Lewin & Sagara LLP LAWYERS

June 24, 2021

BY EMAIL

The Honourable Minister, Patty Hajdu
Minister of Health
Government of Canada
Email address: Patty.Hajdu@parl.gc.ca
Email address: hcminister.ministresc@canada.ca

Dear Honourable Minister,

Re: section 56 exemption applications supported by TheraPsil

I have been retained by TheraPsil to address the applications and application process under section 56 of the *Controlled Drugs and Substances Act* S.C. 1996, c.19 ("*CDSA"*). Section 56 exemption applications supported by TheraPsil have been delayed causing harm to patients. Further, the s. 56 application process is flawed which is causing harm to patients. I have been directed to start bringing court proceedings which will include mandamus applications and, soon after, an application challenging the constitutionality of the *CDSA* (probably also the *Food and Drugs Act* R.S.C., 1985, c. F-27 and *Food and Drug Regulations* C.R.C., c. 870 ("*FDRs*")) if the s. 56 exemption applications supported by TheraPsil are not granted within 14 days and the government does not move towards reasonable regulation.

TheraPsil have been assisting Canadians with serious health issues obtain therapeutic access to psilocybin mushrooms. TheraPsil have also been helping health care practitioners obtain legal access to psilocybin mushrooms so that they may conduct psilocybin-assisted psychotherapy in a safer and more therapeutic manner. There are 10 patient applications and 29 health care practitioner applications currently under consideration. Applications have been under consideration since early February 2021.

The test under s. 56 requires that the exemption be necessary for a medical purpose. The s. 56 patient applicants have serious health issues for which they have tried all conventional medications without success. The patient applicants do not just have serious health issues, but in many cases have severe, heart-breaking health issues. The health issues largely concern treatment-resistant depression and anxiety. Some are terminally ill. One patient suffers from cluster headaches and one has addiction issues. This is all confirmed by medical doctors who state that psilocybin-assisted psychotherapy would be, for the patient, a safe and reasonable choice. There is peer-reviewed science supporting the use of psilocybin-assisted psychotherapy for these conditions. These are reasonable choices being made by patients suffering terribly. When a patient suffers from a serious treatment-resistant health issue doing nothing is not an option. The patient applicants meet the test set out in the *CDSA*.

The s. 56 health care practitioner applicants seek legal access to psilocybin mushrooms so that they may conduct psilocybin-assisted psychotherapy in a safer and more therapeutic manner. Improved

knowledge of psilocybin mushrooms permits the psychotherapist to better empathize and anticipate what the patient may be experiencing, to better inform the patient about the process, and build trust before, during and after the session. Trust between patient and psychotherapist contributes to the patient's sense of a stable and safe set and setting. For the patient, this trust is critical. Surely, it is medically necessary that psilocybin-assisted psychotherapy be conducted in a safer and more therapeutic manner. The health care practitioner applicants also meet the test set out at s. 56.

The decision to grant a s. 56 exemption must be made in a manner consistent with the *Charter of Rights and Freedoms* (the "*Charter*"). The Supreme Court of Canada has said,

> The discretion vested in the Minister of Health is not absolute: as with all exercises of discretion, the Minister's decisions must conform to the *Charter*: *Suresh v. Canada (Minister of Citizenship & Immigration)*, 2002 SCC 1, [2002] 1 S.C.R. 3 (S.C.C.). If the Minister's decision results in an application of the *CDSA* that limits the s. 7 rights of individuals in a manner that is not in accordance with *Charter*, then the Minister's discretion has been exercised unconstitutionally.[1]

Section 7 of the *Charter* protects the right to liberty and security of the person and not to be deprived thereof except in accordance with the principles of fundamental justice. Liberty protects the right to make fundamental personal choices free from state interference[2] and it entitles patients to direct the course of their own medical care.[3] Security of the person protects Canadians against criminal prohibitions that interfere with a person's choices concerning their physical and psychological integrity.[4] Security of the person is implicated, independent of a criminal sanction, by the establishment of a regulatory regime which restricts access to drugs reasonably required.[5] There is no doubt whatsoever that the *CDSA* prohibitions on possessing, selling and growing psilocybin mushrooms breach liberty and security of the person.

If a breach of liberty and security of the person is established then the analysis turns to the relevant principle of fundamental justice which, here, would be arbitrariness. 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 in order 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.[6] The objective of the *CDSA* is health and safety.[7] The safety and efficacy revealed by patient experience, doctor opinions, and peer reviewed science shows that the *CDSA's* prohibition undermines health and safety. The anachronistic prohibition not only bars access to psilocybin-assisted psychotherapy for society's most unwell, but it criminalizes the treatment such that it cannot be conducted in a safe and regulated manner. The *CDSA's* prohibition

1 *PHS Community Services Society v. Canada* 2011 SCC 44, at para. 117.
2 *Carter v. Canada (Attorney General)*, 2015 SCC 5, at para. 64.
3 *Carter, supra*, note 2, at para. 67; *Manitoba v. C. (A.)*, 2009 SCC 30, at para. 40.
4 *R. v. Smith*, [2015] 2 S.C.R. 602, at para 18; *R. v. Parker*, [2000] O.J. No. 2787 (Ont. C.A.), at paras 92-97, 106 and 110.
5 *Allard v. The Queen*, 2016 FC 236, at para. 199 (FC).
6 *Bedford v. Canada* [2013] 3 S.C.R. 1101 at paras 107, 111-112, and 118-119; *Carter, supra,* note 2, at para. 83.
7 *Smith*, *supra*, note 4, at para 24.

on psilocybin is arbitrary.

I would further note that 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.[8]

There are two big constitutional problems and they are interrelated. First, the criminal prohibitions on psilocybin mushrooms are unconstitutional absent reasonable and transparent medical regulations. Second, the exemption scheme under s. 56 does not constitute reasonable and transparent medical regulations.

Section 56 fails in many respects. There is no guidance in the legislation or anywhere else as to how it is to be interpreted. The lack of guidance means that patients and doctors are in the dark as to who may be eligible and what must be submitted to obtain the exemption. The lack of guidance also means that there is room for value-laden decisions unrelated to the health of the patient. It is unclear what conditions are eligible, what symptoms must be experienced, how many other drugs must be tried, and what types of accompanying documents are necessary for such an application. Is it necessary to provide an expert report? Is it adequate for the doctor to say it is a safe and reasonable choice? Must the doctor prove efficacy with evidence? Must the doctor be an expert? Must the patient set out where and with whom the treatment will take place? Does anything change on a renewal? Nobody knows and that cannot continue.

In addition, s. 56 provides that the Minister "may" issue an exemption. Even if the test is met the Minister can still refuse applicants for reasons unrelated to medical necessity. That is not a constitutional test. Also, recourse from a denial means a slow, expensive and uncertain judicial review to Federal Court in which a lawyer would be required. That is not practical for those of modest means and in vulnerable health.

The *FDRs'* Special Access Program (SAP) involves similar administrative discretion and similar problems have developed. Medical ethicists who have studied the SAP have found it to be value-laden in its decision making,

> …it is not clear how much data is necessary to satisfy the SAP of a drug's use, safety and efficacy. The standards against which the data are interpreted, the types of data that are considered satisfactory and the study designs that are acceptable remain unknown. The SAP is flawed because it professes to make evidence-based decisions in situations where evidence-based decision making is impossible. Data pertaining to experimental drugs that are in early stages of development or that have not been formally tested cannot meet the standards that constitute evidence.[9]

8 *Parker*, *supra*, note 4, at paras 116-117.
9 Christie, Timothy K.S., Harris, Marianne, Montaner, Julio S.G. "Special Access Denied: A Case Study of Health Canada's Special Access Program." *Healthcare Policy* Vol. 2, No. 2, 2006, at p. 30.

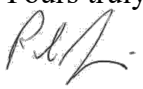
> Our allegiance to evidence-based treatment should not be used as an excuse to justify excluding groups of patients from accessing treatment simply because research has not been done on them. A common mistake when assessing evidence is to assume that 'no evidence of effect' is equal to evidence of no effect. However, as Hartung et al. argued in 1983, the absence of evidence is not evidence of absence". In the absence of evidence, a value judgment has to be made about whether to grant or deny access to treatment. Simply put when decisions cannot be based on evidence, they must be based on values.[10]

The decision whether to use psilocybin mushrooms for medicinal purposes should be the patient's decision made in consultation with the patient's doctor. The decision is a medical decision, not an administrative one. The considerations should be the health of the patient and the risks that the patient is prepared to assume. The solution is a system in which the patient, in consultation with their doctor, makes the decision. The patient would sign a document confirming their health issues and acknowledging that they are assuming the risks. The doctor would sign a document confirming the health issues and indicating that psilocybin mushrooms are a safe and reasonable choice for this patient.

Our request that the patient applications be granted within 14 days may sound aggressive. It is not intended to be. TheraPsil would prefer to work with the government, but these patients are suffering. The delays are negatively impacting their health. The patients have agreed to assume the risks, they are struggling with serious treatment-resistant health issues, and their doctor confirms it is a safe and reasonable choice. That should be enough.

Our request that the government move towards reasonable and transparent medical regulations is necessary. It is reasonable and compassionate to the patients who are suffering. It respects the principle of autonomy as articulated through the doctrine of informed consent. It provides all stakeholders with clarity. It reduces the regulatory burden on the government. It is *Charter* compliant. And, it is the right thing to do. If we brought a constitutional challenge that is what the court would order the government to do. It is TheraPsil's hope we can skip the court challenge and move directly to reasonable regulation. The status quo cannot continue.

Yours truly,



Paul Lewin

cc client

10 Christie, Timothy, Jiwani, Bashir, Asrat, Getnet, Montessori, Valentina,Mathias, Richard, Montaner, Julio. "Ethical and scientific issues surrounding solid organ transplantation in HIV-positive patients: Absence of evidence is not evidence of absence." *Can J Infect Dis Med Microbiol* Vol 17 No 1 January/ February 2006 at p. 17.