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## FOOD AND DRUGS

*Related subjects: Health and Welfare, Practice, Constitutional Law, Administrative Law*

Application for judicial review relating to 96 decisions made by delegate of Minister of Mental Health and Addictions and Associate Minister of Health (respondent), refusing requests for exemption under *Controlled Drugs and Substances Act*, S.C. 1996, c. 19, s. 56(1) (s. 56 Exemption) — All 96 challenged decisions relating to s. 56 Exemption requests made by healthcare practitioners (HCPs), with varied qualifications — Including doctors, psychologists, nurses, social workers, counsellors, other regulated healthcare professionals — HCPs wanting exemption for same reason, namely, to possess, consume raw psilocybin mushrooms in course of their own professional training for psilocybin-assisted psychotherapy — Psilocybin-assisted psychotherapy is form of psychotherapy that includes medicinal session, during which patient consumes therapeutic dose of psilocybin under supervision of qualified practitioner — HCPs' requests for Act, s. 56 Exemption stated that, for optimal results, qualified practitioners should have experience with psychedelic medicines that will be used to treat their patients — Goal of training with psilocybin is to improve HCPs' understanding of psilocybin therapy so they may better help their patients — Psilocybin is hallucinogen, controlled substance under Act, which prohibits possession of psilocybin, except as authorized under regulations — However, Act allows respondent to authorize exemption from prohibitions, if respondent is of opinion that exemption is necessary for medical or scientific purpose or otherwise in public interest — There are 82 applicants in present application for judicial review: 73 applicants are HCPs whose s. 56 Exemption refusals are under challenge; other 23 decisions under challenge are s. 56 Exemption refusals for HCPs who are not parties to proceeding — Applicant TheraPsil non-profit patient advocacy organization dedicated to helping Canadians in medical need access legal psilocybin-assisted psychotherapy — Remaining applicants in proceeding are individuals who contacted TheraPsil because they want to be assessed for, receive psilocybin-assisted psychotherapy — Respondent refused all 96 s. 56 Exemption requests for identical reasons; determined that s. 56 Exemption was not necessary for medical or scientific purpose or otherwise in public interest, as there was alternative option available under *Food and Drug Regulations*, C.R.C., c. 870 (FDR), namely, authorization to obtain controlled drug for purposes of clinical trial — Decisions note TheraPsil's opinion that such regulatory option is unsuitable, would not protect HCPs' best interests — Applicants submitting in particular that respondent's decisions unreasonable; that respondent failed to grapple with central arguments, evidence, including evidence from Health Canada's own Office of Clinical Trials (OCT) that clinical trial for TheraPsil's training program not feasible; that respondent gave unintelligible or non-transparent reasons for her decisions; she failed to address or meaningfully grapple with substantive arguments — Applicants asking Court to set aside all 96 decisions, direct respondent to grant exemptions to HCPs that would permit them to possess, consume psilocybin for experiential training in psilocybin-assisted psychotherapy — Respondent submitting applicants failed to show decisions in question unreasonable, stating that judicial review should be dismissed; that Act, s. 56 conferring broad discretion to grant or refuse exemption; that applicants have not established any errors warranting interference with decisions — Main issues were whether respondent's decisions unreasonable; if respondent's decisions unreasonable, what was appropriate remedy — Applicants not establishing reviewable error based on failure to address arguments about suitability of clinical trial — Respondent adequately addressed arguments — Respondent tasked with deciding whether Act, s.

56 Exemption that would allow HCPs to possess, consume psilocybin as part of their training with TheraPsil, was necessary for medical or scientific purpose or otherwise in public interest — Respondent found that exemption was not necessary because HCPs having option under FDR (namely, to participate in clinical trial) which respondent found was feasible regulatory option — HCPs' arguments that clinical trial would not be timely, ethical, or compatible with training objectives assumed that experiential training was necessary, but evidence not establishing this — Respondent's findings were open to her, supported by record — TheraPsil not regulating or licensing healthcare professionals — Doctors, psychologists, nurses, social workers, counsellors, other regulated healthcare professionals who applied for exemptions are licensed by their respective regulatory bodies — Extent of each HCP's involvement in administering psilocybin-assisted psychotherapy to patients would be limited by their qualifications, healthcare services they are licensed to provide — Respondent not failing to grapple with argument that clinical study would interfere with training objectives; found evidence submitted not supporting training objective of taking psychedelic drug in order to appreciate what patient experiences — In summary, decisions providing complete answer to arguments that clinical trial is unsuitable for therapist training; respondent not required to address each of HCPs arguments separately — Also, no error arising from respondent's assessment of evidence — Respondent's statements about experiential training were transparent, intelligible, justified decisions taken[76] — Applicants not establishing that respondent was under any misapprehension about nature or quality of evidence to support TheraPsil's position on experiential training — Respondent not mischaracterizing evidence as anecdotal experience, opinions by individual health care professionals — Respondent accurately characterized evidence — Respondent not departing from internal authority without justification — Act, s. 56 Exemptions are discretionary, fact-specific — Previously granted practitioner exemptions not representing established internal authority or longstanding practice — Respondent not unreasonably concluding that s. 56 Exemptions would create unacceptable risks, not unreasonably departing from her previous decisions allowing s. 56 Exemptions for practitioners — With respect to *Canadian Charter of Rights and Freedoms*, applicants submitted in particular that decisions engaged HCPs', prospective patients' Charter, s. 7 rights to life, liberty, security of person — Respondent's decisions refusing HCPs' s. 56 Exemptions not engaging HCPs' or patients' Charter rights — Foundation for Charter arguments not supported by evidence before respondent, Court — Evidence not establishing that HCPs need experiential training, or that they need to take psychedelic drug to appreciate what patient experiences — Similarly, evidence not establishing that prospective patients undergoing psilocybin-assisted therapy need to be treated or assisted by doctors, therapists, nurses, or other practitioners who have experience with psychedelic drug — Decisions demonstrating that respondent reasonably, proportionately balanced Charter values with Act's statutory objectives; thus, decisions according with principles of fundamental justice — Decisions refusing HCPs requests for access to psilocybin mushrooms for training purposes not arbitrary, overbroad, or grossly disproportionate in relation to Act's statutory objectives — Therefore, respondent not refusing HCPs' exemption requests by exercise of discretion that was inconsistent with Charter values — Was unnecessary to consider appropriate remedy — However, contrary to applicants' argument, appropriate remedy would not have been to direct respondent to grant exemption — When decision found to be unreasonable, matter should be remitted to decision maker for reconsideration — Present application not presenting scenario that would render it appropriate for Court to substitute its own decision — Application dismissed.

TOTH V. CANADA (HEALTH AND ADDICTIONS) (2023 FC 1283, T-1424-22, Pallotta, J., reasons for judgment dated September 25, 2023, 47 pp.)