioners does nothing to

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[245] Masuda Affidavit, paras 27-30 & 69
[246] Masuda Affidavit, para 30.
[247] Masuda Affidavit, para 32.
[248] Masuda Affidavit, para 31 & Exhibit "B".
[249] Paranthaman Affidavit, para 38.
[250] Masuda Affidavit, paras 68-69; Sadain Affidavit, para 62.

prevent a refusal from infringing patients' and healthcare practitioners' s. 7 interests. There are three reasons for this, each of which is discussed in more detail below:

i. this regulatory pathway is theoretical and, therefore, meaningless because there are no clinical trials presently enrolling healthy healthcare practitioners;

ii. even if access was guaranteed in the future, the delay would violate s. 7; and

iii. even if a clinical trial was available to all healthcare practitioners right now, the restriction to s. 56(1) exemptions would still infringe s. 7 since the availability of alternate paths of access does not negate restrictions to another path.

i) Theoretical Path of Access is Meaningless

182. First, a regulatory pathway that is not practically and presently available is meaningless. No clinical trial is currently enrolling healthy healthcare practitioners,[251] so this pathway is purely theoretical.

183. In *Parker*, the Crown argued that the s. 7 infringement was saved because Parker had a legal path to access cannabis through the Compassionate Use Program. Despite the "theoretical availability" of this pathway, the Ontario Court of Appeal gave it no heed because the pathway ran up against a practical barrier in that there was no licensed source of cannabis.[252] Much like the Minister in this case, the Crown attempted to justify itself by saying the reason for the practical unavailability was because no one had come forward to seek a licence, and therefore it was someone else's duty to apply for a licence and actualize the theoretical pathway. However, the Court soundly rejected this argument, noting Parker's inability to become a licensed dealer.[253] Similarly, the healthcare

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[251] Sadain Affidavit, paras 48-51.
[252] *R v Parker*, 49 OR (3d) 481 at para 165, [2000] OJ No 2787.
[253] *Ibid* at para 165.

practitioners and small non-profit organization, TheraPsil, are unable to conduct a clinical trial.[254]

184. In *Hitzig*, the Ontario Court of Appeal dealt with a similar situation. It noted that the regulations allowed medical cannabis users to access cannabis through a licensed dealer, but the Court called this pathway "meaningless" because there was, at present, no licensed dealer in Canada.[255] In assessing whether the regulations infringed s. 7, the Court gave this "theoretical" pathway no weight.[256]

185. In *Allard*, the Federal Court ruled that the possibility or even probability of access is not sufficient; access must be guaranteed. The Court struck down the MMPR in its entirety because it gave "no guarantee that the necessary quality, strain and quantity will be available when needed".[257]

186. The theoretical pathway of a regulatory trial does not guarantee that all the healthcare practitioners will be able to access psilocybin when needed for experiential training. It does not guarantee access will occur in such a quality of circumstances necessary for optimal training.[258] And it does not guarantee access to psilocybin in the form necessary for optimal training.[259] Rather, limiting access to a clinical trial guarantees the opposite. Training is needed now, and there are no trials currently enrolling healthy healthcare practitioners.[260] Trials do not use psilocybin mushrooms,[261] and trials have goals that conflict with optimal training.[262]

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[254] Sadain Affidavit, paras 56 & 57.
[255] *Hitzig v Canada*, [2003] OJ No 3873 at para 61, 111 CRR (2d) 201.
[256] *Ibid* at para 88.
[257] *Allard v Canada*, 2016 FC 236 at paras 15-16, [2016] 3 FCR 303.
[258] *See* Sadain Affidavit, paras 41-47 & Exhibits "A" & "B".
[259] *See* Sadain Affidavit, para 46; Hartle Affidavit, paras 92-94.
[260] Sadain Affidavit, paras 48-51.
[261] Sadain Affidavit, para 34 & Exhibit "J".
[262] Sadain Affidavit, paras 51 & 72.

ii) Non-Timely Access Infringes Section 7

187. Second, even if all the healthcare practitioners were guaranteed access through a clinical trial in the future, the delay while waiting for that trial to commence would violate s. 7.

188. In *Parker*, the Ontario Court of Appeal found a violation of s. 7 because the administrative delay inherent in the s. 56 application process endangered applicants' health.[263] In *Morgentaler*, the Supreme Court held that administrative inefficiencies that delay medical treatment violate security of the person.[264]

189. In *Hitzig*, the Ontario Court of Appeal declined to suspend the remedy of declaring the MMAR of no force and effect because some of the people who needed medical cannabis were terminally ill and "may die in the meantime."[265] The Court said that in those circumstances failing to immediately ensure access would be "inconsistent with fundamental *Charter* values."[266]

190. In *Sfetkopoulos*, the Federal Court held that even restrictions meant to promote more access in the future violate s. 7 if they restrict access in the present. The Court struck down the limits on DPLs which the government put in place for the "laudable goal" of moving towards a future where medical cannabis would be available on prescription through pharmacies. The Court said, "It is no answer to say that someday there may be a better system. Nor does the hope for the future explain why a designated producer must be restricted to one customer."[267]

191. Even if TheraPsil had the capacity to sponsor a trial (which it does not), it would take at least a year to get to the point where all sites are initiated and ready to enroll

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[263] *Ibid* at para 189.
[264] *R v Morgentaler*, [1988] 1 SCR 30 at 33 & 92, 63 OR (2d) 281.
[265] *Hitzig v Canada*, [2003] OJ No 3873 at para 175, 111 CRR (2d) 201.
[266] *Ibid* at para 175.
[267] *Sfetkopoulos v Canada (Attorney General)*, 2008 FC 33 at para 18, [2008] FCJ No 6.

participants.[268] Any delay to healthcare practitioner training will cause patients to suffer unnecessarily, and possibly even die.[269]

ii) Other Paths of Access Do Not Negate Restriction of One Path of Access

192. Third, even if a clinical trial was available to all healthcare practitioners right now, the restriction to s. 56(1) exemptions would still infringe s. 7 since the availability of alternate paths of access does not negate the fact that s. 7 is infringed by restrictions on another path.

193. In *Hitzig*, the Ontario Court of Appeal struck down regulatory provisions that caused a more "onerous application process" for medical exemptions, because they impeded the right to make fundamentally important personal decisions under s. 7.[270] The Court did so even though there were two clinical trials underway at the time, which were a very real alternate path by which some patients could gain access.[271]

194. In *Sfetkopolous*, the Federal Court recognized that a licensed dealer "certainly does provide an alternative avenue of access."[272] However, it was "not tenable for the government […] to force [users] either to buy from the government contractor, grow their own or be limited to the unnecessarily restrictive system of designated producers."[273] Thus, even with three alternative pathways for access, the government cannot make one of the pathways unnecessarily restrictive.

195. Therefore, even if a clinical trial was open and available today to every single healthcare practitioner who needed it, the denial of a s. 56(1) exemption would still constitute an infringement of s. 7, which would need to accord with the principles of fundamental justice or be saved by s. 1 to stand.

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[268] Sadain Affidavit, para 58.
[269] Sadain Affidavit, para 62.
[270] *Hitzig v Canada*, [2003] OJ No 3873 at para 93, 111 CRR (2d) 201.
[271] *Ibid* at para 27.
[272] *Sfetkopoulos v Canada (Attorney General)*, 2008 FC 33 at para 19, [2008] FCJ No 6.
[273] *Ibid* at para 19.

3) Refusal Violates Principles of Fundamental Justice

196. Refusing the exemptions would violate the principles of fundamental justice. A refusal would be arbitrary, overbroad, and grossly disproportionate because granting the exemptions would increase access to health care and would not have a negative impact on public safety.

A. Arbitrary

197. Arbitrariness asks whether there is a direct connection between the purpose of the law and the effect on the individual. There must be a rational connection between the purpose of the measure that causes the s. 7 deprivation and the limits it imposes on life, liberty, or security of the person.[274]

198. There are two purposes to the *CDSA*: health and public safety.[275] In *PHS*, the Court held that the Minister's failure to grant Insite an exemption was arbitrary because the exemption would have furthered the twin goals, not undermined them.[276] The exemption would have had a positive effect on health and no negative impact on public safety.[277]

199. Accordingly, the Supreme Court stated as a general rule that when evidence indicates that a requested s. 56 exemption would decrease negative health conditions, and there is little or no evidence that it will have a negative impact on public safety, the Minister must grant the exemption.[278] Granting the TheraPsil trainees' exemptions would increase access to health care and have no negative impact on public safety; therefore, their refusal would be arbitrary.

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[274] *Canada (Attorney General) v Bedford*, 2013 SCC 72 at para 111, [2013] 3 SCR 1101.
[275] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at para 41, [2011] 3 SCR 134.
[276] *Ibid* at para 131.
[277] *Ibid* at para 140.
[278] *Ibid* at para 152.

200. Scientific studies demonstrate that psilocybin-assisted psychotherapy has a positive impact on health.[279] Experiential training is a necessary, core competency for practitioners to conduct psilocybin-assisted psychotherapy.[280] This training improves the quality of healthcare and increases the number of qualified practitioners, thereby having a positive impact on health. Studies also conclude that psilocybin-assisted psychotherapy creates no public safety risk.[281]

201. The scientific data is supported also by the Canadian experience from the more than 58 patients and 19 healthcare practitioners granted exemptions for psilocybin-assisted psychotherapy since 2020.[282] Patients have experienced improved health,[283] and healthcare practitioners have been equipped to offer a higher standard of care to their patients.[284]

202. Restricting access to psilocybin to clinical trials is arbitrary because the alleged health and safety benefit of clinical trials (access to GMP psilocybin) does not improve health safety in any real way. For a restriction to be non-arbitrary, it must improve safety above and beyond the level of safety that would exist without the restriction. Even if the safeguard appears on its face to add a safety benefit, it does not do so if the purported safety benefit is redundant. This was evident in *Hitzig* where the Ontario Court of Appeal held that the requirement for a second specialist's approval to access medical cannabis was arbitrary because it did not add significant value in protecting health and safety on top of the value from the first specialist.[285]

203. Non-GMP psilocybin can easily be tested by one of several drug testing services to ensure safety and determine potency. These services have instrumentation and

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[279] Bunn Affidavit, paras 6-40 & Exhibits "A"-"H".
[280] Bunn Affidavit, paras 89, 93-94 & Exhibits "Q" & "R".
[281] Bunn Affidavit, paras 66-84 & Exhibits "I", "M", "N", "O" & "P".
[282] Sadain Affidavit, Exhibit "C".
[283] *See eg* Hartle Affidavit, paras 46-58 & Exhibits "F"-K".
[284] *See eg* Masuda Affidavit, paras 7-8.
[285] *Hitzig v Canada*, [2003] OJ No 3873 at para 145, 111 CRR (2d) 201.

techniques verified and approved by Health Canada.[286] Because of this, limiting access to a clinical trial adds nothing of value in terms of ensuring the safety of the psilocybin consumed. Furthermore, there have not been any negative health or public safety issues resulting from obtaining or consuming psilocybin pursuant to s. 56(1) exemptions, despite these exemptions allowing access to non-GMP psilocybin mushrooms.[287]

204. On the other hand, limiting access to psilocybin to clinical trials negatively impacts health and safety because it hinders training. Trials have competing objectives and are typically incompatible with training best practices.[288] Additionally, the long delay while awaiting a suitable trial to begin enrolling participants would mean patients must wait longer for treatment.[289]

205. Consequently, if the Minister refuses the healthcare practitioners' exemption requests, the Minister will hinder, not further, the purposes of the *CDSA*. Therefore, the refusals will be arbitrary.

B. Overbroad

206. Overbreadth describes situations where a law is so broad in scope that it includes some conduct that bears no relation to its purpose. In this sense, the law is arbitrary in its application to a specific situation.[290]

207. The *CDSA* s. 4(1) prohibition on possession will be overbroad if exemptions are not granted to these healthcare practitioners since the application of s. 4(1) in relation to these healthcare practitioners is arbitrary.

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[286] Sadain Affidavit, paras 17-23 & Exhibits "E" & "F".
[287] Sadain Affidavit, paras 15-16.
[288] Sadain Affidavit, paras 41-47 & 72.
[289] Sadain Affidavit, para 52.
[290] *Canada (Attorney General) v Bedford*, 2013 SCC 72 at para 112, [2013] 3 SCR 1101.

C. Grossly Disproportionate

208. A Minister's exercise of discretion is grossly disproportionate when the seriousness of the deprivation is totally out of sync with the objective of the measure.[291] A grossly disproportionate effect on one person is sufficient to violate the norm.[292]

209. The harm caused by refusing the exemptions will be grossly disproportionate to any benefit that might be derived from requiring healthcare practitioners to go through a clinical trial.

i) Alleged Benefits

210. Health Canada claimed the following as purported benefits of a clinical trial:

a. It would protect the best interests of the participants;

b. It would ensure that the psilocybin consumed complies with good manufacturing practices; and

c. It would ensure that psilocybin is administered in accordance with national and international ethical, medical, and scientific standards.

211. An additional potential benefit, which Health Canada did not mention, is the possibility of obtaining valuable scientific knowledge. Health Canada was correct not to mention this because, as discussed above, there is no valuable research question that needs to be answered by subjecting healthy trainees to a clinical trial.[293]

212. The three purported benefits that Health Canada mentions are either wrong or provide no benefit above that which is available outside a clinical trial. The alleged

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[291] *Ibid* at para 120.
[292] *Ibid* at para 122.
[293] *See* paras 102 & 112-114 above.

benefits are grossly outweighed by the harm caused by refusing the exemption requests.

a. Best Interest of Participants not Protected

213. A clinical trial will not protect the best interests of participants. The purpose of a clinical trial is to evaluate an experimental therapy or intervention, not to provide therapy. Because of this, the clinical trial design may interfere with participants' objectives.[294] The best way to protect participant interests is to make optimal training the sole goal of the training, and not to add a research question as a competing objective to optimal training.

b. No Safety Risk from Non-GMP Psilocybin

214. While a clinical trial may ensure that the psilocybin consumed complies with good manufacturing practices, this has no real-world benefit. There is no evidence of any harm to patients or trainees from the previous 80+ exemptions that were granted. Moreover, expert scientific analysis has found non-GMP psilocybin mushrooms to be the safest of a list of 20 common drugs.[295]

215. Additionally, whatever risk might exist from consuming non-GMP psilocybin can be eliminated by getting the psilocybin tested. There are many services that can test psilocybin mushrooms to ensure they are safe and determine their potency.[296] These services allow clients to send samples through the mail, so they are available to anyone anywhere in Canada,[297] and their instrumentation and techniques are verified and approved by Health Canada.[298]

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[294] Sadain Affidavit, para 72 & Exhibit "T", Ch 11, s A, "Therapeutic Misconception".
[295] Bunn Affidavit, para 43 & Exhibit "I".
[296] Sadain Affidavit, para 17.
[297] Sadain Affidavit, paras 20 & 22 & Exhibits "E" & "F".
[298] Sadain Affidavit, para 23 & Exhibit "F".

c. Non-Compliance with Standards

216. Health Canada's final purported benefit is partially untrue, and to the extent it is true, it provides no additional benefit. A clinical trial would not ensure psilocybin is administered in accordance with national and international standards. As discussed above, a clinical trial would violate Canadian and American ethical standards for clinical trials because it would be a waste of resources and unjustifiably burden participants.[299]

217. To the extent that a clinical trial would ensure compliance with various standards, this provides no additional benefit. TheraPsil's training program already ensures compliance with national and international ethical, medical, and scientific standards. The training program is carefully designed to reflect best practices in psilocybin-assisted psychotherapy training.[300] Experiential training is always conducted according to TheraPsil's Clinical Protocol,[301] which aligns with these standards.[302] Any departures from the Clinical Protocol must be documented, and written reasons must be provided for the departure.[303]

ii) Immeasurable Harm

218. The enormous harm that will be caused by refusing these exemptions far outweighs any negligible benefit that refusing these exemptions might confer.

219. Many individuals for whom psilocybin-assisted psychotherapy may be a safe and effective treatment are unable to access the treatment because of a lack of trained healthcare providers. They suffer from debilitating depression, anxiety, and post-traumatic stress disorder, among other conditions.

220. These individuals suffer immensely every day. The effects from which they suffer include overwhelming negative emotion, a lack of hope and joy, an inability to

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[299] *See* paras 101-114 above.
[300] Sadain Affidavit, para 42.
[301] Sadain Affidavit, para 10.
[302] *See* Bunn Affidavit, paras 86-99 & Exhibits "Q", "R" & "S".
[303] Sadain Affidavit, Exhibit "B".

regulate emotions, self-hatred, low concentration, low motivation, and constant fatigue. Many are impaired in their daily functioning, finding it challenging to complete daily tasks like grocery shopping. Many are unable to work and are forced to rely on long-term disability for decades. Many are prevented from having children, a career, or academic success. Many have described with great sadness how their mental health conditions have stopped them from having close, nurturing relationships, or from holding onto any relationships at all. Some have panic attacks, nightmares, flashbacks, dissociation, and memory problems. Some feel like they are unable to experience a life worth living or to even be a worthwhile human being.[304] Many have had suicidal thoughts. Some have attempted suicide.[305]

221. Until there are enough trained healthcare practitioners in Canada, and until they are located throughout Canada in all the places where patients need them, individuals will continue to be prevented from accessing the health care they need.

222. Some of these individuals will, out of desperation, turn to underground practitioners who are not licensed or regulated. This can lead to serious psychological and physical injury.[306] Others will wait months or years for treatment. Each day that they suffer is a day they cannot get back. Some people will die. Some will die of natural causes before they are able to be treated and have a final good day. Others will die of their mental illness. They may succumb to a suicidal thought that might not have been there or might not have been so strong if they had been treated.

223. No bureaucratic preferences can justify such immeasurable suffering and needless loss of life. A refusal would cause grossly disproportionate harm, would frustrate the *CDSA*'s purposes, and would violate s. 7 of the *Charter*.

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[304] Waitlisted Patient Affidavits.
[305] Alves Affidavit, para 3; McLaren Affidavit, para 2; Pietryszyn Affidavit, para 5; Marykuca Affidavit, para 9; Westlake Affidavit, para 3; Moore Affidavit, para 3.
[306] Masuda Affidavit, para 65.

4) Not Saved by Section 1

224. The s. 7 violation cannot be saved by s. 1. The objectives of the *CDSA* under s.1 are the same as under s. 7: protecting health and safety. Since the infringement is not rationally connected to the statutory objectives under s. 7, it cannot be rationally connected under s. 1.[307]

225. The infringement is also not minimally impairing. The *CDSA*'s goals can be met without imposing this restriction by simply granting the exemptions. If desired, the Minister can require healthcare practitioners to get their psilocybin tested before consuming it.

226. Finally, the infringement is grossly disproportionate. As discussed above, the enormous harm to patients vastly outweighs the non-existent benefits of restricting access to a clinical trial.

PART V – RELIEF SOUGHT

227. Based on the foregoing, the Applicants respectfully request that each of the healthcare practitioners' s. 56(1) exemption requests be granted.

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[307] *R v Smith*, 2015 SCC 34 at para 29, [2015] 2 SCR 602.

ALL OF WHICH IS RESPECTFULLY SUBMITTED THIS 15 November 2022

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PART VI – LIST OF AUTHORITIES

Legislation

1 *Canadian Charter of Rights and Freedoms*, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11

2 *Controlled Drugs and Substances Act*, SC 1996, c 19

3 *Food and Drug Regulations*, CRC, c 870

4 *Marihuana for Medical Purposes Regulations*, SOR/2013-119

5 *Marihuana Medical Access Regulations*, SOR/2001-227

Jurisprudence

6 *Allard v Canada*, 2014 FC 280, [2014] FCJ No 412

7 *Allard v Canada*, 2016 FC 236, [2016] 3 FCR 303

8 *Canada (Attorney General) v Bedford*, 2013 SCC 72, [2013] 3 SCR 1101

9 *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44, [2011] 3 SCR 134

10 *Canada (Attorney General) v Sfetkopoulos*, 2008 FCA 328, [2008] FCJ No 1472

11 *Canada v Allard*, 2014 FCA 298, [2014] FCJ No 1241

12 *Carter v Canada (Attorney General)*, 2015 SCC 5, [2015] 1 SCR 331

13 *Hitzig v Canada*, [2003] OJ No 3873, 111 CRR (2d) 201

14 *R v Krieger*, 2000 ABQB 1012, 307 AR 349

15 *R v Krieger*, 2003 ABCA 85, 18 Alta LR (4th) 227

16 *R v Morgentaler*, [1988] 1 SCR 30, 63 OR (2d) 281

17 *R v Parker*, 49 OR (3d) 481, [2000] OJ No 2787

18 *R v Smith*, 2015 SCC 34, [2015] 2 SCR 602

19 *Rodriguez v British Columbia (Attorney General)*, [1993] 3 SCR 519, [1993] ACS no 94

20 *Sfetkopoulos v Canada (Attorney General)*, 2008 FC 33, [2008] FCJ No 6