

Court File No.

FEDERAL COURT

B E T W E E N:

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 THIBAUT LÉVESQUE, SUSAN MCAFEE, LARA ELLISON, ELANA ANGUS, KATHERINE MARYKUĆA, SHANNON MCKENNEY, JESSICA PIETRYSZYN, JEREMY MOORE, MATTHEW HUNTER, KATHLEEN WESTLAKE, WILLIAM ALVES, MELISSA SLADE and THERAPSIL

Appellants

-and-

MINISTER OF MENTAL HEALTH AND ADDICTIONS AND ASSOCIATE MINISTER OF HEALTH

Respondent

NOTICE OF APPEAL

TO THE RESPONDENT:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the appellant. The relief claimed by the appellant appears below.

THIS APPEAL will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court directs otherwise, the place of hearing will be as requested by the appellant. The appellant requests that this appeal be heard at *(place where Federal Court of Appeal (or Federal Court) ordinarily sits)*.

IF YOU WISH TO OPPOSE THIS APPEAL, to receive notice of any step in the appeal or to be served with any documents in the appeal, you or a solicitor acting for you must prepare a notice of appearance in Form 341A prescribed by the [Federal Courts Rules](#) and serve it on the appellant's solicitor or, if the appellant is self-represented, on the appellant, WITHIN 10 DAYS after being served with this notice of appeal.

IF YOU INTEND TO SEEK A DIFFERENT DISPOSITION of the order appealed from, you must serve and file a notice of cross-appeal in Form 341B prescribed by the [Federal Courts Rules](#) instead of serving and filing a notice of appearance.

Copies of the [Federal Courts Rules](#), information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPEAL, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

October 25, 2023

Issued by:

(Registry Officer)

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Lawyer for the Respondent

APPEAL

THE APPELLANTS APPEAL to the Federal Court of Appeal from the order of Madam Justice Pallota dated September 25, 2023, by which the Federal Court dismissed the Appellants' application for judicial review of 96 decisions made by a delegate of the Minister of Mental Health and Addictions and Associate Minister of Health ("**Minister**") refusing requests for exemptions under subsection 56(1) ("**Exemption**") of the *Controlled Drugs and Substances Act*, SC 1996, c 19 ("**CDSA**") for the 96 healthcare practitioners listed in Schedule "A" to possess psilocybin to undergo experiential training in psilocybin-assisted psychotherapy ("**Decisions**").

I. Appellants

The Appellant TheraPsil is an organization incorporated under the *Canada Not-for-profit Corporations Act*, SC 2009, c 23. It runs a psilocybin-assisted psychotherapy training program for healthcare practitioners that includes an experiential training module. TheraPsil cannot provide this module unless trainees are granted s. 56(1) exemptions.

The Appellant Katherine Marykuca is a patient suffering from treatment-resistant depression, a condition that is treatable by psilocybin-assisted psychotherapy. She suffers from suicidal ideation. She has tried electroconvulsive therapy and dozens of medications to no avail. Her psychiatrist wrote her a letter in support of psilocybin-assisted psychotherapy, but he was not sufficiently trained to provide it. Despite extensive efforts, Ms. Marykuca has been unable to find a trained healthcare practitioner to treat her with psilocybin-assisted psychotherapy.

The Appellants Shannon McKenney, Jessica Pietryszyn, Jeremy Moore, Matthew Hunter, Kathleen Westlake, William Alves, and Melissa Slade are patients who have conditions that are treatable by psilocybin-assisted psychotherapy. Despite extensive efforts, they have been unable to find any trained healthcare practitioners to assess, support, or treat them with psilocybin-assisted psychotherapy. (Together with Katherine Marykuca, these patients will be referred to as the "**Patient Appellants**".)

The other 73 Appellants are 73 of the 96 healthcare practitioners in TheraPsil's training program whose s. 56(1) exemption requests for experiential training were refused by the Decisions ("**Healthcare Practitioner Appellants**").

II. Factual Background

A. Need for Trained Healthcare Practitioners

Clinical studies have indicated that psilocybin-assisted psychotherapy is safe and effective to treat treatment resistant depression, major depressive disorder, and end-of-life distress. Because of this, in 2020, the Minister of Health started granting exemptions under s. 56(1) of the *CDSA* to allow patients to undergo the treatment. In 2022, it became possible for a physician to request authorization for patients to possess psilocybin through the Special Access Program ("**SAP**").

However, there are very few healthcare practitioners in Canada who are trained in administering psilocybin-assisted psychotherapy. These few practitioners are unable to meet the overwhelming need. To ensure the maximum number of patients are treated by these few practitioners, patients are triaged, and practitioners' time is only used to assess a patient if there is a practitioner available to treat them. If this were not done, even fewer patients could be treated. Due to the scarcity of trained healthcare practitioners, many patients are unable to receive treatment, and many more are unable to even begin the process by being assessed.

B. Exemption Requests

The best practice for psilocybin-assisted psychotherapy is that healthcare practitioners should have experiential training to ensure the highest levels of safety and efficacy. This was agreed upon by all the experts Health Canada consulted in its own internal consultations.

Because of this, in December 2020 and January 2021, the Minister granted s. 56(1) exemptions to nineteen healthcare practitioners to participate in the experiential

training module of TheraPsil's training program. Healthcare practitioners reported that the training improved their ability to treat patients, and no negative effects have resulted from this training or the exemptions.

However, the nineteen s. 56(1) exemptions were not sufficient to train enough healthcare practitioners to meet patient need. As of February 2022, TheraPsil had a waitlist of more than 800 patients. So, from March 2021 to February 2022, the 96 healthcare practitioners listed in Schedule "A" requested exemptions under s. 56(1) of the *CDSA* to participate in TheraPsil's training program.

C. Notices of Intent to Refuse

Between January 31 and March 4, 2022, Health Canada sent these healthcare practitioners notices of intent to refuse the exemption requests on the sole basis that the healthcare practitioners could complete their training by obtaining psilocybin through a clinical trial.

D. Healthcare Practitioners' Submissions

On February 28, 2022, a lawyer retained by TheraPsil sent a submission to Health Canada responding to the notices of intent to refuse on behalf of the 96 healthcare practitioners listed in Schedule "A". The written representations made two central arguments.

First, the submission argued the exemptions should not be refused because of the theoretical possibility of access to psilocybin through a clinical trial since no trial was currently available, and TheraPsil sponsoring a trial would not be sufficient because 1) the twelve or more months it would take to set up a trial would delay patient treatment; 2) conducting a clinical trial primarily to satisfy bureaucratic preferences rather than to answer an important research question would violate scientific ethics; and 3) a clinical trial's competing purposes would interfere with providing optimal training.

Second, the submission argued that s. 7 of the *Charter* requires that the exemptions be granted because refusals would violate healthcare practitioners' rights to liberty by the threat of imprisonment, and refusals would violate patients' rights to liberty and security

of the person by delaying their treatment or forcing them to choose less safe and effective treatment by a non-experientially trained healthcare practitioner.

III. Decisions Under Review

On June 10, 2022, Health Canada sent virtually identical final refusal letters to all 96 healthcare practitioners. The refusals did not demonstrate any consideration of the arguments made under s. 7 of the *Charter*.

The Minister acknowledged that no clinical trial was accessible to the healthcare practitioners at the time. However, the Minister denied the exemption requests on the basis that the healthcare practitioners could access psilocybin for training if TheraPsil conducted its own clinical trial. In doing so, the Minister briefly noted that the Appellants had made three central arguments about clinical trials, but the Minister did not meaningfully grapple with any of them.

The Minister also stated that the evidence about the benefit of experiential training that TheraPsil provided was not “peer-reviewed clinical evidence” and that “other therapists have been able to offer psychedelic-assisted psychotherapy to patients without having personal experience”. However, the Minister did not state that she had concluded that personal experience was unneeded for the safest and most effective treatment.

The Minister also stated that risks from a lack of regulated supply of psilocybin were part of the reason for denying the exemptions, but the Minister did not reference any evidence of these risks.

IV. Federal Court Decision

Justice Pallota dismissed the Appellants’ application for judicial review and held that the Patient Appellants do not have standing.

Justice Pallota held that the Minister did not fail to account for any of the evidence regarding the need for experiential training since the Minister had stated, “TheraPsil’s evidence was reviewed and assessed”, but Justice Pallota did not make any finding regarding whether the Minister failed to account for the evidence from Health Canada’s

own experts, who stated that experiential training is necessary for safe treatment.

Justice Pallota held that the standard of review for the question of whether the *Charter* was engaged is reasonableness, contrary to the decision of the Federal Court of Appeal in *Canadian Broadcasting Corporation v Canada (Parole Board)*, 2023 FCA 166, which was released after the hearing, but prior to Justice Pallota’s decision being released.

Justice Pallota held that the Healthcare Practitioner Appellants’ s. 7 right to liberty was not engaged by the criminal sanction of imprisonment for possessing psilocybin since the Healthcare Practitioner Appellants were not required to take psilocybin.

Justice Pallota held that the Minister’s failure to specifically mention the *Charter* was not unreasonable because the Minister’s reasons impliedly provided the rationale for rejecting the *Charter* arguments by disagreeing with their foundation: that healthcare practitioners need experiential training to provide the most safe and effective care to patients. However, earlier in the decision, Justice Pallota had explicitly stated the opposite: the Minister did not conclude that experiential training is not needed to provide the safest or most effective form of treatment, “nor can such a conclusion be implied.”

THE APPELLANTS ASK that

- a) The appeal be allowed, and the Order of Justice Pallotta, dated September 25, 2023, be set aside;
- b) The Federal Court’s order that 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, be overturned;
- c) The Decisions be quashed and the Minister be directed to grant the 96 requested Exemptions;
- d) In the alternative, the Decisions be quashed and remitted back to the Minister

for redetermination within 14 days;

e) Costs be awarded to the Appellants throughout; and

f) The Court grant such further and other relief as counsel may request and this Honourable Court may deem just.

THE GROUNDS OF APPEAL are as follows:

1. The Federal Court erred in law by finding that the Patient Appellants do not have standing;
2. The Federal Court erred in law by selecting the wrong standard of review for the question of whether an administrative decision engages the *Charter*;
3. The Federal Court erred in law by not finding the Decisions unreasonable on the basis that the Minister failed to address *Charter* arguments when the Minister failed to expressly engage in a *Charter* analysis or expressly opine on whether *Charter* rights are engaged;
4. The Federal Court based its finding that Minister provided a rationale for rejecting the Appellants' *Charter* arguments on an overriding and palpable error of fact: the Federal Court erroneously stated at paragraph 112 that the Minister had addressed whether healthcare practitioners "need experiential training to provide the most safe and effective care" when the Federal Court had found earlier, at paragraph 79, that "[t]he Minister did not conclude [...] that experiential training is not needed to provide the safest or most effective form of treatment, nor can such a conclusion be implied";
5. The Federal Court erred in law by finding the Healthcare Practitioner Appellants' s. 7 right to liberty was not engaged by the risk of imprisonment for possession of psilocybin under s. 4(1) of the *CDSA*;
6. The Federal Court erred in law by finding the Patient Appellants' s. 7 rights to life, liberty, and security of the person were not engaged by inhibiting their ability to access the safest and most effective version of psilocybin-assisted psychotherapy –

that done by an experientially trained healthcare practitioner;

7. The Federal Court erred in law by finding the Minister reasonably and proportionately balanced *Charter* values with the statutory objectives of the *CDSA* despite the Minister not demonstrating by way of her reasons that she did so;
8. The Federal Court erred in law by finding the Decisions were not arbitrary, overbroad, or grossly disproportionate;
9. The Federal Court erred in law by not finding the Decisions unreasonable on the basis that the Minister failed to account for the following evidence that squarely contradicts one of the Minister's key conclusions and the Minister did not explicitly mention:
 - a. A consultation summary provided by Health Canada stating that all the experts Health Canada consulted "strongly indicated personal experience with psilocybin is required in order to safely guide patients";
 - b. A letter from the Drug Science Advisory Committee, the leading scientific body on drugs in the UK, stating that personal experience with psilocybin is essential to improve patients' safety; and
 - c. Six letters from academic researchers stating that experiential training with psilocybin is necessary or crucial for practitioner skill development before treating patients;
10. The Federal Court erred in law by not finding unreasonable the Minister's conclusion that consuming psilocybin mushrooms in a responsible clinical setting would result in greater health and safety risks than consuming psilocybin in a clinical trial, when there is no evidence on record upon which the Minister could have based this conclusion, nor did the Minister explain her reasoning;
11. The Federal Court erred in law by not finding the Decisions unreasonable on the basis that the Minister failed to meaningfully grapple with the Appellants' three central arguments about the unsuitability of a clinical trial to access psilocybin;
12. The Federal Court erred in law by not finding the Decisions unreasonable on the

basis that the Minister failed to demonstrate that she had considered the harsh consequences of the Decisions and that the Decisions best reflect the legislature's intention;

13. The Federal Court erred in law by buttressing the Minister's reasons to provide justifications the Minister did not herself provide regarding

- a. The balancing of *Charter* values;
- b. The safety risks of consuming psilocybin in a clinical setting as compared to a clinical trial; and
- c. The Minister's response to the Appellant's arguments about the unsuitability of a clinical trial;

14. The Federal Court erred in law by determining that, if the Decisions are unreasonable, it would not be the most appropriate remedy to decline to remit the Decisions and direct the Minister to grant the exemptions;

15. Sections 7 and 24(1) of the *Canadian Charter of Rights and Freedoms*, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11;

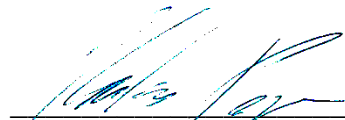
16. Subsection 56(1) of the *Controlled Drugs and Substances Act*, SC 1996, c 19;

17. Sections 18, 18.1, and 27 of the *Federal Courts Act*, RSC 1985, c F-7;

18. *Federal Courts Rules*, SOR/98-106; and

19. Such further and other grounds as counsel may advise and this Honourable Court may permit.

October 25, 2023



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**Lawyer for the Appellants,
JEFF TOTH et al**

SCHEDULE "A"

LIST OF HEALTHCARE PRACTITIONERS

A. Provided Submissions February 28, 2022

	NAME	CITY/TOWN	PROV	PROFESSION
1	Lorraine Reimer	Abbotsford	BC	RCC
2	Adele Phillips	Abbotsford	BC	RN
3	Danielle Braun-Kauffman	Abbotsford	BC	RCC
4	Parveen Sihota	Abbotsford	BC	RSW, MSW
5	Jodi Krahn	Armstrong	BC	RCC
6	Dr. John Gyra	Chilliwack	BC	RCC
7	Lisa Frede	Chilliwack/Yarrow	BC	RCC
8	Laurie Schulz	Chilliwack	BC	RCC
9	Jon Wieser	Cloverdale/Surrey	BC	RCC
10	Dr. Steven Griffith-Cochrane	Comox	BC	MD
11	Sarah Hoffman	Cumberland	BC	RCC
12	Trina Woods	Duncan	BC	MSW, RCC
13	Vanathy Paranthaman	Harrison Hot Springs	BC	RN
14	Tamara Smith	Kelowna	BC	RCC
15	Dr. Ellen Domm	North Vancouver	BC	Ph.D., R.Psych
16	Dr. Marilyn Chotem	North Vancouver	BC	Ph.D. R.Psych
17	Dorothy Gamble	North Vancouver	BC	RN
18	Kerry Chutter	North Vancouver	BC	RCC
19	Lara Ellison	Roberts Creek	BC	MSW
20	Dale Trimble	Roberts Creek/Vancouver	BC	RCC
21	Scott Kouri	Saanich	BC	Ph.D., RCC
22	Tracy Lowe	Saanich	BC	RCC, CCC
23	Sallyjane Bodnar	Vancouver	BC	RCC
24	Dr. Sharon Jeyakumar	Vancouver	BC	Ph.D., R.Psych
25	Dr. Rick Miners	Vancouver	BC	Ph.D., R.Psych
26	Dr. Gordon Reid	Vancouver	BC	Ph.D, R.Psych
27	Dr. Michael Sheppard	Vancouver	BC	Ph.D., R.Psych
28	Peter Lagrand	Vancouver	BC	RCC
29	Dr. Barbara Griffin	Vancouver	BC	MD
30	Yassie Pirani	Vancouver	BC	MSW/RCC
31	Janie Brown	Vancouver	BC	RN
32	Dr. Hillary McBride	Victoria	BC	RCC

33	Adrian Oberg	Victoria	BC	RCC
34	Anne-Marie Armour	Victoria	BC	MSW
35	Kathleen Herbinson	Victoria	BC	RCC
36	Dr. Fraser Black	Victoria	BC	MD
37	Beth Trotter	Victoria	BC	RCC
38	Elana Angus	Victoria	BC	RCC, RSW
39	Dr. Christian Wiens	Victoria	BC	MD
40	Dr. Stephanie Marchal	Victoria	BC	Ph.D., R.Psych
41	Elinor Bazar	Victoria	BC	RCC
42	Dana Simard	Victoria	BC	RCC
43	Michael Simard	Victoria	BC	RTC
44	Jennifer Nagel	White Rock/South Surrey	BC	RCC
45	Claire Weiss	Langley	BC	RCC
46	Brodin Anderson	Manitoba	MB	Counsellor
47	Bryce Koch	Winnipeg	MB	RN, NP candidate
48	Grant Hutchinson	Flesherton	ON	Psychotherapist
49	Dr. Jonathan Grek	Kenora	ON	MD
50	Becky Shorrocks (Kamm)	Kenora	ON	RN
51	Dayna Myles	London	ON	RP Candidate
52	Anthony Di Virgilio	Ottawa	ON	RP
53	Jenna Fletcher	Ottawa	ON	RP
54	Julia MacArthur	Thunder Bay	ON	RSW
55	Karlie Chalmers	Toronto	ON	OT
56	Rajveer Soos	Toronto	ON	NP
57	Keyanna Ehsani	Toronto	ON	RP
58	Dr. Prachi Soneji	Toronto	ON	MD
59	Dr. Nikhita Singhal	Toronto	ON	Psychiatrist
60	Aamir Subhan	Toronto	ON	MSW
61	Elizabeth Bleakley	Toronto	ON	Palliative RPN
62	Shawna Alvis	Toronto	ON	RP
63	Jane Harrison	Toronto	ON	MSW, RN, Psychotherapist
64	Dr. Sabrina Akhtar	Toronto	ON	MD
65	Dr. Houman Farzin	Montreal	QC	MD
66	Elena Willis	Montreal	QC	Psychotherapist
67	Dr. Harvey Chang	Montreal	QC	MD
68	Dr. Jean Francois Stephan	Montreal	QC	MD, Psychotherapist
69	Julien Thibault Lévesque	Montreal	QC	MSW
70	Sani Karam	Montreal	QC	MD
71	Jessica Drury	Montreal	QC	Resident Psychiatrist

72	Melanie White	Antigonish	NS	MSW
73	Dr. Shauna Sutherland	Cape Breton	NS	Ph.D., R.Psych
74	Alex Doley	Dartmouth	NS	RCT
75	Dr. Susie McAfee	Halifax	NS	Ph.D., R.Psych
76	Jeff Toth	Halifax	NS	RN
77	Erin Montgomery	Halifax	NS	RCT
78	Amanda Grinter	Halifax	NS	RCT, CCC
79	Dr. Anne Kwasnik-Krawczyk	New Glasgow	NS	MD
80	Nathan Torti	Portuguese Cove	NS	RCT
81	Dr. Stacey Smith	St. John's	NL	Ph.D., R.Psych
82	Dr. Danusia Kanachowski	Whitehorse	YK	MD

B. Added to Submissions March 25, 2022

	NAME	CITY/TOWN	PROV	PROFESSION
1	Myrna Martin	Comox	BC	MD, RCC, RCST
2	Heidi Voelker	Garibaldi Highlands	BC	RN
3	Graham Bergstra	Hazelton	BC	MD
4	Richard Tatomir	Langley	BC	CCC
5	Valentina Chichiniova	Procter	BC	RCC, CCC
6	Barb Fehlau	Royston	BC	MD
7	Jill Koehler	Squamish	BC	RCC
8	Shelley Genovese	Squamish	BC	RPN
9	Gregory Cohen	Vancouver	BC	MC, Psychiatry
10	Danielle Schroeder	Vancouver	BC	RCC
11	Daphne Lobb	Vancouver	BC	MD
12	Allison Prinsen	Vancouver	BC	RCC
13	Christine Dennstest	Whistler	BC	RCC
14	Kyle Greenway	Montreal	QC	MD, Psychiatry