EMERGE LAW GROUP

KATHRYN TUCKER
Admitted in Washington
(206) 595-0097
kathryn@emergelawgroup.com

621 SW Morrison St., Suite 900, Portland, OR 97205

January 15, 2021

VIA E-MAIL (*dea.registration.help@usdoj.gov*) **AND U.S. FIRST CLASS REGISTERED MAIL**

Drug Enforcement Administration
Attn: Regulatory Section/DRG
8701 Morrissette Drive
Springfield, VA 22152

Dear DEA Regulatory Section:

The Advanced Integrative Medical Science Institute (AIMS) is an integrative oncology clinic located in Seattle, WA. I am counsel to the clinic and its co-director, Dr. Sunil Aggarwal. Dr. Aggarwal is a palliative care specialist who treats patients with advanced cancer. He holds a DEA registration to prescribe controlled substances (DEA # FA4274926). Dr. Aggarwal seeks additional registration to obtain psilocybin, a Schedule I drug (code 7437), for therapeutic use with terminally ill cancer patients suffering anxiety and/or depression. This registration is sought pursuant to the Washington and U.S. Right to Try (RTT) Acts.[1] This letter provides background information about the RTT, and we seek your guidance on how DEA will accommodate RTT so that Dr. Aggarwal and the AIMS Institute can obtain psilocybin for therapeutic use with terminally ill patients.

Brief Background on Psilocybin's Utility in Relief of Anxiety and Depression in Terminally Ill Patients

Medical research demonstrates the powerful therapeutic uses of psilocybin in the treatment of anxiety and depression associated with terminal illness. Patients with advanced cancer suffering from treatment resistant anxiety and/or depression experience significant reductions in both anxiety and depression, and improvements of mood, following a single guided treatment with psilocybin, with no safety concerns or clinically significant adverse events.[2] This is important because people experiencing late stage terminal disease experience

[1] RCW 69.77 et seq; 21 U.S.C.A. § 360bbb-0a.

[2] Grob et al., *Pilot study of psilocybin treatment for anxiety in patients with advanced- stage cancer*, 68 ARCH GEN PSYCHIATRY 71, 71 (2011) (anxiety levels measured at one, three, and six months after treatment "demonstrated a sustained reduction in anxiety"); Griffiths et al., *Psilocybin Produces Substantial and Sustained Decreases in Depression and Anxiety in Patients With Life-Threatening Cancer: A Randomized Double-Blind Trial,* 30 J. Psychopharmacology 1181, 1195 (2016) (single dose of psilocybin produced large and significant decreases in depression, anxiety or mood disturbance, and increases in measures of quality of life, life meaning, death acceptance, and optimism in patients with a life-threatening cancer diagnosis; effects sustained at 6 months.); Johnson & Griffiths, *Potential Therapeutic Effects of Psilocybin*, 30 Neurotherapeutics 734, 734 (2017); Ross S., *Therapeutic use of classic psychedelics to treat cancer-related psychiatric distress.* Int Rev Psychiatry, 2018 Aug;30(4):317-330. doi: 10.1080/09540261.2018.1482261. Epub 2018 Aug 13(review of clinical trials from 1960-2018 researching therapeutic use of psychedelic treatment in patients with serious or terminal illnesses and related psychiatric illness; psychedelic-assisted treatment can produce rapid, robust, and sustained improvements

emotional suffering to a greater extent than those in the general population.[3] Dying patients frequently suffer depression and anxiety.[4] For such patients, psychotherapy facilitated with psychedelics may provide much needed relief: *"People in the psychedelic trip often experience being at one with the world or even the universe. It's as if they have died, as if they've gone out to another place. They exist beyond their body. That experience can give them a sense of perpetuity, of permanence, of being part of the cycle of life, which of course we all are."*[5] Patients able to access psychedelic therapy express compelling positive experiences: *"I felt like I was being shown what happens after [death], like an afterlife. I'm not a religious person and I'd be hard pushed to say I was anything near spiritual either, but I felt like I'd experienced some of that, and experienced the feeling of an afterlife, like a preview almost, and I felt totally calm, totally relaxed, totally at peace. So that when that time comes for me, I will have no fear of it at all."*[6] This is great news as: "Anxiety is one of the most common reasons for psychiatric consultation in terminally ill cancer patients and has been linked to lower levels of quality of life, increased levels of insomnia, decreased trust in physicians, and poor treatment compliance."[7]

The Right to Try

The state and federal "Right to Try" (RTT) acts[8] are statutes intended to allow terminally ill patients access to drugs still in investigational stages, recognizing that such patients do not have the luxury of time to await the slow process of new drug approval. Psilocybin qualifies as such a drug.[9]

To qualify as an eligible investigational drug ("EID") under the federal RTT, a drug must satisfy four requirements. First, it must have completed an FDA-approved Phase I clinical trial.[10] Second, the drug must not be approved or licensed for any use through the federal Food, Drug, and Cosmetic Act ("FD&C Act") or the

---

in cancer-related psychological and existential distress.) See also, *Individual Experiences in Four Cancer Patients Following Psilocybin-Assisted Psychotherapy,* Pharmacol., 03 April 2018 (participants with anxiety, depression, and other existential distress achieved relief with psilocybin treatment, and benefits were sustained throughout follow-up). https://www.frontiersin.org/articles/10.3389/fphar.2018.00256/full. See generally, M. Pollan, *How to Change Your Mind* (2018); Lauren Slater, *How Psychedelic Drugs Can Help Patients Face Death*, NEW YORK TIMES MAGAZINE (Apr. 20, 2012), ("[T]he results showed that administering psilocybin to terminally ill subjects could be done safely while reducing the subjects' anxiety and depression about their impending deaths.").

[3] *See, e.g.*, H. Chochinov, *Psychiatry and Terminal Illness*, 45 Can. .J. Psychiatry 413,146– 48 (2000); W. Lichtenthal et al., *Do Rates of Mental Disorders and Existential Distress Among Advanced Stage Cancer Patients Increase as Death Approaches?* 18 Psycho-Oncology 50, 54 (2009); A. Mitchell et al., *Prevalence of Depression, Anxiety, and Adjustment Disorder in Oncological, Haematological, and Palliative-Care Settings: A Meta-Analysis of 94 Interview-Based Studies*, 12 Lancet Oncology 160, 167 tbl.2 (2011).

[4] Research shows that 18% of terminally ill cancer patients experience moderate anxiety, while 12% suffer severe anxiety. E. Kolva, et al. Anxiety in Terminally Ill Cancer Patients, *42(5)* Journal of Pain and Symptom Management, 691 – 701 (2011).

[5] Id.

[6] Id.

[7] E. Kolva, et al., *Anxiety in Terminally Ill Cancer Patients,* 42*(5)* J. Pain and Sympt. Management*,* 691 – 701 (2011).

[8] RCW 69.77 et seq; 21 U.S.C.A. § 360bbb-0a.

[9] See supra n. 2, citing clinical trial studies with psilocybin. See also, Usona Institute, Investigator's Brochure https://www.usonainstitute.org/wp-content/uploads/2020/08/Usona_Psilocybin_IB_V3.0_08.31.2020_cc.pdf; https://clinicaltrials.gov/ct2/results?cond=&term=psilocybin&cntry=&state=&city=&dist=.

[10] 21 U.S.C. § 360bbb-0a(a)(2)(A).

Public Health Services Act ("PHSA").[11] Third, the drug must either: (a) have an application filed under the FD&C Act or PHSA, or (b) be under investigation in a clinical trial that is "intended to form the primary basis of a claim of effectiveness in support of approval" and be the subject of an active IND application under the FD&C Act or PHSA.[12] Fourth, the drug's active development and production must be ongoing, not discontinued by the manufacturer, and not subject to a clinical hold.[13] Similarly, under the Washington RTT, a drug is "investigational" when it has successfully completed Phase 1 and is currently in a subsequent phase of an FDA-approved clinical trial assessing its safety.[14] Psilocybin meets all of these requirements.

The AIMS Institute intends to purchase psilocybin from Organix, a company which holds an IND for this drug and is registered as a Distrubuter of this drug.[15] It is clearly within the intention of the RTT to allow this, even though psilocybin is a Schedule I drug. This is evident as neither the U.S. RTT nor the Washington State RTT exclude Schedule I substances from their scope.[16]

Issuance of a registration to enable Dr. Aggarwal to obtain psilocybin for the intended purpose is fully consistent with the public interest. None of the public interest factors that might counsel against issuance of a registration are present.[17]

The underlying scope of authority by the DEA is limited to effectuating controls against diversion of controlled substances, and not determinations of the practice of medicine. *Gonzales v. Oregon*, 126 S.Ct. 904.

I look forward to your guidance as to how DEA will accommodate RTT so that Dr. Aggarwal and the AIMS Institute can obtain psilocybin for therapeutic use with terminally ill patients. The existing DEA forms do not appear to accommodate the RTT, which may be due to the fact that it was relatively recently enacted; hence it is confusing to use the existing forms for this purpose. Should Dr. Aggarwal seek registration as a "researcher", though his intention is therapeutic use as a palliative care clinician, treating terminally ill patients, not a "researcher" in the traditional sense? If not a researcher registration, how ought we proceed?

In the interest of the terminally ill patients with refractory anxiety and/or depression, we hope DEA can promptly advise on how to proceed.

---

[11] *Id*. § 360bbb-0a(a)(2)(B). Specifically, the drug may not be approved or licensed for any use under Section 355 of the FD&C Act or Section 351 of the PHSA.

[12] *Id.* § 360bbb-0a(a)(2)(C). Specifically, the application in (1) must be under Section 355(b) of the FD&C Act or Section 351(a) of the PHSA. For brevity's sake, "IND application" in this memo means anything meeting these criteria.

[13] *Id*. § 360bbb-0a(a)(2)(D).

[14] RCW 69.77.020(4).

[15] Organix, Inc. 240 Salem Street, Woburn, MA 01801 www.organixinc.com

[16] In contrast, some RTT statutes explicitly exclude Schedule I substances from RTT shelter. For example, Missouri's RTT statute, in defining what qualifies as an "investigational drug", states that an "Investigational drug …**shall not include Schedule I controlled substances.")** Revised Statutes of Missouri, Section 191.480(2014) (2)(emphasis added). Compare: RCW 69.77.020((4) "Investigational product" means a drug, biological product, or device that has successfully completed phase one and is currently in a subsequent phase of a clinical trial approved by the United States Food and Drug Administration assessing the safety of the drug….").

[17] The only pertinent factor relates to assuring effective controls against diversion. Effective controls can and will be established at AIMS, which already stores controlled substances.

January 15, 2021

Respectfully submitted,

Kathryn Tucker

Kathryn L. Tucker

Counsel to AIMS Institute and Dr. Sunil Aggarwal

Cc via email: Heather Danner-Ryan, Group Supervisor, Diversion Group 1, New England Field Division, Boston Heather.A.Danner-Ryan@usdoj.gov

Edwin Dizon, Diversion Investigator, Seattle Field Division Edwin.S.Dizon@usdoj.gov