No. _____

In the United States Court of Appeals for the Ninth Circuit

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

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION; MERRICK GARLAND, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE UNITED STATES; AND ANNE MILGRAM, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION,

Respondents.

PETITION FOR REVIEW

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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.

July 22, 2022

/s/ James F. Williams
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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, FAAHPM, and two of Dr. Aggarwal's patients, Erinn Baldeschwiler and Michal Bloom, hereby petition for review of the United States Drug Enforcement Administration's ("DEA's") final agency action issued on June 28, 2022, attached as **Exhibit 1** (the "Final Agency Decision"). This Petition for Review ("Petition") regards how the agency will abide by the "Right to Try" ("RTT"), as codified in both federal and state law. *See* 21 U.S.C.A. § 360bbb, *et seq.*; RCW 69.77, *et seq.*

This case is a related matter to *AIMS v. Garland,* No. 21-70544 (9th Cir. 2022). Petitioners request assignment to the same panel.

I. SUMMARY

Petitioners are a physician, two of his patients with advanced terminal cancer, and his clinic. Petitioners seek to exercise their rights under federal and state law to try an eligible investigational drug to address these patients' therapeutic needs.

Instead, the DEA stands between the physician and his patients, in violation of federal and state law. Under federal law, 21 U.S.C. § 360bbb-0a — part of the larger Food, Drug, & Cosmetic Act ("FDCA") — physicians like

Petitioner Dr. Aggarwal have the ability to try eligible investigational drug therapies with eligible patients like Petitioners Baldeschwiler and Bloom. Specifically, federal RTT permits distribution of yet unapproved investigational drugs for therapeutic use by patients with life-threatening illness who have exhausted available treatment options. Psilocybin is such an eligible investigational drug.

In denying Petitioners' requested accommodation in the Final Agency Action, DEA hides behind a smokescreen, neglecting its duty to implement the federal RTT and violating the state RTT. It is attempting to use the Controlled Substances Act ("CSA") as a cudgel to thwart state medical practice, to the detriment of dying patients. Specifically, the agency claims that it has no authority to craft policies to address the RTT. The agency is wrong: just because the DEA *chooses not to do something*, does not mean that the agency *has no authority to do so*. Here, the DEA is violating federal law and federalism principles. For example, the CSA itself prohibits the DEA from construing the CSA provisions "in any way" that would "affect[ ], modify[ ], repeal[ ], or supersed[e]" the provisions of the FDCA. 21 U.S.C. § 902. In other words, the FDCA — and thus the federal RTT that it incorporates — take precedence over the CSA's provisions, *by the CSA's very*

terms. So, by failing to provide a pathway for the federal RTT, the DEA is *violating*, not administering, the CSA.

The DEA's Final Agency Action also violates core aspects of federalism. With its final decision here, the DEA unlawfully intrudes into the practice of medicine, a state police power. Further, the agency's position contradicts Supreme Court law prohibiting the agency from passing "anterior judgment" about what constitutes accepted medicine or medical treatment. *Gonzales v. Oregon*, 546 U.S. 243, 272 (2006).

Petitioners include two dying patients who do not have the luxury of waiting for byzantine, opaque administrative machinations. They attempted to litigate this matter over the past year in this Court after DEA claimed it had "no authority" to address the RTT. The agency was wrong. Petitioners filed suit, ultimately leading to a published opinion in January 2022. *See AIMS v. Garland,* 24 F.4th 1249 (9th Cir. 2022). In the earlier case, this Court held that the agency's disclaimer of any "authority" to provide a regulatory pathway for eligible patients to access eligible investigational drugs under the federal RTT was not clear enough to constitute an appealable final agency action.

Petitioners heard the Court. On the heels of its decision, Petitioners filed a formal Request for Waiver in February 2022, asking the DEA to allow

Petitioner Aggarwal to lawfully access to psilocybin for therapeutic use for his terminally-ill patients. The DEA provided its Final Agency Decision in June 2022, finding expressly that "the legal and factual considerations remain unchanged." To make doubtless that the DEA's Final Agency Decision was actually *final*, Petitioners requested the agency's confirmation within 14 business days. The DEA did not respond. That brings us to today, and Petitioners bring this suit with a simple demand: that the DEA follow the law.

In the prior action, this Court determined that Petitioners needed to ask the agency and clearly "apply for relief." *AIMS*, 24 F.4th at 1261 (decided on January 31, 2022). Petitioners did so on February 10, 2022, asking the DEA squarely to provide Petitioners with a waiver to obtain the eligible investigational drug psilocybin. Instead of engaging with this precise ask, the agency on June 28, 2022 termed Petitioners' request for a waiver as a "request for reconsideration," doubling down on its determination that the DEA has had "no authority" to address the RTT. In so doing, the DEA made it clear that the agency was not at the beginning of its decision-making process, as this Court had held previously. *Id.* But rather the agency's process is final and has been for some time. The DEA has misconstrued the statutes to divest it of authority to accommodate RTT, and that's that. Any further

requests, petitions, inquiries, or demands to the DEA would unequivocally result in the requester being directed back to DEA's earlier final conclusion that the agency lacks authority to waive any aspect of the CSA to accommodate the RTT. The Final Agency Decision demonstrates the agency's game plan: instead of responding to Petitioners' new request — sent per the direction of this Court — the agency simply deemed it a "request for reconsideration" and did not engage with the request for waiver of CSA provisions as applied to the RTT, instead reaffirming its prior reasoning and clearly communicating the finality of its decision. There can be no further doubt that DEA's decision is clearly final and subject to consideration as such by this Court.

The RTT is binding upon the DEA, and this Court should mandate that the agency recognize this reality.

II. PRIOR ADJUDICATION

Petitioners, including two terminally-ill patients and their physician, seek immediate review of the DEA's Final Agency Decision. Petitioners previously sought review of an earlier DEA determination (the "2021 Letter") regarding the interplay between the RTT and the CSA in its 2021 Letter, attached here as **Exhibit 2**, the agency detailed that "the RTT does not waive the requirements of any provision of the Controlled Substances Act (CSA) or

its implementing regulations," and concluded that the agency had "no authority to waive any of the CSA's requirements pursuant to the RTT." *See AIMS,* 24 F.4th at 1255. In this prior case, the Ninth Circuit determined that the challenged letter did not constitute a final agency action. *Id.* at 1260-61. The panel explained that the letter revealed only that (a) "DEA's decision making process had not yet begun"; and (b) DEA provided mere "straightforward guidance" about the RTT and CSA. *Id.* at 1261.

Subsequent to the Ninth Circuit's determination, Petitioners submitted a formal Petition for Waiver to the DEA on February 10, 2022, requesting a waiver to allow Dr. Aggarwal to lawfully access psilocybin for therapeutic use for his terminally-ill patients, including for Petitioners Baldeschwiler and Bloom. That Petition is attached here as **Exhibit 3**, and the included the following request:

> Dr. Aggarwal and AIMS request that DEA authorize him to access psilocybin for therapeutic use with his terminally ill patients under the RTT Acts. Dr. Aggarwal and AIMS further request that DEA grant them immunity from prosecution under the CSA with respect to the therapeutic use of psilocybin described here. To the extent DEA concludes any registration requirement in the CSA or in DEA's implementing regulations applies to this request, Dr. Aggarwal and AIMS request that DEA waive or make an exception as necessary to accommodate this

> request. Dr. Aggarwal and AIMS are eager to work with DEA to facilitate the granting of this request, including through the execution of an MOU imposing security and diversion controls as necessary.

Exhibit 3 at 6.[1]

The DEA responded to the Request for Waiver on June 28, 2022, with its Final Agency Decision, wherein the agency expressly considered the Petition as a "request for reconsideration" of the DEA's 2021 Letter. The DEA further concluded explicitly that the agency saw "no basis for reconsideration" of its earlier determination because "the legal and factual considerations remain unchanged." Final Agency Decision at 1.

In response to DEA's Final Agency Decision, Petitioners submitted a letter on June 29, 2022, the very next day, asking the DEA to confirm that the Final Agency Decision was indeed its final decision as an agency. In this letter, attached here as **Exhibit 4**, Petitioners asked if the agency somehow regarded its Final Agency Decision as *not final*, to inform Petitioners when to "expect that final decision to issue or if there is a further avenue of

[1] Petitioners AIMS and Aggarwal are parties to a separate FOIA action, filed in the Southern District of Texas, requesting, in relevant part, public records generated by DEA in response to the Petition for Waiver after February 10, 2022. *AIMS Institute, PLLC, et al. v. Garland, et al.,* No. 4-:22-cv-02396 (S.D. Tex. Jul. 19, 2022).

administrative review that [Petitioners] should pursue before seeking judicial review under [S]ection 877 of the Controlled Substances Act." Exhibit 4 at 2. Petitioners then put DEA on notice of their intent to regard the Final Agency Decision as indeed *final* — and therefore subject to judicial review — if no response was provided within 14 business days. The DEA did not respond, and Petitioners have thus filed this Petition for Review.

In light of the procedural history and urgency of the terminally-ill Petitioners' situation, Petitioners' request that the Court expedite review of this matter.

III. THE RTT MANDATES THAT PETITIONERS BE ALLOWED TO TRY ELIGIBLE INVESTIGATIONAL DRUGS

In 2018, following a wave of state RTT enactments, including that of Washington State, Congress enacted a federal RTT law "[t]o authorize the use of unapproved medical products by patients diagnosed with a terminal illness in accordance with State law." Pub. L. 115-176. The Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 added § 360bbb-0a to the FDCA, establishing an exception to the statute's safety/efficacy requirements for premarket approval for unapproved investigational drugs that have successfully completed Phase 1 trials. Where it applies, the law permits distribution of yet unapproved

investigational drugs for therapeutic use by patients with life-threatening illness who have exhausted available treatment options.

Federal RTT effects a paradigm shift in the availability of investigational drugs for patients with life threatening illness, effectively reverting to the FDCA's safety-only paradigm for these individuals. Rather than impose the general safety/efficacy norm, the federal RTT allows states to choose whether and to what extent this patient population should have the right to try eligible investigational drugs. In fact, Congress expressly constructed an interplay between the FDCA and the CSA, requiring the CSA's provisions to yield to those of the FDCA. *See* 21 U.S.C. § 902. The CSA itself forbids DEA from construing CSA provisions "in any way" that would "affect[ ], modify[ ], repeal[ ], or supersed[e]" FDCA provisions. *Id.* By construing the CSA to supersede the FDCA's RTT provisions, however, DEA's Final Agency Decision does just that.

Similarly, 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 the 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, allowing for: "terminally ill patients to use potentially lifesaving investigational drugs[.]" *Id.*

Despite federal and state legislators' intent that terminally ill patients be permitted to make informed decisions with their health care providers about the use of 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"). Specifically, the federal RTT allows for the use of "eligible investigational drugs" "by patients diagnosed with a terminal illness in accordance with State law." 21 C.F.R. § 360bbb-0a. However, DEA has thus far failed to permit such treatments, notwithstanding that controlling federal law requires it to do so.

IV. PSILOCYBIN IS AN ELIGIBLE INVESTIGATIONAL DRUG UNDER THE RTT

Psilocybin is a naturally occurring compound found in more than 200 fungus species. Congress placed psilocybin in Schedule I when first enacting the CSA, 84 Stat. 1249 (1970), and it remains in that category today, notwithstanding its myriad medicinal benefits.[2] Contrary to this Schedule I placement, which requires that the substance has no therapeutic use, myriad research has indicated that there are significant medicinal benefits of psilocybin. Studies have consistently found that psilocybin treatment can significantly and rapidly reduce symptoms of mental and emotional distress in patients with life-threatening cancer with no clinically significant adverse effects.[3]

Phase 1 clinical trials have shown that psilocybin was "well tolerated." *See* Michael W. Jann, *Psilocybin Revisited: The Science Behind the Drug*

[2] *See, e.g.,* Roland R. 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. PSYCHOPHARM. 1181, 1195 (2016). *See* Stephen Ross, *et al., Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial*. 30 J PSYCHOPHARM. 1165 (2016); Stephen Ross, *et al.*, *Acute And Sustained Reductions In Loss Of Meaning And Suicidal Ideation Following Psilocybin-Assisted Psychotherapy For Psychiatric And Existential Distress In Life-Threatening Cancer*, 4 ACS PHARMACOLOGY & TRANSLATIONAL SCIENCE 553-562 (2021).

[3] *See, e.g.,* Ben Sessa, *Turn on and tune in to evidence-based psychedelic research* 2 LANCET PSYCH 10 (2015); Robert H. Dworkin, *et al.*, *If The Doors Of Perception Were Cleansed, Would Chronic Pain Be Relieved? Evaluating The Benefits And Risks Of Psychedelics*. JOURNAL OF PAIN (2022).

and Its Surprising Therapeutic Potential, 38 PSYCHIATRIC TIMES (Mar. 9, 2021). Phase 2 trials are underway, and plans for Phase 3 trials are already in place. *Id.* Psilocybin has thus been shown to be safe per FDA standards, *see id.*, and it has also shown significant indications of effectiveness.

Psilocybin is an "eligible investigational drug," as defined by the federal RTT. To qualify as an "eligible investigational drug," the drug must have, among other things, completed an FDA-approved Phase I clinical trial, not be currently approved for use by federal authorities, and have ongoing and active drug development. Psilocybin meets all the criteria for "eligible investigational drug" under the federal statute; Petitioner Aggarwal and his eligible patients, Petitioners Baldeschwiler and Bloom, should be permitted access to psilocybin to relieve the depression and anxiety associated with end of life.

V. DEA HAS DECIDED THAT PSILOCYBIN IS NOT AVAILABLE TO PETITIONERS, NOTWITHSTANDING BOTH FEDERAL AND STATE RIGHT TO TRY LAWS

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 DEA's 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 DEA, which administers the CSA. The agency has declared that it "has no authority to waive" any of the CSA'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.

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 accommodate valid requests made from qualified health care providers for the therapeutic use of the eligible investigation drug psilocybin.

***

Dated: July 22, 2022

Respectfully submitted,

/s/ James F. Williams

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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 22nd day of July, 2022, and copy of the Petition was sent via non-electronic service to the following:

The Honorable Merrick Garland
Attorney General
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
8701 Morrissette Dr.
Springfield, VA 22152

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

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 is in response to your letter dated February 10, 2022, to the Drug Enforcement Administration (DEA) regarding the Right to Try Act (RTT), 21 U.S.C. 360bbb-0a, and your client, Advanced Integrative Medical Science Institute and its co-director, Dr. Sunil Aggarwal, M.D. In your correspondence, you again inquired about the use of psilocybin, a schedule I controlled substance, for "therapeutic use" for terminally ill patients suffering anxiety and/or depression, as well as "immunity from prosecution" for such use under the Controlled Substances Act. This latest request effectively restates the grounds that you previously submitted to DEA, to which DEA responded via letter on February 12, 2021 (attached). Accordingly, DEA considers your latest correspondence as a request for reconsideration of the agency's letter to you dated February 12, 2021. DEA finds no basis for reconsideration of its February 12, 2021 letter because the legal and factual considerations remain unchanged.

Nonetheless, as DEA previously indicated, the agency welcomes applications for registration by practitioners seeking to conduct bona fide research with schedule I controlled substances, including psilocybin.

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

Sincerely,

Thomas W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division

Enclosure

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
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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

Exhibit 3

Exhibit 3

EMERGE LAW GROUP
621 SW Morrison St., Suite 900, Portland, OR 97205

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

February 10, 2022

VIA USPS Certified Mail Return Receipt Requested

U.S. Drug Enforcement Administration
Attn: Anne Milgram, Administrator
8701 Morrissette Drive
Springfield, VA 22152

U.S. Drug Enforcement Administration
Diversion Control Division/DC
Attn: Kristi O'Malley, Senior Advisor to the Administrator
8701 Morrissette Drive
Springfield, VA 22152

Re: Access to Psilocybin for Limited Therapeutic Use Under State and Federal Right to Try Laws

Dear Administrator Milgram:

I write on behalf of Dr. Sunil Aggarwal of the Advanced Integrative Medical Science ("AIMS") Institute who seeks authorization to obtain psilocybin under the Washington and federal Right to Try ("RTT") Acts.[1] He seeks (1) authorization to access psilocybin for therapeutic use under state and federal RTT Acts and (2) immunity from prosecution under the Controlled Substances Act ("CSA"). The federal statute and DEA's regulations permit the agency to grant Dr. Aggarwal's request on various grounds, discussed in detail below.

In recent years, psilocybin has shown enormous promise in early clinical trials in relieving the debilitation anxiety and depression suffered by terminally ill patients. Psilocybin remains a Schedule I controlled substance under the CSA (although Dr. Aggarwal submitted a petition to reschedule dated 2/2/22.)

As a result, no supplier would provide psilocybin to Dr. Aggarwal without DEA's approval. When Dr. Aggarwal sought DEA's guidance regarding how he might obtain such approval, DEA responded that "[a]bsent an explicit statutory exemption to the Controlled Substances Act (CSA)," it lacked "authority to waive any of the CSA's requirements pursuant to the RTT." As detailed below, the agency was mistaken in this assessment of its authority.

Dr. Aggarwal sought judicial review of DEA's determination in the United States Court of Appeals for the Ninth Circuit. *AIMS v. Garland,* 21-70544 (9th Cir. Jan. 31, 2022).[2] The Ninth Circuit recently dismissed the petition, concluding that DEA's decision disclaiming authority to accommodate Dr. Aggarwal's request was not "final" for purposes of judicial review under 21 U.S.C. § 877. Even so, the Court did recognize and describe the interplay between the provisions of the FDCA, which includes the federal RTT , and the CSA. Id. @ 6-10. With

1 See RCW 69.77 et seq. (Washington RTT); Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, Pub. L. No. 115-176, § 1, 132 Stat. 1372, codified at 21 U.S.C. § 360bbb-0a (Federal RTT).

2 Because the Court dismissed the petition for lack of jurisdiction, it did not address the merits of petitioners' claims.

this letter, Dr. Aggarwal formally requests the agency's authorization to obtain psilocybin for therapeutic use for his terminally ill patients as well as immunity from prosecution for this authorized therapeutic use.

Dr. Aggarwal and His Terminally Ill Patients Seek to Exercise Their Rights Under the Federal and State RTT Acts

Dr. Aggarwal is Co-Founder and Co-Director of the AIMS Institute, an integrative oncology clinic based in Seattle, Washington. A well-credentialed palliative care specialist, Dr. Aggarwal is registered with DEA (DEA Registration No. FA4274926) to prescribe schedule II-V drugs. In January 2021, Dr. Aggarwal sought guidance from DEA regarding how he might access the investigational drug psilocybin for therapeutic use with his terminally ill patients, Michal Bloom and Erinn Baldeschwiler, under the federal and state RTT Acts.

In his professional practice, Dr. Aggarwal treats many patients with advanced-stage cancer, including some who suffer from severe anxiety and depression that does not respond to therapy with approved medicines. Michal Bloom and Erinn Baldeschwiler are two such patients. Bloom, a DOJ attorney who retired due to her illness, has been undergoing extensive treatment for advanced ovarian cancer since 2017 with a multitude of burdensome complications. She experiences severe anxiety and depression, which approved FDA therapies have not abated. Baldeschwiler has Stage IV metastatic breast cancer with tumors all over her body. A mother of two, the prospect of an imminent death preventing her from raising her children to adulthood causes her severe mental and emotional pain. She suffers from anxiety and depression that currently approved treatments have failed to address.

Based on his professional experience and assessment of (1) Bloom and Baldeschwiler's condition and symptoms and (2) recent research on psilocybin therapy, including successful clinical trials, Dr. Aggarwal discussed the possibility of psilocybin therapy, including the potential risks and rewards, with Bloom and Baldeschwiler. Both patients indicated a desire to try the treatment and gave informed consent. That is exactly what Dr. Aggarwal seeks to do here: allow terminally ill patients the ability to try an investigational drug therapy, consistent with state and federal RTT Acts and the will of Congress.

Dr. Aggarwal seeks to travel the pathway intended to be created by the state and federal RTT Acts. Washington's RTT law recognized that "the process for approval of investigational drugs ... often takes many years" and that patients with terminal illnesses do not have the luxury of waiting until an investigational drug obtains final approval the FDA.[3] Washington legislators voted unanimously to approve access to investigational drugs for "patient[s] with a terminal illness in consultation with the patient's health care provider."[4] At the federal level, Congress embraced the "will of the American people" after a supermajority of states, including Washington, passed RTT legislation.[5] "To open the door to innovative, experimental drugs for terminally ill patients without necessarily compromising the vital work and mission of [FDA]," the federal RTT exempts investigational drugs from the FDA's premarketing approval requirements, permitting state law to govern. Federal RTT thus "empower[s] terminally ill patients and their doctors who, together with the cooperation of the developers of potentially life-saving therapies, should be in charge of making a determination about their own course of treatment."[6]

Dr. Aggarwal's patients qualify for the right to try. Federal RTT allows states to choose whether and to what extent the eligible patient population should have the right to try EIDs, and Washington has made its choice to allow physicians and patients the right to try investigational drugs, weighing the risks and benefits of therapy

[3] RCW 69.77.010.
[4] Id.
[5] 164 Cong. Rec. H4355, H4356 (2018).
[6] Id. At H4360

for the preservation of their quality of life. At the federal level, an "eligible patient" may use an "eligible investigational drug" ("EID") and "no liability in a cause of action shall lie" against a manufacturer, sponsor, prescriber, or dispenser providing EIDs to an eligible patient in compliance with compliance with the federal RTT law. To qualify as an "eligible patient," a person must have (1) been diagnosed with a life-threatening disease or condition, (2) exhausted approved treatment options and is unable to participate in a clinical trial involving the EID and (3) given informed consent regarding the drug. 21 U.S.C. § 360bbb-0a(a)(1). To qualify as an EID, a drug must (1) have completed an FDA-approved Phase 1 clinical trial; (2) not be approved or licensed for any use through the Food, Drug, & Cosmetic Act or the Public Health Service Act. Washington's RTT law operates similarly at the state level.[7]

Applying these RTT Acts to Dr. Aggarwal and his terminally ill patients, psilocybin is an EID. Ms. Bloom and Ms. Baldeschwiler are eligible patients with terminal illnesses who have provided informed consent for the therapy. The federal and state RTT Acts *should* allow them to access psilocybin, but they cannot because of the DEA's failure, as yet, to create a pathway to access.

Dr. Aggarwal's patients are terminally ill, and they are suffering. This suffering could be immediately relieved with access to this investigational drug. He therefore requests a "final decision of the Attorney General" on this urgent matter as soon as possible. *See* 21 U.S.C. § 877.

Dr. Aggarwal and His Patients Have Already Attempted to Exercise Their Rights Under the RTT Acts Via Litigation

In January 2021, Dr. Aggarwal requested DEA provide instructions and guidance on how he could obtain psilocybin for therapeutic use with his suffering terminally ill patients under Washington and federal RTT Acts. He advised that a DEA-registered manufacturer and distributor of psilocybin had agreed to provide the investigational drug on receipt of evidence of DEA's approval.

DEA responded on February 12, 2021, declaring that it could not accommodate Dr. Aggarwal's RTT request. According to DEA, it has "no authority to waive" any of the CSA's requirements to accommodate RTT. DEA provided no avenue to obtain an exception, exemption, or waiver. Instead, it suggested Dr. Aggarwal consider registering as a schedule I researcher under the CSA.

Dr. Aggarwal, AIMS, Michal Bloom, and Erinn Baldeschwiler filed a petition for review of DEA's decision in the United States Court of Appeals for the Ninth Circuit, arguing that DEA was obligated to accommodate petitioners' request for access to psilocybin under RTT. Dr. Aggarwal and his patients' opening brief is attached here as **Exhibit A**, and incorporated herein.[8] The Ninth Circuit dismissed the petition without reaching the merits, concluding that DEA's decision was not a not "a final decision of the Attorney General," under 21 U.S.C. § 877.

DEA Can and Should Grant Dr. Aggarwal's Request Outright and Forthwith

Dr. Aggarwal's request may seem novel or extraordinary. DEA has never yet permitted anyone to obtain access to a schedule I substance under a RTT law. In fact, however, DEA has permitted access to schedule I substances in similar circumstances throughout its history. Recently, for example, it supported physician-initiated therapeutic use of a schedule I cannabis-derived experimental drug by over 300 *children* under FDA's expanded

[7] See RCW 69.77 et seq.
8 Exhibit A outlines the historical and legal background of controlled substance regulation as applied to psilocybin.

access program. In testimony before the Senate Caucus on International Narcotics Control, DEA's then-Deputy Administrator touted the agency's support of access to schedule I controlled substances for therapeutic purposes:

> DEA is committed, consistent with the CSA and the FDCA, to assisting with the healthcare needs of patients. In this regard, the DEA supports research involving CBD and its potential capacity to treat multiple conditions. In June 2014, FDA granted Fast-Track designation to the investigational CBD product, Epidiolex, for study in the treatment of a rare form of childhood epilepsy. FDA has also authorized the use of Epidiolex under Expanded Access, which is designed to facilitate the availability of investigational drug products to patients while those drugs are being studied for approval. DEA supports the use of Expanded Access, which provides access to treatments for patients with serious or immediately life-threatening diseases or conditions, while preserving important protections for those patients. This is a separate process that is available to patients, distinct from the Clinical Trials process. GW Pharmaceuticals, the manufacturer of Epidiolex, has publicly announced that there are over 300 patients being treated through this program, including many pediatric patients with seizure disorders.

Statement of Joseph T. Rannazzissi Dep'y Admin., DEA, Hrg. Before the Sen. Caucus on Int'l Narcotics Control, Cannabidiol: Barriers to Research and Potential Medical Benefits (June 15, 2015).

DEA has every legal and public policy reason to support Dr. Aggarwal's similar request for access to psilocybin for therapeutic use under RTT. After all, expanded access and RTT both involve experimental drugs that have completed Phase I clinical trials. Indeed, Congress described expanded access and RTT as alternative programs that were designed to operate "alongside" each other. 21 U.S.C. § 360bbb-0a(b) note, 132 Stat. 1374-75 (RTT "is consistent with, and will act as an alternative pathway alongside, existing expanded access").

DEA's support of single patient INDs in the context of the Federal Medical Marijuana Program also demonstrates that there is nothing novel or extraordinary about Dr. Aggarwal's request for access to a schedule I substance for therapeutic use. If physicians and pharmacists were permitted to dispense schedule I marijuana to John Randall and the other patients who participated in that program for years, then there is no reason Dr. Aggarwal ought not be permitted to dispense psilocybin to his patients under RTT. It is consistent with prior determinations by DEA, federal and state law, and the underlying public policy rationale that the United States takes care of their own.

Just as the practitioners involved in these programs were permitted to obtain access to schedule I substances without obtaining any additional or special DEA registration, Dr. Aggarwal should be permitted to obtain psilocybin for therapeutic use with his patients without additional registration as well. While Dr. Aggarwal does seek to "dispense" psilocybin, DEA-registered practitioners do not need special registration from DEA to dispense drugs to ultimate users as long as they do so for legitimate medical or scientific purposes. 21 U.S.C. § 829. Given Congress's express endorsement of the dispensing Dr. Aggarwal seeks to undertake—administering an "eligible investigational drug" to an "eligible patient" under RTT—there can be no question that his planned use of psilocybin is legitimate, lawful, and consistent with DEA's mandate and authority. *See also Gonzales v. Oregon*, 546 U.S. 243 (2005) (DEA lacks authority to decide what counts as a legitimate medical purpose under the CSA).

Simply put, the mere fact that the request arose in a novel legal or factual context has never impeded access before, and it should not now.

To the Extent Dr. Aggarwal's Request Requires Additional Registration, DEA Should Waive That Requirement – at Least Temporarily

None of the registration categories available under current DEA regulations applies to Dr. Aggarwal's request. He does not seek to conduct research with psilocybin. Nor does he seek to manufacture it. He does seek to dispense it, but no special registration is generally required when a physician seeks to administer a drug to an ultimate user for legitimate therapeutic purposes.

When confronted with similar circumstances in the past, DEA has either (1) created a new registration classification that does apply to the new activity or (2) concluded no registration was necessary for the activity because it did not constitute an essential link in the closed system of distribution. The development of the reverse distributor industry is instructive on this point.

Reverse distributors collect controlled substances, including schedule I substances, from registrants and either return them to the manufacturer or arrange for their disposal. *See* 68 Fed. Reg. 41222 (July 11, 2003). Because these companies "process" controlled substances, they are in some technical sense "manufacturers" under DEA's definition of that term. *Id.* at 41223 (acknowledging that reverse distributors manufacture controlled substances because they "process them). Nevertheless, DEA permitted them to handle controlled substances for years without registration because "they were not considered an essential link in the closed distribution system that the Controlled Substances Act established ...." *Id.* at 223.

As the industry grew, however, reverse distributors came to play a more vital role in the "closed system." In response, DEA sought to require reverse distributors to register as manufacturers. *Id.* But comments from the industry convinced DEA that the regulations applicable to registered manufacturers were not appropriate or necessary in the reverse distribution context. *Id.* Accordingly, DEA created a new registration category especially for reverse distributors. *Id.* In the meantime, it continued to permit the industry to operate without registration. In doing so, DEA did not ignore security and diversion risks. Rather, it imposed those requirements through memoranda of understanding (MOUs) with each company. *Id.*

Just as reverse distributors in the early days did not constitute "an essential link in the closed distribution system that the Controlled Substances Act established," neither do physicians seeking access to controlled substances to treat terminally ill patients under RTT. Indeed, as far as Dr. Aggarwal is aware, he is in a category all his own in this respect. As such, he should not be required to register under the Act at all. *Id.* Instead, DEA should impose whatever diversion controls it deems necessary through an MOU with Dr. Aggarwal. In the event DEA later decides that registration is appropriate and necessary, it could issue establish a special registration category for RTT practitioners at that time, just as it did for reverse distributors.

In its response to Dr. Aggarwal's earlier request for guidance, DEA suggested that Dr. Aggarwal might apply for registration to conduct research with a schedule I substance. But Dr. Aggarwal does not seek to conduct research. Indeed, the point of RTT is to create an avenue for terminally ill patients to access experimental drugs outside of the clinical trial process, for therapeutic use. Common sense dictates that Congress recognized this need in passing the RTT law, given that patients suffering from terminal illness do not have the luxury of time.

Furthermore, requiring Dr. Aggarwal to obtain a schedule I research license would risk violating the CSA itself. Under § 823(f), DEA would need to refer Dr. Aggarwal's "research protocol" to FDA for approval before Dr. Aggarwal could be permitted administer the eligible investigational drug to his eligible patients. Yet the entire purpose of RTT is to permit a patient, doctor, and drug company to proceed to treatment with an eligible investigational drug without having to seek FDA's permission first. *See AIMS*, Op. 8 n.4 (noting that RTT exempts the administration of eligible investigational drugs from the otherwise-applicable FDA-approval

requirements of the FDCA). Requiring registration under § 823(f) in this context re-imposes the FDA-approval requirement that Congress expressly removed from the equation through the enactment of RTT. The CSA prohibits DEA from construing the research-registration requirement of § 823(f) "as in any way affecting, modifying, repealing, or superseding the provisions of the [FDCA]." 21 U.S.C. § 902. Accordingly, DEA may not construe § 823(f) to apply to physicians like Dr. Aggarwal who seek to administer schedule I substances to ultimate users for therapeutic purposes.

To the extent DEA nevertheless believes registration under § 823(f) is required, Dr. Aggarwal asks that DEA waive that requirement at least temporarily because doing so is "consistent with the public health and safety." *Id.* § 822(d). Registration is not necessary for DEA to ensure appropriate security and diversion controls are in place. In these circumstances, DEA can easily impose any diversion controls it deems necessary through an MOU. For the same reasons, to the extent DEA concludes its related regulations apply, *e.g.*, 21 C.F.R. §§ 1301.18, 1301.32, Dr. Aggarwal requests that it make an exception to them to accommodate his request.

Conclusion

For the reasons stated herein, Dr. Aggarwal and AIMS request that DEA authorize him to access psilocybin for therapeutic use with his terminally ill patients under the RTT Acts. Dr. Aggarwal and AIMS further request that DEA grant them immunity from prosecution under the CSA with respect to the therapeutic use of psilocybin described here. To the extent DEA concludes any registration requirement in the CSA or in DEA's implementing regulations applies to this request, Dr. Aggarwal and AIMS request that DEA waive or make an exception as necessary to accommodate this request. Dr. Aggarwal and AIMS are eager to work with DEA to facilitate the granting of this request, including through the execution of an MOU imposing security and diversion controls as necessary.

With this letter, Dr. Aggarwal returns to DEA. He does not seek "guidance" or "advice" but instead the allowance for him to access psilocybin for therapeutic use with his terminally ill patients, consistent with federal and state RTT laws to dramatically improve the quality of life of these patients.

Respectfully submitted,

/s/*Kathryn L. Tucker*

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Exhibit 4

Exhibit 4

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June 29, 2022

VIA USPS Certified Mail Return Receipt Requested and Email to Anne.milgram@dea.gov
Kristi.n.omalley@dea.gov

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Springfield, VA 22152

U.S. Drug Enforcement Administration
Diversion Control Division/DC
Attn: Kristi O'Malley, Senior Advisor to the Administrator
8701 Morrissette Drive Springfield, VA 22152

Re: Access to Psilocybin for Therapeutic Use Under State and Federal Right to Try Laws

Dear Ms. Milgram and Ms. O'Malley,

I write on behalf of Dr. Sunil Aggarwal of the Advanced Integrative Medical Science ("AIMS") Institute who seeks authorization to obtain psilocybin under the Washington and federal Right to Try ("RTT") Acts. *See* RCW 69.77 et seq. (Washington RTT); Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, Pub. L. No. 115-176, § 1, 132 Stat. 1372, codified at 21 U.S.C. § 360bbb-0a (Federal RTT). Attached for your reference is the February 10, 2022, petition submitted to you. As you'll recall, that petition made several specific requests of DEA, repeated below for convenience:

> Dr. Aggarwal and AIMS request that DEA authorize him to access psilocybin for therapeutic use with his terminally ill patients under the RTT Acts. Dr. Aggarwal and AIMS further request that DEA grant them immunity from prosecution under the CSA with respect to the therapeutic use of psilocybin described here. To the extent DEA concludes any registration requirement in the CSA or in DEA's

> implementing regulations applies to this request, Dr. Aggarwal and AIMS request that DEA waive or make an exception as necessary to accommodate this request. Dr. Aggarwal and AIMS are eager to work with DEA to facilitate the granting of this request, including through the execution of an MOU imposing security and diversion controls as necessary.

On June 28, 2022, I received a letter from Thomas W. Prevoznik Deputy Assistant Administrator of the Diversion Control Division denying our request. That letter, also attached here, says, in relevant part:

> This latest request effectively restates the grounds that you previously submitted to DEA.... Accordingly, DEA considers your latest correspondence as a request for reconsideration of the agency's letter to you dated February 12, 2021. DEA finds no basis for reconsideration of its February 12, 2021, letter because the legal and factual considerations remain unchanged."

Please confirm that the June 28 letter is DEA's final decision denying the February 10, 2022, petition. Please also confirm that it is a final decision of the agency and therefore subject to judicial review under 21 U.S.C. § 877. If Deputy Assistant Administrator Prevoznik's June 28, 2022, letter is *not* the agency's final decision, please let us know when we can expect that final decision to issue or if there is a further avenue of administrative review that we should pursue before seeking judicial review under section 877 of the Controlled Substances Act.

If we do not hear from you within 14 business days— before Wednesday, July 20, 2022—we will assume that Deputy Assistant Administrator Prevoznik's June 28, 2022, letter *is* the agency's last word on my clients' petition and that it is therefore subject to judicial review under section 877 and proceed accordingly.

Respectfully submitted,

/s/Kathryn L. Tucker

Kathryn L. Tucker