

Court File No.

**FEDERAL COURT**

B E T W E E N:



**EMILY GEETING, GAURAV GUPTA 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 27, 2023

Issued by:

Jonathan Macéna  
(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**

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 confirmée  
À l'original déposé au dossier de la Cour fédérale.

Filing Date  
Date de dépôt : 27-FEB-2023

Dated  
Fait le : 27-FEB-2023

## 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 by Dr. Gaurav Gupta on February 11, 2023, on behalf of Emily Geeting (“**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 a 30-year-old Indigenous woman and mother of four children who suffers from treatment resistant depression, chronic pain, post traumatic stress syndrome, and anxiety. She was officially diagnosed 15 years ago and has suffered from these conditions ever since.
2. The Patient Applicant has tried many conventional treatments, including numerous medications, cognitive behavioural therapy, behavioural therapy, yoga, meditation, massage therapy, and occupational therapy but none have made her well. The medications have often produced significant negative side effects, including gastrointestinal distress, weight fluctuations, abdominal pain, headaches, worsening mood, anxiety, insomnia, and drowsiness. She spends thousands of dollars every year on counselling, medication, and alternative therapies, with no success.
3. The Patient Applicant's depression has severely impacted her quality of life. She used to be the director of a non-profit organization and worked in children's services, but now she is unable to work full-time due to her poor mental health. Some days she struggles with her conditions to the point where she can barely get out of bed.
4. The Patient Applicant's four children are, in turn, affected by the Patient Applicant's health conditions, and two of them suffer from anxiety themselves. The Patient Applicant has also lost multiple meaningful romantic relationships because of her poor mental health.

#### **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, Dr. Gaurav Gupta, 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, Vanathy Paranthaman, faxed the SAP Request to Health Canada on February 11, 2023.
10. On February 16, 2023, a person from Health Canada with the first name Jessica called Dr. Gupta.
11. Jessica told Dr. Gupta that the Patient Applicant's impact statement and other information provided was insufficient. Dr. Gupta pointed out that he had included the quantitative score from four different validated diagnostic tests, and a statement of the impact that the Patient Applicant's condition has on the patient's family and work. Dr. Gupta informed Jessica that these were sufficiently severe, in his medical opinion.

12. Jessica also told Dr. Gupta that the statement he included about the Patient Applicant's reasonable refusal of electroconvulsive therapy was insufficient. Dr. Gupta pointed out that he had included the same statement in previous SAP requests, and Health Canada had approved them.
13. Jessica also told Dr. Gupta that the statement he included about the Patient Applicant's reasonable refusal of rTMS was insufficient. Dr. Gupta again pointed out that Health Canada had previously approved SAP requests he submitted with the same statement, verbatim.
14. Jessica asked Dr. Gupta to rule out these treatments on medical grounds and stated that a list of generic side effects was not sufficient. Dr. Gupta told Jessica that the Patient Applicant did not want to risk headaches, which is one of the listed side effects. Jessica said she considered this side effect to be minor and not a valid reason to decline rTMS. Dr. Gupta told Jessica that the Patient Applicant did not want to risk seizures, another listed side effect. Jessica asked if the Patient Applicant had a factor that gave her elevated risk of seizures, and Dr. Gupta told Jessica that even if the Patient Applicant did not have factors elevating the risk, the risk was still present. Jessica said that Health Canada would still consider this an acceptable risk because psilocybin-assisted psychotherapy is not an approved therapy in Canada, but rTMS is.
15. At the end of the call, Jessica said she would talk to Ian MacKay and would send Dr. Gupta an Incompletion Notice. Dr. Gupta and the Patient Applicant waited five days, but they did not receive the promised written notification.
16. On February 21, 2023, Vanathy Paranthaman faxed a letter from Dr. Gupta to Health Canada following up about the SAP Request. Dr. Gupta reminded Health Canada that Jessica had said she would send a written notice, and Dr. Gupta asked that the notice be sent within two days because the delay was causing an increased risk to the Patient Applicant's health.
17. On February 22, 2023, Dr. Gupta received a fax with an Incomplete Notification for the Patient Applicant. The Incomplete Notification stated that additional information

regarding the SAP Request was required.

18. The Incomplete Notification stated that Dr. Gupta needed to provide details and elaborate on the clinical rationales for ruling out electroconvulsive therapy and rTMS. It also stated that treatment cost was not a consideration in the SAP decision-making matrix. However, Dr. Gupta had already provided this information in the SAP Request.
19. The Incomplete Notification also stated that Dr. Gupta needed to “be specific and explain the impacts of the condition on the patient’s daily activities, including employment social interactions and daily life.” However, Dr. Gupta had already provided the results of four validated diagnostic scales and a statement about the impacts on the Patient Applicant’s life, including emotional and physical function, difficulties with psychosocial integration and function, and work-related issues. Dr. Gupta had also included the following statement from the Patient Applicant, in her own words, “I struggle with working full time, I get angry when I’m anxious. I am raising 4 kids and am not the best mom I can be. I have spotty relationships.”
20. That same day, on February 22, 2023, Dr. Gupta updated the SAP Request to include more details on each of the areas Health Canada requested more information about. Vanathy Paranthaman faxed the updated SAP Request along with a cover letter and the Incomplete Notification to Health Canada that same day.
21. In this updated SAP Request, Dr. Gupta provided the following information about the traumatic impact electroconvulsive therapy would likely have on the Indigenous Patient Applicant as one of four paragraphs explaining why it was reasonable for the Patient Applicant to refuse electroconvulsive therapy:

The patient is also unwilling to attempt electroconvulsive therapy because of the role this treatment and similar ones have played in creating the very trauma she is trying to treat. The patient is an Indigenous woman. She reports that her aunt and many others in her culture had electroconvulsive therapy forced upon them in the last 60 years. Her aunt was strapped to a bed and forced to undergo various mental health treatments, including ECT, none of which were successful. My medical opinion is that attempting ECT would likely cause more trauma to the patient and harm her mental health.

22. As of the date of this Notice of Application, 5 days after submitting the updated SAP

Request and 13 days after initially submitting the SAP Request, the Minister has not rendered a decision on the SAP Request.

#### **D. TheraPsil**

23. 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.

24. 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***

25. 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*.

26. Both duties are 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.



27. The duty to render a decision is also owed to TheraPsil and Dr. Gupta since they submitted the SAP Request.

28. 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 11, 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 Applicants 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 13 days to comply with the demand, including 5 days after faxing the updated SAP Request. 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.

29. 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.

30. The order sought will have the practical value and effect of providing the Patient Applicant with access to medical treatment.

31. There is no equitable bar to the relief sought.

32. 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**

33. 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*.
34. 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.
35. TheraPsil and Dr. Gupta have a genuine interest in this dispute's resolution since they have 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 and Dr. Gupta assist in the future.
36. 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**

37. 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.
38. Section C.08.010 of the *Food and Drug Regulations*, CRC, c 870.
39. Sections 18 and 18.1 of the *Federal Courts Act*, RSC 1985, c F-7.
40. *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 27, 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**