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 January 31, February 18 and February 21, 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 a TheraPsil's experiential training program in psilocybin-assisted psychotherapy.

2. The requests should not be refused based on the theoretical possibility of access through a clinical trial. The ATMA trial is not accessible to TheraPsil trainees nor is it compatible with TheraPsil's training program. No other trials exist. 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.

3. 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.

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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*].

4. 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 scientific literature shows that healthcare practitioners need experiential training with the medicine to provide the most safe and effective treatment.

5. The Minister's decision also engages patients' s. 7 rights to life and security of person because 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.

6. If the Minister refuses the exemption requests, the decision will be arbitrary, overbroad, and grossly disproportionate. A refusal will hinder, not further, the *CDSA*'s twin goals of health and public safety, and whatever negligible benefit might come from refusing the exemptions will be vastly outweighed by the immeasurable suffering and unnecessary loss of life that will result from a refusal. A refusal will therefore violate s. 7 of the *Charter*.

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

PART II – STATEMENT OF FACT

1) Psilocybin-Assisted Psychotherapy

8. 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 patient and therapist develop trust and rapport and discuss topics

[3] Affidavit of Natasha Fearnley, Feb 21, 2022 ("**Fearnley Affidavit**"), para 4.

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]

9. 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]

A. Is Effective Medical Treatment

10. 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]

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

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[4] Fearnley Affidavit, paras 11-13. Terminal patients may die before completing all integration sessions.
[5] Affidavit of Julia Joyes, Feb 11, 2022 ("**Joyes Affidavit**"), para 6.
[6] Joyes Affidavit, paras 30-40.
[7] Joyes Affidavit, para 8 & Exhibit "A".
[8] Joyes Affidavit, para 13 & Exhibit "B".

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

12. 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 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]

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[9] Joyes Affidavit, para 19 & Exhibit “C”.
[10] Joyes Affidavit, para 23 & Exhibit “D”.
[11] Joyes Affidavit, para 27 & Exhibit “E”.
[12] Joyes Affidavit, para 31 & Exhibit “F”.
[13] Joyes Affidavit, para 36 & Exhibit “G”.

B. Is Safe

13. 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]

    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]

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[14] Joyes Affidavit, para 19 & Exhibit “C”.
[15] Joyes Affidavit, para 43 & Exhibit “I”.
[16] Equivalent to 1 g or more and 2.5 g or more of dried psilocybin mushrooms respectively. *See* Joyes Affidavit, Exhibit “O”, para 3.
[17] Joyes Affidavit, para 47 & Exhibit “J”.
[18] Equivalent to 5.1 g or more of dried psilocybin mushrooms. *See* Joyes Affidavit, Exhibit “O”, para 3.
[19] Joyes Affidavit, para 53 & Exhibit “K”.
[20] Joyes Affidavit, para 58 & 61, Exhibit “L”.
[21] Joyes Affidavit, para 63 & Exhibit “M”.

C. No Public Safety Risk

14. 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, US, UK, and 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]

    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]

15. 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,[27] and 19 exemptions for healthcare practitioners, allowing them to possess and consume psilocybin for experiential training.[28] There is no evidence of any negative health or public safety impacts resulting from these exemptions. To the contrary, patients have reported

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[22] Joyes Affidavit, para 68 & Exhibit "N".
[23] Joyes Affidavit, para 72 & Exhibit "O".
[24] Joyes Affidavit, para 76 & Exhibit "P".
[25] Joyes Affidavit, para 79 & Exhibit "M".
[26] Joyes Affidavit, para 82 & Exhibit "I".
[27] Affidavit of Yasmeen Sadain, Feb 27, 2022 ("**Sadain Affidavit 3**"), para 2.
[28] Sadain Affidavit, para 12 & Exhibit "C".

that the therapy substantially improved their health,[29] and healthcare practitioners have reported that the experiential training enabled them to provide better care to patients.[30]

2) Canada Needs More Experientially Trained Practitioners

A. There is a Large Medical Need

16. 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]

17. 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] These patients requesting assistance have identified as being in every province and territory in Canada except for Nunavut.[34]

18. The 13 affidavits of waitlisted patients included in these submissions[35] demonstrate that many patients whom TheraPsil has had to turn away are suffering 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.

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[29] Affidavit of Thomas Hartle, Feb 25, 2022 ("**Hartle Affidavit**"), paras 28-31 & Exhibits "F"-"K".
[30] Affidavit of Valorie Masuda, Feb 20, 2022 ("**Masuda Affidavit**"), para 7.
[31] Fearnley Affidavit, para 19.
[32] TheraPsil is a non-profit patient advocacy organization dedicated to helping Canadians in medical need access legal psilocybin-assisted psychotherapy.
[33] Fearnley Affidavit, paras 20-21 & Exhibit "B".
[34] Fearnley Affidavit, para 26 & Exhibit "B".
[35] 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 Ryley William McCafferty, Feb 26, 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 Alisen Michaud, Feb 26, 2022; Affidavit of Shannon Elizabeth McKenney, Feb 24, 2022; Affidavit of Solange Martin, Feb 24, 2022 (collectively "**Waitlisted Patient Affidavits**").

19. 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 fatigue. Many are impaired in their daily functioning, finding it challenging to complete daily tasks like grocery shopping. Many are unable to work, 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.[36]

20. Many have had suicidal thoughts. Some have attempted suicide.[37]

21. 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.[38]

22. They have tried dozens of different types of medications and combinations of medications, including selective serotonin reuptake inhibitors, vitamins, birth control, CBD/THC, herbals, and homeopathic medicine.[39] Some of these medications caused negative side effects including anaphylaxis.[40]

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[36] Waitlisted Patient Affidavits.
[37] Alves Affidavit, para 3; McLaren Affidavit, para 2; Pietryszyn Affidavit, para 5; Marykuca Affidavit, para 9; Westlake Affidavit, para 3; Moore Affidavit, para 3.
[38] Waitlisted Patient Affidavits.
[39] Waitlisted Patient Affidavits.
[40] McCafferty Affidavit, para 9.

23. 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]

24. They 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.[43]

B. It is Time-Intensive

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

26. 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.[44]

27. 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.[45]

28. 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

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[41] Marykuca Affidavit, para 8; Westlake Affidavit, para 4.
[42] Slade Affidavit, para 4.
[43] Waitlisted Patient Affidavits.
[44] Fearnley Affidavit, para 8.
[45] Fearnley Affidavit, para 9; *Food and Drug Regulations*, CRC, c 870, s C.08.010(1).

of the requested drug.[46] The physician must also commit to mandatory reporting requirements, including by completing a follow-up form after each administration of the drug. Dr. Valorie Masuda estimates that each of these forms would take around 2-3 hours to complete.[47]

29. 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.[48]

30. 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.[49] 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.[50]

31. 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.[51]

32. The medicinal session lasts approximately eight hours[52] and takes place in a warm, quiet, private, and aesthetic living-room-like environment.[53] It often takes place in the patient's home.[54]

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[46] Masuda Affidavit, para 26 & Exhibit "C".
[47] Masuda Affidavit, para 30.
[48] Masuda Affidavit, para 31.
[49] Fearnley Affidavit, para 10; Joyes Affidavit, paras 88-89 & 98 & Exhibits "Q" & "S".
[50] Masuda Affidavit, paras 10-11.
[51] Fearnley Affidavit, para 11; Masuda Affidavit, para 14; Joyes Affidavit, para 97; Hartle Affidavit, para 22.
[52] Masuda Affidavit, para 14.
[53] Fearnley Affidavit, para 12.
[54] Masuda Affidavit, para 14.

33. 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.[55]

34. Patients needing more than one treatment must gain approval through a medical consult to repeat the treatment protocol.[56]

C. Practitioners Need Experiential Training

35. Therapists administering psilocybin-assisted psychotherapy need experiential training, in which they undergo the therapy as a patient, to deliver the most safe and effective treatment to their patients. This best practice is demonstrated by scientific literature[57] and personal experience of practitioners,[58] and it is the approach recommended by experts.[59]

36. 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.[60]

37. Scholarship in psychedelic therapy frequently reiterates that psychedelic therapists must have first-hand experience in psychedelic therapy. Therapists who have had psychedelic reactions are able to understand similar reactions in their patients. The Czech model in the 1950s, for example, required five experiential sessions for a therapists' training.[61] As such, a literature review identifies personal experience

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[55] Fearnley Affidavit, para 13; Masuda Affidavit, para 14, Hartle Affidavit, para 27.
[56] Fearnley Affidavit, para 15.
[57] Joyes Affidavit, paras 93-94 & Exhibit "R", p 475.
[58] Masuda Affidavit, paras 6-7.
[59] Joyes Affidavit, para 89 & Exhibit "Q", p 13, bullet 2.
[60] Masuda Affidavit, paras 6-7.
[61] Joyes Affidavit, para 93.

within psychedelics as one of twelve domains of necessary training for psychedelic therapists.[62]

38. In 2021, a Canadian multidisciplinary committee of experts listed personal experience as a core competency for credentialing psychedelic therapists. 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 sense of reality. The committee warns that it may be difficult to guide patients skillfully without direct personal experience with the substance. This committee was composed of experts in psychiatry, clinical psychology, palliative care, anthology, ethics, religious studies, and legal studies.[63]

D. There are Not Enough Trained Practitioners

39. 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.

40. 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 participate in the program.[64]

41. Because of this, there are very few qualified practitioners. There are only three practitioners on TheraPsil's roster of healthcare practitioners that are authorized to act as primary therapists and have undergone experiential training. All three are in

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[62] Joyes Affidavit, para 94 & Exhibit "R", p 475.
[63] Joyes Affidavit, para 89 & Exhibit "Q", p 13, bullet 2.
[64] Sadain Affidavit 3, para 7; Sadain Affidavit, para 12 & Exhibit "C".

southwest British Columbia (North Saanich, Abbotsford, and Duncan). One is a therapist, one is a Registered Clinical Counsellor, and one is a medical doctor.[65]

42. These three practitioners have limited time and resources to treat patients and cannot necessarily treat patients outside of their local area.[66] 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.[67]

43. TheraPsil has been forced to make the difficult decision to allow ten practitioners who have not received an exemption, and therefore not completed experiential treatment, to treat patients without supervision from a training program instructor. These decisions were made after going through an extensive assessment and screening process. Although TheraPsil is confident that this process ensures the safety and efficacy of 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.[68] Seven of these ten practitioners have received notices of intent to refuse their s. 56(1) exemption requests.[69]

44. None of the above-mentioned 13 practitioners are located outside of British Columbia, Ontario, and Quebec.

45. 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.[70] 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

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[65] Sadain Affidavit 3, para 11 & Exhibit “A”.
[66] Masuda Affidavit, para 15.
[67] Fearnley Affidavit, para 16.
[68] Sadain Affidavit 3, para 12.
[69] Sadain Affidavit 3, para 13.
[70] Masuda Affidavit, para 37.

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.[71] 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.[72]

46. The lack of qualified therapists in patients' local areas makes the treatment cost prohibitive for many. Many people who need psilocybin-assisted psychotherapy are unable to work because of their medical condition[73] and cannot afford the cost of flights and accommodations.

47. 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.

48. 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

49. TheraPsil provides a training program in psilocybin-assisted psychotherapy to develop a pool of trained healthcare practitioners whom they can confidently include

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[71] Hartle Affidavit, para 23.
[72] Joyes Affidavit, para 90 & Exhibit "Q", p 14.
[73] *See* Alves Affidavit, para 3; Marykuca Affidavit, para 3; Westlake Affidavit, para 3; McKenney Affidavit, para 11.

on their roster of practitioners able to support treatment. This list is made available to prospective patients seeking assessment and treatment.[74]

50. More than 150 healthcare practitioners have taken TheraPsil's training. Sixty more practitioners are scheduled for training in the next three months, and more than 1,150 healthcare practitioners are on TheraPsil's waitlist to take the training.[75]

51. The training program is comprised of 12 Units.[76] Unit 11 is a 60-hour experiential training module, in which trainees experience the role of both a guide and a patient.[77] 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,[78] which reflects best practices in psilocybin-assisted psychotherapy.[79]

52. 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.[80]

B. Exemption Requests

53. 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.[81]

54. In December 2020 and January 2021, the Minister of Health granted exemptions to 19 healthcare practitioners affiliated with TheraPsil.[82]

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[74] Affidavit of Yasmeen Sadain, Feb 23, 2022 ("**Sadain Affidavit**"), para 4.
[75] Sadain Affidavit, para 6.
[76] Sadain Affidavit, para 8.
[77] Sadain Affidavit, para 9.
[78] Attached at Sadain Affidavit, Exhibit "B".
[79] Sadain Affidavit, para 10.
[80] Sadain Affidavit, para 13.
[81] Sadain Affidavit, para 11.
[82] Sadain Affidavit, para 12 & Exhibit "C".

55. Throughout 2021, TheraPsil assisted many healthcare practitioners in its training program with submitting requests for s. 56(1) exemptions to complete experiential training.[83]

56. Many of these healthcare practitioners reside in areas of Canada that currently have no qualified healthcare practitioners to help the many patients seeking assistance.[84] For example, in Manitoba, there are currently no fully trained and qualified healthcare practitioners, but there are 10 patients on TheraPsil's waitlist.[85] One of these patients is Thaddeus Conrad. He suffers from post-traumatic stress disorder. His affidavit is included in these submissions.[86] Two Manitoba healthcare practitioners have requested exemptions. One, Brodin Anderson, is a counsellor, who could serve as a primary therapist. The other, Bryce Koch, is a Registered Nurse and a Nurse Practitioner candidate, who could serve as secondary therapist. Once qualified as a Nurse Practitioner, Mr. Koch could make requests through the SAP.[87] 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.

57. As another example, there are currently no fully trained and qualified healthcare practitioners in any of the Atlantic provinces, but there are 22 patients on TheraPsil's waitlist from these provinces.[88] There are 10 healthcare practitioners party to these submissions who are in the Atlantic provinces and, if granted an exemption, could help meet this need.[89]

58. 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

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[83] Sadain Affidavit, para 14.
[84] Fearnley Affidavit, para 40.
[85] Fearnley Affidavit, Exhibit "B".
[86] Conrad Affidavit.
[87] List of Healthcare Practitioners Represented, rows 44 & 45.
[88] Fearnley Affidavit, Exhibit "B"; Letter from Dr. Susie McAfee et al, Letters, Tab "M", p 2, para 1.
[89] List of Healthcare Practitioners Represented, rows 70-79.

allow more patients who need psilocybin-assisted psychotherapy to undergo this treatment and address their serious health problems.[90]

C. Notices of Intent to Refuse

59. On January 31, 2022, and on various dates in February 2022, Health Canada sent identical notices of intent to refuse the exemption requests of each of the healthcare practitioners party to these submissions.[91]

60. Health Canada said that it intended to refuse the exemption requests on the sole basis that there is an existing regulatory pathway for the healthcare providers to achieve their purpose: a clinical trial. Specifically, Health Canada said that in January 2022, it had issued a No Objection Letter to the private, for-profit corporation ATMA Journey Centers Inc. ("**ATMA**") for a trial that examines the safety of psilocybin in healthy participants who are part of a training program.[92]

61. 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.[93] A clinical trial would do neither.

4) Clinical Trials Are Not Available

62. No presently approved trial, including the ATMA trial, is accessible to TheraPsil trainees nor compatible with TheraPsil's training program. TheraPsil cannot sponsor its own trial, and it would be unethical for TheraPsil to sponsor a similar trial or require its trainees to participate in such a trial.

A. ATMA Trial is Not Accessible

63. None of the healthcare practitioners party to these submissions can access the ATMA trial. There are only 20 spots, and they are all reserved for ATMA trainees.[94]

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[90] Fearnley Affidavit, para 41.
[91] Sadain Affidavit, para 15.
[92] Sadain Affidavit, para 16; Exhibit "D", paras 4-5; & Exhibit "F", p 2.
[93] Sadain Affidavit, Exhibit "D".
[94] Affidavit of Yasmeen Sadain, Feb 25, 2022 ("**Sadain Affidavit 2**"), paras 3-4.

Even if TheraPsil trainees were eligible, the ATMA trial will not start for many months, prolonging patient suffering. Further, the trial is unlikely to provide sufficient access to the number and geographic spread of healthcare practitioners who were given notices.

64. There is very little information publicly available about the ATMA trial. It is not listed on a public registry, as is encouraged by Health Canada.[95] ATMA's CEO has not responded to TheraPsil's request for information,[96] and the Office of Clinical Trials has refused to disclose any information about eligibility requirements for the trial.[97]

65. ATMA has told its trainees that the trial will initially only have 20 participants, all selected from ATMA's training program alumni. Eventually, at some unknown point in the future, ATMA hopes the trial will be expanded so that all its alumni will be eligible. There is no stated intention to allow trainees from other training programs, such as TheraPsil's, to participate. It would be extraordinarily unlikely for ATMA to allow TheraPsil trainees in its trial since ATMA is a private, for-profit corporation with 230 alumni of its own training program.[98]

66. Even if the ATMA trial were to open to TheraPsil trainees, there will certainly not be enough spots in this trial for all 150 healthcare practitioners who have taken TheraPsil's training program, the 60 set to take training in the next three months, and the 1,150 who are on the waitlist.[99]

67. ATMA is based out of Calgary, Alberta, and there is no indication that ATMA will be hosting trial sites throughout the country, precluding access to the many healthcare practitioners who live far away.[100]

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[95] Sadain Affidavit, paras 30, 34 & 35 & Exhibit "H".
[96] Sadain Affidavit, para 32.
[97] Sadain Affidavit, para 30 & Exhibit "H".
[98] Sadain Affidavit 2, para 3.
[99] Sadain Affidavit, para 37.
[100] Sadain Affidavit, paras 25 & 38.

68. Furthermore, the trial will not begin until mid-2022, and healthcare providers will need to meet certain inclusion criteria and pass a careful screening.[101] The delayed start date will cause many patients to suffer unnecessarily,[102] and the strict inclusion criteria will likely cause some trainees not to be eligible.[103]

B. ATMA Trial is Not Compatible with TheraPsil Training

69. 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 ATMA trial is still not compatible with TheraPsil's training program.

70. 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 quality of the training, potentially decreasing the safety and efficacy of psilocybin-assisted psychotherapy for the patients who desperately need it.[104]

71. For example, in TheraPsil's training program, the trainees work in dyads (preferably of two different genders) and alternate between roles of patient and therapist. It is extraordinarily unlikely that this model would be permitted in a clinical trial with the goal of examining the safety of psilocybin in healthy participants since having participants who also act as the therapist would introduce additional variables, making the experiment less tightly controlled.[105]

72. 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, to guide them, and to determine whether the trainee is ready to support patients. Building this

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[101] Sadain Affidavit, para 26 & Exhibit "G".
[102] Sadain Affidavit, para 38.
[103] Sadain Affidavit, para 39.
[104] Sadain Affidavit, para 41.
[105] Sadain Affidavit, para 42.

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.[106]

73. 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.[107]

74. ATMA's trial will be using synthetic psilocybin, not psilocybin mushrooms.[108] This difference alone makes ATMA's trial unsuitable as a mechanism for practitioner training since the experience resulting from synthetic psilocybin is significantly different from that when a person consumes psilocybin mushrooms. For example, psilocybin mushrooms are known to cause an upset stomach. This is much less frequent with synthetic psilocybin. 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 form in which psilocybin is consumed can result in a different therapy experience.[109]

C. TheraPsil Cannot Sponsor a Clinical Trial

75. Since the ATMA trial is the only psilocybin trial that Health Canada has authorized for healthcare professionals,[110] the Office of Clinical Trials suggested that TheraPsil may wish to consider sponsoring its own trial.[111] This is not realistically possible.

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[106] Sadain Affidavit, para 43.
[107] Sadain Affidavit, para 44.
[108] Sadain Affidavit, para 31 & Exhibit "G".
[109] Sadain Affidavit, para 45.
[110] Sadain Affidavit, para 31 & Exhibit "H".
[111] Sadain Affidavit, Exhibit "H".

76. TheraPsil is a patient advocacy and support organization dedicated to helping Canadians in medical need access psilocybin-assisted psychotherapy. TheraPsil is not a large scientific organization capable of conducting a clinical trial.[112]

77. 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 have to be followed and steps that have to be taken to sponsor a trial.[113] TheraPsil does not have this capacity.[114]

78. 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.[115]

79. 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 take time to analyse the submission and render a decision. Then researchers and participants would need to be recruited and suitable venues obtained.[116]

80. 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.[117]

81. 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.[118]

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[112] Sadain Affidavit, para 52.
[113] Sadain Affidavit, Exhibit “M”.
[114] Sadain Affidavit, para 52.
[115] Sadain Affidavit, para 53.
[116] Sadain Affidavit, para 54.
[117] Sadain Affidavit, para 55.
[118] Sadain Affidavit, para 56.

D. Clinical Trial is Unethical

82. Even if the 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.

83. 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.[119] The effects of psilocybin in healthy human subjects (including therapist trainees) are known,[120] so the principle of clinical equipoise is not met, and there is no valid research question. [121]

84. 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.[122]

85. 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**").

86. The first NIH Principle instructs 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

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[119] Sadain Affidavit, para 58 & Exhibit "N".
[120] Joyes Affidavit, paras 46-61 & Exhibits "J", "K" & "L".
[121] Sadain Affidavit, para 58 & Exhibit "N".
[122] Sadain Affidavit, para 59.

states categorically, “Only if society will gain useful knowledge […] can exposing human subjects to the risk and burden of research be justified.”[123]

87. 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 states categorically, “Invalid research is unethical because it is a waste of resources and exposes people to risk for no purpose.”[124]

88. The Canadian standard, TCPS2, instructs that “[c]linical trials should not be conducted unnecessarily on questions that have already been definitively answered”.[125] There must be a genuine uncertainty on the part of the relevant expert community about the research question at issue.[126]

89. 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”.[127] They can likewise interfere with training objectives.

90. TCPS2 prohibits conducting trials for any reason other than a bona fide scientific purpose. It specifically warns against trials that are conducted for commercial reasons.[128] The ATMA trial is being conducted by a for-profit corporation to facilitate paid participation in its training program.[129]

91. TCPS2 also warns against unnecessary duplication of studies. It states that unnecessary duplication should be avoided to “reduce the burden on participants.”[130] ATMA’s trial is not meaningfully different from many other trials in

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[123] Sadain Affidavit Exhibit “O”.
[124] Sadain Affidavit Exhibit “O”.
[125] Sadain Affidavit, para 64 & Exhibit “P”, Ch 11, s A, “Systemic Review”.
[126] Sadain Affidavit, para 65 & Exhibit “P”, Ch 11, s A, “Clinical Equipoise”.
[127] Sadain Affidavit, para 66 & Exhibit “P”, Ch 11, s A, “Therapeutic Misconception”.
[128] Sadain Affidavit, para 67 & Exhibit “P”, Ch 11, s B, “Pharmaceutical Trials, “Phase IV”.
[129] Sadain Affidavit, para 25; Sadain Affidavit 2, para 2.
[130] Sadain Affidavit, para 69 & Exhibit “P”, Ch 11, s D.

healthy participants.[131] If TheraPsil or any other organization were to sponsor a similar trial, it would undoubtedly be unnecessarily duplicative, contrary to TCPS2.

92. 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. As such, it would not be ethical for TheraPsil to require its trainees to participate in a study into the safety of psilocybin for healthy healthcare practitioners in a training program, nor would it be ethical for TheraPsil to sponsor such a study itself.

PART III – POINTS IN ISSUE

93. The Applicants submit that the following issues are to be determined:

ISSUE 1: Should the exemptions be refused because of the theoretical possibility of access to psilocybin through a clinical trial?

ISSUE 2: Does s. 7 of the *Charter* require that the exemptions be granted?

PART IV – SUBMISSIONS

94. The Applicants submit that the exemptions should not be refused because of the theoretical possibility of access through a clinical trial, and s. 7 of the *Charter* requires that the exemptions be granted.

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[131] For example, those at Joyes Affidavit, paras 46-61 & Exhibits “J”, “K” & “L”.

Issue 1: Clinical Trial is Not Reason to Refuse

95. The exemptions should not be refused because of the theoretical possibility of access to psilocybin through a clinical trial.

A. Health Canada's Reason

96. Health Canada stated that it intended to refuse the exemption requests on the sole basis that there is an existing regulatory pathway for the healthcare providers to achieve their purpose: a clinical trial.[132] Health Canada claimed clinical trials would be suitable for completing TheraPsil's training and would protect the best interests of the healthcare practitioners.[133]

97. Health Canada specifically noted two possibilities, neither of which are suitable nor protect the best interests of healthcare practitioners:

    a. Participation in the ATMA trial;[134] and

    b. TheraPsil sponsoring its own trial.[135]

B. Clinical Trials in General

98. No clinical trial will be suitable for achieving the healthcare practitioners' training objectives nor would a clinical trial protect the best interest of the healthcare practitioners because such a clinical trial would be unethical, would interfere with training objectives, and would not be available in a timely manner.

99. A clinical trial would be unethical. There is no genuine uncertainty in the expert community about the safety of psilocybin for healthy adults in a training program.[136] Best practices for experiential training are also already well documented.[137] It is unethical to conduct a clinical trial on questions that have already been answered

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[132] Sadain Affidavit, Exhibit "D", para 4.
[133] Sadain Affidavit, Exhibit "D", para 5.
[134] Sadain Affidavit, para 16; Exhibit "D", paras 4-5; & Exhibit "F", p 2.
[135] Sadain Affidavit, para 50; Exhibit "H", para 3.
[136] Joyes Affidavit, paras 46-61 & Exhibits "J", "K" & "L".
[137] Joyes Affidavit, paras 86-99 & Exhibits "Q", "R" & "S".

because this imposes unnecessary burden on participants.[138] It is unethical to conduct a trial when there is no genuine uncertainty in the expert community about the research question at issue (clinical equipoise).[139]

100. A clinical trial would interfere with training objectives. Clinical trials are focused on evaluating an experimental therapy or intervention, not on providing a benefit to participants. Because of this competing purpose, there are many ways in which elements of clinical trial design could interfere with the participants' own training objectives.[140]

101. A clinical trial would not be available in a timely manner. There is currently only one trial approved, ATMA's, and it will not start until mid-2022.[141] Any other trials will take even longer, unquestionably more than a year.[142] Patients need help now. They suffer from extreme distress, some from suicidal ideation.[143] A delay of even a few months could mean that lives are lost. It will certainly mean that many people suffer.[144]

C. ATMA Trial

102. The ATMA trial is not accessible to TheraPsil trainees nor suitable for their training purposes.

103. The ATMA trial is not accessible. It is available only to 20 participants in ATMA's training program.[145] It is also not set to start until mid-2022.[146]

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[138] Sadain Affidavit, paras 61, 62, 64 & 69; Exhibit "P", Ch 11, s A, "Systemic Review"; Exhibit "P", Ch 11, s D; Exhibit "O".
[139] Sadain Affidavit, para 65 & Exhibit "P", Ch 11, s A, "Clinical Equipoise".
[140] Sadain Affidavit, para 66 & Exhibit "P", Ch 11, s A, "Therapeutic Misconception".
[141] Sadain Affidavit, para 26 & Exhibit "G".
[142] Sadain Affidavit, para 53; *see* paras 51 & 54.
[143] *See* Alves Affidavit, para 3; McLaren Affidavit, para 2; Pietryszyn Affidavit, para 5; Marykuca Affidavit, para 9; Westlake Affidavit, para 3; Moore Affidavit, para 3.
[144] Sadain Affidavit, para 56.
[145] Sadain Affidavit 2, paras 3-4.
[146] Sadain Affidavit, para 26 & Exhibit "G".

104. The ATMA trial is not suitable for TheraPsil's training program. TheraPsil's training program is carefully designed to reflect best practices. Deviation from these best practices risks reducing the quality of training, thereby decreasing the safety and efficacy of treatment for patients.[147] TheraPsil's training program uses psilocybin mushrooms,[148] but the ATMA trial uses synthetic psilocybin.[149] In TheraPsil's training program, the trainees work in dyads and alternate roles of patient and therapist, this is unlikely to be the case in ATMA's trial.[150] TheraPsil's trainees are supervised and assessed by one of TheraPsil's head trainers during their experiential session. This is necessary to determine whether the trainee is ready to support patients and to build trust prior to engaging in Unit 12, in which the trainer supervises the trainee for a minimum of ten hours while the trainee supports patients.[151] It is unlikely ATMA's trial would allow for this level of close supervision and contact by TheraPsil's head trainers – if ATMA even did allow TheraPsil trainees to participate.

D. TheraPsil Sponsored Trial

105. A trial sponsored by TheraPsil would not meet practitioners' training objectives nor is it in the best interest of practitioners because TheraPsil does not have the resources and capacity to sponsor a trial. Even if TheraPsil had the resources, the process would take too long, the trial would be unethical, and the trial would interfere with training objectives.

106. TheraPsil does not have the resources or capacity to sponsor a trial. TheraPsil is a patient advocacy and support organization, not a large scientific organization capable of meeting the strict regulatory and ethical requirements to conduct a clinical trial.[152] The Notice to Stakeholders clarifying the requirements for clinical

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[147] Sadain Affidavit, para 41.
[148] Sadain Affidavit, para 44.
[149] Sadain Affidavit, para 31 & Exhibit "G".
[150] Sadain Affidavit, para 42.
[151] Sadain Affidavit, para 43.
[152] Sadain Affidavit, para 52.

research with psilocybin sets out numerous regulatory requirements and steps that must be taken.[153] TheraPsil does not have the necessary resources or capacity to meet these requirements.[154]

107. Even if TheraPsil had the capacity to sponsor a trial, the process would take too long. It is estimated that it would take at least a year to get to the point where all sites are initiated and ready to enroll participants.[155] This is not suitable for the healthcare practitioners' training objectives, nor in their best interest, since they need training now, not in one or two years from now. Any delay to healthcare practitioner training will cause patients to suffer unnecessarily, and possibly even die.[156]

108. As discussed above, a clinical trial would be unethical because it would be a waste of resources[157] and would subject participants to unnecessary burden.[158]

109. Finally, as discussed above, a clinical trial would interfere with training objectives because clinical trials are focused on evaluating an experimental therapy or intervention, and not primarily directed at providing a benefit to the participants.[159]

E. Conclusion

110. The Applicants submit that the exemptions should not be denied because of the theoretical possibility of access to psilocybin through a clinical trial since no trial will be suitable for the healthcare practitioners' training purposes, nor will a trial protect healthcare practitioners' best interests.

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[153] Sadain Affidavit, Exhibit "M".
[154] Sadain Affidavit, para 52.
[155] Sadain Affidavit, para 53.
[156] Sadain Affidavit, para 56.
[157] Sadain Affidavit, paras 59 & 62; Exhibits "N" & "O".
[158] Sadain Affidavit, paras 61, 62, 64 & 69; Exhibit "P", Ch 11, s A, "Systemic Review"; Exhibit "P", Ch 11, s D; Exhibit "O".
[159] Sadain Affidavit, para 66 & Exhibit "P", Ch 11, s A, "Therapeutic Misconception".

Issue 2: *Charter* s. 7 Compels Exemptions

111. Section 7 of the *Charter* requires the Minister grant the exemption requests because a refusal would infringe on patients' rights to life and security of person and 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.

A. Duty to Grant Exemptions Furthering *CDSA*'s Purposes: *Canada v PHS*

112. 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.[160]

113. 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.[161] It also engaged the clients' life and security of 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.[162]

114. The Supreme Court held that s. 4 was not arbitrary, overbroad, and grossly disproportionate solely because s. 56 acted as a "safety valve", excluding from s. 4's blanket prohibition the cases that did not further the *CDSA*'s twin goals: health and public safety.[163]

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[160] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at para 152, [2011] 3 SCR 134 [*PHS*].
[161] *Ibid* at para 90.
[162] *Ibid* at para 91.
[163] *Ibid* at paras 113-114.

115. Consequently, the Court stated that, “If 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.”[164] The Minister’s discretion, therefore, is not absolute. It must conform with the *Charter*.[165]

116. 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 arbitrary and grossly disproportionate.[166] 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 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.[167]

117. 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.[168]

B. Duty to Ensure Practical and Timely Access: *R v Parker*

118. The Ontario Court of Appeal, in *R v Parker*, held that the government cannot refuse access to medical treatment on the basis that another way of obtaining the medical treatment is available unless that other way is accessible in a practical and timely manner.

119. In *R v Parker*, the accused required marijuana to control his epilepsy. He was charged with possession under s. 4 of the CDSA. The Court struck down the

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[164] *Ibid* at para 114.
[165] *Ibid* at para 117.
[166] *Ibid* at para 150.
[167] *Ibid* at para 136.
[168] *Ibid* at para 152, *see also* para 140.

marijuana prohibition in s. 4 because it violated Parker's s. 7 rights to liberty and security of person.[169]

120. 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",[170] and the delays involved in s. 56 applications endangered applicants' health.[171] The Court specifically noted that 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.[172]

C. Section 7 is Engaged

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

i) Healthcare Practitioners

122. 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 most safe and effective care to patients. Healthcare practitioners risk imprisonment if they attempt to obtain crucial experiential training without an exemption.

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[169] *R v Parker*, 49 OR (3d) 481 at para 210, [2000] OJ No 2787 [*Parker*].
[170] *Ibid* at paras 163 & 174.
[171] *Ibid* at para 189.
[172] *Ibid* at para 165.

ii) Patients

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

124. Decisions that prevent access to health care deprive patients of their security of person. Where the decision creates a risk not just to health but also to life, the deprivation is even clearer.[173]

125. Patients are suffering from chronic major depressive disorder, post-traumatic stress disorder, end-of-life distress, and extreme anxiety, among other conditions. These conditions affect every aspect of their lives and cause them to suffer immeasurably.[174] Some contemplate or attempt suicide.[175]

126. Psilocybin-assisted psychotherapy is a safe and effective treatment for these conditions.[176] 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.[177] This lack of trained practitioners prevents access to health care.

127. If the Minister grants exemptions to these healthcare practitioners, there will be more trained practitioners in Canada and in patients' local areas.[178] More patients will be treated. Fewer patients will die.

128. 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

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[173] *PHS*, *supra* note 160 at para 93.
[174] *See* Waitlisted Patient Affidavits.
[175] Alves Affidavit, para 3; McLaren Affidavit, para 2; Pietryszyn Affidavit, para 5; Marykuca Affidavit, para 9; Westlake Affidavit, para 3; Moore Affidavit, para 3.
[176] Joyes Affidavit, paras 6-65 & Exhibits "A"-"M".
[177] Fearnley Affidavit, paras 19-38; Masuda Affidavit, paras 16, 32, 34-35, 38; Hartle Affidavit, paras 34-35; Waitlisted Patient Affidavits.
[178] Fearnley Affidavit, para 41.

practitioners. Some will turn to unlicensed, unregulated, and untrained therapists, risking serious harm.[179] Others will receive treatment only after waiting months or years. Some will never be treated. Many will unnecessarily suffer. Some will die.

D. Refusal Violates Principles of Fundamental Justice

129. 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.

i) Arbitrary

130. 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.[180]

131. There are two purposes to the *CDSA*: health and public safety.[181] 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.[182] The exemption would have had a positive effect on health and no negative impact on public safety.[183]

132. 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.[184] Granting the TheraPsil

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[179] Masuda Affidavit, para 36.
[180] *Canada (Attorney General) v Bedford*, 2013 SCC 72 at para 111, [2013] 3 SCR 1101 [*Bedford*].
[181] *PHS*, *supra* note 160 at para 41.
[182] *Ibid* at para 131.
[183] *Ibid* at para 140.
[184] *Ibid* at para 152.

trainees' exemptions would increase access to health care and have no negative impact on public safety, so their refusal would be arbitrary.

133. Scientific studies demonstrate that psilocybin-assisted psychotherapy has a positive impact on health.[185] Experiential training is a necessary, core competency for practitioners to conduct psilocybin-assisted psychotherapy.[186] 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.[187]

134. 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.[188] Patients have experienced improved health,[189] and healthcare practitioners have been equipped to offer a higher standard of care to their patients.[190] There have not been any negative public safety issues resulting from the possession or consumption of psilocybin pursuant to those exemptions.

135. 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.

ii) Overbroad

136. 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.[191]

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[185] Joyes Affidavit, paras 6-40 & Exhibits "A"-"H".
[186] Joyes Affidavit, paras 89, 93-94 & Exhibits "Q" & "R".
[187] Joyes Affidavit, paras 66-84 & Exhibits "I", "M", "N", "O" & "P".
[188] Sadain Affidavit, Exhibit "C"; Sadain Affidavit 3, para 2.
[189] *See eg* Hartle Affidavit, paras 28-31 & Exhibits "F"-K".
[190] *See eg* Masuda Affidavit, para 7.
[191] *Bedford*, *supra* note 180 at para 112.

137. 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.

iii) Grossly Disproportionate

138. 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.[192] A grossly disproportionate effect on one person is sufficient to violate the norm.[193]

139. 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.

Alleged Benefits

140. 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 the psilocybin is administered in accordance with national and international ethical, medical, and scientific standards.[194]

141. 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.[195]

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[192] *Ibid* at para 120.
[193] *Ibid* at para 122.
[194] Sadain Affidavit, Exhibit "D", para 5.
[195] *See* paras 83 to 91 above.

142. The three purported benefits that Health Canada mentions are either wrong or provide little to no benefit. They are grossly outweighed by the harm caused by refusing the exemption requests.

143. As discussed above, 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.[196] 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.

144. While a clinical trial may ensure that the psilocybin consumed complies with good manufacturing practices, this has almost no real-world benefit. There is no evidence of any harm to patients or trainees from the previous 77+ exemptions that were granted. Moreover, expert scientific analysis has found psilocybin mushrooms to be the safest of a list of 20 common drugs when considered in the context of their use in society – ie. outside of a clinical setting with good manufacturing practices.[197]

145. Health Canada's final purported benefit is partially untrue. A clinical trial would not ensure psilocybin is administered in accordance with national and international standards. As discussed above, a clinical trial would violate certain American and Canadian ethical standards for clinical trials because it is a waste of resources and unjustifiably burdens participants.[198]

146. 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.[199] Experiential training is always conducted

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[196] Sadain Affidavit, para 66 & Exhibit "P", Ch 11, s A, "Therapeutic Misconception".
[197] Joyes Affidavit, para 43 & Exhibit "I".
[198] *See* paras 83 to 91 above.
[199] Sadain Affidavit, para 41.

according to TheraPsil's Clinical Protocol,[200] which aligns with these standards.[201] Any departures from the Clinical Protocol must be documented, and written reasons must be provided for the departure.[202]

Immeasurable Harm

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

148. 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. Some suffer from debilitating depression, some anxiety, and some from post-traumatic stress disorder, among other conditions.

149. 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 fatigue. Many are impaired in their daily functioning, finding it challenging to complete daily tasks like grocery shopping. Many are unable to work, 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.[203] Many have had suicidal thoughts. Some have attempted suicide.[204]

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[200] Sadain Affidavit, para 10.
[201] *See* Joyes Affidavit, paras 86-99 & Exhibits "Q", "R" & "S".
[202] Sadain Affidavit, Exhibit "B", p 11.
[203] Waitlisted Patient Affidavits.
[204] Alves Affidavit, para 3; McLaren Affidavit, para 2; Pietryszyn Affidavit, para 5; Marykuca Affidavit, para 9; Westlake Affidavit, para 3; Moore Affidavit, para 3.

150. 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.

151. Some of these individuals will, out of desperation, turn to underground practitioners who are not licensed or regulated. They may suffer harm and abuse. 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.

152. 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*.

PART V – RELIEF SOUGHT

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

ALL OF WHICH IS RESPECTFULLY SUBMITTED THIS 28 February 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

Jurisprudence

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

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

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