Court File No.

FEDERAL COURT

SIMPLIFIED ACTION

B E T W E E N:

THOMAS HARTLE, JANIS HUGHES, JAMES DOSWELL, BRUCE TOBIN, SHANNON McKENNEY, KATHERINE MARYKUCA, JESSE MERKS, and JANE HARRISON

Plaintiffs

and

HER MAJESTY THE QUEEN

Defendant

STATEMENT OF CLAIM

FACTS

I. THE PARTIES

1. The Plaintiff, Thomas Hartle, is a resident of Saskatchewan. His address for service is care of Lewin & Sagara LLP, 2175 Danforth Ave., Toronto, ON M4C 1K4.

2. The Plaintiff, Janis Hughes, is a resident of Manitoba. Her address for service is care of Lewin & Sagara LLP, 2175 Danforth Ave., Toronto, ON M4C 1K4.

3. The Plaintiff, James Doswell, is a resident of British Columbia. His address for service is care of Lewin & Sagara LLP, 2175 Danforth Ave., Toronto, ON M4C 1K4.

4. The Plaintiff, Bruce Tobin, is a resident of British Columbia. His address for service is care of Lewin & Sagara LLP, 2175 Danforth Ave., Toronto, ON M4C 1K4.

5. The Plaintiff, Shannon McKenney, is a resident of British Columbia. Her address for service is care of Lewin & Sagara LLP, 2175 Danforth Ave., Toronto, ON M4C 1K4.

6. The Plaintiff, Katherine Marykuca, is a resident of the Northwest Territories. Her address for service is care of Lewin & Sagara LLP, 2175 Danforth Ave., Toronto, ON M4C 1K4.

7. The Plaintiff, Jesse Merks, is a resident of Ontario (together with the above Plaintiffs, the "**Patient Plaintiffs**"). His address for service is care of Lewin & Sagara LLP, 2175 Danforth Ave., Toronto, ON M4C 1K4.

8. Each of the Patient Plaintiffs has private interest standing to bring this claim. Each of the Patient Plaintiffs has a constitutional right to access psilocybin for medicinal purposes that has been interfered with by the prohibitions in the *Controlled Drugs and Substances Act*, S.C. 1996, c. 19 (the "***CDSA***"), *Food and Drugs Act*, R.S.C. 1985, c. F-27 (the "***FDA***"), and *Food and Drug Regulations*, C.R.C., c. 870 (the "***FDR***") (collectively, the "**Prohibitions**"). This interference is not cured by access available through any presently available exemptions or authorizations.

9. Each of the Patient Plaintiffs, or the Patient Plaintiffs as a group, also have public interest standing to bring this claim. Each of the Patient Plaintiffs have a demonstrated serious and genuine interest in the subject matter of this litigation. This claim is, in all the circumstances, a reasonable and effective way to bring the issue before the courts.

10. The Patient Plaintiffs bring this claim pursuant to the *Federal Court Act*, R.S.C 1985, c. F-7 (the "***FCA***"), the *Federal Courts Rules*, S.O.R. 98-106 (the "***Rules***"), and sections 1, 7, 24(1) and 52(1) of the *Charter of Rights and Freedoms*, Part 1 of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c. 11 (the "***Charter***") on behalf of themselves as persons ordinarily resident in Canada that reasonably require access to psilocybin and psilocin for the treatment of a serious health issue, and on behalf

of all other persons approved by a medical practitioner for the use of psilocybin or psilocin for medical purposes ("**Medically Approved Patients**").

11. The Plaintiff, Jane Harrison, is a resident of Ontario (the "**HCP Plaintiff**"). Her address for service is care of Lewin & Sagara LLP, 2175 Danforth Ave., Toronto, ON M4C 1K4.

12. The HCP Plaintiff is a health care professional who requires access to psilocybin and psilocin for the purpose of training for the administration of psilocybin-assisted psychotherapy.

13. The HCP Plaintiff has private interest standing to bring this claim. She has a direct, personal interest in the impugned provisions as they prevent her from effectively treating her patients and practicing her chosen profession.

14. The HCP Plaintiff also has public interest standing to bring this claim. The HCP Plaintiff has a demonstrated serious and genuine interest in the subject matter of this litigation. This claim is, in all the circumstances, a reasonable and effective way to bring the issue before the courts.

15. The HCP Plaintiff brings this claim pursuant to the *FCA*, the *Rules*, and sections 1, 7, 24(1) and 52(1) of the *Charter* on behalf of herself as a health care professional ordinarily resident in Canada who reasonably requires access to psilocybin for training purposes, and other similar persons in this class. Health care professionals are professionals who work in health care and are regulated by a provincial professional licensing authority.

16. The Defendant, Her Majesty the Queen, as represented by the Attorney General of Canada, is named as the representative of the Government of Canada and the Minister of Health for Canada (the "**Minister**"), who is the minister responsible for Health Canada and certain aspects of the *CDSA* and the *FDA*, including the *FDR*.

II. BACKGROUND

A. Safety and Efficacy of Psilocybin and Psilocin for Medical Purposes

17. Psilocybin and psilocin are naturally-occurring tryptamines found in certain species of fungi ("**Natural Psilocybin Mushrooms**"). Psilocin is a metabolite of psilocybin produced in the human body after ingestion of psilocybin. Psilocin, whether present in the material or as resulting from metabolism of psilocybin, is responsible for the psychoactive effects of Natural Psilocybin Mushrooms or of synthetic psilocybin or psilocin (synthetic psilocybin or psilocin, alone or in combination, being the "**Synthetic Tryptamines**").

18. Psilocybin has long been studied as a therapeutic treatment for a wide range of conditions. Recent studies and anecdotal evidence have exposed psilocybin as a highly effective treatment for a number of conditions, including depression, anxiety, existential distress, addiction, cluster headaches, neurological pain, obsessive compulsive disorder and Post Traumatic Stress Disorder.

19. These are conditions which are often ineffectively treated with the medical options available in the Canadian healthcare system. They are also deeply serious conditions. Without effective treatment, these conditions cause significant suffering to millions of Canadians, drastically impacting their well-being on a daily basis. For some, the resultant suffering from these ill-treated conditions can have fatal consequences.

20. In addition to its efficacy, study after study has shown that psilocybin is safe for medical use. Psilocybin is not addictive and does not result in dependence or compulsive use. The risk of overdose from psilocybin is virtually non-existent, and there is little evidence of any negative long-term physiological or psychological impacts. In comparison to many of the pharmaceuticals readily available by prescription today, psilocybin is considered to be an exceedingly low-risk drug.

B. Forms of Psilocybin

21. There are two predominant sources of psilocybin: Natural Psilocybin Mushrooms and Synthetic Tryptamines. Natural Psilocybin Mushrooms contain the psilocybin and psilocin that is naturally biosynthesized by, and found in, Natural Psilocybin Mushrooms. Synthetic Tryptamines, on the other hand, are manufactured synthetically, and often in a lab. While both Natural Psilocybin Mushrooms and Synthetic Tryptamines provide forms of psilocybin and psilocin, Natural Psilocybin Mushrooms and Synthetic Tryptamines are not interchangeable for therapeutic purposes.

22. Synthetic Tryptamines lack other tryptamines, nutrients, chemical salts, and other molecules found in Natural Psilocybin Mushrooms. Similarly, different compounds within Natural Psilocybin Mushrooms work synergistically to create uniquely beneficial effects. This "entourage effect" of synergy, as it is referred to, cannot be easily duplicated with Synthetic Tryptamines. It would likely require many years of research to create a formulation that reasonably replicates the entourage effect found in Natural Psilocybin Mushrooms using a combination of Synthetic Tryptamines. For some, these variations between Natural Psilocybin Mushrooms and Synthetic Tryptamines lead to differences in the onset and effects of either substance, resulting in therapeutic differences between the two.

23. There is also an inherent price discrepancy between Natural Psilocybin Mushrooms and Synthetic Tryptamines. Natural Psilocybin Mushrooms are relatively easy to cultivate and can be grown for personal use for less than $100. Synthetic Tryptamines, conversely, are manufactured by pharmaceutical companies who may charge thousands of dollars per treatment. As many people who require psilocybin for medical reasons face debilitating conditions that make working difficult or impossible, for some, funding treatment with Synthetic Tryptamines is simply not an option.

24. Some Plaintiff Patients and Medically Approved Patients also prefer Natural Psilocybin Mushrooms over Synthetic Tryptamines based on a preference to consume natural, rather

than manufactured, substances. That is, some patients find consuming natural substances to be more therapeutic than consuming a manufactured pharmaceutical. In addition, some patients have a reasonable distrust of pharmaceuticals, and pharmaceutical companies, which have provided them with ineffective and often damaging treatments over the course of their condition. A patient's experience during psilocybin-assisted psychotherapy is influenced by their mindset entering treatment. A patient's perception of the source of their psilocybin can affect their mindset and thereby alter their experience, for better or worse.

25. Similarly, there are Plaintiff Patients and Medically Approved Patients who have had positive experiences with Natural Psilocybin Mushrooms and reasonably want to continue treatment using the substance they know works for them. There are at least 116 species of Natural Psilocybin Mushrooms, and thousands of strains in cultivation. There are differences in the therapeutic effect between different species and strains. A Plaintiff Patient or Medically Approved Patient who has had positive experiences with Natural Psilocybin Mushrooms may reasonably want to continue treatment using the species and strain they know works for them. The knowledge that a particular species or strain of Natural Psilocybin Mushrooms has been effective in the past can also enhance the therapeutic impacts of treatment by creating a positive mindset. Many of these species and strains will not be available from licensed dealers.

26. In contrast, some patients prefer Synthetic Tryptamines because of the controls in place for the manufacture of Synthetic Tryptamines consistent with good manufacturing practices ("**GMP**"). Compliance with GMP is simpler for Synthetic Tryptamines than for Natural Psilocybin Mushrooms, improving standards for quality, traceability, production and analysis. Some patients take comfort in consuming substances that are held to GMP standards, and this feeling of safety can assist in the therapeutic impacts of their treatment.

27. Together, these differences demonstrate that Natural Psilocybin Mushrooms and Synthetic Tryptamines are not equivalent as sources of psilocybin and psilocin. Based on these differences, many patients have a reasonable preference between Natural Psilocybin

Mushrooms and Synthetic Tryptamines. Constitutionally viable access to psilocybin must permit a patient to access their reasonably preferred form of psilocybin.

C. Legal Status of Psilocybin

28. Psilocybin and psilocin are "controlled substances" listed in Schedule III to the *CDSA.* The *CDSA* prohibits the possession, production, growing, selling, sharing, importing and exporting of psilocybin and psilocin, including for medical purposes, unless otherwise permitted under regulations pursuant to the *CDSA*, or where an exemption has been granted under subsection 56(1) of the *CDSA*.

29. Psilocybin and psilocin are also "restricted drugs" listed in the Schedule to Part J of the *FDR*. The *FDR* therefore regulate and restrict production for sale, and sale, of psilocybin and psilocin, including for medical purposes unless otherwise permitted for limited purposes.

30. The *FDR* provide a framework for the production of psilocybin and psilocin by licensed dealers. However, psilocybin and psilocin may only be provided by licensed dealers to the Minister, institutions for research purposes, or to a physician for administration to a patient pursuant to an authorization issued through the Special Access Program (the "**SAP**") under subsection C.08.010(1) of the *FDR*. The psilocybin and psilocin cannot be consumed by the licensee, nor can they be provided directly to a patient.

D. The Current Means of Legal Access to Psilocybin Are Insufficient

31. Under Canadian law, there are currently only three ways to access psilocybin for medical purposes in compliance with the *CDSA*:

    a. Obtain a personal exemption from the Minister of Health under subsection 56(1) of the *CDSA* (a "**Section 56 Exemption**")*;*

    b. In conjunction with a doctor, obtain an authorization through the SAP; or

c. Enroll in a clinical trial.

(collectively, the "**Flawed Exemptions/Authorizations**").

32. None of these Flawed Exemptions/Authorizations are practical or timely for patients suffering from serious health conditions. They do not adequately serve the needs of patients. They do not provide constitutionally viable access to psilocybin and therefore fail to rectify the infringement on patients' rights under section 7 of the *Charter* caused by the Prohibitions in the *CDSA*, *FDA*, and *FDR*.

33. Each of these Flawed Exemptions/Authorizations are discussed, in turn, below.

i. Section 56 Exemptions

34. Under subsection 56(1) of the *CDSA* the Minister may exempt a person or class of persons from some or all of the *CDSA*:

> 56 (1) The Minister may, on any terms and conditions that the Minister considers necessary, exempt from the application of all or any of the provisions of this Act or the regulations any person or class of persons or any controlled substance or precursor or any class of either of them if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

35. The flaws in providing access to psilocybin through Section 56 Exemptions are many.

36. First, the Section 56 Exemption process is highly inaccessible. Many patients do not know that applying for a Section 56 Exemption is an option. For those that do know, no guidance is provided on how to apply. Applicants are not told which documents, information or research are necessary to be successful. Patients must either navigate the application process on their own or find an organization to assist them. For many, the energy required for either of these options is prohibitive given their health conditions.

37. Second, the Section 56 Exemption process is invasive. It requires applicants to disclose personal health details and potentially incriminating activities with controlled drugs to the Minister.

38. Third, the Section 56 Exemption process is highly uncertain. Decisions under subsection 56(1) are entirely discretionary. The Minister may therefore refuse an application for a Section 56 Exemption for any reason, including reasons unrelated to the applicant's health. Patients therefore must expend energy and resources to apply without knowing whether they will receive any benefit for their efforts, and with no guidance or direction on how to improve their chances of receiving a Section 56 Exemption.

39. Fourth, the Section 56 Exemption process is accompanied by untenable delays. If patients require assistance in applying for a Section 56 Exemption, they are often forced to wait until non-profit organizations have space within their limited resources to assist. Once an application is sent, there are undeniable delays before a decision is made. For applicants with health conditions that cause daily suffering, they remain untreated and suffering in the interim. For some applicants, this delay is catastrophic as they suffer with terminal conditions.

40. Fifth, a Section 56 Exemption is time-limited. If applicants are able to wade through the hurdles set out above, and obtain an exemption, they can only legally access the care they need for a limited amount of time. Most often, a Section 56 Exemption issued for medical purposes has a term of one year, after which patients must file a new application for a Section 56 Exemption. Such applications for a second Section 56 Exemption have in all cases, to the Plaintiffs' knowledge, been rejected by Health Canada.

41. Psilocybin-assisted psychotherapy is an effective treatment, but in many cases it is not a permanent solution. While the needs of patients vary, treatment is often required multiple times each year. A single year Section 56 Exemption may in many cases leave patients back where they started a year earlier – suffering and without access to effective care.

42. Finally, the Section 56 Exemption process does not provide a safe means of accessing psilocybin. To the Plaintiff's knowledge, no Section 56 Exemption has been provided to cultivate Natural Psilocybin Mushrooms either by the Section 56 Exemption holder or a person designated to grow on an exemption-holder's behalf. Similarly, to the Plaintiff's

knowledge, no Section 56 Exemption has been provided that allows the Section 56 Exemption holder to purchase from a licensed dealer. Rather, the Section 56 Exemptions that have been granted for the therapeutic use of psilocybin require the Section 56 Exemption holders to either purchase psilocybin from individuals or organizations that are contravening the *CDSA*, the *FDA* and the *FDR*, or to forage for Natural Psilocybin Mushrooms in the wild. An individual lacking training in mycology attempting to forage for Natural Psilocybin Mushrooms in the wild could inadvertently poison themself. Neither of these options is controlled or safe.

43. In light of the above, it is evident that patients do not have constitutionally viable access to psilocybin through the Section 56 Exemption process. Exemptions make treatment difficult to access, uncertain, and heavily delayed. This unduly prolongs the suffering of patients, sometimes indefinitely.

ii. Authorizations Under the SAP

44. Section C.08.010 of the *FDR* provides that, on application by a practitioner, the Minister may permit the provision of psilocybin to a practitioner for use in the emergency treatment of a person under their care. The burdens on practitioners, restrictions in the SAP, and Ministerial involvement in the SAP, result in a number of barriers to patient access.

45. First, the SAP is not suitable for all patients who may benefit from the medical use of psilocybin. The *FDR* does not define "emergency treatment". However, Health Canada has interpreted this term as serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or are unavailable in Canada. This seemingly limits access through the SAP to those with critical conditions who have exhausted all other available remedies. In other words, a patient cannot get access to a safe and effective treatment without first becoming critically ill and prolonging their illness by facing the failures of other, often more harmful remedies. For those with chronic but not critical conditions, care may never be available under the SAP.

46. Second, the SAP is not intended to provide continuous care. Health Canada has stated that emergency access is intended to be exceptional, and access to any drug through the SAP is intended to be limited in duration and quantity to meet emergency needs only. The SAP is not designed to meet the ongoing needs of those with chronic conditions. This again makes it an inappropriate means of access for many patients who would benefit from the medical use of psilocybin.

47. Third, many patients struggle to find a physician to assist in accessing psilocybin through the SAP. The SAP places a heavy burden on physicians applying for access and following treatment. As a result, many physicians are reluctant to engage with the SAP.

48. To apply for SAP, a physician must provide details about the medical emergency for which they are applying. This includes information about their patient's medical history, including why other therapies are not a reasonable option.

49. The physician must also provide details about the use, safety and efficacy of psilocybin that supports the decision to recommend psilocybin to their patient. This may include but is not limited to data, references, and articles from medical literature, treatment guidelines, investigator brochures, and foreign prescribing information.

50. If approved, the physician then assumes liability and responsibility for the use of the psilocybin. The physician is responsible for monitoring their patient and the outcome of the use of the drug. The physician must then provide a report to the manufacturer and to the Minister regarding the outcome experienced by the patient and any observed adverse drug reactions.

51. This burden on physicians makes it more difficult for patients to find a physician willing to apply on their behalf.

52. Fourth, the SAP does not provide access to psilocybin for physicians or other health care professionals for the purposes of training. This contributes to the underdeveloped network

of healthcare providers, as there is no means for healthcare providers to properly train on the administration of psilocybin-assisted psychotherapy.

53. Fifth, the SAP is costly. Not only are there few participating practitioners, but many of those practitioners who do work with the SAP are working with large psychedelic companies. Those psychedelic companies charge thousands of dollars to assist patients in accessing psilocybin. Further, these physicians are most often located in large urban centres. Patients must travel to the participating practitioner, at their own expense. Given that many patients rely on disability assistance as income, paying for treatment or for travel costs associated with treatment is not an option.

54. Sixth, the SAP forces patients into situations of substandard care with unfamiliar doctors. Where patients do have the means to access a physician willing to assist them with the SAP, it often involves an unfamiliar physician and therapist in an unfamiliar city. Psilocybin's effects rely on the patient having a good mindset, or "set", and being in a comfortable "setting". Together, the set and setting are integral to the success of psilocybin-assisted psychotherapy. When forced to be treated away from home by new medical personnel, the set and setting dissipate and the therapeutic effects of the treatment suffer.

55. Seventh, the SAP is heavily biased toward the provision of Synthetic Tryptamines over Natural Psilocybin Mushrooms. This bias is a result of a requirement that any application for access to Natural Psilocybin Mushrooms as an active pharmaceutical ingredient ("**API**") must include evidence that the specific Natural Psilocybin Mushrooms used as an API are safe and efficacious for the purposes listed in the SAP application. The Plaintiffs are unaware of any such evidence at a standard appropriate for the SAP being available at this time. As a result, under the SAP, the applying physician is required to purchase Synthetic Tryptamines from a licensed dealer. Many patients have a reasonable medical preference for Natural Psilocybin Mushrooms, as discussed above. Absent significant, and currently unavailable, results based on research related to specific examples of Natural

Psilocybin Mushrooms, these patients cannot access their reasonably preferred medical treatment through the SAP.

56. Eighth, the SAP process is accompanied by untenable delay. Because the Government must provide a decision on SAP applications once a doctor has applied, there is an inherent delay that results from that added step. For some it may only be days, but for others, decisions take months. This is time that patients spend suffering when they would have already received treatment if the decision were with their physician.

57. Ninth, the SAP process is invasive. It requires applicants to disclose personal health details and potentially incriminating activities with controlled substances to the Minister.

58. Finally, the SAP is uncertain. Similar to section 56, the Minister is not obliged to grant special access in any circumstance. The decision is entirely discretionary. Patients therefore must expend energy and resources to apply without knowing if they will receive any benefit for their efforts.

59. In light of the above, it is evident that patients do not have constitutionally viable access to psilocybin through the SAP. The SAP is not designed to provide continuous treatment, and makes treatment difficult to access, uncertain, and heavily delayed. This unduly prolongs the suffering of patients, sometimes indefinitely.

iii. Clinical Trials

60. The Government of Canada has stated that patients attempting to access psilocybin should try and seek access through clinical trials. Clinical trials are not a proper means of accessing ongoing medical treatment and they do not represent a reasonable means of access to psilocybin for several reasons.

61. First, many patients do not know how to find or enroll in clinical trials. This creates an initial barrier to access which requires patients to expend limited mental resources to overcome.

62. Second, where patients are aware that clinical trials may be an option, they often struggle to find a trial that will accept them as a subject. Patients have to find a trial which is still enrolling patients, which is seeking patients with their condition, and which they are not disqualified from for any number of reasons. This can be particularly difficult for patients who have experience with psilocybin, which makes a double-blind study impossible.

63. If patients are unable to travel, either for physical or financial reasons, the pool of appropriate clinical trials shrinks even further.

64. Third, patients risk landing in a placebo group in a clinical trial, leaving them without effective treatment. This is one of many reasons that clinical trials cannot be considered equivalent to "treatment". A patient may expend resources seeking out, enrolling in, and traveling for a clinical trial just to receive a placebo dose and see no benefits.

65. Fourth, clinical trials can be delayed or cancelled. Clinical trials require various approvals and funding that can interrupt their operation at any point. Patients may then be left without timely care.

66. Fifth, many patients find the idea of being studied invasive and non-therapeutic. Patients may reasonably prefer to have their care focused on their betterment, and not on the needs of the study. Further, they may find unfamiliar scientists studying their condition dehumanizing and uncomfortable. Given the importance of set and setting to the impacts of psilocybin-assisted psychotherapy, this can impact the benefits of the treatment.

67. Finally, clinical trials are not intended to provide long-term, patient-focused care. Clinical trials are finite in duration, and often provide set parameters for the care the patient receives. This is not customized to the needs of the patient. Therefore, even where patients find a clinical trial that will accept them, and even if they are enrolled in the active arm rather than the placebo arm, when the trial ends, they will ultimately be left without access to care once again.

68. In summation, clinical trials are not an acceptable substitute for ongoing access to treatment. They are difficult to access, put patients at risk of ineffective treatment, and are simply not designed to provide continuing care. They do not provide patients with constitutionally viable access to psilocybin.

E. TheraPsil

69. TheraPsil is a not-for-profit corporation committed to safe, equitable and legal access to psilocybin-assisted therapy for those in need. It assists patients in navigating their options for legal access to psilocybin for medical purposes and guides them through the application process, including connecting patients with doctors and therapists to assist in the application processes. TheraPsil has also supplemented patient applications with a large public relations campaign and extensive lobbying for patient access.

70. TheraPsil has been overrun by applications for assistance from patients needing help accessing care. As of February 2022, TheraPsil had a waitlist of more than 800 patients requesting assistance in obtaining psilocybin-assisted psychotherapy.

71. TheraPsil cannot help them all. Being a non-profit, TheraPsil has very limited resources. While they do receive some marginal donations from patients, these donations do not cover real costs associated with assisting patients. It operates with a small staff and a small network of trained providers.

72. As a result, TheraPsil has had to turn away a large percentage of its applicants, focusing its mandate on terminal cancer patients seeking treatment for end-of-life distress. While many other applicants are suitable candidates for psilocybin-assisted psychotherapy, and would benefit from same, TheraPsil simply cannot help everyone, nor can they continue to assist patients in this manner indefinitely.

73. Without the assistance of TheraPsil, many patients are not equipped to obtain a Section 56 Exemption. Most of the Patient Plaintiffs who have applied for and received treatment

through the Section 56 Exemption and SAP processes were only able to obtain that care because of TheraPsil.

74. The constitutional rights of patients to access reasonable care cannot be foisted onto the shoulders of non-profit groups. Care which requires the assistance of a non-governmental non-profit to access is not constitutionally viable.

F. Training of Health Care Professionals

75. Studies have shown that health care practitioners who use psilocybin to train in the administration of psilocybin-assisted psychotherapy are able to administer safer and more productive treatment. To create a system in which patients have constitutionally viable access to effective psilocybin treatments, health care practitioners must therefore also have a reasonable means of access for training purposes.

76. It is important that health care practitioners who administer or assist in psilocybin-assisted psychotherapy have a personal understanding of the experience of using psilocybin. Without that knowledge, it can be difficult for practitioners to properly guide or relate to patient experiences. Further, a mutual understanding of the experience resulting from ingesting psilocybin can help build trust between the practitioner and the patient, which contributes to a stable and safe set and setting.

77. In the past, Health Canada granted 19 health care practitioners Section 56 Exemptions in order to possess and consume psilocybin for training purposes. However, since March 18, 2021, over 96 health care practitioners have applied for a Section 56 Exemption and, to the Plaintiffs' knowledge, all were rejected. For all of the same reasons that Section 56 Exemptions do not provide reasonable access to care for patients, they do not provide reasonable access to training for health care practitioners.

78. Further, health care practitioners cannot access psilocybin for training purposes through the SAP, nor are clinical trials a reasonable means of accessing this training.

79. There are not enough health care practitioners properly trained in psilocybin-assisted therapy to assess, support and treat patients in need of psilocybin-assisted therapy. Without a growing network of properly trained practitioners, patients will continue to face hurdles to access. Therefore, a scheme which provides constitutionally viable access to psilocybin-assisted psychotherapy must also provide reasonable access to psilocybin for health care practitioners for the purposes of training.

G. Constitutionally Viable Access Requires a Doctor-As-Gatekeeper Model

80. The fundamental issue with the current Flawed Exemptions/Authorizations is the imposition of the Minister as the gatekeeper of patient treatment. This creates unnecessary barriers and delay, and is fundamentally unsuitable for determinations related to personalized and patient-centered healthcare. Rather, it must be the patients' physicians who determine what care is most appropriate for the patient based on their knowledge of the patient's history and their medical expertise.

81. Physicians have professional commitments to the well-being of their patients. They have a duty to put the well-being of their patient first, to always act for the benefit of the patient, and to promote the good of the patient. These commitments exist to protect patients and to ensure they receive care in their best interests. It is therefore crucial that the body making medical decisions have this commitment to patient well-being. To leave that decision with any other entity risks substandard care for patients.

82. Physicians are also most knowledgeable about their patients' needs and have the medical expertise necessary to inform and guide patients to suitable treatment. Physicians are therefore capable of making informed and safe decisions regarding the use of psilocybin for patients, just as they are capable of making decisions regarding the suitability of pharmaceuticals that includes as API opioids, amphetamines, benzodiazepines, and many other higher-risk controlled substances that physicians are able to prescribe.

83. Finally, physicians are trained in and mandated to provide patient-centered care. Patient-centered care is medical care that is aligned around the values and needs of patients. It is a holistic approach to deliver respectful and individualized care, allowing negotiation of care and offering choice through a therapeutic relationship in which persons are empowered to be involved in healthcare decisions. When the gatekeeper is the patient's physician who is applying a patient-centered approach, the patient is empowered and the therapeutic potential of treatment is greater.

84. Having the Minister as the gatekeeper for psilocybin treatments imposes barriers and delays to access, prolonging the suffering of many Canadians. It places unnecessary burdens on patients and doctors that make care difficult to access. These barriers are arbitrary given the harm caused by these barriers, and the relative lack of risk associated with psilocybin-assisted treatments. Just as a physician can make informed decisions about the prescription of other pharmaceuticals that include controlled substances as API, which often carry higher-risk profiles, doctors are capable of safely authorizing psilocybin.

85. The government-as-gatekeeper model which currently exists for psilocybin is therefore arbitrary. Constitutionally viable access requires a doctor-as-gatekeeper model.

H. Constitutionally Viable Access Must Allow Options to Grow for Personal Use

86. As stated above, but for the Prohibitions in the *CDSA*, the *FDA* and the *FDR*, growing Natural Psilocybin Mushrooms is a relatively easy and cost-effective way to access psilocybin for medical use. Given the financial barriers to accessing Synthetic Tryptamines, and the multitude of reasons a patient may reasonably prefer to consume Natural Psilocybin Mushrooms, constitutionally viable access to psilocybin must also include constitutionally viable exemptions to grow Natural Psilocybin Mushrooms for personal use.

87. A framework for constitutionally viable access through growing already exists in the context of cannabis law. Under the *Cannabis Regulations* SOR/ 2018-144 (the "***CR***"), medical consumers can either:

    a. Purchase cannabis that was grown by a commercial licensed grower;

    b. Grow their own medical cannabis in accordance with a personal registration certificate; or

    c. Designate a trusted friend or caregiver to grow medical cannabis for the medical consumer in accordance with a designated grower registration certificate. Designated growers are not permitted to grow for more than two medical cannabis patients.

88. Each option has its own benefits, and each is necessary for a system that provides constitutionally viable access. The same options must exist for constitutionally viable access to psilocybin for medical purposes.

89. Having access to Natural Psilocybin Mushrooms and Synthetic Tryptamines from licensed dealers would provide patients an option for hassle-free access to ready-made psilocybin products if they are not themselves capable of growing, and do not have anyone they trust who can grow for them. Some patients also may find comfort in consuming a regulated product.

90. For others, growing a designated amount of Natural Psilocybin Mushrooms is feasible, and can provide barrier-free access at a very low cost to the substances they need for treatment. It can also be therapeutic for some patients to cultivate their own medicine.

91. For other patients still, they are uncomfortable with, or unable to purchase, plant medicine produced by companies about which they know little, but are also unable to grow for themselves. Not all patients know how or have the time, circumstances or resources suitable for growing Natural Psilocybin Mushrooms. In this case, designating a trusted

friend or caregiver to grow on their behalf can provide them natural and cost-effective treatment, despite their personal barriers to growing. As with cannabis, a designated grower for Natural Psilocybin Mushrooms could be limited in the number of patients on whose behalf they can grow.

92. Together, the medical cannabis access system regulated under the *CR* provides one example of a constitutionally viable system of exemptions to grow psilocybin.

I. Experiences of the Patient Plaintiffs

i. Thomas Hartle

93. In 2016, at the age of 48, Thomas Hartle was diagnosed with stage four colon cancer. Despite efforts through chemotherapy and surgery, the cancer spread to Mr. Hartle's abdomen. He now has tumours in 42 locations throughout his abdominal cavity which cannot safely be removed. Over forty of these tumours are not detectable by medical scans. Without being able to see his tumours, doctors have no means of assessing the progression of Mr. Hartle's cancer. They cannot tell him how much time he has left.

94. Mr. Hartle's condition has left him with extreme daily anxiety, which has caused him immense suffering, including daily mental and emotional distress, physiological strain, and difficulty maintaining relationships.

95. Mr. Hartle has tried to treat his anxiety and distress with a wide range of pharmaceuticals. However, every medication he has tried has only temporarily masked the symptoms of his anxiety. Further, none have effectively helped alleviate his feelings of existential despair. With the options currently available to him through medical prescription, Mr. Hartle is still left suffering.

96. Fearing that he may spend his remaining time suffering with daily anxiety and distress, Mr. Hartle began reviewing literature on the benefits of psilocybin-assisted psychotherapy.

97. In early 2020, Mr. Hartle approached his family doctor for information on psilocybin-assisted psychotherapy. Unfortunately, his doctor did not have sufficient knowledge about the therapeutic potential of psilocybin to provide Mr. Hartle with any information or support.

98. In the spring of 2020, Mr. Hartle found TheraPsil. TheraPsil's staff referred him to a psychiatrist who assessed Mr. Hartle's condition. That psychiatrist determined that psilocybin-assisted psychotherapy would be beneficial in treating Mr. Hartle's anxiety and end-of-life distress. He encouraged Mr. Hartle to apply for a Section 56 Exemption and provided him a supporting letter to assist in his application.

99. Mr. Hartle was entirely unaware of the option to apply for a Section 56 Exemption before he became involved with TheraPsil. Without the assistance of TheraPsil, Mr. Hartle does not believe he would ever have known that a Section 56 Exemption was an option, and would not have known how to properly complete and submit an application.

100. Mr. Hartle's application for a Section 56 Exemption was submitted on June 2, 2020. Health Canada requested further information, which was provided by supplementary letters to Health Canada on July 13, 2020 and July 30, 2020.

101. Mr. Hartle was eventually granted a Section 56 Exemption to possess and consume psilocybin for the purposes of psilocybin-assisted psychotherapy on August 4, 2020, more than 60 days after he initially applied. For those 60 days, Mr. Hartle was left with no effective means of relief from his daily suffering. Mr. Hartle's Section 56 Exemption was only valid for one year.

102. Mr. Hartle underwent psilocybin-assisted psychotherapy on August 12, 2020. Through this session, Mr. Hartle reported that he had newfound comfort in the prospect of death. He reported feeling as though he could cope in ways that he was not able to before. Most importantly, he saw a significant decrease in his anxiety and distress.

103. These improvements lasted several months. Mr. Hartle underwent psilocybin-assisted psychotherapy two more times before his exemption expired on August 4, 2021, with great results each time. However, as is the nature of this treatment, his anxiety and existential distress returned some months after his exemption expired.

104. Mr. Hartle submitted an application for a second Section 56 Exemption on October 4, 2021, to continue his treatment. As of the date of filing, Mr. Hartle's second application has not been decided. Because of this delay, for months after submitting his second application, Mr. Hartle suffered daily with extreme distress and anxiety without access to effective treatment.

105. In January of 2022, Mr. Hartle was admitted to a program for terminally ill patients which included a psilocybin-assisted psychotherapy session. It required him to obtain access to psilocybin through the SAP and travel to British Columbia, at his own expense, to attend the session. Mr. Hartle was fortunate to have the means to complete this program, using a doctor in British Columbia provided by TheraPsil to apply for psilocybin through the SAP on his behalf. He was again alleviated of his symptoms through this session.

106. Since that session, Mr. Hartle has had no legal access to treatment.

107. As stated, his second application for a Section 56 Exemption has not been decided, more than nine months after it was submitted.

108. Further, Mr. Hartle has no access to the SAP in Saskatchewan. His doctor in Saskatchewan is not knowledgeable enough to assist him in seeking access through the SAP. Given his condition, the time and energy required to wade through a sea of doctors to find one willing and able to assist him with the SAP is prohibitive. While he may be able to access the SAP through doctors in British Columbia, he does not have the financial resources to continuously travel for treatment, nor is it without risk for him to travel given his physical condition.

109. Mr. Hartle is not aware of any clinical trials that would admit him, particularly because his prior treatment eliminates the potential of a blind study. Further, Mr. Hartle is interested in treatment tailored to his needs on an ongoing basis, rather than treatment designed within the confines of a trial. He does not feel that accessing psilocybin through a clinical trial would meet his needs, and it is his reasonable preference not to access psilocybin through a clinical trial.

110. Mr. Hartle is therefore left with no access to treatment. He is acutely aware that the relief he experienced from his SAP-facilitated treatment is expiring, and his anxiety will soon return. He must expend time, financial resources, and mental energy searching for his next opportunity to legally access relief. In the interim, Mr. Hartle suffers.

ii. Janis Hughes

111. Janis Hughes has struggled with depression since adolescence. In the summer of 2021, Ms. Hughes was diagnosed with stage four breast cancer. At the time of diagnosis, it had already spread to her bones and right lung. She was deemed terminal and was given two years to live. As a result of this diagnosis, she experienced severe anxiety and end-of-life distress.

112. In the past, Ms. Hughes has tried prescription pharmaceuticals to treat her depression. However, she found they left her numb, unable to feel either the highs or lows of life. She has predominantly relied on maintaining a healthy lifestyle to cope with her disorders. However, when her anxiety and distress became severe, her coping mechanisms were no longer enough. She began to suffer without relief from her disorders.

113. Ms. Hughes began looking into the effectiveness of psilocybin-assisted psychotherapy for her condition. In October 2021, she reached out to TheraPsil for assistance in submitting an application for a Section 56 Exemption. As Ms. Hughes was terminal, TheraPsil agreed to assist. However, due to the volume of applicants TheraPsil was assisting, and the limited number of trained medical professionals, it took several

months before TheraPsil could complete her application. Ms. Hughes did not feel equipped to properly complete an application without the assistance of TheraPsil. She therefore was forced to suffer as she awaited help through TheraPsil's limited resources to access the exemption process.

114. On January 12, 2022, Ms. Hughes' application for a Section 56 Exemption was finally submitted to Health Canada. She received a rejection from Health Canada two weeks later.

115. Health Canada justified its rejection on the basis that Ms. Hughes had not submitted evidence that she tried to access psilocybin through a clinical trial or the SAP before seeking an exemption. Ms. Hughes searched and found no clinical trials in Manitoba. She asked her oncologist, her day-to-day doctor, and her general practitioner to assist her in accessing psilocybin through the SAP. All declined. Ms. Hughes was turned away from the exemption process to a sea of further rejection.

116. As a result of TheraPsil's assistance, Ms. Hughes found a doctor in British Columbia who would assist her with an application through the SAP. However, it would require her to travel from Winnipeg to British Columbia on short notice. In addition, she would have to stay in unfamiliar accommodations, in an unfamiliar city, and be treated by an unfamiliar doctor and therapist. Given the importance of set and setting to the success of psilocybin-assisted psychotherapy, these were profoundly substandard conditions for treatment. As a further barrier, Ms. Hughes is immunocompromised. Travel posed additional and unacceptable health risks. She was ultimately unable to travel to British Columbia and could not gain access through the SAP. She continued to suffer daily without access to treatment.

117. On February 8, 2022, Ms. Hughes emailed the Minister of Health, Jean-Yves Duclos, asking that her section 56 application be reconsidered. She explained that there were no clinical trials recruiting anywhere in the country, and that accessing psilocybin through the SAP was not feasible.

118. On March 8, 2022, Ms. Hughes had a Zoom meeting with the Chief Medical Advisor and a representative from the Exemptions Section of Health Canada. Ms. Hughes continued to advocate for herself, but the Government representatives continued to insist that Ms. Hughes use the SAP process to access the care she needed. Ms. Hughes continued to suffer.

119. In April 2022, tired of waiting for relief through the Government's systems, Ms. Hughes, in contravention of the *CDSA*, accessed psilocybin and began micro-dosing with a therapist. She found this provided her with some new insight, although it did not alleviate her symptoms.

120. On June 23, 2022, using her illegal supply of psilocybin, Ms. Hughes took her first "middle-dose", being more than a micro-dose, but less than a full therapeutic dose. Ms. Hughes experienced significant relief from her anxiety and depression as a result of her middle-dose. In particular, she reportedly gained insight into how she may repair damaged relationships, which helped alleviate anxiety about dying before healing those relationships. Ms. Hughes was happy to have found some relief, if illegally, but believes there is more benefit to be achieved from additional sessions.

121. On May 17, 2022, Ms. Hughes was advised that her application for a Section 56 Exemption was being reconsidered. However, as of the time of filing, over two months later, she has not received any further response from Health Canada.

122. Ms. Hughes was given two years to live. She has now spent a full year waiting for relief from the anxiety and distress her disease has caused her. Had Ms. Hughes not illegally accessed treatment, she would have spent half of her remaining time suffering because Canada's legal system barred her from the treatment she requires to alleviate her suffering.

iii. James Doswell

123. James Doswell has experienced anxiety the majority of his life, associated with undiagnosed Attention Deficit Disorder and trauma from time spent working in dangerous conditions. This anxiety was exacerbated by a cancer diagnosis in 2014, leading to an official anxiety diagnosis in 2015. Although he currently is cancer-free, Mr. Doswell's anxiety persists.

124. Ultimately, in September 2017, Mr. Doswell's anxiety caused him to leave his career. He became reclusive, staying home but for necessary outings and disconnecting from his personal relationships. He formed an unhealthy relationship with alcohol as a means of coping with his anxiety.

125. Mr. Doswell has been treated for anxiety by multiple psychologists and psychiatrists. He has been prescribed several pharmaceuticals for his anxiety, none of which were effective. Rather, he experienced, at best, that pharmaceuticals temporarily masked his symptoms and left him feeling fatigued and dulled. He could not experience even minimal relief without also losing sensation. Mr. Doswell has also undergone Cognitive Behavioural Therapy, with minimal success. He continued to suffer daily from his anxiety despite his efforts through available medicine and therapies.

126. In February of 2021, Mr. Doswell discovered TheraPsil. It was at this time that he first became alive to the potential for psilocybin-assisted psychotherapy to alleviate his symptoms. He worked with TheraPsil to file an application for a Section 56 Exemption on June 9, 2021. Mr. Doswell did not receive a response from Health Canada for over six months.

127. In November 2021, after five months of continuing to suffer while awaiting a response from Health Canada, Mr. Doswell illegally accessed psilocybin and completed psilocybin-assisted psychotherapy. He found immediate relief from his anxiety symptoms through this single session. He reported no desire to drink alcohol, better sleep, and a return

to the outdoor activities that he had lost as a result of his anxiety. He felt that, while the anti-anxiety pharmaceuticals he had tried only masked his trauma, psilocybin allowed him to confront his trauma, leading to lasting positive change. Where he lost himself to anxiety, he found himself again through psilocybin.

128. On December 30th, 2021, Mr. Doswell's application for a Section 56 Exemption was ultimately approved. Had he waited for this approval to legally access the treatment he needed, Mr. Doswell would have spent nearly 7 months suffering through daily anxiety and its related impacts. His exemption will expire on December 30th, 2022, leaving him again with no legal means of accessing relief.

129. On May 12, 2022, Mr. Doswell submitted an application to access psilocybin through the SAP. As of the time of filing, almost two months after his application was submitted, Mr. Doswell has not received a decision.

130. Further, it is Mr. Doswell's reasonable medical choice to use Natural Psilocybin Mushrooms, rather than Synthetic Tryptamines. If granted access through the SAP, Mr. Doswell will still not be able to access his reasonably preferred medical treatment.

131. Mr. Doswell is not aware of any clinical trials that would grant him access to treatment. Further, he is uncomfortable with the idea of his condition being studied. It is therefore Mr. Doswell's reasonable medical choice not to access psilocybin through clinical trials.

132. As a result of the flaws in the available avenues to access psilocybin, Mr. Doswell now stands in a position of uncertainty. For the moment, he has access to the substance he needs through his Section 56 Exemption. However, he is acutely aware that his legal access to the care he needs may terminate with his Section 56 Exemption. He may again be left with no means of relief from his suffering.

iv. Bruce Tobin

133. Bruce Tobin has suffered from anxiety and depression since childhood. In September 2020, at the age of 72, Dr. Tobin received a severe cancer diagnosis which exacerbated his anxiety and depression. He underwent a radical procedure and is now believed to be cancer-free. However, his elevated anxiety and depression have not subsided. Dr. Tobin continues to suffer daily with existential distress, anxiety about the possibility of a cancer recurrence, and fear that he may one day lose his basic physical abilities.

134. Dr. Tobin holds a PhD in psychology and is a registered Clinical Counsellor in British Columbia. He has intensively studied the clinical research literature on the therapeutic use of psilocybin for fifteen years. He is knowledgeable on its efficacy in the treatment of anxiety and depression.

135. On December 1, 2020, Dr. Tobin obtained a Section 56 Exemption to use psilocybin as a healthcare practitioner for the purposes of training in the administration of psilocybin-assisted psychotherapy. He underwent his first session in November 2021.

136. While intended to provide professional development, which it did, Dr. Tobin also experienced intense personal relief from his anxiety and depression through this initial session. He reported that his excessive anxiety and depression, both chronic and related to his cancer diagnosis, virtually disappeared. His quality of life and personal relationships drastically improved. He felt he regained much of the life he had lost to anxiety and depression.

137. However, after eight months, Dr. Tobin began to feel the effects of his psilocybin session waning. Dr. Tobin's exemption expired in December 2021. He submitted another application for a Section 56 Exemption on July 7, 2022, this time for personal therapeutic use rather than training. Based on his prior experience with Section 56 Exemptions, however, he anticipates he will face a significant delay before he receives a response.

138. Until this exemption is approved, Dr. Tobin has no legal means of access to treatment.

139. Dr. Tobin has looked for clinical trials that would grant him access to psilocybin-assisted psychotherapy. There are currently no trials available for him to join. Like other patients, he does not have the luxury of waiting for a trial to become available, as his symptoms impact him on a daily basis.

140. Further, it is Dr. Tobin's reasonable medical choice to use Natural Psilocybin Mushrooms, rather than Synthetic Tryptamines. As the SAP only practically provides patients with access to Synthetic Tryptamines, Dr. Tobin cannot access his preferred treatment through the SAP.

141. Put together, this system has left Dr. Tobin without care. Until such time as his Section 56 Exemption is approved, Dr. Tobin is left with no legal means to access the treatment he needs to relieve his anxiety and depression. He will continue to suffer daily until an approval is obtained, if ever that day comes.

v. Shannon McKenney

142. Shannon McKenney suffers chronic pain related to repeated bouts of sepsis. She has survived sepsis a total of four times between April 2011 and July 2019, resulting in adhesions, gastroparesis, and chronic pain.

143. Ms. McKenney also suffers from chronic and intractable migraines. At present, she is suffering with a severe and long-lasting intractable migraine which commenced on July 19, 2018. As of the time of filing, Ms. McKenney is on her 1,467th straight day of suffering from this intractable migraine.

144. Together, Ms. McKenney's conditions cause her intense daily pain and suffering. The consistent and unrelenting pain have led her at times to thoughts of suicide to escape the pain.

145. She has found no relief through prescription pharmaceuticals. Ms. McKenney has tried several prescription pharmaceuticals, including OxyContin, morphine, fentanyl, Tylenol-Codeine No.3, Butrans, abortive migraine medications, and occipital nerve and sphenopalatine ganglion nerve blockers. She has also tried naturopathic and homeopathic remedies, topical creams, and Cognitive Behavioural Therapy. Nothing has provided her with more than twenty minutes of relief. Ms. McKenney suffers immense pain on a daily basis with the treatment options currently available to her.

146. Ms. McKenney began researching alternative treatments and learned that psilocybin-assisted psychotherapy had the potential to alleviate her suffering. Ms. McKenney is Indigenous and sees Natural Psilocybin Mushrooms as an important natural means of healing consistent with her cultural and spiritual beliefs.

147. Ms. McKenney contacted TheraPsil for assistance in gaining legal access to psilocybin through a Section 56 Exemption on September 1, 2021. Ms. McKenney does not feel equipped to properly apply for a Section 56 Exemption on her own, and requires assistance to navigate the process. Unfortunately, due to the volume of applications TheraPsil receives and the lack of trained practitioners, they were not able to assist her at that time.

148. Ms. McKenney then contacted Numinus to see if they might assist her in accessing psilocybin-assisted psychotherapy. However, Numinus informed her that their assistance would cost $4,700. Ms. McKenney relies on disability assistance and her husband's modest income. She could not afford Numinus' fees.

149. Ms. McKenney conducted further searches for another organization to assist her in legally accessing psilocybin. She found this process draining, which was particularly difficult given her medical conditions. Ultimately, she did not find the assistance she sought. She could not apply for a Section 56 Exemption.

150. On February 17, 2022, Ms. McKenney asked her family doctor if he would assist her in accessing psilocybin-assisted psychotherapy through the SAP. While supportive of her use, Ms. McKenney's doctor did not have sufficient knowledge to complete the SAP application or properly conduct the therapy. He did not have anyone he could refer Ms. McKenney to that could assist her in accessing psilocybin through the SAP.

151. TheraPsil assisted Ms. McKenney in submitting a section 56 application on July 10, 2022. However, Ms. McKenney has a reasonably held belief that this application and any application through the SAP is unlikely to receive approval. Health Canada has recently indicated that it will not grant Section 56 Exemptions or SAP exemptions to patients with cluster headaches as Health Canada believes there is inadequate evidence to support the use of psilocybin for cluster headaches. While her condition varies slightly, she believes the same outcome is likely for any application she submits.

152. Ms. McKenney further considered clinical trials, but is not aware of any clinical trials that would grant her access to treatment. Like other patients, Ms. McKenney does not have the luxury of time and cannot wait for a new clinical trial to accept her which fits her particular needs.

153. Ms. McKenney has been left with no options for legal access to psilocybin. As a result, she continues to suffer every day in immense pain from her conditions.

vi. Katherine Marykuca

154. Katherine Marykuca has struggled with symptoms of depression from around the age of nine. She was formally diagnosed with Major Depressive Disorder between 1998 and 2000. Her condition has subsequently been diagnosed as treatment-resistant and chronic, at times being labelled as dysthymia. In relation to her condition, Ms. Marykuca has suffered from suicidal ideation.

155. Eventually, Ms. Marykuca's condition made it impossible for her to work. Ms. Marykuca left the workforce because of her condition, and now relies on disability assistance for income.

156. In the ten years following her initial diagnosis, Ms. Marykuca tried an estimated twenty pharmaceuticals available through prescription. None provided effective or long-term relief from her symptoms. More often, they left Ms. Marykuca feeling fatigued, dulled, anxious, irritable, and still depressed.

157. She has further undergone regular individual and group therapy sessions. While they provided her with some coping mechanisms, they did nothing to alleviate the suffering she experiences as a result of her disorder. Ms. Marykuca has also undergone electroconvulsive therapy and has explored naturopathic and homeopathic remedies. Nothing has effectively alleviated the symptoms of her depression.

158. On June 15, 2021, Ms. Marykuca contacted TheraPsil for assistance in legally accessing psilocybin-assisted psychotherapy. She learned about Section 56 Exemptions. Unfortunately, due to the volume of applications received by TheraPsil and the scarcity of trained practitioners, TheraPsil informed Ms. Marykuca that they could not assist her in completing an application. She did not feel equipped to complete an application without assistance and did not know where else to turn for help. Ms. Marykuca therefore did not have practical access to an exemption, and she continued to suffer.

159. Ms. Marykuca spoke to a psychiatrist, family doctor, psychiatric nurse, and counsellor about psilocybin therapy. While all were supportive of the pursuit, none had the knowledge or training to assist her. Accessing psilocybin through the SAP therefore was not an option to Ms. Marykuca. Again, she continued to suffer.

160. It is Ms. Marykuca's reasonable medical choice not to seek access to psilocybin through clinical trials. She believes patients should not have to seek treatment through clinical trials. It concerns her that clinical trials are not designed for the patient's treatment,

but rather focused on other objectives. She does not find this to be an ethical means of providing treatment. She is also aware that some subjects in a clinical trial often receive a placebo dose. The stress and strain of this process would aggravate her health issues. She does not believe clinical trials to be a reasonable means of treating her condition.

161. Without the help of an organization like TheraPsil to assist her in accessing a Section 56 Exemption, or a knowledgeable medical professional to assist her in applying through the SAP, Ms. Marykuca is left with no relief from her symptoms. She suffers from a life-threatening condition daily because of this lack of access to psilocybin.

vii. Jesse Merks

162. At the age of 18, Jesse Merks tore a ligament in his knee and shattered his ankle. He was prescribed opioids to manage the pain. His opioid use transitioned from prescription opioids to heroin and eventually fentanyl. Mr. Merks became dependent on opioids, resulting in him becoming homeless in Vancouver's Downtown Eastside.

163. Mr. Merks desperately wanted to recover from his substance use disorder. He tried every avenue available to him for recovery. He tried a number of physician-prescribed opiate agonist therapies. He attended detox programs an estimated thirty times. He attended six in-patient treatment centre programs, and has seen a number of substance use counsellors. Despite these efforts and Mr. Merks' fervent desire to recover, he continued to relapse. He continued to be dependent on a substance that threatened his life with each use.

164. In 2018, Mr. Merks began familiarizing himself with the potential of psilocybin to aid in recovery from substance use disorders. Not knowing how to legally access psilocybin, Mr. Merks turned to illegal sources. He began micro-dosing psilocybin every three days and saw immediate results. The frequency of his relapses significantly decreased, he had less anxiety about his disorder, and overall felt improvement to his mental health.

165. With the help of TheraPsil, Mr. Merks submitted an application for a Section 56 Exemption to legally access psilocybin for the purposes of psilocybin-assisted psychotherapy on June 9, 2021. He did not receive a decision for ten months.

166. Tired of waiting and in imminent threat of death from his disorder, Mr. Merks turned again to illegal supplies of psilocybin in December 2021. This time, he ingested a larger dose, and underwent psilocybin-assisted psychotherapy with the assistance of two therapists.

167. His results were immediate and astounding. Mr. Merks has not relapsed since that session. He found gainful employment and has worked seven days a week since January 2022. He reports that his entire perspective shifted through that session, and he has regained the life he lost to his substance use disorder.

168. Four months later, on April 26, 2022, Mr. Merks received a rejection from Health Canada to his section 56 application. Without illegally accessing treatment, Mr. Merks would have spent ten months at risk of a fatal overdose, only to be further denied treatment.

169. As of the time of filing, Mr. Merks has no legal means of accessing treatment to assist in his recovery.

170. Having found relief by illegally accessing psilocybin, Mr. Merks has not attempted to access psilocybin through the SAP or through clinical trials.

171. The Canadian medical system failed Mr. Merks in many ways. Providing reasonable and timely legal access to psilocybin is one of those failures. Mr. Merk's resort to illegally accessing psilocybin does not right that wrong.

viii. <u>The HCP Plaintiff</u>

172. Jane Harrison is a registered social worker and psychotherapist practicing in Toronto, Ontario. She has extensively researched the benefits of psilocybin therapy and

has developed a deep understanding of the benefits it can provide to patients. Ms. Harrison is also Indigenous and sees Natural Psilocybin Mushrooms as an important natural means of healing consistent with her cultural and spiritual beliefs. She is therefore a proponent of psilocybin-assisted psychotherapy.

173. Ms. Harrison believes that it is important that she be properly trained in order to administer psilocybin-assisted psychotherapy. Ms. Harrison has completed the vast majority of a training program offered through TheraPsil, designed to train health care practitioners in the administration of psilocybin-assisted psychotherapy. However, part of that training requires Ms. Harrison to have access to psilocybin and to undergo psilocybin treatment, which would allow her to experience what her future patients will experience. She considers this portion of the training to be critical if she hopes to administer psilocybin-assisted psychotherapy safely and effectively.

174. With the assistance of TheraPsil, on July 1, 2021, Ms. Harrison applied for a Section 56 Exemption to consume psilocybin for the purpose of training. She received a notice of intent to refuse on January 31, 2022. She sent a personal letter to the Minister pleading her case and a lawyer's letter in support on February 9, 2022. She received her final refusal dated June 9, 2022. She is seeking a judicial review of that decision with a lawyer provided by TheraPsil.

175. With no other means of applying for access to psilocybin, Ms. Harrison cannot currently complete her training, and therefore cannot assist patients in need.

III. THE CONSTITUTIONAL VIOLATIONS ALLEGED – SECTION 7

176. The Plaintiffs plead and rely on sections 1, 7, 24(1) and 52(1) of the *Charter*. The Patient Plaintiffs claim that the Prohibitions to the medical use of psilocybin, and the cultivation of Natural Psilocybin Mushrooms for that purpose, under the *CDSA*, *FDA* and *FDR* violate section 7 of the *Charter*. The Patient Plaintiffs further claim that they are

entitled to constitutionally viable access to psilocybin, as is the HCP Plaintiff. The Flawed Exemptions/Authorizations do not provide constitutionally viable access to psilocybin.

177. The Prohibitions prohibit patients from accessing a safe and effective treatment that is needed to alleviate serious conditions which cause daily suffering and, in some cases, pose a risk of death. This infringes the rights of the Patient Plaintiffs and all Medically Approved Patients to 'life' under section 7 of the *Charter*.

178. The Prohibitions also place the Patient Plaintiffs, and all Medically Approved Patients, in a position to choose between their liberty and their health. They prohibit patients from making reasonable medical choices without threat of criminal prosecution. This infringes the rights of the Patient Plaintiffs and all Medically Approved Patients to 'liberty' under section 7 of the *Charter*.

179. The Prohibitions further interfere with patients' bodily integrity and have profound effects on patients' physical and mental health. They result in serious, state-imposed psychological stress. This infringes the rights of the Patient Plaintiffs and all Medically Approved Patients to 'security of the person' under section 7 of the *Charter*.

180. As a result of these impacts and others not enumerated herein, the Prohibitions infringe the rights of the Patient Plaintiffs, and Medically Approved Patients, to life, liberty, and security of the person pursuant to section 7 of the *Charter*. This interference is not in accordance with the principles of fundamental justice. In particular, the Prohibitions are arbitrary, overbroad, and grossly disproportionate to their purpose. This infringement is not saved by section 1 of the *Charter*.

181. The Flawed Exemptions/Authorizations do not provide sufficient access to psilocybin to rectify this infringement. None of the Flawed Exemptions/Authorizations are intended for ongoing, patient-centred care. Access to the Flawed Exemptions/Authorizations is discretionary and limited, excluding certain Plaintiff Patients and Medically Approved Patients from treatment. Further, the Flawed

Exemptions/Authorizations are burdensome and inaccessible for the vast majority of patients, and are accompanied by delays which prolong patient suffering. Together, these Flawed Exemptions/Authorizations do not provide reasonable access to psilocybin. They do not restore the rights of the Patient Plaintiffs and Medically Approved Patients to life, liberty, and security of the person under section 7 of the *Charter*. They do not provide constitutionally viable access to psilocybin.

182. The Flawed Exemptions/Authorizations further infringe the Plaintiffs' right to privacy protected under section 7 of the *Charter.* The Flawed Exemptions require the Plaintiffs to provide the Government with intensely personal information about their health, lifestyle, and personal choices, over which the Plaintiffs have a reasonable expectation of privacy. The confidentiality of this information is crucial to a therapeutic and trusting relationship between the Plaintiffs and their health care providers. By compelling the Plaintiffs to provide such information in order to access the care they require, the Flawed Exemptions constitute unreasonable intrusions into patient privacy and a contravention of section 7. This infringement of section 7 is not saved by section 1 of the *Charter.*

THE RELIEF SOUGHT

183. The Plaintiffs therefore claim as follows:

Declarations

a. A Declaration pursuant to subsection 52(1) of the *Charter*, that, with respect to psilocybin and psilocin to be used for medical purposes, sections 4, 5, and 7 of the *CDSA* are inconsistent with section 7 of the *Charter*, are not saved by section 1 of the *Charter,* and are therefore of no force and effect.

b. A Declaration pursuant to subsection 52(1) of the *Charter* that Part C of the *FDR*, section J.01.014 of Part J of the *FDR*, and such other sections in the *FDA*, the *CDSA* and the *FDR* that prohibit possessing, producing, assembling, providing, transporting,

sending, delivering, growing or selling psilocybin or psilocin intended to be used for medical purposes are inconsistent with section 7 of the *Charter*, are not saved by section 1 of the *Charter*, and are therefore of no force and effect.

c. A Declaration pursuant to subsection 52(1) of the *Charter* that the following exemptions and authorizations do not provide constitutionally viable access to psilocybin and psilocin for persons needing access to psilocybin and psilocin for medical purposes, and therefore do not rectify the infringement of their rights under section 7 of the *Charter* caused by the Prohibitions:

    a. Exemptions granted pursuant to subsection 56(1) of the *CDSA*;

    b. Authorizations provided through the SAP, pursuant to subsection C.08.010(1) of the *FDR*; and

    c. Access provided to subjects of clinical trials pursuant to Part C, Division 5 and Part J of the *FDR*, and subsection 56(1) of the *CDSA.*

Subsection 24(1) Order for Patients

d. An Order pursuant to subsection 24(1) of the *Charter* in the nature of a permanent constitutional exemption from sections 4 and 7 of the *CDSA* and such other sections in the *FDA*, *CDSA* and *FDR* that prohibit possessing psilocybin or psilocin, or growing Natural Psilocybin Mushrooms, for the Patient Plaintiffs and all Medically Approved Patients.

Subsection 24(1) Order for Health Care Professionals

e. An Order pursuant to subsection 24(1) of the *Charter* in the nature of a permanent constitutional exemption, from sections 4 and 7 of the *CDSA* and such other sections in the *FDA*, *CDSA* and *FDR* that prohibit possessing psilocybin or psilocin, or growing Natural Psilocybin Mushrooms, for the HCP Plaintiff and all health care professionals who require access to psilocybin or psilocin to be adequately trained in the administration of psilocybin-assisted psychotherapy.

Subsection 24(1) Order for Individual Growers of Natural Psilocybin Mushrooms Supplying Patients or Health Care Professionals

f. An Order pursuant to subsection 24(1) of the *Charter* in the nature of a permanent constitutional exemption, from sections 4, 5 and 7 of the *CDSA*, Part C of the *FDR*, section J.01.014 of Part J of the *FDR*, and such other sections in the *FDA*, *CDSA* and *FDR* that prohibit individuals from possessing, producing for, assembling, providing, transporting, sending, delivering, growing and selling Natural Psilocybin Mushrooms to, or on behalf of, the Patient Plaintiffs and Medically Approved Patients for use for medical purposes, having been designated by the Patient Plaintiffs and the Medically Approved Patients (such individuals being the "**Designated Persons**").

g. An Order pursuant to subsection 24(1) of the *Charter* in the nature of a permanent constitutional exemption, from sections 4, 5 and 7 of the *CDSA*, Part C of the *FDR*, section J.01.014 of Part J of the *FDR*, and such other sections in the *FDA*, *CDSA* and *FDR* that prohibit Designated Persons from possessing, producing, assembling, providing, transporting, sending, delivering and growing Natural Psilocybin Mushrooms to, or on behalf of, the HCP Plaintiff and to other health care professionals who require access to psilocybin or psilocin to be adequately trained in the administration of psilocybin-assisted psychotherapy.

Subsection 24(1) Order for Licensed Dealers Growing Natural Psilocybin Mushrooms for Patients or Health Care Professionals

h. An Order pursuant to subsection 24(1) of the *Charter* in the nature of a permanent constitutional exemption, from sections 4, 5 and 7 of the *CDSA*, Part C of the *FDR*, and such other sections in the *FDA*, *CDSA* and *FDR* that prohibit licensed dealers authorized to grow Natural Psilocybin Mushrooms from selling a substance without a drug identification number, namely, Natural Psilocybin Mushrooms, to the Patient Plaintiffs and Medically Approved Patients.

i. An Order pursuant to subsection 24(1) of the *Charter* in the nature of a permanent constitutional exemption, from sections 4, 5 and 7 of the *CDSA*, Part C of the *FDR*, and such other sections in the *FDA*, *CDSA* and *FDR* that prohibit licensed dealers authorized to grow Natural Psilocybin Mushrooms from selling a substance without a drug identification number, namely, Natural Psilocybin Mushrooms, to the HCP Plaintiff and other health care professionals that require access to psilocybin and psilocin in order to be adequately trained in the administration of psilocybin-assisted psychotherapy.

Subsection 24(1) Order for Licensed Dealers of Synthetic Tryptamines Supplying Patients or Health Care Professionals

j. An Order pursuant to subsection 24(1) of the *Charter* in the nature of a permanent constitutional exemption, from sections 4, 5 and 7 of the *CDSA*, Part C of the *FDR*, and such other sections in the *FDA*, *CDSA* and *FDR* that prohibit licensed dealers authorized to manufacture Synthetic Tryptamines from selling a substance without a drug identification number, namely, Synthetic Tryptamines, to the Patient Plaintiffs and Medically Approved Patients.

k. An Order pursuant to subsection 24(1) of the *Charter* in the nature of a permanent constitutional exemption, from sections 4, 5 and 7 of the *CDSA*, Part C of the *FDR*, and such other sections in the *FDA*, *CDSA* and *FDR* that prohibit licensed dealers authorized to manufacture Synthetic Tryptamines from selling a substance without a drug identification number, namely, Synthetic Tryptamines, to the HCP Plaintiff and other health care professionals that require access to psilocybin and psilocin in order to be adequately trained in the administration of psilocybin-assisted psychotherapy.

Costs and Other Remedies

l. Costs, including special costs, and the Harmonized Sales Tax on those costs, is appropriate; and

m. Such further and other relief as this Honourable Court deems appropriate and just in all the circumstances.

The Plaintiffs propose this action be tried as a Simplified Action in the City of Toronto, in the Province of Ontario.

DATED at Toronto, Ontario, this 27th day of July, 2022.

Per: 

Counsel to the Plaintiffs:

Paul Lewin
Lewin & Sagara LLP
Barrister & Solicitor
2175 Danforth Avenue
Toronto, ON M4C 1K4
Tel: (416) 499-7945 ext. 100
Fax: 1 (877) 459-9747
Email: paullewin@bellnet.ca
Solicitor#: 34348C

Nicholas Pope
Hameed Law
Barrister & Solicitor
43 Florence Street
Ottawa, ON K2P 0W6
Tel. # (613) 656-6917
Fax # (613) 232-2680
Email: npope@hameedlaw.ca

Emily Amirkhani
Barrister & Solicitor
855 2nd Street SW, Suite 3500
Calgary, AB T2P4J8
Tel:403-260-9716
Email: emily.amirkhani@blakes.com

David Wood, PhD.
R-Group Legal
Barrister & Solicitor
7777 10 St NE #102
Calgary, AB T2E 8X2
Tel. 403-463-5091
Email: david@rgrouplegal.com

Jack Lloyd
Barrister & Solicitor
43 Front Street East, Suite 400
Toronto, ON M5E1B3
Tel. 647-235-3972
Fax: 416-352-5524
Email: jacklloydman@gmail.com