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

June 29, 2022

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 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