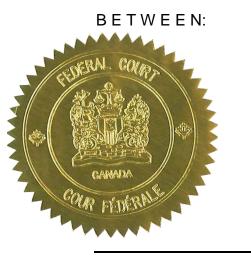
Court File No. T-251-23

#### FEDERAL COURT



#### **KRISTINE PORTER and THERAPSIL**

Applicants

-and-

**MINISTER OF HEALTH** 

Respondent

#### NOTICE OF APPLICATION (Pursuant to section 18.1 of the Federal Courts Act)

TO THE RESPONDENT:

A PROCEEDING HAS BEEN COMMENCED by the Applicant. The relief claimed by the Applicant appears on the following pages.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of the hearing will be as requested by the Applicant. The Applicant requests that this application be heard at Ottawa.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must prepare a notice of appearance in Form 305 prescribed by the *Federal Courts Rules* and serve it on the Applicant's solicitor, or where the Applicant is self-represented, on the Applicant, WITHIN 10 DAYS after being served with this notice of application.

Copies of the *Federal Courts Rules*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

# IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

February 7, 2023

Issued by:

Kadara Thompson

(Registry Officer)

Federal Court of Canada 90 Sparks Street, 1<sup>st</sup> Floor Ottawa, Ontario K1A 0H9 Tel: 613-992-4238 Fax: 613-947-2141

TO: Nathalie Drouin Deputy Attorney General of Canada

> National Capital Region Civil Litigation Section Department of Justice Canada 50 O'Connor Street, 5th Floor Ottawa, Ontario K1A 0H8 Tel: 613-670-6214 Fax: 613-954-1920 Email: <u>AGC\_PGC\_OTTAWA@JUSTICE.GC.CA</u>

Lawyer for the Respondent

#### APPLICATION

This is an application for the writ of *mandamus*, pursuant to sections 18 and 18.1 of the *Federal Courts Act*, R.S.C., 1985, c. F-7 for the Minister of Health ("Minister") to grant the Special Access Program ("SAP") request submitted on January 30, 2023 on behalf of the Kristine Porter ("Patient Applicant") for the Minister to issue a letter of authorization to Filament Health pursuant to s. C.08.010 of the *Food and Drug Regulations*, CRC, c 870 ("*Food and Drug Regulations*") to provide the Patient Applicant with psilocybin so that the Patient Applicant can undergo emergency treatment with psilocybin-assisted psychotherapy to treat the Patient Applicant's treatment resistant depression ("SAP Request").

The Applicants also seek a declaration that the Minister's delay in responding to the SAP Request violated the Patient Applicant's rights to life, liberty, and security of the person under s. 7 of the *Canadian Charter of Rights and Freedoms* ("*Charter*").

#### THE APPLICANTS MAKE APPLICATION FOR:

- a) An order compelling the Minister of Health to immediately grant the SAP Request;
- b) In the alternative, an order compelling the Minister of Health to immediately render a decision on the SAP Request;
- c) A declaration that the Minister of Health's delay in responding to the SAP Request violated the Patient Applicant's rights to life, liberty, and security of the person under s. 7 of the *Charter*,
- d) The costs of this application; and
- e) Such further and other relief as counsel may request and this Honourable Court may permit.

# THE GROUNDS FOR THE APPLICATION ARE:

## I. Factual Background

# A. Patient Applicant's Background

- 1. The Patient Applicant is a 47-year-old mother of four, who lives in Shawnigan Lake, British Columbia.
- The Patient Applicant grew up on the streets of the Downtown East Side of Vancouver. As a youth, she was exploited and fell into drug use. She was held against her will, raped, and beaten.
- 3. In 2003, she managed to get clean from intravenous drugs, and in 2009, she went to school for social work and became an addictions counsellor.
- 4. She excelled at school and in her career until January 1, 2015, when she discovered a client dead by suicide. She was severely traumatized and was shortly thereafter diagnosed with post-traumatic stress disorder.

# **B.** Patient Applicant's Medical Condition

- 5. Over the next few years, the Patient Applicant saw many different psychiatrists and psychologists. She was diagnosed with major depressive order, which, due to its resistance to treatment, has since been classified as treatment resistant depression.
- 6. These conditions have caused her anxiety, an eating disorder, depression, suicidal ideation, self harm, substance misuse, poor self image, emotional insecurity, fear, hopelessness, anger, overthinking, and an inability to maintain healthy relationships.
- 7. She has tried every conventional treatment that the doctors could think of, including counseling, treatment centres, medication, eye movement desensitization and reprocessing therapy, and physical activity, but none of them have worked.
- 8. She has been in and out of the hospital around fifty times because of self-harm from cutting herself.

- 9. She has come close to committing suicide countless times. For about a year, she kept a belt hanging in her closet, ready to hang herself. In her mind, it was not a matter of if it would happen, but when. She put her head through the belt many times, but something always stopped her from taking that final step.
- 10. During this time, she wandered through the woods many times, hoping she would fall off a cliff and die. Someone in her neighbourhood had recently taken off and not come back. That is what she hoped would happen to her. On one occasion, the police searched for her, and found her. She sat in a ditch with the police as they tried to convince her to go to the hospital. She did not think they could help her because she had done everything she could for her condition, and it had not worked.
- 11. The Patient Applicant currently experiences passive suicidality on a daily basis, so any delay in treatment increases risk of self-harm or suicide.

#### C. Psilocybin-Assisted Psychotherapy

- 12. Psilocybin-assisted psychotherapy is the professionally guided use of psilocybin in combination with psychotherapy. Clinical trials have demonstrated that it is effective at treating treatment-resistant depression, major depressive disorder, end-of-life distress, and substance use disorder, among other conditions. It is equally or more effective than conventional antidepressant drugs and has fewer adverse side effects.
- 13. Clinical trials have also proven that psilocybin-assisted psychotherapy is safe, both in the long and short term. There have been no long-term adverse effects from psilocybin administered in a responsible clinical setting, and short-term adverse reactions are extremely uncommon and can be resolved by healthcare practitioners' support. Studies have also demonstrated that psilocybin-assisted psychotherapy has no negative impact on public safety.
- 14. In light of this strong evidence of psilocybin-assisted psychotherapy's safety and efficacy, the Minister has granted more than 80 exemptions to patients to possess and consume psilocybin mushrooms for psilocybin-assisted psychotherapy. The Minister has also previously authorized more than 50 patients to access psilocybin

through the Special Access Program.

# D. Special Access Program Request

- 15.Dr. Steven Griffith-Cochrane assessed the Patient Applicant and determined that psilocybin-assisted psychotherapy would be a reasonable medical choice for the Patient Applicant and had the potential to have a positive impact on the Patient Applicant's health.
- 16.Because of this, Dr. Griffith-Cochrane submitted a SAP Request on behalf of the Patient Applicant by faxing it to Health Canada on January 30, 2023. Dr. Griffith-Cochrane strongly recommended that SAP authorization be granted within 48 hours to avoid additional health risks that may result from delayed treatment.
- 17. As of the date of this Notice of Application, more than 8 days later, the Minister has not rendered a decision on the SAP Request.

# E. TheraPsil

- 18. TheraPsil is a non-profit coalition, incorporated under the *Canada Not-for-profit Corporations Act*, SC 2009, c 23, dedicated to helping Canadians in medical need access legal, psilocybin-assisted psychotherapy. TheraPsil was formed in 2019 and has helped many patients access legal, psilocybin-assisted psychotherapy, including by assisting patients and healthcare practitioners in applying for access through the Special Access Program.
- 19. TheraPsil is directly affected by the matters at issue in this application. Many patients that TheraPsil has assisted have encountered lengthy delays after submitting Special Access Program requests. This pattern of systemic delay hinders TheraPsil's ability to assist patients now and in the future.

# II. Legal Grounds for Mandamus

- 20. The Minister has the public legal duties
  - a. To grant the SAP Request under s. 7 of the Charter since failure to grant

the SAP Request in a timely manner inhibits the Patient Applicant from making a reasonable medical choice, which violates the Patient Applicant's rights to life, liberty and security of the person, and this violation would be arbitrary because granting the SAP Request would have a positive effect on the Patient Applicant's health and have no negative health or safety impact; and

- b. To render a decision under s. C.08.010 of the *Food and Drug Regulations* and s. 7 of the *Charter*.
- 21. The duty is owed to the Patient Applicant, as the Patient Applicant is the person upon whose behalf the SAP Request was made, and the SAP Request decision implicates the Patient Applicant's s. 7 *Charter* rights.
- 22. There is a clear right to the performance of the duty, in particular,
  - a. The Patient Applicant has satisfied all conditions precedent giving rise to the duty since
    - i. The SAP Request was submitted on January 30, 2023;
    - ii. The practitioner provided all of the information set out in s.C.08.010(1)(a) of the *Food and Drug Regulations*; and
    - iii. The practitioner agreed to fulfill all the requirements set out in C.08.010(1)(b) of the *Food and Drug Regulations*.
  - b. The Patient Applicant made a demand to the Minister to perform the duty within 48 hours of receipt of the SAP Request.
  - c. The Applicants provided a reasonable time of more than 8 days to comply with the demand. This is more than reasonable since SAP requests are generally processed within 1-2 working days, according to Health Canada's statement published in the Canada Gazette pertaining to psilocybin access through the Special Access Program.
  - d. A subsequent refusal is implied by the unreasonable delay.

- 23.No other adequate remedy is available since an exemption under s. 56(1) of the *Controlled Drugs and Substances Act*, SC 1996, c 19, cannot provide the Patient Applicant with a legal source of psilocybin, and there are no clinical trials currently enrolling for which the Patient Applicant is eligible that would ensure timely access.
- 24. The order sought will have the practical value and effect of providing the Patient Applicant with access to medical treatment.
- 25. There is no equitable bar to the relief sought.
- 26. The balance of convenience favours granting *mandamus* since no harm will result from granting the Patient Applicant access to this medical treatment; rather the medical treatment will likely have a positive impact on the Patient Applicant's health and wellbeing.

#### **III. Legal Grounds for Declaration**

- 27. The Federal Court has the jurisdiction to hear this issue and grant a declaration under ss. 18 and 18.1 of the *Federal Courts Act*.
- 28. The dispute is real and not theoretical since the Patient Applicant cannot legally access the medical treatment without authorization under the SAP. Even if the Minister grants the SAP Request prior to the hearing in this proceeding, the issues of systemic delay and its impact on patients' rights under s. 7 of the *Charter* will remain.
- 29. TheraPsil has a genuine interest in this dispute's resolution since it has assisted many patients who have made Special Access Program requests for psilocybin and have encountered lengthy delays, and these delays will likely continue to affect patients that TheraPsil assists in the future.
- 30. The Patient Applicant has a genuine interest in this dispute's resolution since the Patient Applicant is inhibited from obtaining timely medical treatment. Additionally, the Patient Applicant may need to submit another Special Access Program request in the future to obtain further treatment.

#### **IV. Legal Authorities**

- 31. Sections 7 and 24(1) of the *Canadian Charter of Rights and Freedoms*, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11.
- 32. Section C.08.010 of the Food and Drug Regulations, CRC, c 870.
- 33. Sections 18 and 18.1 of the Federal Courts Act, RSC 1985, c F-7.
- 34. Federal Courts Rules, SOR/98-106.

## THE APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

- a) Supporting affidavits and exhibits attached thereto; and
- b) Such further and other materials as counsel may advise and this Honourable Court may permit.

February 7, 2023

HAMEED LAW 43 Florence Street Ottawa, Ontario, K2P 0W6

Nicholas Pope Tel: 613-656-6917 Fax: 613-232-2680 Email: npope@hameedlaw.ca

I HEREBY CERTIFY that the above document is a true copy of the original filed in the Court./

JE CERTIFIE que le document ci-dessus est une copie confirme À l'original déposé au dossier de la Cour fédérale.

Filing Date Date de dépôt : February 7 2023 Lawyer for the Applicants

Dated Fait le : February 8, 2023