Federal Court Cour fédérale

Date: 20230925

Docket: T-1424-22

Citation: 2023 FC 1283

Ottawa, Ontario, September 25, 2023

PRESENT: Madam Justice Pallotta

BETWEEN:

JEFF TOTH, ADELE PHILLIPS, ALEX DOLEY, ALLISON PRINSEN, ANTHONY DI VIRGILIO, BARBARA FEHLAU, BARBARA GRIFFIN, CHRISTINE DENNSTEDT, DALE TRIMBLE, DANIELLE SCHROEDER, DANUSIA KANACHOWSKI, DAPHNE LOBB, GRAHAM BERGSTRA, GREGORY COHEN, HILLARY MCBRIDE, JENNA FLETCHER, JILL KOEHLER, JOHN GYRA, JONATHAN WIESER, KEYANNA EHSANI, KYLE GREENWAY, LAURIE SCHULZ, LISA FREDE, MYRNA MARTIN, RICHARD TATOMIR, SALLYJANE BODNAR, SARAH HOFFMAN, STACY SMITH, VALENTINA CHICHINIOVA, VANATHY PARANTHAMAN, AAMIR SUBHAN, AMANDA GRINTER, ANNE-MARIE ARMOUR, BETH TROTTER, BRODIN ANDERSON, BRYCE KOCH, CLAIRE WEISS, DAYNA MYLES, DOROTHY GAMBLE, ELINOR BAZAR, ELIZABETH BLEAKLEY, GORDON REID, JANE HARRISON, JANIE BROWN, JEAN-FRANÇOIS STEPHAN, JENNIFER NAGEL, JULIA MACARTHUR, KATHLEEN HERBINSON, KERRY CHUTTER, LORRAINE REIMER, MARILYN CHOTEM, MICHAEL SHEPPARD, NATHAN TORTI, NIKHITA SINGHAL, PARVEEN SIHOTA, RAJVEER SOOS,

RICHARD MINERS, SCOTT KOURI, SHAUNA SUTHERLAND, STEPHANIE MARCHAL, STEVEN GRIFFITH-COCHRANE, TAMARA SMITH, TRACY LOWE, TRINA WOODS, YASSIE PIRANI, DANA SIMARD, MICHAEL SIMARD, ANNE KWASNIK-KRAWCZYK, GRANT HUTCHINSON, JULIEN THIBAULT LÉVESQUE, SUSAN MCAFEE, LARA ELLISON, ELANA ANGUS, AND THERAPSIL

Applicants

and

MINISTER OF MENTAL HEALTH AND ADDICTIONS AND ASSOCIATE MINISTER OF HEALTH

Respondent

JUDGMENT AND REASONS

I. Introduction

[1] This application for judicial review relates to 96 decisions made by a delegate of the Minister of Mental Health and Addictions and Associate Minister of Health (Minister), refusing requests for an exemption under subsection 56(1) (Section 56 Exemption) of the *Controlled Drugs and Substances Act*, SC 1996, c 19 [*CDSA*].

[2] Generally, an application for judicial review challenges only one administrative decision: *Federal Courts Rules*, SOR/98-106, Rule 302. The applicants were permitted to challenge more than one decision by an order of this Court dated September 14, 2022.

[3] For the reasons below, this application for judicial review is dismissed.

II. **Background**

[4] All 96 challenged decisions relate to Section 56 Exemption requests made by healthcare practitioners, with varied qualifications (HCPs). They include doctors, psychologists, nurses, social workers, counsellors and other regulated healthcare professionals. The HCPs want the exemption for the same reason, namely, to possess and consume raw psilocybin mushrooms in the course of their own professional training for psilocybin-assisted psychotherapy.

[5] Psilocybin-assisted psychotherapy is a form of psychotherapy that includes a medicinal session, during which the patient consumes a therapeutic dose of psilocybin under the supervision of a qualified practitioner. The therapy can help patients who are suffering from certain types of depression, distress associated with life-threatening or terminal illness, and other conditions.

[6] The HCPs' requests for a Section 56 Exemption stated that, for optimal results, qualified practitioners should have experience with the psychedelic medicines that will be used to treat their patients. The goal of training with psilocybin is to improve HCPs' understanding of psilocybin therapy so they may better help their patients. While undergoing training, the HCPs would likely consume five grams of raw psilocybin mushrooms for three exposures over a six-month period, and they would supply the mushrooms themselves, from a "trusted source" they did not identify.

[7] Psilocybin is a hallucinogen and a controlled substance under the *CDSA*. The *CDSA* prohibits possession of psilocybin, except as authorized under the regulations: *CDSA* s 4. However, the *CDSA* allows the Minister to authorize an exemption from the prohibitions, if the Minister is of the opinion that the exemption is necessary for a medical or scientific purpose or otherwise in the public interest: *CDSA* s 56.

[8] There are 82 applicants in this application for judicial review. 73 applicants are HCPs whose Section 56 Exemption refusals are under challenge (Exemption Applicants). The other 23 decisions under challenge are Section 56 Exemption refusals for HCPs who are not parties to this proceeding.

[9] The applicant TheraPsil describes itself as a non-profit patient advocacy organization dedicated to helping Canadians in medical need access legal psilocybin-assisted psychotherapy. One of the aims of the organization is to connect prospective patients—people who wish to be assessed for and receive psilocybin-assisted psychotherapy—with qualified practitioners. To this end, TheraPsil maintains a roster of practitioners whose names can be provided to prospective patients.

[10] TheraPsil offers a psilocybin-assisted psychotherapy training program in order to "develop a pool of trained healthcare practitioners whom they can confidently include on their roster of practitioners able to support treatment". TheraPsil's training program includes an experiential training module, which requires the trainees to consume psilocybin mushrooms. The HCPs are in TheraPsil's training program and require a Section 56 Exemption to participate

in the experiential training module. TheraPsil coordinated the Section 56 Exemption requests on the HCPs' behalf, and retained counsel to provide submissions to the Minister in respect of those requests.

[11] The remaining 8 applicants in this proceeding are individuals who contacted TheraPsil because they want to be assessed for and receive psilocybin-assisted psychotherapy (Patient Applicants). TheraPsil placed the Patient Applicants on a waitlist; it states it was forced to do so due to a shortage of properly qualified and trained practitioners in Canada. Affidavits from the Patient Applicants (as well as five other waitlisted patients) were submitted to the Minister to support the HCPs' Section 56 Exemption requests.

[12] There is no evidence that any of the Patient Applicants have requested their own Section 56 Exemptions to access psilocybin for the purpose of receiving psilocybin-assisted psychotherapy.

[13] The applicants rely on a common set of materials. TheraPsil's counsel made representations on behalf of all applicants in this proceeding.

III. **Minister's Decisions and Overview of Parties' Positions**

[14] The Minister refused all 96 Section 56 Exemption requests in June 2022, for identical reasons. The Minister determined that a Section 56 Exemption was not necessary for a medical or scientific purpose or otherwise in the public interest, as there was an alternative option

available under the *Food and Drug Regulations*, CRC, c 870 [*FDR*], namely, authorization to obtain a controlled drug for the purposes of a clinical trial.

[15] The decisions note TheraPsil's opinion that this regulatory option is unsuitable and would not protect HCPs' best interests, and pursuing a clinical trial to allow practitioners to gain experience with psilocybin for training purposes would be unethical, interfere with training objectives, and cause delay. The Minister's view was that Health Canada had recently authorized a clinical trial for healthcare professionals to use psilocybin for training purposes, and while a clinical trial might not be available to all healthcare professionals, the authorization demonstrated that a clinical trial was a feasible regulatory option that may be available to HCPs. A clinical trial would protect the best interests of the participants, ensure that the psilocybin complies with good manufacturing practices (GMP) and is administered in accordance with ethical, medical and scientific standards, and would address prohibitions under the *FDR* as well as under the *CDSA*, unlike a Section 56 Exemption. The decisions recommend that the HCPs reconsider their position that clinical trials are unsuitable to achieve their purposes, and develop an appropriate clinical trial design that would allow a better understanding of the various effects of psilocybin on humans. The decisions provide information on clinical trials and funding opportunities supporting clinical trials involving psilocybin.

[16] The Minister noted in her decisions that 19 practitioner exemptions were approved in late 2020, but since then, Health Canada had engaged with a number of stakeholder groups in order to emphasize the importance of building evidence about the safety and efficacy of psilocybin through clinical trials. The decisions refer to Health Canada's efforts in this regard and its

efforts to reduce barriers to clinical research with psilocybin, including by holding information sessions, meeting with interested researchers, and supporting clinical trial sponsors. Health Canada addressed meeting requests in an expedited manner. The decisions state that as a result of these actions, the number of clinical trial applications for psilocybin grew significantly. Prior to 2021, Health Canada had authorized only one clinical trial involving psilocybin. As of May 2022, Health Canada had authorized 10 additional trials to evaluate the use of psilocybin in the treatment of mental health and substance use disorders, and collect valuable evidence on psilocybin's effectiveness in different populations and under different conditions. The decisions refer to "multiple conversations" with TheraPsil over the prior two years, conveying the message that Section 56 Exemptions are granted on an exceptional basis when other legal regulatory options are not available.

[17] The decisions state Health Canada was not aware of any peer-reviewed clinical evidence demonstrating that healthcare professionals need to take a psychedelic drug in order to appreciate what the patient experiences, and none of the evidence TheraPsil had provided was based on findings of peer-reviewed clinical evidence. The Minister found that while TheraPsil's training program requires personal experience with psilocybin, other therapists have been able to offer psilocybin-assisted psychotherapy without personal experience consuming psilocybin. The Minister also found there were potential health and safety risks associated with obtaining and consuming illegally sourced psilocybin as opposed to accessing psilocybin through the clinical trial pathway.

[18] The applicants submit the Minister's decisions are unreasonable. The applicants state the Minister: failed to grapple with central arguments and evidence, including evidence from Health Canada's own Office of Clinical Trials (OCT) that a clinical trial for TheraPsil's training program is not feasible; gave unintelligible or non-transparent reasons for her decisions; failed to address or meaningfully grapple with substantive arguments; failed to account for evidence about the benefits of experiential training or misapprehended the evidence; departed from the 19 previous decisions approving practitioner exemptions without justifying the departure; and did not address arguments about the impact a refusal would have on the HCPs' and patients' rights under section 7 of the *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11 [*Charter*].

[19] The applicants state there are hundreds of patients on TheraPsil's waitlist for psilocybin-assisted psychotherapy, and a shortage of experientially trained practitioners in Canada. While the Minister approved 19 psilocybin exemption requests made by TheraPsil-affiliated practitioners in 2020, the applicants allege that more Section 56 Exemptions are needed to address the shortage of providers and serve patients' needs. The applicants contend the Minister's refusals prevent the HCPs from becoming fully trained.

[20] The applicants submit that, collectively, they have standing to bring this application for judicial review in respect of all 96 decisions. Each of the 73 Exemption Applicants has standing to challenge their own decisions. In addition, the applicants state TheraPsil and the Patient Applicants are directly affected by all 96 decisions—TheraPsil because it requested the Section 56 Exemptions on the HCPs' behalf and it cannot run the experiential training module of its

program unless the practitioners being trained are granted Section 56 Exemptions, and the Patient Applicants because a delay and denial of the HCPs' training delays and denies their assessment and treatment.

[21] The applicants ask this Court to set aside all 96 decisions, and direct the Minister to grant exemptions to the HCPs that would permit them to possess and consume psilocybin for experiential training in psilocybin-assisted psychotherapy.

[22] The Minister does not contest the Exemption Applicants' standing, or TheraPsil's standing to challenge all 96 decisions. However, the Minister submits the Patient Applicants do not have standing, and asks for an order removing them as applicants to this proceeding.

[23] Also, the Minister submits that the Minister of Health, the sole respondent named in the notice of application, is not the proper respondent. The Minister asks for an order amending the style of cause to substitute the Minister of Mental Health and Addictions and Associate Minister of Health as respondent.

[24] The Minister submits the applicants have not shown the decisions in question are unreasonable, and this application for judicial review should be dismissed. Section 56 of the *CDSA* confers broad discretion to grant or refuse an exemption and the applicants have not established any errors that warrant interference with the decisions. The Minister states she considered the medical evidence, made supported findings about whether the evidence demonstrated that experiential training is required for administering psilocybin-assisted therapy

to patients, and the Court on judicial review should not reweigh the evidence or decide scientific debates. The decisions refusing the exemption requests addressed the risks to HCPs, the previous 19 practitioner exemptions, the need for clinical trial evidence, and the feasibility of a clinical trial with HCPs. The Minister states she came to a reasonable conclusion, the decisions do not limit *Charter* protections, and in any event the decisions reflect a proportionate balancing of any *Charter* values at play.

IV. **Issues**

[25] I would frame the issues on this application as follows:

A. Preliminary Issue: Who are the proper parties to this application?

B. Main Issue 1: What is the appropriate standard of review?

C. Main Issue 2: Are the Minister's decisions unreasonable?

D. Main Issue 3: If the Minister's decisions are unreasonable, what is the appropriate remedy?

V. **Analysis**

A. *Preliminary Issue: Who are the proper parties to this application?*

[26] As noted above, the Minister raises two questions for determination regarding the proper parties to this proceeding.

(1) Patient Applicants

[27] First, the Minister submits the Patient Applicants are not proper applicants. They do not have private interest standing or public interest standing, and they should be removed as applicants to this proceeding.

[28] The Minister submits the Patient Applicants do not have private interest standing because they are not directly affected by the matter in respect of which relief is sought: *Federal Courts Act*, RSC 1985, c F-7, ss 18.1(1) [*FC Act*]. A party has a direct interest under subsection 18.1(1) of the *FC Act* when their legal rights are affected, legal obligations are imposed upon them, or they are prejudicially affected in some direct way: *Forest Ethics Advocacy Association v Canada (National Energy Board)*, 2013 FCA 236 at para 20 [*Forest Ethics*]. The Minister states the evidentiary record does not establish the Patient Applicants have a direct interest in challenging the 96 decisions. At best, their connection to the decisions is speculative and remote. The Patient Applicants are effectively "strangers to the Court".

[29] The Minister states that the notice of application alleges the Patient Applicants have conditions that are treatable by psilocybin-assisted psychotherapy, that they have been unable to find anyone to treat them due to a lack of trained practitioners, and that the Minister's refusals delay or deny healthcare practitioner training, which in turn delays or denies treatment and violates the Patient Applicants' section 7 *Charter* rights. However, a notice of application is not evidence, and the Minister submits the evidence does not establish the Patient Applicants are directly affected by the 96 decisions. There is no evidence that any Patient Applicant is a patient of an HCP who was denied a Section 56 Exemption, or that they have been prescribed

psilocybin-assisted psychotherapy by a healthcare practitioner, have access to psilocybin, or applied for their own Section 56 Exemption. The Patient Applicants' affidavits submitted in support of the HCPs' requests for a Section 56 Exemption indicate that these individuals believe they would benefit from psilocybin-assisted psychotherapy based on their personal research. Moreover, the Minister submits there is no evidence that any Patient Applicant needs to undergo therapy with an experientially trained practitioner. Experiential training is a practitioner qualification that TheraPsil has imposed.

[30] The Minister submits the Patient Applicants also lack public interest standing. There is no automatic right to public interest standing—it is a matter within the Court's discretion. In determining whether to grant public interest standing, the Court must consider whether: (1) there is a serious justiciable issue raised; (2) the public interest litigant has a real stake or a genuine interest in the issue raised; and (3) in all the circumstances, the public interest litigant's involvement is a reasonable and effective way to bring the issue before the Court: *Canada (Attorney General) v Downtown Eastside Sex Workers United Against Violence Society*, 2012 SCC 45 at para 2. The Minister argues none of these considerations favours granting public interest standing to the Patient Applicants in the circumstances of this case.

[31] While the application raises a serious justiciable issue, the Minister states the Patient Applicants' participation does not raise or add a serious justiciable issue beyond those raised by the other applicants, and the Patient Applicants' participation in the application is frivolous. In addition, the Minister states there is no evidence the Patient Applicants have a real stake in the outcome. The fact that they gave evidence to support the HCPs' Section 56 Exemption requests

does not give the Patient Applicants a stake or genuine interest in this proceeding. The Patient Applicants will not be bound by the Court's decision on this application or entitled to anything because of it—the decision will not give them access to psilocybin or a right to undergo psilocybin-assisted therapy. Lastly, the Minister argues the Patient Applicants have not demonstrated their presence is a reasonable and effective way to bring issues before the Court. Generally, parties with standing as of right are the preferred applicants, and the Minister contends the directly affected litigants are able to challenge the decisions effectively. Public interest standing will be denied if directly affected parties have brought a matter forward: *Canadian Council of Churches v Canada (Minister of Employment and Immigration)*, [1992] 1 SCR 236 at 255-256.

[32] The applicants submit the Patient Applicants are directly affected by the Minister's decisions because the delay and denial of HCP training delays and denies their assessment and treatment. The Patient Applicants are individuals who had approached TheraPsil for assistance in being assessed for psilocybin-assisted psychotherapy, and if suitable, to be supported in gaining access to psilocybin and connected to practitioners who can provide the treatment. TheraPsil was unable to assist the Patient Applicants due to the scarcity of trained healthcare professionals, which has forced TheraPsil to implement an intake protocol and restrict its assistance to those individuals with the most urgent or life-threatening needs. According to the applicants, the Minister's argument that Patient Applicants have not been prescribed psilocybin-assisted psychotherapy misses the point. Due to the shortage of trained practitioners, the Patient Applicants cannot even be assessed for psilocybin-assisted psychotherapy. Furthermore, two of the Patient Applicants stated in their affidavits that their attending healthcare practitioners

supported their efforts to pursue psilocybin-assisted therapy. The applicants contend this is the best evidence that can be expected in the circumstances.

[33] The applicants state there are over 800 people on TheraPsil's waitlist. The *Charter* argument made to the Minister was that patient access to psilocybin does not equate to patient access to psilocybin-assisted psychotherapy. Patients in need who are granted Section 56 Exemptions themselves, or granted access to psilocybin via Special Access Program (SAP) requests made under the *FDR*, do not have access to psilocybin-assisted psychotherapy unless there are enough trained practitioners in Canada to assess, support, and treat them. The applicants state that the Patient Applicants' affidavits speak to their unsuccessful efforts to access psilocybin-assisted therapy. They turned to TheraPsil because they were unable to find healthcare practitioners to assess, support, and treat them.

[34] The applicants submit the lack of trained practitioners prevents patient access to health care, the Minister's refusals are the greatest barrier to being assessed, supported, and treated with psilocybin-assisted therapy, and denying standing to the Patient Applicants would insulate the Minister's decisions from a *Charter* challenge.

[35] I agree with the Minister that the Patient Applicants do not have private interest standing.

[36] The Patient Applicants are prospective patients—individuals who approached TheraPsil for assistance in being assessed for psilocybin-assisted therapy, and if they are found to be suitable, to benefit from TheraPsil's assistance in gaining access to psilocybin and being

connected to practitioners who could provide the treatment. Their affidavits (as well as the affidavits of the five other waitlisted patients who are not parties to this proceeding) make the same main points. Each affiant describes their medical condition, and states:

- the treatments they have tried have not worked;
- they believe, based on research they are aware of, that psilocybin-assisted psychotherapy will likely have a positive impact on their health;
- they contacted TheraPsil requesting assistance to be assessed for psilocybin-assisted psychotherapy, and if suitable, to be supported in efforts to gain legal access to psilocybin and be connected to practitioners who could provide treatment;
- TheraPsil informed them that it could not assist, because it lacked capacity to help the large number of people seeking similar assistance and support;
- TheraPsil informed them that it lacked capacity due to the scarcity of trained healthcare professionals, it had been forced to adopt patient inclusion criteria, and they did not meet the criteria (e.g. facing a life-threatening cancer diagnosis);
- they were unable to find any other person or organization in Canada to assist.

[37] As the Minister correctly notes, there is no evidence that the Patient Applicants are patients of HCPs who were denied a Section 56 Exemption. There is no basis to conclude that the Minister's decisions prevent the Patient Applicants from being assessed as candidates for psilocybin-assisted psychotherapy, and I do not accept the applicants' contention that the Patient Applicants cannot be expected to provide evidence that they are suitable candidates for psilocybin-assisted psychotherapy. TheraPsil's position is that experiential training is required for practitioners to administer a form of psilocybin-assisted psychotherapy that is optimally safe and effective. The evidence does not establish that experiential training is required to assess patient suitability for the treatment. Furthermore, even if the Patient Applicants are suitable candidates for psilocybin-assisted psychotherapy, the evidence does not establish that any of them requires treatment by an experientially trained practitioner.

[38] The Section 56 Exemption refusals do not affect the Patient Applicants' legal rights, impose legal obligations upon them, or prejudicially affect them in a direct way: *Forest Ethics* at para 20. The connection between the Patient Applicants and the decisions under challenge is an indirect connection, through TheraPsil, and it only arises because of the training model TheraPsil chose to adopt. TheraPsil placed the Patient Applicants on a waitlist in accordance with an intake protocol it implemented, to ration access to practitioners it has admitted to its roster. If an HCP successfully completes TheraPsil's training program, TheraPsil may add the HCP to the roster and give their name to waitlisted patients who may, after assessment, be considered suitable candidates for psilocybin-assisted psychotherapy and choose to undergo treatment with the HCP.

[39] The Patient Applicants are in the same position as other individuals TheraPsil placed on a waitlist for the same reason—in this sense, they are essentially representative applicants. However, TheraPsil's decision to place individuals on a waitlist does not give rise to private interest standing to challenge the decisions under review. In my view, the Patient Applicants' connection to the decisions is too remote to support private interest standing. The connection is even more remote for the 23 decisions issued to HCPs who chose not to challenge the Minister's decision to deny their Section 56 Exemption requests.

[40] I also find that the considerations for granting public interest standing do not favour granting such standing to the Patient Applicants in the circumstances of this case.

[41] I agree with the Minister that the Patient Applicants' participation does not raise a serious justiciable issue. The Patient Applicants do not bring a different perspective from other applicants on the central issue before the Court—that is, whether the Minister committed a reviewable error in refusing Section 56 Exemptions so HCPs can complete TheraPsil's experiential training module. The Patient Applicants do not present distinct arguments or a helpful perspective on the reasonableness of the Minister's decisions or the question of whether HCPs should be experientially trained. From the record, it appears that the Patient Applicants' knowledge in this regard is what they learned from TheraPsil.

[42] For similar reasons, I am not satisfied the Patient Applicants have a real stake or genuine interest in the issues raised in this proceeding. The affidavits that were submitted to support the HCPs' Section 56 Exemption requests indicate the Patient Applicants want treatment; they do not express a need for an experientially trained practitioner to provide it. Many of the affidavits describe the affiants' unsuccessful efforts to find a person or organization to assist them, including: inquiries through their attending healthcare practitioners; searches for other healthcare practitioners; contacting private clinics or centres within or outside Canada, or organizations that support patients who want to be assessed for and receive psilocybin-assisted psychotherapy; joining clinical trials; and requesting access to psilocybin through the SAP. The Patient Applicants have been pursuing different avenues to access psilocybin-assisted psychotherapy, and TheraPsil is one of the avenues they pursued without success. Apart from being one avenue that may lead to psilocybin-assisted psychotherapy, the applicants have not adequately explained how the Patient Applicants have a stake or genuine interest in the central issue of experiential training for HCPs.

[43] The 73 Exemption Applicants who are directly affected by decisions refusing their exemption requests are able to effectively challenge the decisions, particularly with TheraPsil's support. In all the circumstances, I am not satisfied the Patient Applicants' participation as applicants is a reasonable and effective way to bring issues before the Court.

[44] I note that while the Minister does not contest TheraPsil's standing, I have reservations about TheraPsil's standing to challenge at least the 23 decisions for HCPs who are not parties to this proceeding. Those 23 HCPs chose not to challenge the Minister's refusals, despite TheraPsil's support. However, it is unnecessary to say more on this point. In view of my decision to dismiss this application, questions about TheraPsil's standing make no difference to the result.

(2) Proper Respondent

[45] The second question raised by the Minister relates to the proper respondent. The Minister states that the Minister of Health is not the proper respondent to this application, and asks that the style of cause be amended to substitute the Minister of Mental Health and Addictions and Associate Minister of Health. Order-in-Council 2022-0549, which was effective May 26, 2022, transferred the powers, duties, and functions under the *CDSA* from the Minister of Health to the Minister of Mental Health and Addictions and Associate Minister of Health. The decisions challenged in this application post-date this change.

[46] I agree that the responsible decision maker is the Minister of Mental Health and Addictions and Associate Minister of Health, and the style of cause will be amended accordingly.

B. *Main Issue 1: Standard of Review*

[47] According to the Supreme Court of Canada's (SCC) decision in *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 [*Vavilov*], the presumptive standard of review is reasonableness. The reasonableness standard is a deferential but robust form of review. In applying the reasonableness standard, the Court must ask if the decision under review bears the hallmarks of reasonableness—justification, transparency and intelligibility—and whether it is justified in relation to the relevant factual and legal constraints that bear on the decision: *Vavilov* at para 99. The robust form of reasonableness review described in *Vavilov* recognizes that what is reasonable in a given situation will always depend on the constraints imposed by the legal and factual context of the particular decision under review: *Vavilov* at paras 90, 105. The contextual constraints dictate the limits and contours of the space in which the decision maker may act and the type of solutions it may adopt: *Ibid*. The party challenging the decision bears the onus of demonstrating that it is unreasonable: *Vavilov* at para 100.

[48] The applicants submit the reasonableness standard of review applies to the Court's review of the Minister's decisions, with one exception. The applicants submit that when this Court is reviewing the Minister's approach to *Charter* issues, it should adopt a correctness standard of review for part of the analysis. The Minister disagrees, and submits the standard of review for all issues on this application, including *Charter* review, is reasonableness.

[49] Both parties addressed the standard for *Charter* review at some length, and I intend to address this question below in the context of the parties' *Charter* arguments. In this section I will simply state that in my view, the standard of review for all issues raised in this case, including *Charter* review, should be reasonableness; however, the result on this application does not turn on the standard of review.

C. *Main Issue 2: Are the Minister's decisions unreasonable?*

[50] The applicants identify five problem areas with the Minister's decisions, and allege that each presents a sufficient basis to overturn the decisions. The applicants allege the Minister: (1) failed to meaningfully grapple with three central arguments that a clinical trial is unsuitable to achieve the goals of practitioner training; (2) did not account for OCT evidence that a clinical trial for TheraPsil's training program would not be possible; (3) made unclear statements about experiential training, rendering the decisions unintelligible and non-transparent, and demonstrating a fundamental misapprehension of the evidence and failure to account for relevant evidence; (4) relied on an unreasonable conclusion that Section 56 Exemptions would create unacceptable risks, and that a clinical trial would reduce the risks; and (5) failed to balance the infringement of HCPs' and patients' section 7 *Charter* rights with statutory objectives, or even acknowledge the *Charter* arguments.

[51] The Minister submits subsection 56(1) of the *CDSA* confers broad discretion, and significant leeway in the exercise of her discretion: *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at para 112 [*PHS*]. The Minister states there is no right to an exemption; she may refuse an exemption based on her opinion, as long as the decision

is reasonable and reflects a proportionate balancing of *Charter* rights and values with statutory objectives. With respect to the decisions at issue, the Minister states she formed the opinion that a Section 56 Exemption was not "necessary for a medical or scientific purpose or otherwise in the public interest" given the option of a clinical trial. She did not accept that the HCPs need to consume psilocybin in order to provide psilocybin-assisted psychotherapy to patients in a safe and effective manner.

[52] The Minister states the applicants disagree with her findings and seek to reargue scientific and medical issues related to psilocybin-assisted psychotherapy, such as the risks associated with psilocybin acquisition and use, ethical considerations regarding clinical trials, and whether experiential training is necessary and improves patient outcomes. In reviewing a decision under subsection 56(1) of the *CDSA*, it is not the Court's role to settle or determine scientific and medical debates: *Vavilov* at para 125.

[53] The Minister states she was not required to provide formal reasons, and in any event, the reasons were as comprehensive as required in the circumstances. Administrative reasons need not be perfect, address every argument, or make an explicit finding on each constituent element leading to the conclusion: *Vavilov* at paras 91-92 and paras 127-128.

(1) Did the Minister fail to meaningfully grapple with central arguments about the unsuitability of a clinical trial?

[54] The applicants state the Minister did not meaningfully grapple with three central arguments that a clinical trial is unsuitable to achieve the goals of practitioner training: a clinical trial is not available in a timely manner and would cause delay; the effects of psilocybin in

healthy human subjects are already known and it would be unethical to conduct a clinical trial for therapist training without a specific research question; a clinical trial is not compatible with training objectives and many elements of clinical trial design could interfere with participants' training objectives. The applicants contend the Minister merely summarized these arguments and stated a peremptory conclusion, which is inadequate: *Vavilov* at para 102; *Paul v Canada (Attorney General)*, 2022 FC 1157 at paras 32-34. The applicants state that while there are a number of paragraphs in the decision related to clinical trials, they do not actually address the HCPs' central arguments. For example, the Minister's recommendation that TheraPsil reconsider its position on a clinical trial is simply a statement of disagreement, and her statement that Health Canada addressed meeting requests in a timely manner does not address the concerns with delay. Similarly, the Minister's remarks about Health Canada's efforts to encourage clinical trials and the benefits of clinical trials studying the efficacy of psilocybin-assisted psychotherapy for patients were not responsive to the arguments related to clinical trials involving practitioners, and the remarks are irrelevant. Reasons must be justified, not merely justifiable, and the failure to grapple with central arguments constitutes a reviewable error: *Vavilov* at paras 86, 128.

[55] The Minister states that while the decisions do not explicitly articulate a response to each of the HCPs' three arguments, the decisions address them. The arguments that a clinical trial would be unethical and interfere with training objectives are addressed by the finding that TheraPsil's experiential training requirement is a choice, and not a necessity. The Minister noted that providers can be trained in psychedelic-assisted psychotherapy without consuming psilocybin themselves, and thus the HCPs had not shown that experiential training is necessary.

In any event, TheraPsil could apply for a clinical trial, which would allow access to psilocybin for training purposes through a legal avenue. The Minister states the decision adequately explained this regulatory pathway, and also explained developments in the pathway since the 19 exemptions were previously granted to practitioners—this met any "justificatory burden" to explain a departure from past practice: *Vavilov* at para 131. While the applicants prefer to avoid the clinical trial process and instead obtain exemptions, the Minister states she reasonably determined that Section 56 Exemptions are not necessary for a medical or scientific purpose, or otherwise in the public interest.

[56] I find the applicants have not established a reviewable error based on a failure to address the three arguments about suitability of a clinical trial. The Minister adequately addressed the arguments.

[57] As noted above, the Minister was tasked with deciding whether a Section 56 Exemption, that would allow HCPs to possess and consume psilocybin as part of their training with TheraPsil, was necessary for a medical or scientific purpose or otherwise in the public interest. The Minister found that an exemption was not necessary because the HCPs have an option under the *FDR*—namely, to participate in a clinical trial. The Minister explained that Health Canada's recent authorization of a clinical trial for healthcare professionals' use of psilocybin for training purposes demonstrated that a clinical trial is a feasible regulatory option.

[58] The HCPs' arguments that a clinical trial would not be timely, ethical, or compatible with training objectives assume that experiential training is necessary. The evidence did not establish

that experiential training is necessary. The HCPs' arguments were fully addressed by the Minister's findings that there is no peer-reviewed clinical evidence demonstrating that HCPs need to take a psychedelic drug in order to appreciate what the patient experiences, and while TheraPsil's training program requires trainees to consume psilocybin, it is not required for therapists to offer psilocybin-assisted psychotherapy.

[59] The Minister's findings were open to her, and supported by the record. TheraPsil does not regulate or license healthcare professionals. The doctors, psychologists, nurses, social workers, counsellors, and other regulated healthcare professionals who applied for exemptions are licensed by their respective regulatory bodies. The extent of each HCP's involvement in administering psilocybin-assisted psychotherapy to patients would be limited by their qualifications, and the healthcare services they are licensed to provide. For example, a physician who was granted one of the prior Section 56 Exemptions and completed TheraPsil's training program states in her affidavit, "Because I am not a trained therapist, I rely on therapists to support patients with psilocybin-assisted psychotherapy." Furthermore, the HCPs' submissions to the Minister state that TheraPsil had "allowed" ten practitioners who did not receive a Section 56 Exemption, and did not complete experiential training, to treat patients without being supervised by a training program instructor. TheraPsil's evidence was that it was forced to make this decision "because the alternative in many instances is no care at all". Nonetheless, TheraPsil's decision was made "after going through an extensive assessment and screening process", and TheraPsil was "confident that this process ensures the safety and efficacy of the treatment". TheraPsil's concern was that the lack of experiential training means that patients "may be subject to suboptimal care".

[60] The Minister did not fail to grapple with the argument that a clinical study would interfere with training objectives; she found the evidence did not support the training objective of taking a psychedelic drug in order to appreciate what the patient experiences. While the applicants contend clinical trials cannot be designed to address a question for which there is already a scientific consensus, the Minister did not accept there was scientific consensus. The Minister recommended that TheraPsil reconsider its position on a clinical trial, in order to develop an appropriate clinical trial design that would allow a better understanding of the various effects of psilocybin on humans.

[61] The applicants submit that if the Minister had relied solely on a finding that HCPs do not need experience with psilocybin to provide psilocybin-assisted psychotherapy, she might not have been obliged to address the arguments that a clinical trial is unsuitable. Since the Minister maintained that a clinical trial is a feasible regulatory option, and the pathway these HCPs should pursue, the applicants say she was required to address arguments that were directly on point.

[62] I disagree. The Minister's reasoning regarding the nature of the existing evidence for experiential training is not a separate and distinct basis justifying her refusal. It is very much connected to and supportive of the Minister's reasoning about the clinical trial pathway. The HCPs asked for exemptions to access psilocybin-containing mushrooms for professional training, in order to provide the "highest quality of training" to health care professionals. The Minister found the evidence for experiential training to be deficient, and gave the option of developing the evidence through a clinical trial that would test, in a scientifically rigorous manner, whether experiential training affects the safety or efficacy of psilocybin-assisted

psychotherapy. The clinical trial pathway does not need to accomplish training goals or offer an experience that is equivalent to TheraPsil's training program in order to represent a viable alternative to the Section 56 Exemptions the HCPs requested.

[63] I would add that the concerns with the lack of evidence were not new concerns. Emails in August 2020 and November 2020 (related to the previous exemption requests by 19 practitioners) also expressed concerns about the lack of evidence to support therapeutic use of psilocybin, and the need for clinical trial studies to develop the evidence and investigate the outcomes of TheraPsil's training model. The OCT had offered to provide guidance to TheraPsil regarding the clinical trial process, should it be of interest to TheraPsil in the future.

[64] In summary, the decisions provide a complete answer to the arguments that a clinical trial is unsuitable for therapist training and the Minister was not required to address each of the HCPs arguments separately.

(2) Did the Minister err by failing to account for OCT evidence that contradicted her conclusion?

[65] The applicants submit the Minister failed to account for evidence from the OCT that a clinical trial for TheraPsil's training program is not possible. They point to the August 2020 email, which sets out the OCT's concerns and opinion that a clinical trial is not possible for the situation TheraPsil is requesting. The applicants state the Minister was required to address this evidence because it contradicted her conclusion: *Cepeda-Gutierrez v Canada (Minister of Citizenship and Immigration)*, [1999] 1 FC 53 at para 17; *Vavilov* at para 126.

[66] The Minister submits she was not required to specifically address this evidence because the OCT's opinion evolved between August and November 2020, and this was communicated to TheraPsil. The November 2020 email states there are ways that a clinical trial could be designed in order to investigate the outcomes of the training model, and the OCT had offered to work with TheraPsil to design an effective clinical trial.

[67] The applicants counter that it is not clear from the November 2020 email that the OCT retracted its earlier position, and if the Minister preferred the OCT's later position she should have said so in her reasons. The presence of evidence supporting the Minister's conclusion does not relieve her from the obligation to address contradictory evidence.

[68] I agree with the applicants that it is not clear the OCT's position described in the November 2020 email represents retraction, or in the Minister's words, an evolution of the OCT's position in August 2020. The OCT's view in August 2020 was that a clinical trial was not possible "for the situation TheraPsil is requesting". The OCT expressed a number of concerns in this regard, including concerns about physicians treating themselves and self-prescribing controlled drugs, the need for practitioners to refrain from treating patients until there is no more drug in their system, and a preference for studies that use GMP synthetic psilocybin instead of mushrooms. The OCT also stated it would be unethical for investigators to "switch" between observing and participating unless they suffer from the condition being treated. These concerns were directed at TheraPsil's specific proposal, and it is not clear the OCT changed its position in November 2020 when it stated there are ways to design a clinical trial in order to

investigate the outcomes of an experiential training model, and offered to give TheraPsil guidance in this regard.

[69] However, I do not agree with the applicants that the OCT's 2020 position contradicts the Minister's decisions, and for this reason, she was not required to address it as contradictory evidence. The Minister's statement that a clinical trial may be a suitable regulatory pathway to achieve the HCPs' purpose does not represent a departure from the OCT's 2020 position that, while TheraPsil's proposal was problematic, a clinical trial can investigate an experiential training model. The Minister encouraged the HCPs to reconsider their position that a clinical trial would not be suitable for their purpose, and to contact the OCT for guidance to develop an appropriate clinical trial design. The message to TheraPsil since 2020 remained the same—there are ways to design a clinical trial to investigate an experiential training model, and the OCT is willing to help.

[70] The Minister also explained why the clinical trial pathway had become more accessible since 2020. She explained the initiatives to encourage clinical trial research with psilocybin, and that they were working. Clinical trials were happening. In a short period, Health Canada had authorized ten new psilocybin clinical trials, including one specifically for healthcare professionals' use of psilocybin for training purposes.

[71] The applicants have not established that the Minister's decisions are inconsistent with the OCT's 2020 position on a TheraPsil trial, and therefore she was not required to address the OCT's 2020 statements as contradictory evidence.

(3) Did the Minister err by making unclear statements about experiential training, rendering the decisions unintelligible and non-transparent, and demonstrating a fundamental misapprehension of the evidence and failure to account for relevant evidence?

[72] The applicants submit that in the tenth paragraph of the decisions, the Minister "shifts topics" from the clinical trial pathway to the need for experiential training. In this paragraph, the Minister describes TheraPsil's evidence as anecdotal evidence and opinions, and states that other therapists are able to offer psilocybin-assisted therapy without experiential training. The applicants assert that the decisions do not explain what conclusions the Minister draws from those facts, or whether she relied on the facts, or any conclusion she drew from them, to reach her ultimate decision. Consequently, the applicants say the decisions are not transparent or intelligible.

[73] The applicants also say that any unstated or implicit conclusion that experiential training is not needed to provide the safest or most effective form of treatment would be unreasonable because the Minister fundamentally misapprehended the evidence and failed to account for relevant evidence. The applicants contend the Minister mischaracterized the evidence on experiential training as solely "anecdotal experience and opinions by individual health care professionals", when the evidence included two peer-reviewed scientific articles: one that sets out the findings of a six-member expert committee after completing a literature review and broad consultations, and one based on a literature review that surveyed more than 150 publications spanning seven decades. In addition, the Minister failed to account for experts' letters in the record that supported exemptions, and the opinions of experts Health Canada had consulted in

2020 who “strongly indicated that personal experience with psilocybin is required to safely guide patients through treatment sessions”.

[74] The applicants state the Minister departed from established internal authority without justification, in that she previously authorized 19 exemptions to consume psilocybin for training purposes because it “would allow the [healthcare practitioners] to improve their knowledge of psilocybin-assisted psychotherapy and better support patients”.

[75] The Minister submits the applicants’ evidence was not ignored—she acknowledged the evidence and explained why it was insufficient. The Minister submits she reviewed and assessed the evidence, and drew a different conclusion from the evidence than what the applicants argued. The Court should not reweigh or reassess the evidence on judicial review: *Vavilov* at para 125.

[76] I am not persuaded of any error arising from the Minister’s assessment of the evidence. The Minister’s statements about experiential training are transparent and intelligible, and justify her decisions.

[77] In her decisions, the Minister specifically referred to the evidence on experiential training, including the experts’ letters, and I agree with the Minister that the record demonstrates that TheraPsil’s evidence was reviewed and assessed. Reports on safety and efficacy data for psilocybin, its clinical uses and risks, and a memorandum summarizing TheraPsil’s evidence and submissions were prepared for the Minister, and they appear to be comprehensive.

[78] The applicants have not established the Minister was under any misapprehension about the nature or the quality of the evidence to support TheraPsil's position on experiential training. I am not persuaded the Minister mischaracterized the evidence as anecdotal experience and opinions by individual health care professionals. The memorandum prepared for the Minister described the evidence relied on to support the use of psilocybin by therapists as falling into two categories: anecdotal evidence and opinions, and journal articles. The memorandum noted that the research submitted by TheraPsil "is not peer reviewed clinical evidence, nor does the quality of the evidence fall high in the evidence pyramid hierarchy". While experts Health Canada consulted in connection with the previous 19 exemptions "strongly indicated" that personal experience with psilocybin is required to safely guide patients through treatment sessions, Health Canada had concerns with the lack of evidence supporting therapeutic uses of psilocybin. As noted above, even in 2020 Health Canada identified a need for clinical trial studies to develop the evidence and investigate the outcomes of TheraPsil's training model. In my view, the Minister accurately characterized the evidence.

[79] The Minister did not conclude, as the applicants suggest, that experiential training is not needed to provide the safest or most effective form of treatment, nor can such a conclusion be implied. The Minister's conclusion was that the available evidence did not demonstrate that healthcare professionals need experience with a psychedelic drug. She explained how the evidence could be developed. This was not a shift in topics, but rather, part of the justification for the Minister's decision to refuse the HCPs' requests in view of the clinical trial option.

[80] The Minister did not depart from internal authority without justification. Section 56 Exemptions are discretionary and fact-specific. The previously granted practitioner exemptions do not represent established internal authority or a longstanding practice, particularly when the OCT had identified the need for "a blinded clinical study with appropriate controls and research ethics board oversight" to develop the evidence, and offered to provide guidance to TheraPsil on the clinical trial process. Furthermore, even a decision that departs from longstanding practice or established internal decisions will be reasonable if that departure is justified: *Vavilov* at para 131. The Minister's decisions explain that circumstances had changed since she granted 19 practitioner exemptions two years earlier. Since then, Health Canada had made progress in its efforts to build the evidence base for psilocybin through clinical trials, including by authorizing multiple new clinical trials.

(4) Did the Minister unreasonably conclude that Section 56 Exemptions would create unacceptable risks, and a clinical trial would reduce the risks?

[81] The applicants submit the Minister's conclusion that granting Section 56 Exemptions would create unacceptable health and safety risks that would be ameliorated by a clinical trial is unreasonable, and a departure from the previous decisions that allowed practitioner exemptions. The applicants submit that the only evidence of health and safety risks in the record relates to consuming psilocybin outside of a clinical setting, and the HCPs in TheraPsil's training program would consume psilocybin in a clinical setting. The applicants submit the Minister did not grapple with submissions directly refuting the claim that a clinical trial would provide meaningful safety benefits over granting Section 56 Exemptions.

[82] The Minister submits that the evidence that was before her supports the finding that the requested exemptions would pose a risk to health and public safety. Evidence summaries prepared for the Minister noted that the use of psilocybin comes with risks that include increased heart rate and blood pressure, flashbacks, and the risk of "bad trips" that can lead to risk-taking behaviour, traumatic injuries, and even death. There was evidence that the strength of "magic mushrooms" can vary greatly, and unlike clinical studies using pharmaceutical-grade psilocybin, it is challenging to estimate dose when consuming mushrooms. Also, the HCPs propose to procure mushrooms from an unknown and illegal source. The HCPs exemption requests ask "for the dignity to take a risk" and get the mushrooms from a trusted source they have.

[83] In my view, the record reasonably supported the potential health and safety risks that the Minister identified, namely, risks associated with obtaining and consuming illegally sourced psilocybin as opposed to accessing psilocybin through the clinical trial pathway. The applicants have not established any error in the Minister's finding that consuming psilocybin in the context of a clinical trial can offer greater protection to HCPs by ensuring that the psilocybin complies with GMP, and is administered in accordance with national and international ethical, medical, and scientific standards.

[84] The Minister did not unreasonably conclude that Section 56 Exemptions would create unacceptable risks, and for the reasons above, the Minister did not unreasonably depart from her previous decisions allowing Section 56 Exemptions for practitioners.

(5) Did the Minister fail to balance the infringement of section 7 of the *Charter* with the statutory objective, or unreasonably fail to address the applicants' *Charter* arguments?

[85] The applicants submit they had squarely raised the violation of HCPs' and patients' section 7 *Charter* rights in their submissions to the Minister, yet the Minister did not address whether the *Charter* was engaged. The Minister was required to balance *Charter* values with the statutory objectives of the *CDSA*, and she failed to do so. Of the five problem areas identified, the applicants submit this is the Minister's clearest error.

[86] When reviewing an administrative decision for compliance with the *Charter*, the Court is to apply a two-step approach. The first step requires the Court to determine whether the decision under review engaged the *Charter* by limiting a *Charter* protection. If it did, the second step requires an examination of whether, in exercising its statutory discretion, the decision maker properly balanced the relevant *Charter* protection with the statutory objectives: *Doré v Barreau du Québec*, 2012 SCC 12 at para 57 [*Doré*]; see also *Loyola High School v Quebec (Attorney General)*, 2015 SCC 12 at para 39 [*Loyola*] and *Law Society of British Columbia v Trinity Western University*, 2018 SCC 32 at para 28.

[87] The applicants submit the appropriate standard of review for the first step of the analysis under the *Doré* framework is an unsettled question, and they argue the Court should apply the correctness standard. In this regard, the applicants rely on *Robinson v Canada (Attorney General)*, 2020 FC 942 [*Robinson FC*], where this Court adopted the correctness standard for the first step of the *Doré* framework: *Robinson FC* at paras 42 and 59, citing *Canadian Broadcasting*

Corporation v Ferrier, 2019 ONCA 1025 [*Ferrier*]. For the second step under the *Doré* framework, the applicants submit that reasonableness is the appropriate standard of review.

[88] However, the applicants contend it is not strictly necessary to decide the standard of review question, and a full *Doré* analysis is not required where the decision maker did not address the *Charter* issue at all. The applicants submit the decisions are automatically unreasonable because the submissions to the Minister had squarely raised, as a central argument, the impact a refusal would have on HCPs' and patients' rights under section 7 of the *Charter* and the Minister's decisions do not address the *Charter* issue at all. An unexplained failure to address whether the *Charter* was engaged cannot survive reasonableness review: *Canada (Attorney General) v Robinson*, 2022 FCA 59 at para 28 [*Robinson FCA*]. The applicants argue that, even if the Minister's decision is otherwise reasonable, she was required to address the *Charter* issue. According to the applicants, even if the Minister's conclusions about the clinical trial pathway and experiential training are reasonable, she was not excused from analyzing a *Charter* violation arising from a delay in patients' treatment or from patients receiving less safe and less effective treatment from a non-experientially trained practitioner.

[89] The Minister disagrees with the applicants' approach on standard of review and submits that all issues on this application should be reviewed on the reasonableness standard. Reasonableness is the presumptive standard of review, and none of the exceptions warranting a correctness standard applies to the present application—for example, the applicants do not challenge the constitutional validity of legislative provisions or raise questions of central importance to the legal system as a whole: *Vavilov* at paras 57, 62. With respect to *Robinson*

FC, the Minister submits that the Federal Court of Appeal in *Robinson FCA* declined to comment on the Federal Court's approach to the *Doré* framework, and expressly declined to decide whether to adopt the *Robinson FC* and *Ferrier* approach for the first step under the *Doré* framework: *Robinson FCA* at para 29.

[90] The Minister submits that when the Court is faced with a review of a discretionary administrative decision that implicates *Charter* rights, the proper approach requires the Court to consider whether the administrative decision reflects a proportionate balancing of the *Charter* protections at play: *Doré* at para 57. This exercise involves considering (i) whether and to what extent an administrative decision engages *Charter* protections, and (ii) whether the administrative decision reflects a proportionate balancing of the *Charter* protections at play with the relevant statutory mandate: *Doré* at paras 57-58. The Minister states that in applying the *Doré* approach, the Court is not assessing the decision maker's opinion as to whether a *Charter* right is or is not engaged, and the Court should not artificially carve out a freestanding question that the decision maker must address and "get right" according to a correctness standard of review. The proper approach considers whether *Charter* protections are engaged in reviewing the reasonableness of the decision as a whole.

[91] Applying these principles to the case, the Minister submits her decisions to refuse the Section 56 Exemption do not engage *Charter* rights, and the jurisprudence the applicants rely on is distinguishable. However, even if *Charter* rights are engaged, the Minister contends the decisions show that she considered the arguments alleging that a negative decision would affect *Charter* rights, and the decisions reflect a proportionate balancing between the *Charter* rights

that were asserted and the statutory objectives of the *CDSA*. The Minister states she was alive to the *Charter* issues presented and engaged with them by addressing the effects of the decisions that could potentially engage section 7 of the *Charter*. This was sufficient. The failure to specifically refer to the *Charter* does not render the decisions unreasonable: *Ktunaxa Nation v British Columbia (Forests, Lands and Natural Resource Operations)*, 2017 SCC 54 at para 139 [*Ktunaxa*].

(a) *The standard of review is reasonableness*

[92] I agree with the Minister that reasonableness is the appropriate standard of review for the issues the applicants raise in this case.

[93] I am not persuaded by the applicants' arguments that I should follow the standard of review approach that the Court adopted in *Robinson FC*. In *Robinson FC*, the applicant had relied on the Ontario Court of Appeal's decision in *Ferrier* to argue that the correctness standard of review applies in circumstances where an administrative decision maker refuses to consider or fails to consider an applicable *Charter* right: *Robinson FC* at para 39, citing *Ferrier* at paras 34-38. The Court in *Robinson FC* accepted that the *Ferrier* decision supported the applicant's position that the question of whether a *Charter* right has a bearing on an administrative decision is governed by the correctness standard. However, the Court also observed that this principle "arguably represents an evolution from *Doré*".

[94] Ultimately, the result in *Robinson FC* did not turn on an application of the correctness standard of review: *Robinson FC* at para 71. Furthermore, as the Minister correctly notes, the

Federal Court of Appeal declined to decide whether it should adopt the standard of review approach set out in *Robinson FC* and *Ferrier*: *Robinson FCA* at para 29. While the Court in *Robinson FCA* upheld the decision in *Robinson FC*, it did so by applying the reasonableness standard of review—finding that the decision maker's failure to respond to a question framed by the applicant in circumstances where that question was called on to be answered was unreasonable: *Robinson FCA* at para 28, citing *Vavilov* at paras 81 and 86.

[95] The Federal Court of Appeal noted in *Robinson FCA* that a decision maker does not have to address the *Charter* in every decision he or she makes: *Robinson FCA* at para 28, citing *Loyola* at para 4. The *Doré* framework is a review framework for courts to apply, and I agree with the Minister that in applying the *Doré* framework, the Court should not carve out a freestanding question that an administrative decision maker must address, and which is subject to a correctness standard of review.

[96] If a decision engages the *Charter*, the parties agree that the question of proportionate balancing under the second part of the *Doré* framework calls for the reasonableness standard. The SCC has said that when *Charter* values are applied to an individual administrative decision, they are being applied in relation to a particular set of facts that should attract deference: *Doré* at para 36. The alternative of adopting a correctness review in every case that implicates *Charter* values would lead to courts retrying a range of administrative decisions that would otherwise be subjected to a reasonableness standard: *Doré* at para 51. In this case, whether the decisions are compatible with the *Charter* under the second part of the *Doré* framework would depend on factual findings that are entitled to deference.

(b) *The decisions do not engage the* Charter

[97] In applying the *Doré* framework, I must first determine whether the Minister's decisions engage *Charter* rights.

[98] The applicants submit the decisions engage the HCPs' section 7 *Charter* rights to liberty because practitioners need to train with psilocybin to provide optimal care to their patients, and possession of psilocybin contrary to section 4 of the *CDSA* carries the possible punishment of imprisonment. The applicants submit the decisions engage prospective patients' section 7 *Charter* rights as follows: (i) the decisions infringe prospective patients' right to liberty by inhibiting the ability to make a reasonable medical choice; (ii) the decisions infringe the right to security of the person by preventing access to the safest and most effective version of psilocybin-assisted psychotherapy; (iii) the decisions infringe on the right to life by increasing the risk of death by suicide, or medical assistance in dying for patients with depression or end-of-life distress.

[99] The Minister argues that apart from the potential deprivation of physical liberty arising from the possibility of imprisonment for those who choose to break the law, the Minister's denial of the exemptions to possess and consume psilocybin for training purposes does not limit, on a personal basis, any interest protected by section 7. The Minister argues that to the extent section 7 of the *Charter* protects the right to make medical choices without the threat of criminal sanctions, the right only protects reasonable medical choices supported by evidence and/or medical advice, in response to serious medical conditions. The Minister submits the applicants have not adduced sufficient evidence to demonstrate that experiential training is medically

necessary to provide adequate access to psilocybin-assisted psychotherapy. Furthermore, the applicants have failed to demonstrate the HCPs have a legitimate need to access psilocybin. A desire to enhance one's professional competency does not engage section 7 *Charter* protections.

[100] In my view, the Minister's decisions refusing the HCPs' Section 56 Exemptions do not engage the HCPs' or patients' *Charter* rights. The foundation for the *Charter* arguments is not supported by the evidence before the Minister and before this Court. The evidence does not establish that the HCPs need experiential training, or that they need to take a psychedelic drug to appreciate what the patient experiences. Similarly, the evidence does not establish that prospective patients undergoing psilocybin-assisted therapy need to be treated or assisted by doctors, therapists, nurses, or other practitioners who have experience with a psychedelic drug, or that treatment by a practitioner who has completed TheraPsil's training program (or a similar training program with an experiential module) will be safer and more effective.

[101] This case is distinguishable from *PHS*, where the Minister's refusal to grant a Section 56 Exemption to healthcare practitioners working at a safe injection site for drug addicts engaged their section 7 *Charter* rights. The site was a government-sanctioned facility established in the late 1990s in response to a declared public health emergency, and it had been operating under a Section 56 Exemption for 5 years. The practitioners supervising the injections were staff who were employed by the facility. They argued that their section 7 liberty interests were engaged because denying an exemption would expose them to the threat of being imprisoned "for carrying out their duties": *PHS* at para 87. Even though the practitioners were not buying drugs or assisting with their injection, the SCC found that the practitioners' minimal involvement with

clients' drugs may constitute illegal possession contrary to section 4 of the *CDSA*. Without a Section 56 Exemption, they would be unable to offer medical supervision and counselling. The site could not continue to operate.

[102] In the present case, the HCPs seek a Section 56 Exemption for their own consumption, to complete a training program. The training program is not mandated, and the record does not support a conclusion that HCPs are unable to offer psilocybin-assisted psychotherapy without experiential training. The evidence does not establish that experiential training results in safer or more effective care to patients. The Minister explained an alternative, legal method of accessing psilocybin through clinical trials. Clinical trials would have the benefit of building the evidence on psilocybin safety and efficacy, and could mitigate potential health and safety risks associated with obtaining and consuming illegally sourced psilocybin mushrooms.

[103] For similar reasons, I am not persuaded that the decisions engage prospective patients' rights to life, liberty, and security of the person. As noted above, the evidence does not establish that psilocybin-assisted psychotherapy by an experientially trained practitioner is safer and more effective, and the decisions do not prevent patients from accessing psilocybin under their own exemption or accessing psilocybin-assisted psychotherapy. Furthermore, the waitlisted patients who submitted affidavits to support the HCPs' Section 56 Exemption requests have not been assessed for psilocybin-assisted psychotherapy, and there is no evidence any of them requires psilocybin-assisted psychotherapy administered by an experientially trained practitioner. The evidence does not establish that the Minister's decisions engage prospective patients' *Charter* rights.

[104] In any event, the decisions demonstrate that the Minister reasonably and proportionately balanced *Charter* values with the statutory objectives of the *CDSA*, and the decisions accord with the principles of fundamental justice.

[105] The decisions to refuse the HCPs requests for access to psilocybin mushrooms for training purposes are not arbitrary, overbroad, or grossly disproportionate in relation to the *CDSA*'s statutory objectives. The decisions describe the potential health and safety risks associated with obtaining and consuming illegally sourced psilocybin, which aligns with the statutory objectives of protecting public health and safety, and the decisions present a viable alternative to an exemption. The decisions do not prevent a patient who can establish a reasonable medical need from seeking access to psilocybin, nor do they prevent HCPs from providing psilocybin-assisted psychotherapy. While the applicants' position is that nothing short of TheraPsil's experiential training regimen will achieve the HCPs' purposes, there is insufficient evidence to demonstrate a need for, or benefit of, experiential training with psilocybin. The effect of the decisions only prevents the HCPs from consuming psilocybin for training purposes in their preferred manner in accordance with TheraPsil's training program, which is not grossly disproportionate to *CDSA* objectives.

(c) *The decisions adequately address the* Charter *arguments*

[106] This does not end the analysis, however, as the applicants also contend the decisions cannot survive reasonableness review because the Minister failed to address *Charter* arguments that had been squarely raised in their submissions: *Robinson FCA* at para 28.

[107] In response, the Minister states the failure to specifically refer to the *Charter* does not render the decisions unreasonable, relying on *Ktunaxa* at paragraph 139.

[108] I note that paragraph 139 of *Ktunaxa* is in the partially concurring reasons of Justices Moldaver and Côté. Justice Moldaver was of the view that the Minister did not need to specifically refer to the *Charter* claim, as the Minister addressed the substance of the asserted *Charter* right and it was implicit from the Minister's reasons that he proportionately balanced the *Charter* protections at stake with the relevant statutory objectives: *Ktunaxa* at paras 138-139. However, relying on *Newfoundland and Labrador Nurses' Union v Newfoundland and Labrador (Treasury Board)*, 2011 SCC 62 [*Newfoundland Nurses*], Justice Moldaver went on to state that reasonableness review entails a respectful attention to the reasons offered or which could be offered in support of a decision, and if the reasons do not seem wholly adequate to justify the outcome, a reviewing court should seek to first supplement the reasons of the decision maker before substituting its own: *Ktunaxa* at para 140. *Vavilov* directly contradicts this reasoning. The SCC stated in *Vavilov* that it is not open to a reviewing court to disregard a flawed basis for a decision and substitute its own justification for the outcome. *Vavilov* states that, to the extent cases such as *Newfoundland Nurses* have been taken as suggesting otherwise, such a view is mistaken: *Vavilov* at para 96.

[109] In my view, it is unnecessary to parse the principles of *Ktunaxa* set out in the above paragraphs, as I should rely on the guiding principles for reasonableness review in *Vavilov*. In my view, the Minister's failure to specifically mention the *Charter* does not render her decisions unreasonable based on the principles set out in *Vavilov*.

[110] Administrative decisions must be understood in context. Decisions should be read in light of the record, and the review of an administrative decision should not be divorced from the institutional context in which the decision was made, nor from the history of the proceedings: *Vavilov* at paras 91, 94. Context includes, for example, the evidence and parties' submissions that were before the decision maker: *Vavilov* at para 94.

[111] The HCPs' submissions to the Minister had argued that Section 56 Exemptions must be granted, because the Minister's discretion is constrained by the *Charter*. The argument was that HCPs' liberty interests were engaged by the *CDSA* prohibition on possession of psilocybin and by the Minister's exemption decisions because HCPs need to possess psilocybin to undergo experiential training and provide the most safe and effective care to patients, and HCPs risk imprisonment if they attempt to obtain crucial experiential training without an exemption. With respect to patients' section 7 rights, the argument hinged on the lack of experientially trained HCPs, which effectively denied patients the ability to be assessed for and treated with psilocybin-assisted psychotherapy.

[112] The Minister's reasons provide the rationale for rejecting the *Charter* arguments by addressing their very foundation, which is that 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. Therefore, the question I must decide is whether the Minister's failure to expressly engage in a *Charter* analysis or expressly opine on whether *Charter* rights are engaged and explain her opinion in this regard

resulted in a failure of transparency, intelligibility, or justification that renders the decision unreasonable and warrants setting it aside. In my view it does not.

[113] 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.

[114] In conclusion, the Minister did not refuse the HCPs' exemption requests by an exercise of discretion that was inconsistent with *Charter* values. The decisions do not deprive the HCPs or prospective patients of their section 7 *Charter* rights in a manner that does not accord with principles of fundamental justice.

D. *Main Issue 3: What is the appropriate remedy?*

[115] In view of my decision to dismiss this application, it is unnecessary to consider the appropriate remedy. For completeness, I will simply state that I disagree with the applicants that the most appropriate remedy is for the Court to direct the Minister to grant the exemptions. If a

decision is found to be unreasonable, most often the matter should be remitted to the decision maker for reconsideration: *Vavilov* at para 141. This application does not present a scenario that would render it appropriate for the Court to substitute its own decision.

VI. **Conclusion**

[116] The applicants have not established the Minister's decisions are unreasonable. Accordingly, this application is dismissed.

[117] With respect to costs, the parties agree that a $9,500 award in favour of the successful party is appropriate. They submit this would represent a reasonable award in view of the Tariff under the *Federal Courts Rules*, the pre-hearing steps, and the nature of the issues raised in this proceeding. I am satisfied that the parties' proposed cost award is reasonable, and represents a fair cost award in this case. Costs shall be awarded in favour of the Minister in the all-inclusive amount of $9,500.

JUDGMENT IN T-1424-22

THIS COURT'S JUDGMENT is that:

1. The style of cause is amended to name the Minister of Mental Health and Addictions and Associate Minister of Health as respondent.

2. Katherine Marykuca, Shannon McKenney, Jessica Pietryszyn, Jeremy Moore, Matthew Hunter, Kathleen Westlake, William Alves and Melissa Slade do not have standing, and are removed as parties to this application.

3. This application for judicial review is dismissed.

4. Costs are awarded to the respondent, in the all-inclusive amount of $9,500.

"Christine M. Pallotta"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1424-22
STYLE OF CAUSE:	JEFF TOTH, ET AL v MINISTER OF HEALTH
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	MARCH 28, 2023
JUDGMENT AND REASONS:	PALLOTTA J.
DATED:	SEPTEMBER 25, 2023

APPEARANCES:

Nicholas Pope	FOR THE APPLICANTS
Jennifer Francis Brooklynne Eeuwes	FOR THE RESPONDENT

SOLICITORS OF RECORD:

Hameed Law Barristers and Solicitors Ottawa, Ontario	FOR THE APPLICANTS
Attorney General of Canada Ottawa, Ontario	FOR THE RESPONDENT