Court File No. T-1881-23

FEDERAL COURT

B E T W E E N:

JODY LANCE and WILLIAM JEPTHA DAVENPORT

Applicants

-and-

MINISTER OF HEALTH

Respondent

APPLICATION RECORD

Volume 3 of 4

Memorandum of Fact and Law

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PART I – STATEMENT OF FACT

A. Overview

1. This is an application for judicial review of the Minister of Health's ("**Minister**") decision to refuse Dr. William Jeptha Davenport's Special Access Program ("**SAP**") request to treat Jody Lance's cluster headaches with psilocybin, under s. C.08.010(1) of the *Food and Drug Regulations*, CRC, c 870.[1]

2. In the SAP request, the Applicants submitted evidence demonstrating that psilocybin is a reasonable medical choice for Mr. Lance, and they made legal submissions arguing that Mr. Lance has the right to make this choice under s. 7 of the *Charter*. But the Minister's delegate did not address this argument, neglecting his duty under *Doré* to balance *Charter* values with the statutory objectives.[2]

3. The Applicants submitted that Mr. Lance's *Charter* right to make reasonable medical choices can be based on anecdotal evidence and personal experience when there is a lack of evidence from clinical trials, as held in *Hitzig*[3] and *Allard*,[4] but the Minister's delegate did not address this argument. He instead fettered his discretion by a non-binding policy requiring at least one clinical trial demonstrating positive outcomes for a SAP request to be approved, and he denied the application because such a trial had not been completed.

4. The Applicants also submitted that a patient does not need to attempt all conventional treatments before exercising their right to make reasonable medical choices, as held in *Kreiger*,[5] but the Minister's delegate did not address this argument, and he denied the application because Mr. Lance had not tried all alternatives treatments.

5. The Minister's delegate made numerous other justificatory errors including failing to explain departures from past practice, straying beyond the limits of the statutory

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[1] *Food and Drug Regulations*, CRC, c 870 [*FDR*], s C.08.010(1).
[2] *Doré v Barreau du Québec*, 2012 SCC 12 at paras 55-56.
[3] *Hitzig v Canada*, 231 DLR (4th) 104 at paras 8-10, 177 OAC 321 (ONCA).
[4] *Allard v Canada*, 2016 FC 236 at paras 87 & 211.
[5] *R v Krieger*, 2003 ABCA 85 at para 3, affirming *R v Krieger*, 2000 ABQB 1012 at para 28.

language, and failing to provide responsive justification.

6. The Court should not remit the decision for redetermination but should direct the Minister to grant the SAP authorization since the outcome is inevitable. In *PHS*, the Supreme Court said that the Minister must grant exemptions to possess controlled substances where there is some evidence it improves health and little to no evidence of negative effects on safety.[6] The Minister's delegate informed Dr. Davenport, "Safety is established," and, "I know it works for the patient." Based on these factual findings, the *Charter* limits the Minister's discretion, and he must grant the SAP authorization.

B. Mr. Lance's Cluster Headaches

7. Mr. Lance has suffered from severe cluster headaches for the past seven years.[7] Cluster headaches, often known as "suicide headaches", are one of the most painful conditions known to humanity. The attacks can occur up to eight times a day, remain for up to three hours, and come in clusters that last 6-12 weeks.[8]

8. Mr. Lance's headaches are debilitating. They have taken control of every aspect of his life. 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 he may be struck with the unspeakable pain of a cluster attack in a foreign environment. He lives in constant fear of the next attack, sometimes going into a panic when he feels them coming on.[9]

9. There have even been times when the pain has become so unbearable that Mr. Lance has contemplated suicide or medical assistance in dying.[10]

10. There is no cure for cluster headaches. Mr. Lance has tried numerous treatments,

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[6] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at paras 150 & 152.
[7] Affidavit of Jody Lance, July 17, 2023 ("**Lance Affidavit**"), para 5, **Application Record Vol 1 ("AR1"), Tab ("T") 18, p 298**.
[8] Lance Affidavit, para 6, **AR1, T 18, p 298**; Organisation for the Prevention of Intense Suffering, Policy Paper, Lance Affidavit, Exhibit "B", **AR1, T 18A, pp 318-320**.
[9] Lance Affidavit, paras 13-20, **AR1, T 18, pp 299-300**.
[10] Lance Affidavit, para 21, **AR1, T 18, p 300**.

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 caused him significant negative side effects.[11]

C. Psilocybin's Efficacy

11. After many failed treatments, Dr. Davenport, a neurologist specializing in cluster headaches, told Mr. Lance that another of his patients had tried psilocybin mushrooms, and it had stopped their cluster cycles. Mr. Lance sought out psilocybin mushrooms and consumed them, and his cluster headaches stopped for a while.[12]

12. Since that first experience, Mr. Lance tried taking different amounts of psilocybin at different intervals to determine what works best. After trying many different dosages and intervals, he found a dosing regimen that works best to alleviate his pain. Upon the onset of a regular-strength cluster attack, he takes four 300 mg capsules of dried psilocybin mushrooms per day, divided into two or more doses, 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.[13]

13. The psilocybin often resets the cluster cycles, giving him temporary reprieve. It relaxes his body, reducing the muscle knots in his neck and shoulders. It also helps his mind relax, alleviating the anxiety and panic that makes the headaches even worse.[14] It does not produce any significant negative side effects. In fact, studies have shown that psilocybin has a better safety profile than aspirin.[15] There is no risk of overdose since a 60 kg human would need to consume 170 g of pure psilocybin to overdose, which is 14,167 times more than the 12 mg of psilocybin contained within each 600 mg dose of dried mushrooms that Mr. Lance takes.[16]

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[11] Lance Affidavit, paras 23-35, **AR1, T 18, pp 300-303**.
[12] Lance Affidavit, paras 36-40, **AR1, T 18, p 303**.
[13] Lance Affidavit, paras 41, 44 & 46, **AR1, T 18, pp 303-304**.
[14] Lance Affidavit, paras 49-52, **AR1, T 18, p 305**.
[15] Lowe 2021, p 20, **Application Record Vol 2 ("AR2"), T 1(45), p 550**; SAP Form A, **AR1, T 16, p 264**.
[16] Roberts et al, Perceived harm, motivations for use and subjective experiences of recreational psychedelic 'magic' mushroom use, *J Psychopharmacology*, 2020, **AR2, T 56, p 762**.

14. Since starting to take psilocybin, Mr. Lance has been able to regain some control over his life. He can do more activities than before and participate in 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.[17]

D. Special Access Program Request

15. On July 26, 2023, Dr. Davenport submitted a Special Access Program request to legally procure purified psilocybin, produced by a Health Canada approved supplier, Filament Health, to treat Mr. Lance's cluster headaches ("**SAP Request**"). In the request, Dr. Davenport provided all the information required by the SAP, including the condition's impact on Mr. Lance's life, all treatments attempted or declined, psilocybin's mechanism of action, the calculation of the appropriate dosage, and all available scientific research regarding psilocybin's safety and efficacy for cluster headaches.[18] 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.[19]

16. Dr. Gaurav Gupta, a physiatrist and adult chronic pain specialist, also assessed Mr. Lance. Dr. Gupta reviewed the SAP Request and provided an expert second opinion agreeing with Dr. Davenport that psilocybin is a reasonable medical choice.[20]

17. Jagpaul Deol, a pharmacist who specializes in psilocybin and psychedelic medicines, also reviewed the SAP Request. Ms. Deol provided her expert opinion that psilocybin is a reasonable medical choice for Mr. Lance; the requested dosage is accurate and appropriate; the dosage is not likely to result in an altered state of consciousness; and the use of psilocybin aligns with current medical and scientific understanding.[21]

18. The Applicants also submitted legal representations, arguing that the Minister's

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[17] Lance Affidavit, para 53, **AR1, T 18, p 305**.
[18] SAP Form A, **AR1, T 16, pp 254-270**.
[19] SAP Form A, ss. E.1.a.1 "Patient Summary and Current Diagnosis" & E.1.b.1 "Medical Opinion", **AR1, T 16, pp 257 & 262**.
[20] Affidavit of Gaurav Gupta, July 18, 2023 ("**Gupta Affidavit**"), **AR1, T 19, pp 397-398**.
[21] Affidavit of Jagpaul Deol, July 25, 2023 ("**Deol Affidavit**"), **AR1, T 20, pp 406-408**.

discretion was limited by s. 7 of *Charter*, which protects Mr. Lance's right to make reasonable medical choices and receive timely medical treatment.[22] This was supported by an affidavit from Mr. Lance, a package of supporting documents, and a package of medical and scientific journal articles.[23]

19. On August 21, 2023, the Minister's delegate, Haddad Bechara, had a phone call with Dr. Davenport. In this call, the Minister's delegate told Dr. Davenport

    a. "Safety is established" for psilocybin,[24] and

    b. "I know it has worked for the patient".[25]

20. The Minister's delegate asked Dr. Davenport whether he knew of any more published clinical trials regarding psilocybin for cluster headaches; whether he had considered an open label individual patient ("**OLIP**") trial; and whether CGRP monoclonal antibodies had been considered as a treatment.[26]

21. On August 28, 2023, Dr. Davenport sent the Minister's delegate a letter responding to each inquiry:

    a. 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 indicate the probability of efficacy in the general population.[27]

    b. Dr. Davenport stated that an OLIP trial would not be feasible, and he gave several reasons for this.[28]

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[22] Legal Representations, July 25, 2023, **AR1, T 17, pp 271-296**.
[23] SAP Request Cover Letter, July 26, 2023, **AR1, T 15, p 253**; *see* **AR1, T 18 & 21** & **AR2, T 1**.
[24] Transcript of Call: Minister's Delegate and Dr. Davenport, Aug 21, 2023, ("**Aug 21, 2023, Call Transcript**") at 02:09, Affidavit of William Jeptha Davenport, Sept 28, 2023 ("**Davenport Affidavit**"), Exhibit "B", **AR1, T 3A, p 24**.
[25] Aug 21, 2023, Call Transcript at 05:23, **AR1, T 3A, p 27**.
[26] Aug 21, 2023, Call Transcript at 03:59, 05:23 & 06:03, **AR1, T 3A, pp 26, 27 & 28**.
[27] Letter from Dr. Davenport to Minister's delegate, August 23, 2023, ("**Aug 23, 2023, Letter**"), **AR1, T 13, pp 248-249**.
[28] Aug 23, 2023, Letter, **AR1, T 13, pp 249-250**.

c. Dr. Davenport reiterated that all alternative treatments are unsuitable, specifically that CGRP monoclonal antibodies are unsuitable because of the side effects, cost, and high likelihood that they would not be effective.[29]

E. Refusal

22. On August 30, 2023, Dr. Davenport received the Decision 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.[30]

23. The Applicants' *Charter* argument is not mentioned in any of the records disclosed in the Certified Tribunal Record ("**CTR**"), nor is there any information that impliedly addresses it. The only analysis Health Canada conducted was about whether Mr. Lance's condition met Health Canada's definition of a "medical emergency". There was no analysis as to whether the proposed treatment was a "reasonable medical choice", which is the question relevant to Mr. Lance's s. 7 *Charter* right.

PART II – POINTS IN ISSUE

24. The Applicants submit that the following issues are to be determined:

ISSUE 1: Are the affidavits admissible?

ISSUE 2: What is the standard of review?

ISSUE 3: Is the Decision unreasonable?

ISSUE 4: What is the appropriate remedy?

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[29] Aug 23, 2023, Letter, **AR1, T 13, pp 250-251**.
[30] Letter of Denial, Aug 30, 2023, **AR1, T 2, pp 16-17**.

PART III – SUBMISSIONS

ISSUE 1: Admissibility of Affidavits

25. Paragraphs 12-15, 17-27, and 29 of the Affidavit of Ian MacKay ("**Mackay Affidavit**") are inadmissible, but the three affidavits submitted by the Applicants are admissible.

26. New evidence is not admissible in an application for judicial review unless the receipt of the evidence is consistent with the differing roles of the judicial review court and the administrative decision maker. There are three recognized situations where new evidence tends to comply with this, but the list of exceptions is not closed:

    a. General background information where it might assist the court in understanding the issues relevant to the judicial review;

    b. To bring procedural defects to the attention of the court; and

    c. To highlight a complete absence of evidence before a decision maker.[31]

27. Paragraphs 12-15 of the MacKay Affidavit,[32] which contain information about the size of the SAP team and the number of requests received, are inadmissible because this information was not before the Minister's delegate and does not fall into any of the three exceptions. Even if it were considered general background information, this information is not relevant to any issues in the judicial review.

28. Paragraphs 17-22 of the MacKay Affidavit (which contain information about clinical trials) and paragraphs 23-27 (which explain how Health Canada weighs evidence for SAP requests)[33] are inadmissible because this information was not before the Minister's delegate and does not fall into any of the three exceptions. The introduction of this information is inconsistent with the court's role in judicial review because the

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[31] *Association of Universities and Colleges of Canada v Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22 at para 20.
[32] **AR1, T 6, pp 65-66**.
[33] **AR1, T 6, pp 66-69**.

only use for this evidence could be to impermissibly buttress the decision maker's reasoning after the fact.[34]

29. Paragraph 29 of the MacKay Affidavit[35] is inadmissible because it was not before the Minister's delegate and does not fall into any of the three exceptions. Furthermore, it is a legal opinion, not a statement of fact,[36] and the legal opinion is patently incorrect since, contrary to the affiant's statement, the class exemption does not exempt patients from any provisions of the *Controlled Drugs and Substances Act.*[37]

30. By contrast, the Affidavit of Dr. Davenport[38] is admissible because it only contains information that was before the Minister's delegate in making the decision. The affidavit contains the recording of a phone call with the Minister's delegate that was essentially a reconsideration hearing in which the Minister's delegate informed Dr. Davenport of his factual findings and reasoning, and Dr. Davenport made submissions.

31. Although the material in the Affidavits of Matthew Hunter and Corey Pettipas[39] were not before the Minister's delegate, they fall within the first *Access Copyright* exception as background information that assists the court. Their purpose is to provide evidence of the SAP's past practice. The Court needs this evidence to assess whether the decision is unreasonable due to an unexplained departure from past practice.[40] If this information were not allowed, the decision maker would be immunized from review on this ground because SAP decisions are not published on CanLII or other public services in a way that allows a court to take judicial notice.[41]

ISSUE 2: Standard of Review

32. The default standard of review of reasonableness[42] applies to all issues except one.

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[34] *See Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 96.
[35] **AR1, T 6, p 70**.
[36] *See Duyvenbode v Canada (Attorney General)*, 2009 FCA 120 at paras 2-3, [2009] FCJ No 504.
[37] *Controlled Drugs and Substances Act*, SC 1996, c 19 [*CDSA*].
[38] **AR1, T 3, pp 18-32**.
[39] **AR1, T 4 & 5, pp 33-61**.
[40] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 131.
[41] *See Lukács v Canada (Transportation Agency)*, 2016 FCA 103 at para 7.
[42] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 10.

For the Respondent's failure to balance the *Charter* infringement with statutory objectives, there is a two-step approach. For the first step, whether the *Charter* is engaged, the standard is correctness. For the second, whether the decision reflects a proportionate balance, the standard is reasonableness.[43]

ISSUE 3: Decision is Unreasonable

33. It is not good enough for a decision to be *justifiable*; the decision must be *justified* by its reasons.[44] Even if the outcome of the decision could be reasonable under different circumstances, it is "not ordinarily appropriate for the reviewing court to fashion its own reasons in order to buttress the administrative decision."[45] The Decision is unreasonable due to each of the eight justificatory failures outlined below.

3.1 Failure to Balance *Charter* Values

34. The Decision is unreasonable because the Minister's delegate failed to demonstrate that he balanced the relevant *Charter* values with the statutory objectives.[46] The Applicants squarely raised the violation of Mr. Lance's s. 7 *Charter* rights, yet the Minister's delegate did not even address whether the *Charter* was engaged.

3.1.1 *Charter* Arguments Raised

35. The Applicants made submissions arguing that psilocybin is a reasonable medical choice, and Mr. Lance has a right to make this choice under s. 7 of the *Charter*.[47] The Applicants submitted that according to the Supreme Court in *PHS*, the Minister must grant exemptions where there is some evidence in improves health and little to no

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[43] The Federal Court adopted this approach in *Robinson v Canada (Attorney General)*, 2020 FC 942 at paras 42 & 59, following the Ontario Court of Appeal in *Canadian Broadcasting Corporation v Ferrier*, 2019 ONCA 1025 at para 35. The Federal Court of Appeal upheld *Robinson*, summarizing the Federal Court's approach in *Canada (Attorney General) v Robinson*, 2022 FCA 59 at paras 17-18, but finding it unnecessary to decide whether to adopt the approach (para 29). However, in *Canadian Broadcasting Corporation v Canada (Parole Board)*, 2023 FCA 166 at paras 32-33, the Federal Court of Appeal adopted the approach; *see also Commission scolaire francophone des Territoires du Nord-Ouest v Northwest Territories (Education, Culture and Employment)*, 2023 SCC 31 at para 73.
[44] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 86.
[45] *Ibid* at para 96.
[46] *Doré v Barreau du Québec*, 2012 SCC 12 at paras 55-56.
[47] Legal Representations, **AR1, T 17, pp 273-294**.

evidence of negative effects on safety.[48] The Minister's delegate told Dr. Davenport, "Safety is established,"[49] and, "I know it works for the patient,"[50] so on his own factual findings, he must grant the exemption.

36. The Applicants submitted arguments that Mr. Lance's *Charter* right to make reasonable medical choices can be based on anecdotal evidence and personal experience where evidence from clinical trials is lacking, as per *Hitzig* and *Allard*,[51] but the Minister's delegate did not address this argument, instead denying the application because of a non-binding policy that there must be at least one clinical trial demonstrating positive outcomes.[52]

37. The Applicants also submitted that a patient does not have to attempt all conventional treatments before being allowed to exercise their right to make reasonable medical choices, per *Kreiger*,[53] but the Minister's delegate did not address this argument, instead denying the application on the basis that Mr. Lance had not attempted all alternatives.[54]

3.1.2. Lack of Analysis is Unreasonable

38. Administrative decision makers must balance the statutory objectives with the *Charter* values at issue when a decision limits a *Charter* right.[55] This must be "a robust proportionality analysis",[56] one that works "the same justificatory muscles" as the *Oakes* test, not a "watered-down version".[57]

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[48] Legal Representations, paras 59-63, **AR1, T 17, pp 285-287**; *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at paras 150 & 152.
[49] Aug 21, 2023, Call Transcript at 02:09, **AR1, T 3A, p 24**.
[50] Aug 21, 2023, Call Transcript at 05:23, **AR1, T 3A, p 27**.
[51] Legal Representations, paras 33, 50 & 72, **AR1, T 17, pp 279, 283-284 & 288-289**; *Hitzig v Canada*, 2003 CanLII 30796 (ONCA) at paras 8-10, 231 DLR (4th) 104; *Allard v Canada*, 2016 FC 236 at paras 83, 85, 87, 91 & 211.
[52] Aug 21, 2023, Call Transcript at 03:35, **AR1, T 3A, pp 25-26**.
[53] Legal Representations, para 30, **AR1, T 17, p 279**; *R v Krieger*, 2003 ABCA 85 at para 3; affirming *R v Krieger*, 2000 ABQB 1012 at para 28.
[54] Letter of Denial, **AR1, T 2, p 16**.
[55] *Doré v Barreau du Québec*, 2012 SCC 12 at paras 55-56.
[56] *Loyola High School v Quebec (Attorney General)*, 2015 SCC 12 at para 3.
[57] *Law Society of British Columbia v Trinity Western University*, 2018 SCC 32 at paras 79-82; *Lauzon v Ontario (Justices of the Peace Review Council)*, 2023 ONCA 425 at para 145.

39. Judicial review of this balancing typically involves a two-step approach.[58] However the full analysis is not required where, as here, the decision maker did not address the *Charter* issue at all. In this situation, the decision is automatically unreasonable. As stated by the Federal Court of Appeal in *Robinson*, "where […] a *Charter* protection is squarely raised by a party, the unexplained failure to address whether the *Charter* was engaged cannot survive reasonableness review."[59]

40. Nowhere in the reasons for the decision, or even in internal records, does the Minister's delegate mention the *Charter*. Nor can it be said that the Minister's delegate implicitly concluded the *Charter* is not engaged since he did not address whether psilocybin is a reasonable medical choice for Mr. Lance.

3.1.3 Disproportionate Balancing is Unreasonable

41. Even if the Minister's delegate had addressed whether the *Charter* was engaged, the Decision would still be unreasonable because it does not reflect a proportionate balancing of *Charter* rights and statutory objectives. "In cases where the reviewing court finds that 'there was an option or avenue *reasonably* open to the decision-maker that would reduce the impact on the protected right while still permitting him or her to sufficiently further the relevant . . . objectives', the administrative decision will be unreasonable".[60] The Minister's delegate could have approved the SAP Request, which would have reduced the impact on Mr. Lance's rights and furthered the statutory objectives of improving health and safety. Thus, the Decision is unreasonable.

3.2 Failure to Meaningfully Grapple with Central Arguments

42. The Decision is unreasonable because it fails to meaningfully grapple with any of the

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[58] *Canada (Attorney General) v Robinson*, 2022 FCA 59 at para 17; citing *Law Society of British Columbia v Trinity Western University*, 2018 SCC 32 at para 28.
[59] *Canada (Attorney General) v Robinson*, 2022 FCA 59 at para 28.
[60] *Commission scolaire francophone des Territoires du Nord-Ouest v Northwest Territories (Education, Culture and Employment)*, 2023 SCC 31 at para 72, citing *Law Society of British Columbia v Trinity Western University*, 2018 SCC 32 at para 81, emphasis in original.

Applicants' central arguments.[61] Reasons that simply "summarize arguments made, and then state a peremptory conclusion" are not adequate.[62] Nor is a decision maker's statement that it has not been persuaded by a particular submission.[63]

43. This is a shift from the pre-*Vavilov* approach. The Federal Court of Appeal noted this shift in in *Farrier*, when it found a decision unreasonable for failing to provide reasons on two issues raised by the applicant. The Court explained, "Before *Vavilov* I would probably have found, as did the Federal Court, that, in light of the presumption that the decision-maker considered all of the arguments and the case law before it and after having read the record, the decision was reasonable."[64] But as a result of the shift in the law, the Court held that "the reasons do not meet the standard of reasonableness described by the Supreme Court in *Vavilov*."[65]

44. In their initial submissions and in Dr. Davenport's August 28, 2023, letter, the Applicants made three central arguments:

    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*;[66]

    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;[67] and

    c. All alternative treatments have been deemed clinically unsuitable due to the side effects, high cost, and low likelihood of efficacy.[68]

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[61] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 128; *Canada (Attorney General) v Zalys*, 2020 FCA 81 at para 98; *Turner v Canada (Attorney General)*, 2022 FCA 192 at para 8.
[62] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 102.
[63] *Paul v Canada (Attorney General)*, 2022 FC 1157 at paras 32-34.
[64] *Farrier v Canada (Attorney General)*, 2020 FCA 25 at para 12.
[65] *Ibid* at para 19.
[66] Legal Representations, **AR1, T 17, pp 273-294**.
[67] Aug 23, 2023, Letter, **AR1, T 13, p 249**; Legal Representations, paras 7 & 72, **AR1, T 17, pp 274 & 288**.
[68] Aug 23, 2023, Letter, **AR1, T 13, p 250-251**; SAP Form A, ss. E.1.b.3 "Treatments Considered" & E.1.b.4 "Studies Indicating Lack of Efficacy of Other Treatments", **AR1, T 16, pp 262-263**.

45. The two-sentence Decision fails to meaningfully grapple with any of these arguments. The *Charter* argument was not addressed anywhere, neither in the Decision, nor the phone call the Minister's delegate had with Dr. Davenport, nor any of the internal Health Canada memos or communications. The arguments about psilocybin's efficacy and the unsuitability of alternatives were partially mentioned in internal Health Canada records, but they were not meaningfully grappled with, nor could any discussion in internal records cure the failure since it is "unacceptable" for a decision to "be upheld on the basis of internal records that were not available to that party."[69]

3.3 Failure to Justify Departure from Binding Precedent

46. The Decision is unreasonable because it fails to justify the departure from binding precedents that were squarely raised by the Applicants. Where "there is a relevant case in which a court considered a statutory provision, it would be unreasonable for an administrative decision maker to interpret or apply the provision without regard to that precedent."[70] And "to be reasonable, an administrative decision must, among other things, provide reasons for departing from decided authority."[71]

47. The Applicants relied on seven medical cannabis decisions and four other Supreme Court decisions that interpreted and applied s. 7 of the *Charter*. The Decision departed from the precedent of each, 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;[72]

    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

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[69] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 95.
[70] *Ibid* at para 112.
[71] *Turner v Canada (Attorney General)*, 2022 FCA 192 at para 8.
[72] Legal Representations, para 50, **AR1, T 17, pp 283-284**; *Allard v Canada*, 2016 FC 236 at paras 87 & 211.

evidence" are sufficient evidence of efficacy;[73]

c. *R v Krieger*, 2003 ABCA 85, which held that a person's rights to liberty and security of the person are infringed by denying a treatment that is effective for the person even if the person has not tried all alternative treatments;[74]

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, even if "serious risks […] may flow from the patient's decision";[75] 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.[76]

3.4 Non-Transparent

48. The Decision is unreasonable because it is not transparent about what is meant by its conclusion that there are therapeutic alternatives available. Decisions must be "transparent, not in the abstract, but to the individuals subject to it", and it is "unacceptable" for a decision to "be upheld on the basis of internal records that were not available to that party."[77]

49. The Decision does not identify what alternative treatments are available, and the Minister's delegate did not mention any alternatives treatments in his phone call with Dr. Davenport other than CGRP monoclonal antibodies,[78] for which Dr. Davenport had already explained the unsuitability.[79] The three alternatives that the Minister's

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[73] Legal Representations, para 33, **AR1, T 17, p 279**; *Hitzig v Canada*, 231 DLR (4th) 104 at paras 9-10.
[74] Legal Representations, para 30, **AR1, T 17, p 279**; *R v Krieger*, 2003 ABCA 85 at para 3; affirming *R v Krieger*, 2000 ABQB 1012 at para 28.
[75] Legal Representations, paras 57-58, **AR1, T 17, p 285**; *Carter v Canada (Attorney General)*, 2015 SCC 5 at para 67.
[76] Legal Representations, paras 59-63, **AR1, T 17, p 285-287**; *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at para 150 & 152.
[77] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 95.
[78] Aug 23, 2023, Letter, para 2, **AR1, T 13, p 248**; Aug 21, 2023, Call Transcript, **AR1, T 3A, pp 23-32**.
[79] SAP Form A, Section E.1.b.3 "Treatments Considered", **AR1, T 16, p 263**.

delegate appears to have based his decision upon are only stated in internal documents that were not disclosed to the Applicants until they received the CTR in this Federal Court application.[80] Thus, the decision cannot be upheld on this basis.[81]

3.5 Unexplained Departure from Past Practice

50. The Decision is unreasonable because it does not explain its departure from the Minister's past practice of authorizing SAP requests

    a. for patients who had not tried all therapeutic alternatives available on the market for their condition; and

    b. that contained less information about a drug's use, safety, and efficacy.

51. The Supreme Court in *Vavilov* set out a bright-line rule that an unexplained departure from past decisions always renders a decision unreasonable:

> Where a decision maker does depart from longstanding practices or established internal authority, it bears the justificatory burden of explaining that departure in its reasons. If the decision maker does not satisfy this burden, the decision will be unreasonable.[82]

52. The Minister had previously approved Matthew Hunter's SAP request for psilocybin despite him not attempting many antidepressants, including Remeron, nor attempting osteopathic treatment, massage therapy, group-based education, or occupational therapy support.[83] The Minister's delegate did not explain why Mr. Lance was required to attempt all alternative treatments when others were not.

53. The Minister approved Corey Pettipas' SAP request for MDMA despite it being only eight pages long and referencing four articles.[84] By contrast Mr. Lance's SAP

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[80] The three alternatives mentioned in these internal documents are 1) dihydroergotamine, which Health Canada's records indicate is "probably ineffective" for cluster headaches, 2) octreotide, which is "not indicated for cluster headaches in Canada", and 3) lidocaine: SAP Review Report, Request #173504, **AR1, T 9, pp 206 & 208**.
[81] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 95.
[82] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 131.
[83] Matthew Hunter SAP Form A and SAP Letter of Authorization, Exhibits "A" & "B" to the Affidavit of Matthew Hunter, Sept 19, 2023 ("**Hunter Affidavit**"), **AR1, T 4, pp 41 & 48**.
[84] Corey Pettipas SAP Form A and SAP Letter of Authorization, Exhibits "A" & "B" to the Affidavit of Corey Pettipas, Sept 14, 2023, **AR1, T 5, pp 52-59 & 61**.

Request was seventeen pages long with eighty-six references, including five articles specifically about psilocybin's efficacy in cluster headaches.[85]

3.6 Strays Beyond Limits of Statutory Language

54. The Decision's denial on the basis that the request did not include sufficient information is unreasonable because it strays beyond the limits set by the language of the *Food and Drug Regulations*.[86] A decision "must comport with any more specific constraints imposed by the governing legislative scheme, such as the statutory definitions, principles or formulas that prescribe the exercise of a discretion".[87] It is "impossible for an administrative decision maker to justify a decision that strays beyond the limits set by the statutory language it is interpreting."[88]

55. *FDR* s. C.08.010(1)(a)(iii) 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".[89] The Decision strayed beyond 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";[90] and the Minister's delegate did not question the truthfulness of this.

56. Decision makers must use the modern approach to statutory interpretation. If a decision maker fails to explicitly consider any one of a statutory provision's text, context, or purpose in the reasons for decision, and it "may well" have arrived at a different result had it considered the element, "its failure to consider that element would be indefensible, and unreasonable".[91]

57. In the Minister's delegate's email to the SAP team, the Minister's delegate stated his

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[85] SAP Form A, **AR1, T 16, pp 254-270**.
[86] *Food and Drug Regulations*, CRC, c 870 [*FDR*].
[87] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 108.
[88] *Ibid* at para 110.
[89] *Food and Drug Regulations*, CRC, c 870, s C.08.010(1)(a)(iii), emphasis added.
[90] Aug 23, 2023, Letter, para 3, **AR1, T 13, p 248**.
[91] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 122.

belief that "implicit in the SAP regulations, is the requirement to provide robust scientific evidence."[92] However, there is no indication that the Minister's delegate used the modern approach to statutory interpretation to reach this conclusion. He provides no analysis of the text, context, or purpose of the relevant provisions, and nothing in the text, context, or purpose implies the need for "robust scientific evidence". Rather, consideration of these elements would lead to the conclusion that "robust scientific evidence" is not needed. The text does not contain any words introducing this requirement. The context is Division 8 of the *FDR*, entitled "New Drugs", and "new drugs" are defined as drugs for which the safety and effectiveness have not been established in Canada.[93] The purpose of s. C.08.010 is to allow for the sale of new drugs to treat serious or life-threatening medical conditions.[94] Thus, if the Minister's delegate had considered these elements, he likely would have reached the conclusion that the SAP regulations were meant to allow the sale of drugs when there is not yet strong evidence of safety and efficacy.

3.7 Fettered by Policy

58. Both reasons for the Decision are unreasonable because the Minister's delegate fettered his discretion by policy. A decision maker cannot fetter its discretion if the law grants it wide discretion.[95] No standards other than legal standards can be used:

> Any decision that draws upon something other than the law – for example a decision based solely upon an informal policy statement without regard or cognizance of law, cannot fall within the range of what is acceptable and defensible[96]

59. The 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 at least one published clinical trial to establish efficacy of a drug. The Minister's delegate explicitly stated he was fettering his discretion in

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[92] Email from Minister's Delegate to SAP Team, Aug 29, 2023, **AR1, T 8, p 203**.
[93] *Food and Drug Regulations*, CRC, c 870, s C.08.001.
[94] *Food and Drug Regulations*, CRC, c 870, s C.08.010; SAP Guidance Document, Section 1.1 "Purpose/overview" * Section 1.5 "Background", **AR1, T 11, pp 218 & 220**.
[95] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 108.
[96] *Stemijon Investments Ltd v Canada (Attorney General)*, 2011 FCA 299 at para 24.

this way when he told Dr. Davenport, “From a clinical standpoint, I am not questioning anything from that end, but from a regulatory standpoint, in order to invoke the exception to authorize drugs that are not approved, we really need that piece of data for the Special Access Program. […] I know it has worked for the patient, but we just need at least one clinical trial that shows favourable outcomes and then we can move ahead with it”.[97]

60. The 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.

61. Neither of these bases for denial are found in s. C.08.010 of the *FDR*, nor any other law or regulation. They are solely internal, non-binding policies.

3.8 No Responsive Justification

62. The Decision is unreasonable because it does comply with the principle of responsive justification. This principle means that a decision maker “must explain why its decision best reflects the legislature’s intention” when a decision has “consequences that threaten an individual’s life, liberty, dignity, or livelihood.” [98]

63. The Decision affects Mr. Lance’s liberty because it stops him from making a fundamental personal choice about medical care, and he may be imprisoned if he continues to take psilocybin illegally. The Decision threatens Mr. Lance’s life because he is eligible for medical assistance in dying and may take that route if not allowed legal access to the only medicine he has found that works, psilocybin.[99] The Decision affects his dignity and livelihood because his cluster headaches, untreated, stop him from being able to work or attend social gatherings for fear of falling to the ground in public in crippling pain if hit with a cluster attack.[100]

64. The purpose of the controls on drugs in the *CDSA* and *FDR* are to protect health and

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[97] Aug 21, 2023, Call Transcript at 03:35, **AR1, T 3B, pp 25-26**.
[98] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 133.
[99] Lance Affidavit, paras 21-22, **AR1, T 18, p 300**.
[100] Lance Affidavit, paras 13-20, **AR1, T 18, pp 299-300**.

public safety.[101] The Minister's delegate does not explain how denying access to a medical treatment that he admits is safe and "worked for the patient" best reflects the legislature's intention.[102]

ISSUE 4: Appropriate Remedy is to Grant SAP Authorization

65. The appropriate remedy is to direct the Minister to grant the authorization. It is appropriate to decline to remit a matter where a particular outcome is inevitable.[103] Other factors to consider are delay, urgency, fairness, and whether the decision maker had a genuine opportunity to weigh in on the issue.[104] Each of these factors weighs in favour of declining to remit this case.

4.1 Inevitable Outcome: *Charter* Section 7

66. The outcome is inevitable because a refusal would infringe s. 7 of the *Charter* and could not be saved by s. 1. Due to the uncontradicted evidence before the Minister and the binding jurisprudence, it would not be reasonable for the Minister to refuse the exemption requests, no matter the justification provided.

67. The Supreme Court has held that the Minister has a duty to grant an exemption allowing possession of a controlled substance in certain circumstances. In *PHS*, the Minister had denied Insite's *CDSA* s. 56 exemption request for a safe injection site. The Court held that *CDSA*'s s. 4 prohibition on possession engaged Insite staff's liberty since staff needed to possess illicit drugs to care for clients.[105] It also engaged clients' life and security of the person since, without an exemption, healthcare professionals would be unable to assist clients, depriving them medical care.[106]

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[101] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at paras 41 & 129.
[102] Aug 21, 2023, Call Transcript at 02:09 & 05:23, **AR1, T 3A, pp 24 & 27**.
[103] *Mason v Canada (Citizenship and Immigration)*, 2023 SCC 21 at paras 120-122; *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 142; *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at para 150; *see also Groia v Law Society of Upper Canada*, 2018 SCC 27 at para 161; *Sharif v Canada (Attorney General)*, 2018 FCA 205 at para 55, 50 CR (7th) 1; *Canada (Attorney General) v Chu*, 2022 FCA 105 at para 9; *Canada (Attorney General) v Burke*, 2022 FCA 44 at para 117.
[104] *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 142.
[105] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at para 90.
[106] *Ibid* at para 91.

68. The Supreme Court held that *CDSA* s. 4, was not arbitrary, overbroad, or grossly disproportionate only because s. 56 acted as a "safety valve" excluding cases that did not further the *CDSA*'s twin goals of health and public safety from s. 4's blanket prohibition.[107] Consequently, the Court stated that "[i]f there is a *Charter* problem, it lies not in the statute but in the Minister's exercise of the power the statute gives him to grant appropriate exemptions."[108] The Minister's discretion, therefore, is not absolute. It must conform with the *Charter*.[109]

69. The Court overturned the Minister's refusal of the s. 56 exemption and ordered *mandamus* compelling the Minister to grant the exemption because the refusal was arbitrary and grossly disproportionate.[110] It was arbitrary because it undermined the *CDSA*'s purposes of health and safety, and it was grossly disproportionate because the potential denial of health services and the correlative increase in death and disease to drug users outweighed any benefit that might come from maintaining an absolute prohibition on Insite's premises.[111]

70. The Supreme Court set out a clear test for when the Minister must grant authorization to possess controlled substances: authorization must be granted when evidence indicates it will decrease disease and there is little or no evidence that it will have a negative impact on public safety.[112] In the present case, the Minister's delegate has admitted that these conditions are met in,[113] and there is no evidence to the contrary.

4.1.1 Section 7 is Engaged

71. The SAP Request engages Mr. Lance's rights to life, liberty, and security of the person.

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[107] *Ibid* at paras 113-114.
[108] *Ibid* at para 114.
[109] *Ibid* at para 117.
[110] *Ibid* at para 150.
[111] *Ibid* at para 136.
[112] *Ibid* at para 152, *see also* para 140.
[113] Aug 21, 2023, Call Transcript at 02:09 & 05:23, **AR1, T 3A, pp 24 & 27**.

4.1.1.1 Restricting Reasonable Medical Choices Engages Liberty

72. Liberty includes the right to make decisions of fundamental personal importance, including the one's choice of medical treatment:

> "liberty" comprehends the right to make decisions of fundamental personal importance. This would include the right to choose, on medical advice, to use marihuana for treatment of serious conditions, that right implying a right of access to such marihuana. It would also include the right not to have one's physical liberty endangered by the risk of imprisonment from having to access marihuana illicitly. With respect to security, this interest includes the similar right for those with medical need to have access to medication without undue state interference.[114]

73. Foreclosing a reasonable medical choice limits patients' liberty.[115] Any state action that impedes access – such as an onerous application process or stringent conditions – also implicates liberty.[116]

74. Psilocybin is a reasonable medical choice for Mr. Lance. Mr. Lance's neurologist, Dr. Davenport, determined that it is,[117] and this was confirmed by the second opinions of chronic pain specialist Dr. Gaurav Gupta and pharmacist Jagpaul Deol.[118]

75. In *Hitzig*, the Ontario Court of Appeal held that the support of one medical specialist was sufficient for a marihuana to be considered a reasonable medical choice even for conditions where "there is virtually no scientific evidence that marihuana could benefit these persons."[119] The Court held that the regulations' requirement of an opinion from a second specialist was arbitrary.[120] In light of this, Mr. Lance's assessment by two medical specialists and a pharmacist far surpasses the threshold required to demonstrate that it is a reasonable medical choice.

76. Health Canada's own guidelines for requests for psychedelics through the SAP

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[114] *Sfetkopoulos v Canada (Attorney General)*, 2008 FC 33 at para 10.
[115] *R v Smith*, 2015 SCC 34 at para 18; *Carter v Canada (Attorney General)*, 2015 SCC 5 at para 67.
[116] *Hitzig v Canada*, 231 DLR (4th) 104 at para 93, 177 OAC 321.
[117] SAP Form A, ss. E.1.a.1 "Patient Summary and Current Diagnosis", **AR1, T 16, p 257**.
[118] Gupta Affidavit, para 7, **AR1, T 19, p 398**; Deol Affidavit, para 9, **AR1, T 20, p 407**.
[119] *Hitzig v Canada*, 231 DLR (4th) 104 at para 47, 177 OAC 321.
[120] *Ibid* at paras 144-145.

explicitly state that "[t]he role of Health Canada in the context of the SAP is not to question the practitioner's diagnosis or recommended treatment option".[121] Yet, this is precisely what the Minister's delegate did by refusing the SAP request. Thus, the refusal infringes on Mr. Lance's liberty.

4.1.1.2 Denying Medical Treatment Engages Security

77. Decisions that prevent access to health care deprive patients of their right to security of the person:

> Where a law creates a risk to health by preventing access to health care, a deprivation of the right to security of the person is made out[122]

78. The right is infringed even if the patient has not tried alternative treatments that are available. The Alberta Court of Appeal, in *R v Krieger*, held that the right to security of the person was infringed by the denial of treatment with medical cannabis, even though the person had not attempted all alternative treatments.[123]

79. Clinical studies are not needed to establish efficacy for a s. 7 right. Even if the only evidence that psilocybin might be effective for a patient is mere anecdote (which it is not), this evidence would be sufficient. In *Hitzig*, the Ontario Court of Appeal held that a s. 7 right to medical treatment can be established on a much lower evidentiary basis than is required by scientists. In that case, the scientific research regarding cannabis's efficacy was severely lacking, and there was credible research about the cannabis's harms:

> [S]cientists, who approach questions of medical benefit and risk quite differently than do the courts, remain uncertain as to the benefits derived from the use of marihuana and concerned about the potential risks inherent in that use. The scientists regard the anecdotal evidence relied on by the courts as sufficient reason to conduct proper scientific inquiries into the medicinal use of marihuana, but not as justifying any conclusions as to the benefit of the drug. The scientists contend that the medicinal value of marihuana, if any, as a

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[121] Health Canada, Notice to stakeholders: Requests to the Special Access Program (SAP) involving psychedelic-assisted psychotherapy, Feb 27, 2023, Lance Affidavit, Exhibit "H", **AR1, T 18H, p 393**.
[122] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at para 93.
[123] *R v Krieger*, 2003 ABCA 85 at para 3, affirming *R v Krieger*, 2000 ABQB 1012 at para 28.

> treatment for various symptoms can only be determined through properly conducted, rigorously reviewed long-term clinical studies. The same scientists have expressed strong concerns about the health risks attendant upon the long-term use of marihuana, particularly when it is smoked. There is some research indicating that the long-term smoking of marihuana carries with it many of the risks associated with cigarette smoking.[124]

80. Nevertheless, the Court held that individuals' person experiences and anecdotal evidence was sufficient to establish a s. 7 right:

> This support [for cannabis's medical benefits] is based largely on personal experience and anecdotal evidence of individuals and their doctors. […]
>
> [T]he courts, relying on evidence of individuals' personal experiences and anecdotal evidence have determined that some seriously ill persons derive substantial medical benefit from the use of marihuana. The pronouncements in these cases reflect the normal process of judicial fact-finding made in the context of an adjudicative process based on the evidence and arguments led by the parties in a given case. These factual findings have in turn provided the basis for the legal conclusion that s. 7 of the Charter requires that a medical exemption be carved out of any criminal prohibition against the possession of marihuana.[125]

81. In *Allard*, the Federal Court struck down the entire medical cannabis regulatory regime on the basis of anecdotal evidence and personal experience about efficacy of various strains and consumption methods since the regime restricted users to a single supply of medical cannabis without guaranteeing sufficient quality, strains, and quantity would be available at an acceptable price.[126] The plaintiffs argued that patients needed a variety of strains and methods of consumption because they had different effects,[127] but they only had anecdotal evidence of this.[128] There was "no scientific evidence to support the anecdotal claims that certain strains are useful for certain medical conditions",[129] and there was "no scientific evidence that a particular

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[124] *Hitzig v Canada*, 231 DLR (4th) 104 at para 10, 177 OAC 321.
[125] *Hitzig v Canada*, 231 DLR (4th) 104 at paras 8-9, 177 OAC 321.
[126] *Allard v Canada*, 2016 FC 236 at para 15.
[127] *Ibid* at paras 133-134.
[128] *Ibid* at para 85.
[129] *Ibid* at para 91.

method of consumption is required to treat a particular medical condition".[130] In fact, there was not "a single scientific study comparing the therapeutic effects of undried cannabis to dried cannabis."[131] Even so, the Court held that in the absence of more and better studies, "anecdotal evidence is a reasonable substitute".[132]

82. The Federal Court further held that any benefits resulting from aligning treatment with patients' preference "cannot be callously dismissed as something akin to a placebo."[133] Restrictions that deprive patients of their preferred treatment thereby violate patients' rights.

83. Mr. Lance has testified that psilocybin has been effective at treating his cluster headaches.[134] This aligns with the findings of the scientific research articles submitted that indicated psilocybin is likely to be effective at treating cluster headaches.[135] The Minister's delegate did not dispute Mr. Lance's testimony and admitted that he "know[s] it has worked for the patient".[136] Mr. Lance's security of the person is, thus, infringed by the denial of authorization for treatment.

4.1.1.3 Risk of Suicide or MAID Engages Life

84. Decisions that create an increased risk of death for a person, either directly or indirectly, violate the right to life.[137] Mr. Lance has contemplated suicide or medical assistance in dying ("**MAID**") due to his unbearable pain.[138] Mr. Lance is eligible for MAID due to amendments made permitting a person whose death is not reasonably

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[130] *Ibid* para 83.
[131] *Ibid* at para 83.
[132] *Ibid* at paras 87 & 211.
[133] *Ibid* at para 93.
[134] Lance Affidavit, paras 48-53, **AR1, T 18, pp 304-305**.
[135] SAP Form A, Section E.1.c.1 "Psilocybin Research Study Findings", **AR1, T 16, pp 263-264**; Andersson et al, 2017, **AR2, T 6, p 71**; Schindler et al, 2015, **AR2, T 64, p 848**; Shindler et al, 2020, **AR2, T 65, p 859**; Schindler et al, 2022, **AR2, T 66, p 871**; Sewell et al, 2006, **AR2, T 68, p 908**; *see also* Cluster Headache Literature, Lance Affidavit, Exhibit "A", **AR1, T 18A, pp 312-313**; OPIS Policy Paper, "Effectiveness of Psilocybin and Related Chemicals", Lance Affidavit, Exhibit "B", **AR1, T 18B, pp 323-325**.
[136] Aug 21, 2023, Call Transcript at 05:23, **AR1, T 3A, p 27**.
[137] *Carter v Canada (Attorney General)*, 2015 SCC 5 at para 62.
[138] Lance Affidavit, paras 21-22, **AR1, T 18, p 300**.

foreseeable to access MAID.[139] Thus, his right to life is implicated.

4.1.2 Refusal Violates Principles of Fundamental Justice

85. The refusal is arbitrary, overbroad, and grossly disproportionate.

4.1.2.1 Arbitrary

86. To not be arbitrary there must be a rational connection between the purpose of the measure that causes the s. 7 deprivation and the limits the measure imposes.[140] There are two purposes to the *CDSA*, which are the only permissible purposes for the Minister's decision: health and public safety.[141] When evidence indicates that an authorization would improve health, and there is little or no evidence that it will have a negative impact on public safety, the Minister must grant the authorization.[142] The Minister's delegate has acknowledged that psilocybin works for Mr. Lance, and there is no evidence of any negative impact on public safety. Thus, the refusal is arbitrary.

4.1.2.1.1 Theoretical Path of Access is Meaningless

87. The refusal is not rendered non-arbitrary by the theoretical availability of another regulatory pathway that is not practically and presently available. Clinical trials are merely a theoretical pathway.

88. In *Parker*, the Crown unsuccessfully argued that the s. 7 infringement was saved because Parker had a legal path to access cannabis through the Compassionate Use Program. Despite the "theoretical availability" of this pathway, the Ontario Court of Appeal gave it no heed because the pathway ran up against a practical barrier in that there was no licensed source of cannabis.[143] The Crown attempted to justify itself by saying the reason for the practical unavailability was that no one had come forward to seek a licence, and so it was someone else's duty to apply for a licence and

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[139] *Criminal Code*, RSC 1985, c C-46, ss 241.1 & 241.2; *An Act to amend the Criminal Code (medical assistance in dying)*, SC 2021, c 2, preamble.
[140] *Canada (Attorney General) v Bedford*, 2013 SCC 72 at para 111.
[141] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at paras 41 & 129, [2011] 3 SCR 134.
[142] *Ibid* at paras 150 & 152.
[143] *R v Parker*, 49 OR (3d) 481 at para 165, 188 DLR (4th) 385.

actualize the theoretical pathway. But the Court soundly rejected this argument, noting that Parker could not become a licensed dealer.[144] Similarly, neither Mr. Lance nor Dr. Davenport can conduct a clinical trial.

89. In *Hitzig*, the Ontario Court of Appeal dealt with a similar situation. It noted that the regulations allowed medical cannabis users to access cannabis through a licensed dealer, but the Court called this pathway "meaningless" because there was no licensed dealer in Canada.[145] In assessing whether the regulations infringed s. 7, the Court gave this "theoretical" pathway no weight.[146]

90. In *Allard*, the Federal Court ruled that the possibility or even probability of access is not sufficient; access must be guaranteed. The Court struck down the medical cannabis regulations in their entirety because they gave "no guarantee that the necessary quality, strain and quantity will be available when needed".[147] A clinical trial would not guarantee that Mr. Lance will be able to access psilocybin when needed, and no clinical trials for cluster headaches are currently enrolling.[148] Mr. Lance is not eligible for an OLIP trial since one of the necessary conditions for an OLIP trial is that the patient have a life-threatening condition,[149] and cluster headaches, while excruciatingly painful, are not lethal.

4.1.2.1.2 Other Access Paths Do Not Negate Restriction by SAP Refusal

91. Even if another access path were available, it would not negate the fact that s. 7 is infringed by refusing the SAP Request. In *Hitzig*, the Ontario Court of Appeal struck down regulatory provisions that caused a more "onerous application process" for medical exemptions[150] even though there were two clinical trials available at the time, which were very real alternate paths by which some patients could gain access.[151]

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[144] *Ibid* at para 165.
[145] *Hitzig v Canada*, 231 DLR (4th) 104 at para 61, 177 OAC 321.
[146] *Ibid* at para 88.
[147] *Allard v Canada*, 2016 FC 236 at paras 15-16.
[148] Lance Affidavit, paras 61-64 & Exhibit "C", **AR1, T 18, pp 307 & 343**.
[149] Package Provided to Prospective OLIP Sponsors, MacKay Affidavit, Exhibit "F", **AR1, T 6, p 178**.
[150] *Hitzig v Canada*, 231 DLR (4th) 104 at para 93, 177 OAC 321.
[151] *Ibid* at para 27.

92. In *Sfetkopolous*, the Federal Court recognized that a licensed dealer "certainly does provide an alternative avenue of access."[152] But it was "not tenable for the government […] to force [users] either to buy from the government contractor, grow their own or be limited to the unnecessarily restrictive system of designated producers."[153] Thus, even with three alternative pathways for access, it was arbitrary for the government to make one of the pathways unnecessarily restrictive. Likewise, even if there were a clinical trial open to Mr. Lance, this would not cure the arbitrariness of the SAP refusal.

4.1.2.2 Overbroad

93. Overbreadth describes situations where a law is so broad in scope that it includes some conduct that bears no relation to its purpose. In this sense, the law is arbitrary in its application to a specific situation.[154] The *CDSA* s. 4(1) prohibition on possession and the *FDR* s. C.08.002(1) prohibition on selling a new drug will be overbroad if the SAP refusal is maintained since the application of *CDSA* s. 4(1) in relation to Mr. Lance and Dr. Davenport is arbitrary, and so is the application of *FDR* s. C.08.002(1) in relation to Filament Health selling Mr. Lance and Dr. Davenport psilocybin.

4.1.2.3 Grossly Disproportionate

94. A Minister's exercise of discretion is grossly disproportionate when the seriousness of the deprivation is totally out of sync with the objective of the measure.[155] A grossly disproportionate effect on one person is enough to violate the norm.[156]

95. The enormous harm that is caused by refusing the SAP Request far outweighs any negligible benefit that refusing this request might confer. Mr. Lance suffers from excruciating pain and is impaired in his daily functioning. The Minister's delegate has admitted that he knows psilocybin works to treat Mr. Lance's condition and relieve

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[152] *Sfetkopoulos v Canada (Attorney General)*, 2008 FC 33 at para 19; aff'd *Canada (Attorney General) v Sfetkopoulos*, 2008 FCA 328 at para 3.
[153] *Ibid* at para 19.
[154] *Canada (Attorney General) v Bedford*, 2013 SCC 72 at para 112.
[155] *Ibid* at para 120.
[156] *Ibid* at para 122.

him of some of his suffering. By contrast, there is no benefit to health or public safety from denying the request since the Minister's delegate has acknowledged that safety has been sufficiently established for psilocybin.

4.1.3 Not Saved by Section 1

96. The s. 7 violation cannot be saved by s. 1. The objectives of the *FDR* and *CDSA* under s.1 are the same as under s. 7: protecting health and safety. Since the infringement is not rationally connected to the objectives under s. 7, it cannot be connected under s. 1.[157] Further, administrative conveniences cannot justify the resulting suffering.[158]

4.2 Delay and Urgency

97. Time is particularly of the essence because this case involves the denial of medical treatment for someone who is seriously ill and suffering excruciating pain. More than five months have gone by since the Applicants submitted the SAP Request, and even more will have passed by the time this matter reaches a hearing. Mr. Lance's cluster headaches are often triggered by the change of seasons.[159] It is essential that he be authorized for treatment prior to this seasonal change to avoid unnecessary suffering.

98. The Federal Court of Appeal has held that patients suffer irreparable harm when access to medical treatment is limited.[160] Likewise, the Ontario Court of Appeal has found that the exercise of judicial discretion in a way that would delay access to treatment for those who are seriously ill goes against fundamental *Charter* values.[161]

99. Further, the delay resulting from remitting for redetermination would itself cause a *Charter* violation. In *Parker*, the administrative delay in the s. 56 application process violated s. 7 because it endangered applicants' health.[162] In *Morgentaler*, the Supreme Court held that administrative inefficiencies that delay medical treatment

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[157] *R v Smith*, 2015 SCC 34 at para 29, [2015] 2 SCR 602.
[158] *Singh v Minister of Employment and Immigration*, [1985] 1 SCR 177 at para 70, 17 DLR (4th) 422.
[159] Aug 23, 2023, Letter, last para, **AR1, T 13, p 251**.
[160] *Canada v Allard*, 2014 FCA 298 at para 13.
[161] *Hitzig v Canada*, 231 DLR (4th) 104 at para 175, 177 OAC 321.
[162] *R v Parker*, 49 OR (3d) 481 at para 189, 188 DLR (4th) 385.

violate security of the person.[163]

4.3 Minister Had Genuine Opportunity to Weigh In

100. The Minister had a genuine opportunity to weigh in on the issues but chose not to. 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.[164] 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.

4.4 Fairness to the Parties

101. It would be unfair to the Applicants 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.

102. While Courts are understandably cautious about compelling a Ministerial decision, there is no risk in granting the SAP Request. The Minister has granted dozens of SAP authorizations for much larger doses of psilocybin and no harm has arisen.[165] The prescribed dosage for Mr. Lance is a small, non-psychedelic dose, meaning it does not result in an altered state of consciousness.[166] The Minister does not allege any harm will arise from granting the SAP Request. It is solely an administrative preference that has led the Minister to refuse the request.

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[163] *R v Morgentaler*, [1988] 1 SCR 30 at paras 33 & 92, 63 OR (2d) 281.
[164] Legal Representations, **AR1, T 17, pp 271-296**.
[165] Matthew Hunter SAP Letter of Authorization, Hunter Affidavit, Exhibit "B", **AR1, T 4B, p 48**; Legal Representations, paras 9-10, **AR1, T 17, p 274**.
[166] Deol Affidavit, para 12, **AR1, T 20, p 408**; SAP Form A, Section E.1.a.5(iv) "Patient's Usage of Psilocybin – Non-psychedelic Dose", **AR1, T 16, p 259**; Lance Affidavit, para 46, **AR1, T 18, p 304**.

Conclusion

103. Mr. Lance has the right to receive medical assistance in dying. He has the right to die without attempting all alternative treatments, and without any clinical trials proving that medical assistance in dying improves the health of people with cluster headaches.[167] Given his right to die, it cannot be reasonable nor constitutionally compliant to deny Mr. Lance access to a treatment that assists him in living.

PART IV – RELIEF SOUGHT

104. Based on the foregoing, the Applicants seek the following relief:

    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.

ALL OF WHICH IS RESPECTFULLY SUBMITTED THIS 8 January 2024

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[167] *Criminal Code*, RSC 1985, c C-46, s 241.2.

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PART V – LIST OF AUTHORITIES

Legislation

1 *An Act to amend the Criminal Code (medical assistance in dying)*, SC 2021, c 2

2 *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

3 *Controlled Drugs and Substances Act*, SC 1996, c 19

4 *Criminal Code*, RSC 1985, c C-46

5 *Food and Drug Regulations*, CRC, c 870

Jurisprudence

6 *Allard v Canada*, 2014 FC 280, 451 FTR 45

7 *Allard v Canada*, 2016 FC 236, [2016] 3 FCR 303

8 *Association of Universities and Colleges of Canada v Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22

9 *Canada (Attorney General) v Bedford*, 2013 SCC 72, [2013] 3 SCR 1101

10 *Canada (Attorney General) v Burke*, 2022 FCA 44, 468 DLR (4th) 165

11 *Canada (Attorney General) v Chu*, 2022 FCA 105

12 *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44, [2011] 3 SCR 134

13 *Canada (Attorney General) v Robinson*, 2022 FCA 59

14 *Canada (Attorney General) v Sfetkopoulos*, 2008 FCA 328, 382 NR 71

15 *Canada (Attorney General) v Zalys*, 2020 FCA 81

16 *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65, [2019] 4 SCR 653

17 *Canada v Allard*, 2014 FCA 298, 324 CRR (2d) 78

18 *Canadian Broadcasting Corporation v Canada (Parole Board)*, 2023 FCA 166

19 *Canadian Broadcasting Corporation v Ferrier*, 2019 ONCA 1025, 148 OR (3d) 705

20 *Carter v Canada (Attorney General)*, 2015 SCC 5, [2015] 1 SCR 331

21 *Cepeda-Gutierrez v Canada (Minister of Citizenship and Immigration)*, [1999] 1 FC 53, 157 FTR 35

22 *Commission scolaire francophone des Territoires du Nord-Ouest v Northwest Territories (Education, Culture and Employment)*, 2023 SCC 31

23 *Doré v Barreau du Québec*, 2012 SCC 12, [2012] 1 SCR 395

24 *Duyvenbode v Canada (Attorney General)*, 2009 FCA 120, [2009] FCJ No 504

25 *Farrier v Canada (Attorney General)*, 2020 FCA 25, 161 WCB (2d) 531

26 *Groia v Law Society of Upper Canada*, 2018 SCC 27, [2018] 1 SCR 772

27 *Hitzig v Canada*, 231 DLR (4th) 104, 177 OAC 321

28 *Lauzon v Ontario (Justices of the Peace Review Council)*, 2023 ONCA 425

29 *Law Society of British Columbia v Trinity Western University*, 2018 SCC 32, [2018] 2 SCR 293

30 *Loyola High School v Quebec (Attorney General)*, 2015 SCC 12, [2015] 1 SCR 613

31 *Lukács v Canada (Transportation Agency)*, 2016 FCA 103

32 *Mason v Canada (Citizenship and Immigration)*, 2023 SCC 21

33 *Paul v Canada (Attorney General)*, 2022 FC 1157

34 *R v Krieger*, 2000 ABQB 1012, 307 AR 349

35 *R v Krieger*, 2003 ABCA 85, 18 Alta LR (4th) 227

36 *R v Morgentaler*, [1988] 1 SCR 30, 63 OR (2d) 281

37 *R v Parker*, 49 OR (3d) 481, 188 DLR (4th) 385

38 *R v Smith*, 2015 SCC 34, [2015] 2 SCR 602

39 *Robinson v Canada (Attorney General)*, 2020 FC 942

40 *Sfetkopoulos v Canada (Attorney General) (FC)*, 2008 FC 33, [2008] 3 FCR 399

41 *Sharif v Canada (Attorney General)*, 2018 FCA 205, 50 CR (7th) 1

42 *Singh v Minister of Employment and Immigration*, [1985] 1 SCR 177, 17 DLR (4th) 422

43 *Stemijon Investments Ltd v Canada (Attorney General)*, 2011 FCA 299, 341 DLR (4th) 710

44 *Turner v Canada (Attorney General)*, 2022 FCA 192