Court File No. T-1560-22

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

HIS MAJESTY THE KING

Defendant

NOTICE OF CONSTITUTIONAL QUESTION

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1. The Plaintiffs intend to question the constitutional validity of sections 4, 5, and 7 of the *Controlled Drugs and Substances Act*, S.C. 1996, c. 19 (the "***CDSA***"), Part C of the *Food and Drug Regulations*, C.R.C., c. 870 (the "***FDR***"), section J.01.014 of Part J of the *FDR*, and such other sections in the *Food and Drugs Act*, R.S.C. 1985, c. F-27 (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 (collectively, the "**Prohibitions**").

2. The Plaintiffs also intend to question the constitutional validity of the currently available exemptions and authorizations for medical access to psilocybin and psilocin as they do not provide constitutionally viable access for those facing serious health issues. The following

exemptions and authorizations, viewed together with the *CDSA*, contravene the Plaintiffs' section 7 rights under 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***"):

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

b) Authorizations provided through the Special Access Program (the "**SAP**") under 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*

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

3. The question is to be argued on a date to be scheduled at Toronto, Ontario.

4. The Plaintiffs intend to seek declarations of invalidity pursuant to sections 52(1) of the *Charter*.

5. The Plaintiffs intend to seek orders pursuant to 24(1) of the *Charter* as follows:

Subsection 24(1) Order for Patients

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 mushrooms that contain psilocybin and psilocin ("**Natural Psilocybin Mushrooms**"), for Thomas Hartle, Janis Hughes, James Doswell, Bruce Tobin, Shannon McKenney, Katherine Marykuca and Jesse Merks (the "**Patient Plaintiffs**") and all other persons approved by a medical practitioner to use psilocybin or psilocin for medical purposes ("**Medically Approved Patients**").

Subsection 24(1) Order for Health Care Professionals

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 Jane Harrison (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

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**").

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

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.

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

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 psilocybin or psilocin (synthetic psilocybin or psilocin, alone or in combination, being the "**Synthetic Tryptamines**") from selling a substance without a drug identification number, namely, Synthetic Tryptamines, to the Patient Plaintiffs and Medically Approved Patients.

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.

The following are the material facts giving rise to the constitutional question:

I. OVERVIEW

6. The Patient Plaintiffs are all ordinarily resident in Canada. They have serious health issues for which psilocybin is a reasonable treatment. Despite this, they have encountered numerous obstacles trying to access psilocybin for medical use. In some cases, these obstacles have driven certain of the Patient Plaintiffs to procure psilocybin illegally. In all cases, these obstacles have had a negative effect on their health, prolonged their suffering, and, for some, increased their risk of death. The Patient Plaintiffs are not getting reasonable access to psilocybin for medical use. The Prohibitions combined with the Flawed Exemptions / Authorizations contravene their rights under section 7 of the *Charter*.

7. The HCP Plaintiff, Jane Harrison, is ordinarily resident in Canada. She is a health care professional who requires access to psilocybin and psilocin for the purpose of properly training to administer psilocybin-assisted psychotherapy. Training with psilocybin and psilocin is necessary for safety and efficacy reasons. Ms. Harrison, and other health care professionals, do not have reasonable access to psilocybin and psilocin for training purposes. Ms. Harrison's inability to readily access psilocybin and psilocin for training purposes prohibits her from becoming properly trained to effectively administer psilocybin-assisted psychotherapy. This interferes with her right to liberty under section 7 of the *Charter*. Consequently, without adequately trained healthcare professionals, the

Patient Plaintiffs cannot receive the standard of care necessary to treat their conditions. Ms. Harrison's lack of access to psilocybin for training purposes therefore also contravenes the Patient Plaintiffs' rights under section 7 of the *Charter*.

II. BACKGROUND

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

8. Psilocybin and psilocin are naturally-occurring tryptamines found in certain species of fungi. 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 Tryptamines.

9. 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.

10. 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.

11. 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

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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

19. 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*.

20. 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.

21. 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 of Health, institutions for research purposes, or to a physician for administration to a patient pursuant to an authorization issued through 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

22. Under Canadian law, the Flawed Exemptions / Authorizations are currently the only three ways to legally access psilocybin for medical purposes.

23. 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 psilocin, 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*.

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

i. Section 56 Exemptions

25. 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.

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

27. 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. Finally, the Section 56 Exemption process does not provide a safe means of accessing psilocybin. To the Plaintiffs' 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 Plaintiffs' 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.

ii. Authorizations Under the SAP

34. 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.

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

40. 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.

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

42. 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.

43. 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.

44. 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.

45. 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.

46. 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.

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

48. 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.

iii. Clinical Trials

49. 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.

50. 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.

51. 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.

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

53. 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.

54. 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.

55. 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.

56. 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.

E. Training of Health Care Professionals

57. 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.

58. 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.

59. 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.

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

61. 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.

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

62. 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.

63. 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.

64. 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.

65. 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.

66. 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.

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

67. 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.

68. 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.

69. 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.

70. 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.

71. Each option has its own benefits, and each is necessary for a system that provides constitutionally viable access to psilocybin for medical purposes.

H. Experiences of the Plaintiffs

72. The experiences of the Plaintiffs are set out in paragraphs 93-175 of the Statement of Claim.

The following is the legal basis for the constitutional question:

73. The Prohibitions and the Flawed Exemptions / Authorizations violate the rights of the Patient Plaintiffs and all Medically Approved Patients to life, liberty, and security of the person under section 7 of the *Charter*. These violations are not in accordance with the principles of fundamental justice and are not saved by section 1 of the *Charter*.

74. The Prohibitions and the Flawed Exemptions / Authorizations also violate the rights of the HCP Plaintiff and all healthcare professionals to liberty under section 7 of the *Charter.* This violation is not in accordance with the principles of fundamental justice and is not saved by section 1 of the *Charter*.

75. An arbitrary, overbroad or grossly disproportionate effect on one person is sufficient to establish a breach of section 7.[1]

iv. The Life Interest

76. The right to life under section 7 is engaged where the law imposes an increased risk of death, either directly or indirectly.[2]

[1] *Bedford v. Canada*, [2013] 3 SCR 1101 [“***Bedford***”] at para 123.

[2] *Carter v Canada (Attorney General)*, 2015 SCC 5 [“***Carter***”] at para 62.

77. The Patient Plaintiffs, and all Medically Approved Patients, have a right to life under section 7 of the *Charter*. For those requiring access to psilocybin for potentially fatal conditions, like depression, chronic pain and opioid dependence, a lack of reasonable access to psilocybin for therapeutic use imposes an increased risk of death. Given that the Flawed Exemptions / Authorizations do not provide timely or guaranteed access, the Prohibitions impose an increased risk of death, engaging the rights of the Patient Plaintiffs to life under section 7 of the *Charter*.

v. The Liberty Interests – Incarceration

78. An individual's liberty interest is engaged under section 7 wherever the impugned provision provides a threat of incarceration.[3]

79. Each of the Patient Plaintiffs, and all Medically Approved Patients, risk criminal prosecution if they seek access to psilocybin for treatment without access under one of the Flawed Exemptions / Authorizations. Given the barriers to access under the Flawed Exemptions / Authorizations, in order to practically gain consistent and timely access to treatment, the Plaintiff Patients must put themselves at risk of incarceration. This threat of incarceration engages the right of the Patient Plaintiffs to liberty under section 7 of the *Charter*.

vi. The Liberty Interests – Reasonable Medical Choices

80. The right to liberty under section 7 protects the right to make fundamental personal choices free from state interference.[4] This includes the personal autonomy to make inherently

[3] *R v Smith*, 2015 SCC 34 ["***Smith***"] at para 17.

[4] *Carter*, *supra* note 2 at para 64.

private choices,[5] including reasonable medical choices without threat of criminal prosecution.[6] Where state prohibitions affect such choices, section 7 is engaged.

81. This concept that adults should be entitled to direct the course of their own medical care is not only protected by the right to liberty under section 7. It also underlies the concept of informed consent, which ensures the freedom of individuals to make choices that accord with their own values regardless of how unwise or foolish those choices may appear to others.[7] The right of medical self-determination is not vitiated by the fact that serious risks or consequences, including death, may flow from the patient's decision.[8]

82. Using psilocybin in a therapeutic setting for the treatment of a medical condition is a reasonable medical choice. The Patient Plaintiffs and all Medically Approved Patients therefore have the right to make that choice free from threat of criminal prosecution. The Flawed Exemptions / Authorizations do not provide reasonable or timely access to psilocybin for this purpose. Without reasonable access to psilocybin, the Patient Plaintiffs and Medically Approved Patients are placed in a position to choose between the medical care they require, and the consequences of breaching the Prohibitions pertaining to psilocybin, including incarceration. They are therefore unable to make reasonable medical choices without fear of criminal prosecution, and their right to liberty under section 7 is engaged.

vii. <u>The Liberty Interests – Growing and Selling</u>

83. As stated above, an individual's liberty interest is engaged under section 7 wherever the impugned provision provides a threat of incarceration.[9] The liberty interests of growers and sellers are therefore engaged by the Prohibitions related to growing and selling psilocybin.

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[5] *Godbout v Longueuil (City)*, [1997] 3 SCR 844 at para 66.

[6] *Smith, supra* note 3, at para 18.

[7] *Carter, supra* note 2, at para 67; *Malette v. Shulman* (1990), 67 D.L.R. (4th) 321 (Ont.C.A.) at para 19.

[8] *Carter, supra* note 2, at para 67.

[9] *Smith, supra* note 3, at para 17.

By acting compassionately, growers and sellers of Natural Psilocybin Mushrooms for Medically Approved Patients are exposed to the threat of imprisonment on conviction. This engages their right to liberty under section 7.[10]

84. The Prohibitions pertaining to growing psilocybin also engage the liberty interests of the Patient Plaintiffs and Medically Approved Patients, as they could face incarceration if they produce or possess psilocybin for their own therapeutic use.[11]

viii. <u>The Liberty Interests – Right to Privacy</u>

85. It is generally understood that section 7 includes a right to privacy. That includes a right to control the dissemination of confidential information.[12] The section 7 liberty interest is rooted in the fundamental concepts of privacy, human dignity, personal autonomy, and choice in decisions going to the individual's fundamental being.[13] Failure to respect individual privacy undeniably impinges upon an individual's liberty in our free and democratic society.[14]

86. The Flawed Exemptions / Authorizations engage the Plaintiffs' right to privacy protected under section 7 of the *Charter*. The Flawed Exemptions / Authorizations 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 healthcare professionals. By compelling the Plaintiffs to provide such information in order to access the care they require, or in the case of a healthcare professional to obtain the training needed, the Flawed

[10] *Ibid.*

[11] *Ibid.*

[12] *R v Mills*, [1999] 3 SCR 668 at paras. 79-80.

[13] *B.(R.) v Children's Aid Society of Metropolitan Toronto*, [1995] 1 SCR 315 at para. 80.

[14] *R v O'Connor* (1995), 130 DLR (4th) 235 at 114.

Exemptions / Authorizations constitute unreasonable intrusions into patient privacy and engage the liberty interest under section 7.

ix. The Liberty Interests – Healthcare Professionals

87. As stated above, an individual's liberty interest is engaged under section 7 wherever the impugned provision provides a threat of incarceration.[15] The Prohibitions put healthcare professionals at risk of incarceration in order to obtain and consume the substances necessary to properly train for their chosen profession. This engages the HCP Plaintiff's, and all healthcare professionals', right to liberty under section 7 of the *Charter*.

88. The HCP Plaintiff also has standing to bring this claim as her actions in support of the Patient Plaintiffs and other Medically Approved Patients would place her in a position to face criminal prosecution. Accused persons have standing to challenge the constitutionality of the law they are charged under, even if the alleged unconstitutional effects are not directed at them.[16] This same principle must extend to those at risk of prosecution, but not yet charged.

x. The Security of the Person Interests

89. The right to security of the person under section 7 of the *Charter* includes a person's right to control their own bodily integrity. It is engaged where the state interferes with personal autonomy and a person's ability to control their own physical or psychological integrity.[17] Where a criminal prohibition forces a person to choose between a legal but inadequate treatment and an illegal but more effective choice, the law will infringe security of the person.[18]

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[15] *Smith, supra* note 3, at para. 17.

[16] *Ibid*, at para 12.

[17] *Carter, supra* note 2 at 64; *R v Morgentaler*, [1988] 1 SCR 30 at page 56.

[18] *Smith, supra* note 3, at para 18; *R v Parker* (2000), 49 OR (3d) 481 (CA) ["***Parker***"] at paras 106-107.

90. The right of the Patient Plaintiffs and Medically Approved Patients to security of the person is engaged by the Prohibitions which interfere with their right to control their own bodily integrity. The Prohibitions interfere with their right to control their own physical and psychological integrity. As the Flawed Exemptions / Authorizations fail to provide adequate access for ongoing and timely treatment, the Prohibitions place the Patient Plaintiffs and Medically Approved Patients in a position to choose between a legal but inadequate treatment and an illegal but more effective choice. Their right to security of the person is thereby engaged.

91. Security of the person is also engaged where state action has the likely effect of seriously impairing a person's physical or mental health.[19] Delays caused by the Flawed Exemptions / Authorizations seriously impair the physical and mental health of the Patient Plaintiffs and Medically Approved Patients. These patients are left with worsening mental health conditions and physical harm can arise for those who need access to psilocybin to deal with conditions that pose threat to their physical well-being, like depression, anxiety, chronic pain, and opioid dependence. The rights of the Patient Plaintiffs and Medically Approved Patients to security of the person are therefore engaged both by the Prohibitions and the failures of the Flawed Exemptions / Authorizations.

92. The right to security of the person is also engaged where the state action is not itself the cause of the psychological harm, but where the state contributes to psychological harm by prohibiting those suffering the harm from healing.[20]

93. Here, the Patient Plaintiffs and Medically Approved Patients suffer from psychological harm caused by their conditions. However, the Prohibitions are the impediment to their healing. Their right to security of the person is thereby engaged.

[19] *Parker, supra* note 18 at pars 92-97.

[20] *Kazemi Estate v Islamic Republic of Iran,* 2014 SCC 62 at para 133.

xi. Principles of Fundamental Justice - Arbitrariness

94. In all of the above circumstances, the rights of the Patient Plaintiffs and the HCP Plaintiff are infringed in a manner not in accordance with the principles of fundamental justice. In particular, the Prohibitions and the Flawed Exemptions / Authorizations are arbitrary.

95. Arbitrariness is a principle of fundamental justice. A law is arbitrary if it imposes limits on liberty or security of the person that are inconsistent with the law's objectives, have no direct connection to that law's objectives, or are unnecessary to achieve those objectives. Such a law exacts a constitutional price in terms of rights without furthering the public good that is said to be the object of the law.[21]

96. The objectives of the *CDSA*, *FDA* and *FDR* are the protection of public health and safety.

97. The Prohibitions and Flawed Exemptions / Authorizations undermine public health and safety by obstructing reasonable access to psilocybin for medical treatment by those with serious health issues. Rather than improving public health, they prevent beneficial medical treatment. Further, the Prohibitions and Flawed Exemptions / Authorizations have the effect of driving patients to the illegal market, increasing criminal activity and decreasing safety on a micro and macro scale. The Prohibitions and Flawed Exemptions / Authorizations also undermine public health and safety by preventing health care professionals from obtaining proper training, necessary for improving overall public health and safe treatment.

98. Where the criminal law intersects with medical treatment, it is a principle of fundamental justice that an administrative structure made up of unnecessary rules which result in an additional risk to the health of the person, is manifestly unfair and does not conform to the principles of fundamental justice.[22]

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[21] *Bedford*, *supra* note 1, at paras 107, 111-112, and 118-119; *Carter*, *supra* note 2, at para 83.

[22] *Parker*, *supra* note 18, at paras 116-117.

xii. Principles of Fundamental Justice – Overbreadth

99. In all of the above circumstances, the rights of the Patient Plaintiffs and the HCP Plaintiff are infringed in a manner not in accordance with the principles of fundamental justice. In particular, the Prohibitions and the Flawed Exemptions / Authorizations are, if not arbitrary, overbroad.

100. A law violates the overbreadth principle if it is rational in its effect on liberty and security of the person in some cases, but in others it overreaches in its effect and is arbitrary.[23] If it were found that there was a rational connection between the objective of the law and some, but not all, of its impacts then the Prohibitions would be overbroad.[24]

101. As stated above, the objectives of the *CDSA*, *FDA* and *FDR* are the protection of public health and safety. However, the Prohibitions therein are overbroad as they relate to the medical use of psilocybin. Rather than improving public health and safety, the Prohibitions have an adverse effect, decreasing health by prohibiting access to treatment and reducing safety by prohibiting the safe acquisition and administration of psilocybin in a therapeutic setting. The Prohibitions are therefore overbroad.

xiii. Principles of Fundamental Justice – Gross disproportionality

102. In all of the above circumstances, the rights of the Patient Plaintiffs and the HCP Plaintiff are infringed in a manner not in accordance with the principles of fundamental justice. In particular, the Prohibitions and the Flawed Exemptions / Authorizations are, if not arbitrary and/or overbroad, grossly disproportionate.

103. Gross disproportionality considers whether the law's effects on life, liberty or security of the person are so grossly disproportionate to its purposes that they cannot

[23] *Bedford*, *supra* note 1, at paras 112 - 117.

[24] *Allard v Canada*, 2016 FC 236, at para 267.

rationally be supported. Where the seriousness of the deprivation is totally out of sync with the objective of the measure, it will be found to be grossly disproportionate.[25]

104. The harms associated with the use of psilocybin for medical purposes are negligible, whereas the harms that arise from depriving individuals of psilocybin-assisted treatment are substantial. It is therefore grossly disproportionate to prohibit those with serious health issues from using psilocybin medically by threat of criminal sanction. It is out of sync with the objective of the measure, being the protection of public health and safety. The connection between the draconian impact of the law and its object is entirely outside the norms accepted in our free and democratic society.[26]

105. The infringement of the rights of the Patient Plaintiffs to life, liberty, and security of the person under section 7 of the *Charter*, and the infringement of the HCP Plaintiff's right to liberty thereunder, are not made in accordance with the fundamental principles of justice. These infringements are arbitrary, overbroad, and grossly disproportionate to their purpose.

xiv. Section 1

106. The infringements of section 7 caused by the Prohibitions and the Flawed Exemptions / Authorizations are not saved by section 1 of the *Charter*.

107. On a section 1 analysis, the Government bears the onus of proving that the limitation on the *Charter* right is reasonable and demonstrably justified in a free and democratic society. The standard of proof is a preponderance of probabilities and the Government must be rigorously held to this standard.[27] The Government must pass all stages of the section 1 analysis or the legislation fails.

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[25] *Bedford, supra* note 1 at para 120.

[26] *Ibid*.

[27] *R.* v. *Oakes*, [1986] 1 SCR 103 at paras 70-71.

108. The section 1 test is as follows:

i. The legislative objectives must be pressing and substantial to warrant overriding a constitutional right; and

ii. The means chosen to attain those objectives must be proportional to the ends, in that:

a) the limiting measures must be carefully designed or rationally connected to the legislative objective;

b) the limiting measures must impair the right as little as possible; and

c) there must be proportionality between the deleterious effects of the offending legislation and the legislative objective.[28]

109. The legislative objectives here are the protection of public health and safety.

110. The means chosen to attain the legislative objective are not proportionate to the ends. The limiting measures are not rationally connected to the legislative objective. The limiting measures do not impair the right as little as possible. There is no proportionality between the deleterious effects of the offending legislation and the legislative objective.

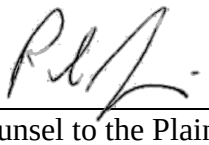
111. Section 1, in contrast to section 7, looks at whether the negative impact on the rights of individuals is proportionate to the overarching public interest, not just the law's purpose. In this case, the law must fail the section 1 test for the same reason it failed the section 7 rational connection test. If the law is not rationally connected to its objective then the limiting measures are not carefully designed or rationally connected to that objective. As

[28] *Ibid* at paras 73-74.

well, the limiting measures do not impair the right as little as possible. The law must fail the proportionality test under section 1.[29]

112. The Prohibitions and the Flawed Exemptions / Authorizations contravene the Plaintiffs' and other Canadians' rights under section 7 of the *Charter*. These contraventions are not saved by section 1.

Dated: October 13, 2022

Per: 

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[29] *Smith*, *supra* note 3, at para 29; *Bedford*, *supra* note 1, at para 125.

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