



T-311-23  
Court File No.

**FEDERAL COURT**

**KATHLEEN WESTLAKE and THERAPSIL**

Applicants

-and-

**MINISTER OF HEALTH**

Respondent

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

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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 15, 2023

Issued by:

**ORIGINAL SIGNED BY  
WAYNE SAWTELL  
A SIGNÉ L'ORIGINAL**

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(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: [AGC\\_PGC\\_OTTAWA@JUSTICE.GC.CA](mailto:AGC_PGC_OTTAWA@JUSTICE.GC.CA)

**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 February 10, 2023, on behalf of Kathleen Westlake (“**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 Medical Condition**

1. The Patient Applicant is 50 years old. She has suffered from depression for the past 35 years, since she was 15 years old. She was formally diagnosed with major depressive disorder in 2002. It has since been characterized as treatment resistant depression because numerous attempted treatments have failed to make her well.
2. She has tried many conventional treatments, including various anti-depressants, cognitive behavioural therapy, supportive psychotherapy, osteopathic treatment, yoga, meditation, massage therapy, repetitive transcranial magnetic stimulation, and electroconvulsive therapy. These treatments only worked partially or for a limited time, and they often produced significant negative side effects. The electroconvulsive therapy, for example, resulted in short- and long-term memory loss and cognitive impairment.
3. The Patient Applicant's depression has severely impacted her quality of life. It has prevented her from having children and from pursuing her desired career in the medical field. She is unable to experience happiness and often feels she does not have a life worth living.
4. Her depression has led her to thoughts of suicide. This was clinically confirmed by her recent score of 9 on the Suicide Behaviors Questionnaire-Revised (SBQ-R), which indicates an elevated risk of suicide. Because of the Patient Applicant's elevated risk of suicide, any delay in treatment increases risk of self-harm or loss of life.

#### **B. Psilocybin-Assisted Psychotherapy**

5. 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.

6. 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.
7. 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.

### **C. Special Access Program Request**

8. The Patient Applicant's healthcare practitioner 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.
9. Because of this, the Patient Applicant's healthcare practitioner completed a SAP Request on behalf of the Patient Applicant. A TheraPsil staff member faxed the SAP Request to Health Canada on February 10, 2023.
10. As of the date of this Notice of Application, 5 days later, the Minister has not rendered a decision on the SAP Request.

### **D. TheraPsil**

11. 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.

12. 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***

13. 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*.

14. 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.

15. 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 February 10, 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 5 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.
16. 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.
17. The order sought will have the practical value and effect of providing the Patient Applicant with access to medical treatment.
18. There is no equitable bar to the relief sought.
19. 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**

20. 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*.
21. 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.
22. 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.

23. 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**

24. 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.

25. Section C.08.010 of the *Food and Drug Regulations*, CRC, c 870.


26. Sections 18 and 18.1 of the *Federal Courts Act*, RSC 1985, c F-7.

27. *Federal Courts Rules*, SOR/98-106.

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

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

February 15, 2023



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

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

**Lawyer for the Applicants**

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 conforme à l'original déposé au dossier de la Cour fédérale.

Filing date 02/15/2023

Date de dépôt \_\_\_\_\_

02/15/2023

Dated \_\_\_\_\_  
Fait le \_\_\_\_\_