Federal Court  Cour fédérale

Date: 20240524

Docket: T-1881-23

Citation: 2024 FC 787

Ottawa, Ontario, May 24, 2024

PRESENT: The Honourable Mr. Justice Fothergill

BETWEEN:

JODY LANCE
WILLIAM JEPTHA DAVENPORT

Applicants

and

ATTORNEY GENERAL OF CANADA

Respondent

JUDGMENT AND REASONS

I. Overview

[1] Dr. William Jeptha Davenport is a neurologist practising in Calgary, Alberta. Jody Lance is his patient. Mr. Lance suffers from cluster headaches, sometimes referred to as “suicide headaches”, which are capable of inflicting some of the most severe pain known to medical science.

[2] After numerous unsuccessful attempts to treat Mr. Lance's cluster headaches with conventional therapies, Dr. Davenport suggested that he try hallucinogenic mushrooms, also known as "magic mushrooms". Another of Dr. Davenport's patients had found this to be an effective treatment for cluster headaches. Mr. Lance discovered that ingesting magic mushrooms in non-hallucinogenic doses helped him to alleviate his condition.

[3] The active ingredient in hallucinogenic mushrooms in psilocybin, a controlled substance in Canada. On July 12, 2023, Mr. Lance and Dr. Davenport submitted a request under Health Canada's Special Access Program [SAP] for access to psilocybin, to be self-administered by Mr. Lance in a non-clinical setting. The application was supported by Dr. Davenport's account of Mr. Lance's medical history and experience of different treatments, the current literature concerning the use of psilocybin for medical purposes, and legal submissions addressing Mr. Lance's rights pursuant to s 7 of the *Canadian Charter of Rights and Freedoms*, Part 1 of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11 [Charter].

[4] The delegate of the Minister of Health [Minister] refused the SAP request on the grounds that the medical efficacy of psilocybin to treat cluster headaches had not been established, and alternative conventional treatments had not been ruled out. The Minister's delegate did not address Mr. Lance's submissions respecting his Charter rights.

[5] The Minister's delegate did not meaningfully grapple with key issues and central arguments raised by the Applicants, calling into question whether he was fully alert and sensitive to the matter before him. The decision to refuse the SAP request was therefore unreasonable.

[6] The Minister's delegate failed entirely to consider the Charter arguments that were squarely raised in the SAP request, and in this further respect the decision to refuse the SAP request was unreasonable.

[7] The application for judicial review is granted, and the matter is remitted to a different delegate of the Minister for redetermination.

II. Background

A. *Cluster Headaches and Psilocybin*

[8] Cluster headaches are extremely painful and debilitating. They can strike suddenly and continue for up to three hours. They can recur several times in a day, and on subsequent days, in a "cluster" lasting between six and 12 weeks.

[9] Due to his condition, Mr. Lance cannot work and is on long-term disability. He has been unable to socialize outside his home. He says he has contemplated suicide and medical assistance in dying [MAID], for which he is potentiality eligible.

[10] There is no known cure for cluster headaches. Mr. Lance has tried numerous treatments, medications, and therapies, but none has provided him with lasting relief. He has experienced significant side effects from conventional treatments.

[11] Psilocybin is a compound found in many species of mushrooms. It is classified as a drug under the *Food and Drugs Act*, RSC, 1985, c F-27 [FDA], and is listed in Schedule III of the *Controlled Drugs and Substances Act*, SC, 1996, c 19 [CDSA]. Its possession and sale are prohibited in Canada.

[12] Following Dr. Davenport's advice, Mr. Lance experimented with different dosages and intervals of psilocybin, and arrived at an administration protocol that he says works best for him. He does not experience any hallucinations or a "high" from this dosage. He says he would have to increase his intake 14,167 times in order to overdose on the drug. Psilocybin does not prevent every cluster headache, but since he began his regimen Mr. Lance has been able to regain some control over his life. He can now venture outside the house, and he sometimes attends social engagements.

[13] Psilocybin has been accessible in a limited way under the SAP since 2022. As of November 2023, 153 requests for psilocybin have been authorized, benefiting 161 patients. However, the Minister has never authorized the use of psilocybin to treat cluster headaches.

B. *The SAP Request*

[14] The SAP provides an exemption from the prohibition against purchasing and possessing unapproved drugs. Drugs obtained through the SAP are exempt from key provisions of the FDA and the *Food and Drugs Regulations*, CRC, c 870 [FDR].

[15] The SAP is intended to address situations of necessity and medical emergency. It is not an alternative means of gaining access to unapproved drugs, nor is it meant to circumvent normal drug development and regulatory procedures. A patient cannot receive open-ended access to a drug via the SAP; access is limited by quantity and time.

[16] C.08.010 of the FDR provides in relevant part:

(1) The Minister may issue a letter of authorization to a manufacturer of a new drug authorizing the sale of a specified quantity of the new drug for human or veterinary use to a practitioner, for use in the emergency treatment of an animal or a person under the care of that practitioner, if	(1) Le ministre peut, si les conditions ci-après sont réunies, délivrer au fabricant d'une drogue nouvelle une lettre d'autorisation permettant la vente à un praticien, pour usage humain ou vétérinaire, d'une quantité déterminée de cette drogue afin que le praticien puisse prodiguer des soins d'urgence à un animal ou à une personne qu'il traite à titre professionnel :
(a) the practitioner provides the following information to the Minister:	a) le praticien fournit au ministre les renseignements suivants :
(i) the name of the new drug and details concerning the medical emergency for which the new drug is required,	(i) le nom de la drogue nouvelle et des précisions concernant l'urgence médicale pour laquelle la drogue est requise,
(ii) the quantity of the new drug that is required,	(ii) la quantité de la nouvelle drogue qui est requise,
(iii) subject to subsection (2), the information in the possession of the practitioner in respect of the use, safety and efficacy of the new drug,	(iii) sous réserve du paragraphe (2), les renseignements qu'il possède concernant l'usage, l'innocuité et l'efficacité de la drogue nouvelle,
(iv) the name and the civic address of the person to whom the new drug is to be shipped, and	(iv) le nom et l'adresse municipale de la personne à qui la drogue nouvelle doit être expédiée,
(v) any other information the Minister may request to enable the Minister to determine whether to	(v) tout autre renseignement que le ministre peut demander pour lui permettre de décider s'il convient

issue the letter of authorization;	de délivrer la lettre d’autorisation;

[17] Dr. Davenport requested authorization to obtain 16 capsules containing 1 mg of psilocybin, and 16 capsules containing 5 mg. These were to be administered within three months of receipt.

[18] Dr. Davenport described Mr. Lance’s history of cluster headaches and the improvement in his condition after taking psilocybin. He explained psilocybin’s mechanism of action, and submitted several studies suggesting some promise for treating cluster headaches. The use of psilocybin for this purpose is considered to be safe, although its general efficacy has yet to be established.

[19] Dr. Davenport listed the other medications and treatments Mr. Lance had tried, noting their ineffectiveness and adverse side effects. Mr. Lance declined some treatments due to their cost or potential side effects. Mr. Lance’s participation in a research trial was ruled out, because his need for treatment was immediate and Dr. Davenport did not consider himself qualified to design or administer such a trial. Funds and resources were also lacking.

[20] Dr. Davenport’s SAP request was supported by his own affidavit and those of two other medical professionals, Dr. Gaurav Gupta and Jagpul Deol. Dr. Gupta is a physician whose practice focuses on pain medicine. He has previously submitted seven SAP requests for psilocybin, all of which were approved. He expressed the view that psilocybin at the doses specified in Mr. Lance’s request is a reasonable medical choice, and it would be impracticable for anyone but Mr. Lance to possess and administer the psilocybin.

[21] Jagpaul Deol is a licensed clinical pharmacist who has worked for many years in psychedelic-assisted therapy, including with psilocybin, as well as in psychedelic harm reduction in Vancouver's Downtown East Side neighbourhood. She has been consulted on several successful SAP requests by physicians in Canada. She works with TheraPsil, a non-profit organization that helps Canadians with a medical need obtain access to psilocybin. She agreed with Dr. Gupta's conclusions. She also confirmed that the doses in the SAP request are not psychedelic, and that there is little risk of harm from diversion of the requested psilocybin to the general public.

[22] The SAP request was accompanied by extensive written representations prepared by Nicholas Pope, counsel for the Applicants in this proceeding and TheraPsil's legal adviser. The representations addressed the jurisprudence governing access to unapproved drugs and s 7 of the Charter.

[23] Mr. Pope argued that Mr. Lance's life, liberty, and security of the person were engaged by the SAP request. Specifically, his liberty was engaged based upon his right to make reasonable medical choices regarding his physical and mental wellbeing; his security of the person was threatened by any delay in gaining access to effective medical treatment; and his life was at risk due to his suicidal ideation and potential eligibility for MAID. Mr. Pope also asserted that the infringement of Mr. Lance's rights could not be justified under s 1 of the Charter.

C. *The Minister's Refusal*

(1) The Initial Review

[24] An initial review of the SAP request prepared for the Minister on July 31, 2023 summarized Mr. Lance's circumstances, the alternative treatment options available, and the medical literature pertaining to the use of psilocybin to treat cluster headaches. The reviewer advised that "[p]silocybin use in cluster headache is not recommended in any medical guidelines" and that "[t]here is no data of safety or efficacy for the requested indication". The reviewer found no clinical reason to rule out the use of other conventional drugs, and concluded that psilocybin is "experimental in nature and would be better suited to the clinical trial setting".

[25] Consistent with Health Canada's usual procedure, the negative recommendation was referred to a senior manager for reconsideration. In this case, the SAP request was referred to Dr. Bechara Haddad, Manager of the SAP Pharmacist Group in Health Canada's Pharmaceutical Drugs Directorate.

[26] On August 21, 2023, Dr. Haddad spoke by telephone with Dr. Davenport about the SAP request. Unbeknownst to Dr. Haddad, Dr. Davenport recorded the conversation. An unofficial transcript of the telephone conversation was appended to Dr. Davenport's affidavit in this proceeding.

(2) The Telephone Call

[27] According to the transcript of the telephone call, Dr. Haddad began by acknowledging that for psilocybin, "the safety is established, but the efficacy point is what's missing for cluster headaches". He noted that there appeared to be only one clinical trial that examined efficacy, but the results were inconclusive. He asked whether Dr. Davenport could produce stronger evidence of psilocybin's efficacy in treating cluster headaches. Dr. Davenport replied that he wished there were more published literature, but noted that physicians do rely on "anecdotal evidence from people who have used microdosing". He continued:

> […] if a person has responded to it before [this] is probably the strongest evidence that we could get, and in situations like this where someone has been able to try it before and has had a good response, then usually that's what we would rely on most heavily.

[28] Dr. Haddad indicated that he was not questioning anything from a clinical standpoint, but additional data were needed for the regulatory purposes of the SAP. He acknowledged that psilocybin had worked for Mr. Lance, but "at least one clinical trial that shows favourable outcomes" was necessary before the Minister could grant the SAP request.

[29] Dr. Haddad also raised the potential availability of conventional therapies, and noted that there were a couple of "modalities" that had not been ruled out. He referred specifically to Galcanezumab, a monoclonal antibody that is administered by injection. Dr. Davenport noted that this treatment is very expensive, and Mr. Lance had no medical plan that would cover the cost. He said that Mr. Lance was also concerned about side effects, noting that he had experienced no side effects from psilocybin.

[30] Dr. Haddad suggested that an Individual Open Label Trial could be set up more easily than a full clinical trial, and could provide a more lenient framework for Mr. Lance to gain access to psilocybin. Dr. Davenport responded that it would be difficult for Mr. Lance to participate in a highly supervised trial that involved regular attendance at a clinic.

[31] Dr. Davenport agreed to look for additional published studies regarding the efficacy of psilocybin in treating cluster headaches, and repeated that there appeared to be no concern about safety. He also agreed to provide a more detailed explanation of why Galcanezumab would not be appropriate for Mr. Lance.

(3) Dr. Davenport's Further Correspondence

[32] In correspondence dated August 23, 2023, Dr. Davenport reiterated that the safety of psilocybin was not in question. He said he had no further studies to offer in support of psilocybin's efficacy to treat cluster headaches, but repeated his understanding of psilocybin's mechanism of action. He stressed the importance of Mr. Lance's positive response to the treatment, noting that this was "stronger than a double-blind, placebo-controlled study, since a clinical trial only tells us that there is a statistically significant likelihood that the treatment will have some efficacy for at least some people". He emphasized that, during the telephone call, Dr. Haddad had accepted the efficacy of psilocybin in treating Mr. Lance's condition.

[33] Dr. Davenport also addressed the impracticability of a clinical trial. Given the urgency of dosing, Mr. Lance's attendance at a clinic for administration would be impossible. Furthermore, Dr. Davenport did not have the time, money, or resources to conduct an individual patient trial.

[34] Dr. Davenport provided further explanation of why the suggested alternative treatments were inappropriate. Mr. Lance had already considered and declined them for valid reasons. With respect to monoclonal antibodies, Dr. Davenport repeated that the treatment is very expensive and Mr. Lance could not afford it. Moreover, in one study, 70% of patients received no clinical benefit, suggesting a low likelihood of success. He also noted the potential risk of significant adverse side effects. Dr. Davenport concluded:

> Under the principles of patient-centred care, I cannot ethically require a patient to impoverish himself to attempt a treatment that is unlikely to be efficacious and carries considerable risk of side effects when he has already found a treatment that is affordable, efficacious, and has no side effects.

(4) The Refusal Letter

[35] Dr. Haddad, acting as the Minister's delegate, refused the SAP request on August 30, 2023. The reasons for refusal were brief:

> Your request for emergency access to the above named product has been denied as it does not meet the requirements of Section C.08.010 of the *Food and Drug Regulations* for the following reasons(s):
>
> 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 specified indication.

(5) The Internal Rationale

[36] On August 29, 2023, Dr. Haddad sent an e-mail message to his colleagues at Health Canada in which he explained his rationale for rejecting the SAP request. He noted that, unlike prior SAP requests for psilocybin, Dr. Davenport had proposed that his patient would possess and administer the drug himself. Dr. Haddad observed that "the bulk of the data evaluating the use of psilocybin in the treatment of cluster headache centers largely around a randomized controlled trial", which "yielded unfavourable results in terms of the treatment's efficacy". He remarked that "there are several anecdotal case reports and retrospective patient surveys that acknowledge the existing gap in research and call for further investigations" into psilocybin's safety and efficacy.

[37] Dr. Haddad noted that Dr. Davenport "was unable to share supplementary data substantiating the efficacy or safety of psilocybin for treating cluster headache". With respect to Mr. Lance's positive experience with the drug, he said that this "may be sufficient to justify an off-label use of a marketed drug, [but] it is not sufficient to justify access to an unauthorized drug through the SAP pathway, particularly when safety and efficacy have not been properly evaluated".

[38] Finally, he commented that the "SAP does not factor in cost when ruling out marketed alternatives".

III. Issues

[39] This application for judicial review raises the following issues:

A. Is new evidence tendered by the parties admissible?

B. What are the Minister's reasons?

C. Was the Minister's refusal of the SAP request reasonable?

D. If not, what is the appropriate remedy?

IV. Analysis

A. *Is new evidence tendered by the parties admissible?*

[40] Both parties have submitted new evidence in support of this application. The Applicants propose to rely on the affidavits of Dr. Davenport, Matthew Hunter, and Corey Pettipas. The Respondent wishes to rely on the affidavit of Ian MacKay.

[41] The test for admitting new evidence on judicial review is well established. According to the Federal Court of Appeal's decision in *Association of Universities and Colleges of Canada v Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22 [*Access Copyright*], new evidence may be admitted where it:

(a) provides general background in circumstances where that information might assist in understanding the issues relevant to the judicial review;

(b) brings to the attention of the judicial review court procedural defects that cannot be found in the evidentiary record of the administrative decision-maker, so that the judicial review court can fulfil its role of reviewing for procedural unfairness; or

(c) highlights the complete absence of evidence before the administrative decision-maker when it made a particular finding.

[42] This list of exceptions is not necessarily closed (*Access Copyright* at para 20).

(1) Dr. Davenport's Affidavit

[43] Dr. Davenport's affidavit appends the transcript of his telephone call with Dr. Haddad. The Applicants say this is admissible because the information was known to and relied upon by the Minister's delegate before he refused the SAP request.

[44] The Respondent accepts that the transcript of the telephone call is *prima facie* admissible, but urges the Court to exercise caution. Dr. Haddad was unaware that the telephone call was being recorded, and he was not asked to consent to the recording in advance. Dr. Davenport could easily have requested Dr. Haddad's consent, and the Court should be reluctant to endorse the surreptitious manner in which the transcript was obtained.

[45] The Respondent acknowledges that there is nothing prejudicial in the transcript, but emphasizes that Dr. Haddad was speaking somewhat informally with a professional colleague. He may have spoken less carefully than he would have if he had known his words would be preserved and used as evidence.

[46] Despite my misgivings about the manner in which the transcript was obtained, I am satisfied that it may be admitted as part of the reasons for the decision under review. The written reasons of the Minister's delegate are very brief, and the telephone call reflects important elements of the decision. I have more to say about this under the heading *What are the Minister's reasons?*

(2) The Hunter and Pettipas Affidavits

[47] Matthew Hunter and Corey Pettipas are patients who were granted access to psilocybin and 3, 4 methylenedioxymethamphetamine [MDMA] through the SAP. The Applicants maintain that the affidavits provide general background information that will assist the Court, consistent with the first exception recognized in *Access Copyright*. They also rely on the affidavits to demonstrate the Minister's departure from past practice, which they say falls within the second *Access Copyright* exception.

[48] The Respondent notes that neither Mr. Hunter nor Mr. Pettipas were granted access to unapproved drugs to treat cluster headaches. Mr. Pettipas was treated with MDMA, not

psilocybin. The Respondent emphasizes that the SAP criteria are applied individually to the facts of each request, and authorization is granted on a case-by-case basis.

[49] Decisions of the Minister's delegate respecting SAP requests are not generally available to the public, and the Court could in principle admit affidavits appending or describing prior decisions to show that the decision of the Minister's delegate was an unexplained departure from past precedent. However, in my view Mr. Hunter's and Mr. Pettipas' SAP requests are too distinct to constitute precedents for the decision in Mr. Lance's case. The decision of the Minister's delegate was highly contextual and discretionary. Furthermore, the application for judicial review may be decided on other grounds.

[50] The affidavits of Mr. Hunter and Mr. Pettipas are therefore not admissible in this proceeding.

(3) The MacKay Affidavit

[51] Ian MacKay is the Manager of the SAP within the Office of Clinical Trials, Pharmaceutical Drugs Directorate, Health Products and Food Branch, Health Canada. His affidavit addresses psilocybin and the applicable regulatory framework; the administration of the SAP; clinical trials; the manner in which Health Canada weighs scientific evidence; and exemptions from the CDSA's prohibitions on the possession of psilocybin by patients and medical practitioners.

[52] The Respondent argues that Mr. MacKay's affidavit is admissible as general background information, the first exception recognized in *Access Copyright*. The Respondent notes that the SAP is "a specialized program within Health Canada whose decisions have been subject to a very limited number of judicial review applications". Mr. MacKay's affidavit appends a number of public documents which the Respondent argues would have been known to the decision-maker. These include two Regulatory Impact Analysis Statements [RIAS] published in the Canada Gazette, and information from government websites.

[53] Paragraphs 12 to 15 of Mr. MacKay's affidavit describe the organization of the SAP and its handling of a high volume of requests of varying urgency. These paragraphs may be admitted as general background information concerning the "institutional context in which the decision was made" (*Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 [*Vavilov*] at para 91).

[54] Paragraphs 17 to 22 provide background information on clinical trials, including single-patient trials. These are intended to provide context for Dr. Haddad's professional assessment that psilocybin should be administered only in the context of a clinical trial, including an Individual Open Label Trial, as suggested to Dr. Davenport. The information is admissible for this purpose. As the Supreme Court of Canada explained in *Vavilov* (at para 93):

> […] In conducting reasonableness review, judges should be attentive to the application by decision makers of specialized knowledge, as demonstrated by their reasons. Respectful attention to a decision maker's demonstrated expertise may reveal to a reviewing court that an outcome that might be puzzling or counterintuitive on its face nevertheless accords with the purposes and practical realities of the relevant administrative regime and represents a reasonable approach given the consequences and the

> operational impact of the decision. This demonstrated experience and expertise may also explain why a given issue is treated in less detail.

[55] Paragraphs 23 to 27 describe Health Canada's principles for weighing scientific evidence. This information was presumably known to the Minister's delegate, and was relied upon in rendering the decision. It is therefore admissible.

[56] Paragraphs 28 and 29 amount to legal opinions, and are outside Mr. MacKay's expertise. The Applicants take issue with some of the conclusions. These paragraphs are not admissible.

B. *What are the Minister's reasons?*

[57] Where an administrative decision maker provides written reasons, those reasons are the means by which the decision maker communicates the rationale for its decision (*Vavilov* at para 84). However, portions of the record that pre-date, and even post-date, the decision may help to demonstrate whether it was reasonable (*9209654 Canada Inc v Canada (Border Services Agency)*, 2022 FC 1390 at para 39).

[58] An essential element is whether the rationale for the decision was made available to the person affected: it is "unacceptable for an administrative decision maker to provide an affected party formal reasons that fail to justify its decision, but nevertheless expect that its decision would be upheld on the basis of internal records that were not available to that party" (*Vavilov* at para 95).

[59] The review of an administrative decision cannot be divorced from the institutional context in which it was made or the history of the proceedings. Administrative decision makers cannot always be expected to deploy the same array of legal techniques that might be expected of a lawyer or judge, nor will it always be necessary or even useful for them to do so (*Vavilov* at paras 91-92).

[60] Where a person affected by a decision communicates with the decision maker, this may inform the reasons for the decision. The exchange is not only part of the history of the matter in respect of which the decision was rendered; it is a part of the history which the applicant itself created (*KIK Custom Products Inc v Canada (Border Services Agency*), 2020 FC 462 at para 68).

[61] The transcript of the telephone call between Dr. Haddad and Dr. Davenport on August 21, 2023 may therefore be considered in assessing the reasonableness of the decision to refuse the SAP request. The same is true of Dr. Davenport's subsequent correspondence to Dr. Haddad dated August 23, 2023.

[62] However, the internal rationale provided by Dr. Haddad to his colleagues on August 29, 2023, after the decision was made, does not form a part of the reasons for the purposes of this application. The internal rationale was never communicated to the Applicants, and was disclosed to them only in the course of this application for judicial review. It is unclear whether it would have been provided to them upon request, and accordingly it does not fall within the exception recognized in *Baker v Canada (Minister of Citizenship and Immigration)*, [1999] 2 SCR 817 (at para 44).

C. *Was the Minister's decision reasonable?*

[63] The Applicants say the decision of the Minister's delegate is unreasonable on its merits, and also because it failed to engage with Mr. Lance's arguments respecting his rights pursuant to s 7 of the Charter.

(1) The Merits of the Decision

[64] The decision of the Minister's delegate is subject to review against the standard of reasonableness (*Vavilov* at para 23). The Court will intervene only if "there are sufficiently serious shortcomings in the decision such that it cannot be said to exhibit the requisite degree of justification, intelligibility and transparency" (at para 100).

[65] The criteria of "justification, intelligibility and transparency" are met if the reasons allow the Court to understand why the decision was made, and determine whether the decision falls within the range of acceptable outcomes defensible in respect of the facts and law (*Vavilov* at paras 85-86, citing *Dunsmuir v New Brunswick*, 2008 SCC 9 at para 47).

[66] The Respondent notes that, according to *Vavilov*, "neither the duty of procedural fairness nor the statutory scheme will require that formal reasons be given at all" (at para 136, citing *Baker* at para 43). The need to give reasons is dependent on the context, and the reasons given need not be perfect. The Respondent argues that the Minister's delegate was not required to respond to every argument or line of possible analysis presented by the Applicants.

[67] Mr. MacKay states in his affidavit that the SAP is a small team that handles a large number of requests of varying complexity and urgency. With approximately 13 employees, the SAP processes roughly 1,000 requests and 800 phone calls each month. The SAP receives an average of 60 requests per day, of which one quarter represent medical emergencies and must be managed within minutes or hours. Requests for a new indication can lengthen the processing time.

[68] That appears to have been the case here, as evidenced by the initial review of the SAP request, the referral to Dr. Haddad, the telephone call between Dr. Haddad and Dr. Davenport, the opportunity for Dr. Davenport to provide further written submissions, the formal letter of refusal, and Dr. Haddad's internal memorandum to his colleagues with the rationale for his decision. A request for psilocybin to treat cluster headaches had never been granted under the SAP.

[69] One can discern from the initial review, the transcript of the telephone call between Dr. Haddad and Dr. Davenport, the subsequent correspondence from Dr. Davenport, and the formal letter of refusal, that the following propositions informed the decision of the Minister's delegate:

(a) the use of psilocybin to treat cluster headaches was not recommended in any medical guidelines, and the data regarding its safety and efficacy were lacking;

(b) the one documented clinical trial of psilocybin as a treatment for cluster headaches, involving 14 subjects, was inconclusive;

(c) the medical literature nevertheless indicated some promise for using psilocybin to treat cluster headaches, based primarily on anecdotal accounts;

(d) Mr. Lance's own experience of using hallucinogenic mushrooms containing psilocybin indicated that the drug was both efficacious and safe for him – in his communications with Dr. Davenport, Dr. Haddad did not question the safety of psilocybin for Mr. Lance, or that it worked for him;

(e) Dr. Davenport considered Mr. Lance's positive response to psilocybin to be "stronger than a double-blind, placebo-controlled study, since a clinical trial only tells us that there is a statistically significant likelihood that the treatment will have some efficacy for at least some people";

(f) Mr. Lance had considered and declined alternative treatments for reasons that Dr. Davenport considered to be valid. With respect to monoclonal antibodies, the treatment is very expensive and Mr. Lance could not afford it. In one study, 70% of patients received no clinical benefit, suggesting a low likelihood of success. There was also a potential risk of significant adverse side effects;

(g) applying the principles of patient-centred care, Dr. Davenport was of the opinion that he could not ethically require a patient to impoverish himself to attempt a treatment that was unlikely to be efficacious and carried a considerable risk of side effects, when he had already found a treatment (psilocybin) that was affordable, efficacious, and had no side effects; and

(h) Dr. Davenport did not consider an Individual Open Label Trial to be a suitable means for Mr. Lance to gain access to psilocybin, because it would be difficult for Mr. Lance to participate in a highly-supervised trial that involved regular attendance at a clinic – furthermore, Dr. Davenport did not consider himself qualified to design or administer such a trial, and funds and other resources were lacking.

[70] Dr. Haddad concluded that the SAP request did not meet the requirements of s C.08.010 of the FDR. He found there was insufficient information respecting the use, safety, and efficacy of psilocybin to treat cluster headaches, and there were therapeutic alternatives available on the market.

[71] In his affidavit, Mr. MacKay explains that Health Canada applies the well-established "hierarchy of scientific evidence", which refers to the principle that scientific evidence and data lie "on a spectrum from anecdotal evidence, such as a physician's impression from an individual patient, to evidence and data gathered from well-designed and executed non-clinical and clinical trials. The latter are considered credible when conducted by scientific and medical experts and subjected to scrutiny by peer review."

[72] Mr. MacKay also observes that "[i]n the context of an emergency, where time is a critical factor, the evidence threshold is lower".

[73] The Applicants concede that the efficacy of psilocybin to treat cluster headaches has not been confirmed by well-designed and executed non-clinical and clinical trials subject to peer review. The one clinical trial identified by both Dr. Davenport and Dr. Haddad, involving 14 subjects, did not demonstrate any material improvement in patients who suffered from cluster headaches who took psilocybin.

[74] According to the RIAS that accompanied the 2022 amendments to the FDA and FDR:

> […] while clinical trials remain the best mechanism to authorize the sale of restricted drugs (or any other unapproved drug) for the treatment of patients, there may be situations where a patient is unable to participate in one. For example, there may not be any clinical trials currently recruiting for a specific drug or in a specific area of the country. Given the growing scientific interest in certain restricted drugs, it is expected that Health Canada will encounter a situation where scientific evidence supports the therapeutic use of a restricted drug within the context of the Special Access Program.

[75] There was nothing to suggest that Mr. Lance might be eligible to participate in a full clinical trial of psilocybin to treat cluster headaches. Dr. Davenport ruled out the possibility of an Individual Open Label Trial, because it would be difficult for Mr. Lance to participate in a highly supervised trial that involved regular attendance at a clinic. Dr. Davenport did not consider himself qualified to design or administer such a trial, and funds and other resources were lacking. There is nothing in the record to indicate that Dr. Haddad grappled in a meaningful way with these considerations.

[76] In the letter of refusal, Dr. Haddad stated that there was insufficient information respecting the use, safety, and efficacy of psilocybin to treat cluster headaches. Even if one

accepts that Dr. Haddad was speaking informally during the telephone call, this conclusion appears to be inconsistent with his acknowledgment to Dr. Davenport that the safety and efficacy of psilocybin to treat Mr. Lance's cluster headaches were established. The SAP request pertained only to Mr. Lance, not a wider population.

[77] Counsel for the Respondent argues that the safety of psilocybin remains an open question, citing *R v Sullivan*, 2022 SCC 19 [*Sullivan*]. In that case, one of the accused became impaired after ingesting hallucinogenic mushrooms containing psilocybin. He attacked his father with a knife and killed him, and seriously injured his father's partner. He was charged with manslaughter and aggravated assault, and argued at trial that his state of intoxication was so extreme that his actions were involuntary.

[78] *Sullivan* is clearly distinguishable. The uncontested evidence before the Minister's delegate was that the dosage of psilocybin sought by Mr. Lance would not cause him to experience hallucinations of any kind, let alone render him intoxicated to the point where his actions would no longer be voluntary. If Dr. Haddad's conclusion respecting the safety of psilocybin, either for the general public or for Mr. Lance, was informed by considerations of the kind raised in *Sullivan*, this is not apparent from the decision or the communications with Dr. Davenport that preceded it. It must be noted that numerous SAP requests for psilocybin have been approved, albeit for other conditions.

[79] Dr. Haddad rejected the SAP request in part because he believed there were "therapeutic alternatives available on the market for the specified indication". The only alternative he

identified to Dr. Davenport was Galcanezumab, a monoclonal antibody that is administered by injection. Dr. Davenport explained that the treatment is very expensive and Mr. Lance could not afford it. Moreover, in one study, 70% of patients received no clinical benefit, suggesting a low likelihood of success. He also noted the potential risk of significant adverse side effects. There is nothing in the record to indicate that Dr. Haddad grappled in a meaningful way with these considerations.

[80] Counsel for the Respondent notes that additional alternative therapies (dihydroergotamine, lidocaine, and octreotide) were listed in the SAP request form. Dr. Davenport provided an explanation for why all of the identified alternative therapies had been attempted unsuccessfully or declined for valid reasons. If Dr. Haddad based his refusal on the potential availability of alternatives other than Galcanezumab, this is not apparent from the decision or the communications with Dr. Davenport that preceded it.

[81] The refusal of the Minister's delegate to approve the SAP request lacks the requisite degree of justification, intelligibility and transparency. Dr. Haddad did not meaningfully grapple with key issues and central arguments raised by the Applicants, calling into question whether he was fully alert and sensitive to the matter before him (*Vavilov* at para 128). The refusal of the SAP request was therefore unreasonable.

(2) The Failure to Engage with Charter Arguments

[82] The parties disagree on the standard of review to be applied to a decision maker's determination of whether an individual's Charter rights are engaged. The Applicants argue the applicable standard of review is correctness, while the Respondent say it is reasonableness.

[83] Judicial review of an administrative decision maker's balancing of Charter rights or values proceeds in two stages (*Commission scolaire francophone des Territoires du Nord-Ouest v Northwest Territories (Education, Culture and Employment)*, 2023 SCC 31 at para 73):

> […] a reviewing court must first determine whether the discretionary decision limits Charter protections. If this is the case, the reviewing court must then examine the decision maker's reasoning process to assess whether, given the relevant factual and legal constraints, the decision reflects a proportionate balancing of Charter rights or the values underlying them. If not, the decision is unreasonable.

[84] As Justice Richard Southcott observed in *Robinson v Canada (Attorney General)*, 2020 FC 942 [*Robinson FC*], if Charter rights are asserted by an applicant and potentially apply to a decision but are not considered, the resulting decision will be neither correct nor reasonable (at para 71). On appeal, the Federal Court of Appeal said the following (*Canada (Attorney General) v Robinson*, 2022 FCA 59 [*Robinson FCA*] at para 28):

> An administrative decision-maker does not have to address the Charter in every decision he or she makes (*Loyola* at para. 4). However, where, as in this case, a Charter protection is squarely raised by a party, the unexplained failure to address whether the Charter was engaged cannot survive reasonableness review. The reasons were not responsive to the question as framed in circumstances where it was called on to be answered (*Vavilov* at

> paras. 81 and 86) and the decision fails on both the transparency and justification metrics. As the Supreme Court said in *Vavilov*, reasons are the primary mechanism by which administrative decision-makers show that their decisions are reasonable (para. 81). For a decision to be justifiable where, as here, reasons are required, the decision must be justified by the reasons (paras. 86-87).

[85] The SAP request was accompanied by lengthy legal submissions respecting Mr. Lance's right under s 7 of Charter to be granted access to psilocybin. These were wholly disregarded by the Minister's delegate. The Respondent argues that Dr. Haddad implicitly found that Mr. Lance's Charter rights were not engaged. However, "it is not ordinarily appropriate for the reviewing court to fashion its own reasons in order to buttress the administrative decision" (*Vavilov* at para 96).

[86] The Respondent relies on Justice Christine Pallotta's decision in *Toth v Canada (Health and Addictions)*, 2023 FC 1283 [*Toth*] (at paras 112-113):

> The Minister's reasons provide the rationale for rejecting the Charter arguments by addressing their very foundation, which is that [healthcare practitioners (HCPs)] need experiential training to provide the most safe and effective care to patients. The Charter arguments hinged on a scientific premise that the Minister found had not been established on the evidence, and the Minister provided a legal route for the HCPs to access psilocybin and build that evidence. […]
>
> This case differs from the circumstances in *Robinson FC* where the Court found that the administrative decision engaged Mr. Robinson's equality rights under section 15 of the Charter as a person with a physical disability, and the decision maker did not take those rights into account in making the decision: *Robinson FC* at para 5. Neither the decision nor the record demonstrated any consideration of the impact of the decision on Mr. Robinson's equality rights, and the decision maker's conclusion missed the thrust of the Charter argument: *Robinson FC* at para 70; see also

> *Robinson FCA* at para 21. Here, the Minister did not miss the thrust of the Charter arguments. The Minister addressed the foundation for the arguments. Unlike Mr. Robinson's case, the Minister's reasons were responsive to the Charter arguments the HCPs framed: *Robinson FCA* at para 28.

[87] *Toth* is readily distinguishable from the present case. The decision arose from a request for access to psilocybin under s 56 of the CDSA, not the SAP. The applicants in *Toth* were healthcare professionals [HCPs] who asserted a Charter right to gain experiential training – by using psilocybin themselves – in order to treat patients who might benefit from the drug. The decision maker found that the HCPs did not require this kind of experiential training to provide the most safe and effective care to their patients.

[88] Here, Mr. Lance sought access to psilocybin to treat his own serious medical condition. The Minister's delegate did not question the safety and efficacy of psilocybin in Mr. Lance's particular circumstances. Mr. Lance's counsel identified three separate rights under s 7 of the Charter that were engaged by a refusal of the SAP request: life, liberty and security of the person.

[89] The decision of the Minister's delegate did not reject the factual foundation for Mr. Lance's assertion of Charter rights, but rather found that the safety and efficacy of psilocybin to treat his condition were not sufficiently established generally, and alternative lawful therapies were available. Mr. Lance's invocation of the Charter was intended to assist in overcoming these potential obstacles (citing *Allard v Canada*, 2016 FC 236; *Carter v Canada (Attorney General)*, 2015 SCC 5; *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44; *Hitzig v Canada*, [2003] OJ No 3873 (QL); and *R v Krieger*, 2003 ABCA 85).

[90] In this respect, Mr. Lance's circumstances resemble those of the applicant in *Robinson FC*, who argued that his right to equality under s 15 of the Charter was engaged by virtue of his physical disability. Mr. Lance's Charter arguments were squarely raised in the SAP request, and it was incumbent on the decision maker to meaningfully grapple with them. He failed to do so, and in this further respect his decision was unreasonable.

D. *What is the appropriate remedy?*

[91] The Applicants ask this Court to order the Minister's delegate to grant the SAP request. They say that remitting the request to the Minister's delegate for redetermination will serve no useful purpose, because the Charter demands that it be approved.

[92] The Court may order the outcome of an administrative decision in only limited circumstances. These include: when remitting the matter for reconsideration would prevent the timely and effective resolution of the matter in a manner not intended by the legislature (*D'Errico v Canada (Attorney General)*, 2014 FCA 95 at paras 18-19); and when a particular outcome is inevitable (*Groia v Law Society of Upper Canada*, 2018 SCC 27 at para 161; *Sharif v Canada (Attorney General)*, 2018 FCA 205 at paras 54-55).

[93] While there is undoubtedly a degree of urgency in this case, the Applicants did not bring a motion pursuant to Rule 385(1)(a) to expedite the proceeding after it was commenced in September 2023. Counsel for the Respondent has provided an assurance that the Minister's delegate will, if so ordered by the Court, redetermine the matter within two weeks.

[94] I have found the decision of the Minister's delegate to be unreasonable due to his failure to grapple with key or central issues raised by the Applicant, and for failing entirely to consider the Applicants' Charter arguments. However, I am unable to say that appropriate consideration of these issues will necessarily result in approval of the SAP request. The Minister's delegate should be given another opportunity to address the key or central issues raised by the SAP request, as elucidated in these Reasons.

[95] These include: (a) whether it is necessary for a peer-reviewed clinical study to confirm the safety and efficacy of psilocybin to treat cluster headaches before granting a SAP request for a patient for whom the safety and efficacy have been established; (b) Dr. Davenport's explanation for why Mr. Lance cannot participate in a clinical trial, including an Individual Open Label Trial; (c) Dr. Davenport's explanation for why Galcanezumab is not a suitable alternative treatment for Mr. Lance; and (d) Dr. Davenport's reasons for ruling out other conventional treatments.

[96] The Minister's delegate must also consider whether the SAP request engages Mr. Lance's rights under s 7 of the Charter and, if so, how the severity of the interference with these rights should be balanced against the regulatory objectives of the SAP.

V. Conclusion

[97] The application for judicial review is granted, and the matter is remitted to a different delegate of the Minister for redetermination. The Minister's delegate must render a decision on

the SAP request within fourteen (14) days of the date of the Judgment that accompanies these Reasons.

[98] The Respondent asks that he be identified in this proceeding as the Attorney General of Canada, rather than the Minister of Health. The style of cause will be amended accordingly.

VI. Costs

[99] According to the Court's *Amended Consolidated General Practice Guidelines* (December 20, 2023), during the hearing of an application the parties should be prepared to inform the Court whether they have agreed on the disposition and/or quantum of costs and, if not, to make submissions respecting those issues. None of the parties were prepared to address costs at the hearing of this matter.

[100] In correspondence dated May 13, 3024, the Applicants requested costs in the amount of $6,860.00, including all disbursements, calculated in accordance with the high end of Column III of Tariff B. The Respondent was given an opportunity to respond to the Applicants' brief written submissions respecting costs but declined to do so, instead requesting additional time following the issuance of the Court's Judgment and Reasons to address costs.

[101] The purpose of requiring the parties to address costs during the hearing of an application is to avoid undue delay and complication of the proceedings, and conserve scarce judicial

resources. In most cases, it should not be necessary for the Court to entertain additional submissions respecting costs after a hearing, necessitating the issuance of a separate Order.

[102] Given the nature of this proceeding, a request by the successful party for costs calculated in accordance with the high end of Column III of Tariff B is eminently reasonable. Mr. Pope represented the Applicants on a *pro bono* basis, on the understanding that any award of costs would be paid to his firm in trust, subject to the following directions:

(a) the Applicants will be reimbursed for all disbursements reasonably and necessarily incurred by them;

(b) any amount that remains may be retained by their counsel; and

(c) if any dispute arises as to the amount to which the Applicants are entitled, a motion may be made to this Court for resolution.

[103] This form of costs award is modelled on the one approved by this Court in *Northcott v Canada (Attorney General)*, 2021 FC 289 (at paras 51-53), citing *Roby v Canada (Attorney General)*, 2013 FCA 251 (at paras 26-29).

[104] Costs will be awarded accordingly.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application for judicial review is granted, and the matter is remitted to a different delegate of the Minister for redetermination.

2. The Minister's delegate shall render a decision on the Applicants' request under the Special Access Program within fourteen (14) days of the date of this Judgment.

3. Costs are awarded to the Applicants in accordance with the high end of Column III of Tariff B in the amount of $6,860.00, including all disbursements.

4. Costs shall be made payable to Hameed Law, Barristers & Solicitors, in trust, subject to the following directions:

    (a) the Applicants will be reimbursed for all disbursements reasonably and necessarily incurred by them;

    (b) any amount that remains may be retained by their counsel; and

    (c) if any dispute arises as to the amount to which the Applicants are entitled, a motion may be made to this Court for resolution.

5. The style of cause is amended to name the Respondent as the Attorney General of Canada, with immediate effect.

"Simon Fothergill"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1881-23
STYLE OF CAUSE:	JODY LANCE AND WILLIAM JEPTHA DAVENPORT v ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	MAY 7, 2024
JUDGMENT AND REASONS:	FOTHERGILL J.
DATED:	MAY 24, 2024

APPEARANCES:

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