No. _____

In the United States Court of Appeals for the Ninth Circuit

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC, DR. SUNIL AGGARWAL, MD, PHD, MICHAL BLOOM, AND ERINN BALDESCHWILER,

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION; MONTY WILKINSON, IN HIS OFFICIAL CAPACITY AS ACTING ATTORNEY GENERAL; AND D. CHRISTOPHER EVANS, IN HIS OFFICIAL CAPACITY AS ACTING ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION,

Respondents.

PETITION FOR REVIEW

Kathryn L. Tucker
EMERGE LAW GROUP
621 SW Morrison Street, Suite 900
Portland, OR 97205
Phone: 206.595.0097
kathryn@emergelawgroup.com

Matthew C. Zorn
YETTER COLEMAN LLP
811 Main Street, Suite 4100
Houston, TX 77002
Phone: 713.632.8000
Fax: 713.632.8002
mzorn@yettercoleman.com

James F. Williams
Andrew J. Kline
Thomas J. Tobin
Holly Martinez
PERKINS COIE LLP
1201 Third Avenue, Suite 4900
Seattle, WA 98101-3099
Phone: 206.359.8000
Fax: 206.359.9000
jwilliams@perkinscoie.com
akline@perkinscoie.com
ttobin@perkinscoie.com
hmartinez@perkinscoie.com

ATTORNEYS FOR PETITIONERS

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, the undersigned counsel of record for Petitioner Advanced Integrative Medical Science ("AIMS") Institute hereby certifies that the AIMS Institute is a professional limited liability company and does not have any parent companies, subsidiaries, or affiliates that have issued shares to the public.

March 8, 2021

/s/ *James F. Williams*
James F. Williams
1201 Third Avenue, Suite 4900
Seattle, WA 98101-3099
Phone: 206.359.8000
Fax: 206.359.9000
jwilliams@perkinscoie.com

Attorney for Petitioners

PETITION FOR REVIEW

Pursuant to 21 U.S.C. § 877 and 21 Fed. R. App. P. 15, Petitioners, the Advanced Integrative Medical Science ("AIMS") Institute, its Co-Director, Dr. Sunil Aggarwal, MD, PhD, FAAPMR, and two of Dr. Aggarwal's patients, Erinn Baldeschwiler and Michal Bloom, hereby petition for review of the United States Drug Enforcement Administration's final agency action issued on February 12, 2021, attached as **Exhibit 1** (the "Final Agency Decision").

This Petition for Review ("Petition") regards how the agency will abide by the "Right to Try," as codified in both federal and state law. *See* 21 U.S.C.A. § 360bbb, *et seq.*; RCW 69.77, *et seq.* In 2017, the Washington state legislature enacted its Right to Try legislation and correctly noted that patients with terminal illnesses, like Petitioners Baldeschwiler and Bloom, "do not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the United States [F]ood and [D]rug [A]dministration." RCW 69.77.010. The state legislature further found that such terminally ill patients "should be permitted to pursue the preservation of their own lives by accessing available investigational drugs," and that decisions about the use of available investigational drugs should be made by the *patient* with a terminal illness in consultation with the *patient's health care provider*. *Id.* Washington legislators

made their decision clear: "to allow terminally ill patients to use potentially lifesaving investigational drugs[.]" *Id.*

Despite the legislators' intent that terminally ill patients can make informed decisions with their health care providers about eligible investigational drugs, the reality is not so straightforward. The Right to Try, as contemplated by both federal and state law, relates to the ability of a treating physician to provide certain investigational drug therapies to terminally ill patients, for whom time is of the essence. *See* RCW 69.77.020(8) (defining a qualifying condition as one "in which there is reasonable likelihood that death will occur within six months or in which premature death is likely without early treatment").

Even if a qualified treating physician wishes to exercise the Right to Try and administer the eligible investigational drug of psilocybin to a qualified terminally-ill patient, they cannot do so pursuant to the Final Agency Decision. Psilocybin is a controlled substance, and is currently a Schedule I drug, meaning that the prescribing of this drug is governed by Respondent, the U.S. Drug Enforcement Administration ("DEA"), which administers the Controlled Substances Act. With the DEA's Final Agency Decision, the agency declared that it "has no authority to waive" any of the Controlled Substances Act's requirements pursuant to the Right to Try. In other words, the DEA's enforcement of the Controlled Substances Act vitiates the Right the Try, as codified by state and federal law. Put differently, qualifying terminally-

ill patients cannot gain access to this eligible investigational drug for which they otherwise qualify because of the DEA's Final Agency Decision.

The DEA's Final Agency Decision was issued in response to an inquiry submitted January 15, 2021, requesting the agency's direction regarding how Dr. Aggarawal could obtain psilocybin for therapeutic use in terminally ill patients. The DEA's letter is attached as **Exhibit 2.**

Petitioners seek review of the Final Agency Decision on the grounds that it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; contrary to constitutional right, power, privilege, or immunity; in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; without observance of procedure required by law; and/or otherwise unsupported by substantial evidence. Petitioners respectfully request that this Court hold unlawful, vacate, and enjoin the Final Agency Decision and mandate, pursuant to the Right to Try, as codified in state and federal law, that the DEA expeditiously consider and accomodate valid requests made from qualified health care providers for the therapeutic use of the eligible investigation drug psilocybin.

Dated: March 8, 2021

Respectfully submitted,

/s/ James F. Williams

Kathryn L. Tucker
EMERGE LAW GROUP
621 SW Morrison Street, Suite 900
Portland, OR 97205
Phone: 206.595.0097
kathryn@emergelawgroup.com

Matthew C. Zorn
YETTER COLEMAN LLP
811 Main Street, Suite 4100
Houston, TX 77002
Phone: 713.632.8000
Fax: 713.632.8002
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James F. Williams
Andrew J. Kline
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Holly Martinez
PERKINS COIE LLP
1201 Third Avenue, Suite 4900
Seattle, WA 98101-3099
Phone: 206.359.8000
Fax: 206.359.9000
jwilliams@perkinscoie.com
akline@perkinscoie.com
ttobin@perkinscoie.com
hmartinez@perkinscoie.com

ATTORNEYS FOR PETITIONERS

CERTIFICATE OF SERVICE

I certify that this Petition for Review and Corporate Disclosure Statement was filed with the Court via the Court's electronic filing system, on the 8th day of March, 2021, and copy of the Petition was sent via nonelectronic service to the following:

The Honorable Monty Wilkinson
Acting Attorney General
U.S. Department of Justice
950 Pennsylvania, NW
Washington, DC 20530

The Honorable D. Christopher Evans
Acting Administrator
Drug Enforcement Administration
7000 Army-Navy Dr.
Arlington, VA 22202

Chief Counsel
Office of General Counsel
Drug Enforcement Administration
8701 Morrissette Dr.
Springfield, VA 22152

Civil Process Clerk
Office of the U.S. Attorney for the District of Columbia
555 4th St NW
Washington, DC 20530

/s/ *James F. Williams*
James F. Williams

Exhibit 1

Exhibit 1

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

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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.

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[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

Exhibit 2

Exhibit 2

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

Kathryn L. Tucker, Esq.
Emerge Law Group
621 S.W. Morrison Street
Portland, Oregon 97205
kathryn@emergelawgroup.com

Dear Kathryn Tucker:

This letter is in response to your letter dated January 15, 2021, to the Drug Enforcement Administration (DEA). In your letter you state that you are counsel to Advanced Integrative Medical Science Institute and its co-director, Sunil Aggarwal, M.D. You state that Dr. Aggarwal is a palliative care specialist who treats patients with advanced cancer and currently holds a DEA registration as a practitioner. Dr. Aggarwal seeks additional authorization or additional registration (from DEA) to obtain psilocybin, a schedule I controlled substance, for therapeutic use for terminally ill cancer patients suffering anxiety and/or depression. You state that Dr. Aggarwal seeks such authorization pursuant to the "Right to Try Act" (RTT), officially designated as the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017. You ask DEA for guidance on how DEA will accommodate the RTT, so that Dr. Aggarwal may obtain psilocybin for therapeutic use with terminally ill patients. DEA appreciates the opportunity to address your request.

DEA understands and appreciates the intent of the RTT, that is, to provide easier access to experimental drugs to patients afflicted with terminal illness. However, absent an explicit statutory exemption to the Controlled Substances Act (CSA), DEA has no authority to waive any of the CSA's requirements pursuant to the RTT. As is made clear in 21 U.S.C. 360bbb-0a(b), excerpted below, the RTT does not waive the requirements of any provision of the Controlled Substances Act (CSA) or its implementing regulations.

> *(b) Exemptions*
>
> *Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 352(f), 353(b)(4), 355(a), and 355(i) of this title, section 351(a) of the Public Health Service Act, and parts 50, 56, and 312 of title 21, Code of Federal Regulations (or any successor regulations), provided that the sponsor of such eligible investigational drug or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section is in compliance with the applicable requirements set forth in sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs.*

A potential avenue for Dr. Aggarwal to pursue is to apply for a schedule I researcher registration with DEA to conduct research with psilocybin, a schedule I controlled substance. The procedures for such application are outlined in 21 U.S.C. 823(f), 21 CFR 1301.18, and 21 CFR 1301.32.

Finally, in your email to DEA, sent on February 2, 2021, you inquire as to the possibility of DEA issuing an exemption from prosecution to Dr. Aggarwal. You state in your email that this would be akin to the exemption provided for in 21 CFR 1316.24, titled, "Exemption from prosecution for researchers." The exemption provided in this regulation, however, only applies to individuals already registered with DEA to engage in research in controlled substances. *See* 21 CFR 1316.24(a) ("Upon registration of an individual to engage in research in controlled substances . . . the Administrator . . . may exempt the registrant when acting within the scope of his registration, from prosecution . . ."). It would therefore not be applicable to Dr. Aggarwal at this time. Should Dr. Aggarwal obtain a schedule I researcher registration from DEA, he may then petition the DEA Administrator for a grant of exemption from prosecution following the procedure set forth in 21 CFR 1316.24(b).

I trust this letter adequately addresses your inquiry. For additional information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have additional questions regarding this issue, please contact the Policy Section at (571) 362-3260.

Sincerely,

Thomas W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division