

FEDERAL COURT

B E T W E E N:

JODY LANCE and WILLIAM JEPHTHA DAVENPORT

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.

September 11, 2023

Issued by:

Kadara Thompson

(Registry Officer)

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

TO: Shalene Curtis-Micallef
Deputy Attorney General of Canada
Department of Justice Canada
Civil Litigation Section
50 O'Connor, Suite 500
Ottawa, Ontario, K1A 0H8

Tel: 613-670-6214
Fax: 613-954-1920
Email: AGC_PGC_OTTAWA@JUSTICE.GC.CA

Lawyer for the Respondent

APPLICATION

This is an application for judicial review of the Minister of Health's ("**Minister**") decision dated August 30, 2023, ("**Decision**") to refuse the Special Access Program request ("**SAP Request**") made by Dr. William Jeptha Davenport on behalf of Jody Lance for the Minister to issue a letter of authorization to Psilo Scientific Ltd. (aka Filament Health) pursuant to s. C.08.010 of the *Food and Drug Regulations*, CRC, c 870 to provide Mr. Lance with psilocybin to treat Mr. Lance's cluster headaches.

The Decision was communicated to the Applicants on August 30, 2023.

THE APPLICANTS MAKE APPLICATION FOR:

- a) An order setting aside the Decision and directing the Minister of Health to grant the SAP Request.
- b) In the alternative, an order setting aside the Decision and referring it back to the Minister for redetermination within 2 days;
- c) The costs of this application; and
- d) 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. Mr. Lance's Cluster Headaches

1. Mr. Lance has suffered from severe episodic and chronic cluster headaches for the past seven years.
2. Cluster headaches are one of the most painful conditions known to humanity. The pain level is similar to childbirth, fractures, and renal stones. The attacks tend to come in clusters that last 6-12 weeks, and they often have a circannual pattern, with more

attacks in the spring or autumn. Upon onset, the pain ramps up very quickly and typically remains for up to 180 minutes. They can occur up to eight times a day.

3. Mr. Lance's headaches are debilitating. They have taken control of every aspect of his life – his ability to work, his capacity to socialize, and his freedom to plan. Mr. Lance is unable to work and is forced to rely on long-term disability. Because of this, he was unable to make his mortgage payments and lost his house. He cannot go freely to social gatherings because of the prospect of being hit with a cluster attack and being forced to survive in an unfamiliar environment while enduring unspeakable pain. He lives in constant fear of when the next cluster attack will occur, sometimes going into a panic when he feels them coming on, anticipating the unbearable pain.
4. There have even been times when the pain has become so unbearable that Mr. Lance has contemplated suicide or medical assistance in dying.
5. There is no cure for cluster headaches. Mr. Lance has tried numerous treatments, medications, and therapies, but none have proven effective. Some treatments had no effect at all, and those that provided some relief stopped working after a period of use. Many treatments he attempted caused him significant negative side effects.

B. Psilocybin's Efficacy at Treating Mr. Lance's Headaches

6. On September 21, 2017, Dr. Davenport, a neurologist specializing in treatment of cluster headaches, started seeing Mr. Lance as a patient. Dr. Davenport prescribed several conventional treatments for Mr. Lance, but none of them worked.
7. After this, Dr. Davenport informed Mr. Lance that another of his patients had taken psilocybin mushrooms, and it had stopped their cluster headaches cycles. Mr. Lance sought out psilocybin mushrooms, consumed them, and his cluster headaches stopped for a while.
8. Since that first experience, Mr. Lance tried taking different amounts of psilocybin at different intervals to determine what works best to alleviate his headaches. After trying many different dosages and intervals, he found a dosing regimen that works best to alleviate his pain.

9. As one part of this regimen, upon the onset of a regular-strength cluster attack, he takes four 300 mg capsules of dried psilocybin mushrooms per day for four days. He does not experience any hallucinations or noticeable “high” effect from this. Rather it allows him to function better and more safely in everyday life because reduces his pain, allowing him to focus on the world around him.
10. The psilocybin often resets the cluster cycles, giving him temporary reprieve. It allows his body to relax, reducing the muscle knots in his neck and shoulders and clearing sinus blockages that come along with the headaches. It also helps his mind relax when the cluster attacks occur, alleviating the anxiety and panic that makes the headaches even worse. It does not produce any significant negative side effects.
11. Since starting to take psilocybin, Mr. Lance has been able to regain some control over his life. He can do a few more activities than before and participate in some social engagements that were not previously possible. It has dramatically improved his quality of life and given him sustainable relief from his suffering in a way that no other treatment has.

C. Special Access Program Request

12. On July 26, 2023, Dr. Davenport submitted a Special Access Program (“**SAP**”) request to legally procure psilocybin to treat Mr. Lance’s cluster headaches. In the request, Dr. Davenport provided all the information required by the SAP, including the impact of the condition on Mr. Lance’s life, all treatments attempted or declined, psilocybin’s mechanism of action for treating cluster headaches, the calculation of the appropriate dosage, and all available scientific research in support of psilocybin’s safety and efficacy for cluster headaches.
13. Dr. Davenport stated that the psilocybin treatment regimen set out in the SAP Request is a reasonable medical choice for Mr. Lance, and that Mr. Lance’s condition has been unresponsive to the standard treatments.
14. Mr. Lance was also assessed by Dr. Gaurav Gupta, a physiatrist and adult chronic pain specialist. Dr. Gupta reviewed the SAP Request and provided an expert second

opinion agreeing with Dr. Davenport that psilocybin is a reasonable medical choice for Mr. Lance; Mr. Lance meets the inclusion criteria for psilocybin treatment; and he does not meet any of the exclusion criteria.

15. The SAP Request was also reviewed by Jagpaul Deol, a pharmacist who specializes in psilocybin and psychedelic medicines. Ms. Deol provided her expert opinion that psilocybin is a reasonable medical choice for Mr. Lance; the requested dosage is accurately calculated and reasonable and appropriate for Mr. Lance; the requested dosage would not be considered a “psychedelic dose” and is not likely to result in an altered state of consciousness for Mr. Lance; and that the use of psilocybin and the recommended dosages are in concordance with the current medical understanding of psilocybin use in cluster headaches.
16. The Applicants also submitted legal representations, arguing that the Minister’s discretion was limited by s. 7 of *Charter*, which protects Mr. Lance’s right to make reasonable medical choices and receive timely medical treatment. They cited binding judicial precedents that dictated that the Minister must grant the SAP Request.
17. The legal representations were supported by an affidavit from Mr. Lance, a package of supporting documents, and a package of medical and scientific journal articles.
18. On August 21, 2023, the Minister’s delegate, Haddad Bechara, had a phone call with Dr. Davenport. In this call, the Minister’s delegate acknowledged to Dr. Davenport that safety is already established for psilocybin and that he knew psilocybin worked for Mr. Lance. However, the Minister’s delegate asked whether Dr. Davenport knew of any more published clinical trials regarding psilocybin for cluster headaches, whether Dr. Davenport had considered an open label individual patient trial, and whether CGRP monoclonal antibodies had been considered as a treatment.
19. On August 28, 2023, Dr. Davenport sent the Minister’s delegate a letter responding to the inquiries. Dr. Davenport stated that he did not have any more published clinical trials other than those already provided, but that efficacy had already been established for Mr. Lance by his personal experience, and that this was stronger evidence than a clinical trial, which would only provide a probability of efficacy in the general

population. Dr. Davenport stated that an open label individual patient trial would not be feasible, and he gave several reasons for this. Dr. Davenport also reiterated that alternative treatments are unsuitable, and specifically that CGRP monoclonal antibodies would not be feasible due to their side effects, cost, and significant chance that the treatment would not be efficacious.

D. Refusal

20. On August 30, 2023, Dr. Davenport received the Decision from the Minister's delegate, refusing the SAP request. The reasons for decision are reproduced below in their entirety:

The request does not include sufficient information with respect to the use, safety, and efficacy of the drug for the requested use.

There are therapeutic alternatives available on the market for the specific indication.

II. Unreasonable Decision

A. Failure to Balance *Charter* Values

21. The Decision is unreasonable because it failed to balance *Charter* values with the statutory objectives, as required by the Supreme Court in *Doré v Barreau du Québec*, 2012 SCC 12. The Decision did not mention the *Charter* anywhere despite the Applicants making extensive legal submissions that s. 7 of the *Charter* would be unjustifiably infringed if the SAP Request was refused.

B. Failure to Meaningfully Grapple with Central Arguments

22. The Decision is unreasonable because it fails to meaningfully grapple with any of the Applicants' central arguments, including that

- a. Mr. Lance has a right to make reasonable medical choices under s. 7 of the *Charter*, and the Minister must grant the SAP authorization because his discretion must be exercised in a way that conforms to the *Charter*;

- b. Psilocybin has been proven efficacious for Mr. Lance by his personal experience which concords with the scientific evidence, regardless of the lack of published clinical studies conducted on other people; and
- c. All alternative treatments have been deemed clinically unsuitable due to the side effects, high cost, and low likelihood of efficacy.

C. Failure to Justify Departure from Binding Precedent

23. The Decision is unreasonable because it fails to justify the departure from binding precedents that were squarely raised by the Applicants, including

- a. *Allard v Canada*, 2016 FC 236, which held that “in the absence of more and better studies about the therapeutic value” of using a controlled substance for medical purposes, “anecdotal evidence is a reasonable substitute” to establish efficacy and a s. 7 right;
- b. *Hitzig v Canada*, [2003] OJ No 3873, which held that a s. 7 right to medical treatment can be established on a much lower evidentiary basis than is required by scientists, and “individuals’ personal experiences and anecdotal evidence” are sufficient evidence of efficacy;
- c. *R v Krieger*, 2003 ABCA 85, which held that a person’s right to security of the person is infringed by denying a treatment that is effective for the person even if the person has not tried all alternative treatments;
- d. *Carter v Canada*, 2015 SCC 5, which held that competent individuals are free to make decisions about their bodily integrity, and this right to “decide one’s own fate” entitles adults to direct the course of their own medical care; and
- e. *Canada v PHS Community Services Society*, 2011 SCC 44, which held that under s. 7 of the *Charter*, the Minister must grant authorizations for medical treatment where evidence indicates the treatment is effective and there is little or no evidence that it will have a negative impact on public safety.

D. Failure to Account for Evidence

24. The Decision is unreasonable because it fails to account for the evidence before the Minister's delegate that squarely contradicted the Minister's delegate's conclusion that the request did not include sufficient information about the use, safety, and efficacy of the drug, including

- a. Mr. Lance's personal testimony that psilocybin is effective at treating his cluster headaches;
- b. The detailed description of psilocybin's mechanism of action set out by Dr. Davenport in Section E.1.a.8 of SAP Form A;
- c. Dr. Davenport's opinion that psilocybin is a reasonable medical choice for Mr. Lance;
- d. Psychiatrist Dr. Gaurav Gupta's opinion that psilocybin is a reasonable medical choice for Mr. Lance;
- e. Pharmacist Jagpaul Deol's opinion that psilocybin is a reasonable medical choice for Mr. Lance;
- f. The scientific article by Sewell et al published in the peer-reviewed journal *Neurology* in 2006, which found that 85% of cluster headache patients who had used psilocybin reported that psilocybin aborted cluster headache attacks; 52% reported cluster period termination; and 95% reported extension in remission periods;
- g. The scientific article published by Schindler et al in the peer-reviewed *Journal of Psychoactive Drugs* in 2015, which found that psychedelics were more effective than, or comparable with, most conventional medications, with increased effectiveness in shortening cluster periods;
- h. The scientific article published by Andersson et al in the peer-reviewed *Harm Reduction Journal* in 2017, which found that psychedelics reduced the frequency and severity of headache attacks for both cluster and

migraine headache sufferers;

- i. The scientific article published by Schindler et al in the peer-reviewed journal *Neurotherapeutics* in 2020, which found that a single administration of psilocybin significantly reduced weekly headache days from baseline as compared to placebo;
- j. The scientific article published by Schindler et al in the peer-reviewed journal *Headache* in 2022, which found that
 - i. Psilocybin's therapeutic effects on cluster headaches are unsurprising since several headache medications have a chemical or pharmacological overlap with psilocybin;
 - ii. Psilocybin reduces cerebral blood flow in the hypothalamus, which is a potential source of acute pain relief in cluster headaches; and
 - iii. Psilocybin has acute secretory effects on pineal tissue, which is the site of melatonin production, and this may impact cluster headaches since they are related to circadian and circannual rhythm;
- k. Dr. Davenport's summary of the above-listed articles in Section E.1.c.1(i) of SAP Form A;
- l. Seven scientific articles published in peer reviewed journals establishing psilocybin's safety;
- m. Dr. Davenport's summary of the above-noted articles in Section E.1.c.1(ii) of SAP Form A;
- n. The Minister's delegate's admissions to Dr. Davenport in a phone call on August 21, 2023, that
 - i. Safety has been established for psilocybin; and
 - ii. He knew psilocybin "has worked for the patient".

25. The Decision is unreasonable because it fails to account for the evidence before the Minister's delegate that squarely contradicted the Minister's delegate's conclusion that

there are therapeutic alternatives available for Mr. Lance's condition, including

- a. Dr. Davenport's list of all the treatments Mr. Lance had considered and declined, and the reasons Mr. Lance had declined them, including side effects, set out in Section E.1.b.3 of SAP Form A;
- b. Dr. Davenport's opinion that other treatments may not be sufficiently efficacious for Mr. Lance, and the reasons for this opinion, set out in Section E.1.b.4 of SAP Form A; and
- c. Dr. Davenport's reasoning for why CGRP monoclonal antibodies are unsuitable for Mr. Lance, set out in Section 3 of Dr. Davenport's August 28, 2023, letter to the Minister's delegate.

E. Non-Transparent

26. The Decision is unreasonable because it is not transparent in the way it states either of its two conclusions.

27. For the first conclusion, the Minister's delegate did not state what specific information is purportedly lacking – whether information regarding all three topics (use, safety, and efficacy) is lacking or of just information regarding one or two topics of the three. The Minister's delegate also did not indicate what type or amount of information would need to be provided to make up for this purported informational deficiency.

28. For the second conclusion, the Minister's delegate did not identify which therapeutic alternatives are purportedly available.

F. Unexplained Departure from Past Practice

29. The Decision is unreasonable because it does not explain the departure from the Minister's past practice of authorizing SAP requests that contained significantly less information about a drug's use, safety, and efficacy.

30. The Decision is unreasonable because it does not explain the departure from the Minister's past practice of authorizing SAP requests for patients who had not tried all therapeutic alternatives available on the market for their condition.

G. Strays Beyond Limits of Statutory Language

31. The Decision's denial on the basis that the request did not include sufficient information about the use, safety, and efficacy of the drug is unreasonable because it strays beyond the limits set by the language in s. C.08.010(1)(a)(iii) of the *Food and Drug Regulations*, which says the practitioner must provide, "the information in the possession of the practitioner in respect of the use, safety and efficacy of the new drug". The Decision strayed beyond the specific constraints of the statutory language by requiring more information than was in Dr. Davenport's possession. Dr. Davenport provided all the information in his possession with respect to the use, safety, and efficacy of psilocybin for cluster headaches; he told the Minister's delegate, "I do not have any more published clinical trials"; and the Minister's delegate did not challenge the truthfulness of this.

H. Fettered by Policy

32. The Decision's denial on the basis that the request did not include sufficient information is unreasonable because the Minister's delegate fettered his discretion by a policy that the practitioner must provide a certain number of published clinical studies to establish efficacy of a drug.

33. The Decision's denial on the basis that there are therapeutic alternatives available is unreasonable because the Minister's delegate fettered his discretion by a policy that the patient must have attempted all alternative treatments.

34. Neither of these policies are requirements in the *Food and Drug Regulations* nor any other law. They are only internal, non-binding policies.

I. No Responsive Justification

35. The Decision is unreasonable because the Decision has consequences that threaten Mr. Lance's life, liberty, dignity, and livelihood, and the reasons do not demonstrate that the Minister's delegate considered the consequences of the decision, nor do they explain why the Decision best reflects the legislature's intention, as required by the

principle of responsive justification.

III. Appropriate Remedy is Directed Verdict

36. The appropriate remedy is to direct the Minister of Health to grant the SAP Request since

- a. There is only one possible *Charter*-compliant outcome;
- b. Serious harm will be caused by any delay from sending the Decision back for redetermination;
- c. The Minister has already had a genuine opportunity to weigh in on the issue; and
- d. It would be unfair to the Applicants to send the decision back for redetermination.

37. There is only one *Charter*-compliant outcome since s. 7 of the *Charter* requires that the Minister authorize medical treatment with controlled substances when evidence indicates the authorization will decrease illness and there is little or no evidence that it will have a negative impact on public safety. There was no evidence before the decision maker to contradict the Applicants' submission that psilocybin is safe and effective at treating Mr. Lance's cluster headaches and has no negative impact on public safety.

38. Serious harm will be caused by the delay from sending the Decision back for redetermination. During that time, Mr. Lance will continue to suffer unnecessarily from debilitating pain or risk imprisonment by continuing treatment illegally.

39. The Minister already had a genuine opportunity to weigh in on all the issues. The Applicants raised all the issues in their initial SAP submission and included a clear and comprehensive legal argument that s. 7 of the *Charter* required the Minister grant the request. The Minister's delegate took 35 days from receiving the submissions to rendering the Decision, allowing for ample time to assess the *Charter* arguments and weigh in. Despite ample time, notice, and opportunity, the Minister's delegate declined

to even mention the *Charter* in the Decision.

40. It would be unfair to the Applicant to delay the matter further. The Minister knew or ought to have known his obligation under administrative law to address the Applicants' central arguments and balance any alleged *Charter* infringements. These obligations are plainly stated in the well-known Supreme Court precedents *Doré* and *Vavilov*. The Applicants were diligent in preparing comprehensive submissions and evidence. It would be unfair to force Mr. Lance to suffer any longer.

V. Legal Authorities

41. Section 7 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.

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

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

44. *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.

RULE 317 REQUEST:

The Applicants request the Minister of Health to send a certified copy to the Applicants and the Registry of the following material that is relevant to the Application and not in the possession of the Applicants but is in the possession of the Minister of Health:

- a) All information considered, or available for consideration, by the Minister of Health, the Minister's delegate, and any other persons involved in making the Decision, including, but not limited to, all records, reports, submissions,

research, assessments, articles, studies, databases, correspondence, emails, Blackberry PIN messages, memos, and notes; and

b) All other SAP requests for psilocybin or MDMA that have been approved.

September 11, 2023



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

Filing Date Sept 11 2023
Date de dépôt : _____

Dated Sept 11 2023
Fait le : _____