



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

www.dea.gov

Sue Sisley, MD
Scottsdale Research Institute, LLC
12815 N. Cave Creek Road
Phoenix, Arizona 85022
SueSisleyMD@srilaboratory.com

Dear Dr. Sisley:

This is in response to your letter dated November 28, 2025, to the Drug Enforcement Administration (DEA), regarding DEA’s interpretation of the [Right to Try Act](#) (RTT), [21 U.S.C. 360bbb-0a](#), for investigational drugs containing schedule I controlled substances, including psilocybin and psilocin.¹ Specifically, you requested clarification on how DEA “reconciles”: (1) “the patient access framework and related protections set forth in [the RTT]”; and (2) the Controlled Substances Act’s (CSA) “registration, labeling prescribing/dispensing and reporting requirements under [21 U.S.C. §§ 823-829](#) and related provisions.” DEA appreciates the opportunity to address your inquiry.

As a general matter, it is DEA’s longstanding policy not to provide legal advice to regulated entities, government partners, or the general public. To comply with the Administrative Procedure Act and ensure fairness, DEA’s interpretations of the law and regulations, as well as its guidance materials, are published in the [Federal Register](#) and/or on DEA’s [Diversion Control Division website](#), which allows all members of the general public to have equal access to such information. At the same time, DEA recognizes the importance of working with regulated entities and members of the public to help guide them toward compliance with the law and regulations. DEA’s response to your inquiry must be limited to directing your attention to the pertinent provisions of the law, regulations, or other publicly disseminated documents issued by DEA. In that vein, DEA can provide general information. Please be advised that this is not meant to be an exhaustive list of every statutory provision or regulation that might apply to your inquiry.

The CSA and its implementing regulations established a closed system of distribution to ensure appropriate medical care and maintain the integrity of the system through an accountability process. A person who seeks to handle (e.g., manufacture, distribute, engage in research, or possess) schedule I controlled substances must be properly registered with DEA. For example, a practitioner who seeks to dispense a schedule I controlled substances must be properly registered as an approved researcher in accordance with the CSA and its implementing regulations. [21 U.S.C. 823\(g\)](#), [823\(n\)](#); [21 CFR 1301.18](#), [1301.32](#). The term “dispense” means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, which includes the prescribing and administering of a controlled substance. [21 U.S.C. 802\(10\)](#).

¹ Psilocybin and psilocin are schedule I controlled substances under the Controlled Substances Act and DEA’s implementing regulations. [21 U.S.C. 812\(c\)](#), [schedule I\(c\)\(15\)](#), (16); [21 CFR 1308.11\(d\)\(29\)](#), (30).

In 2018, Congress enacted the “Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017,” Pub. L. No. 115-176, 132 Stat. 1372, more commonly referred to as the federal “Right to Try Act” (RTT). In enacting the RTT, Congress expressly amended the Federal Food, Drug, and Cosmetic Act (FDCA) to permit the distribution of certain unapproved drug products for use by certain patients with certain conditions. More specifically, the RTT provides that “[e]ligible investigational drugs provided to eligible patients in compliance with this section are exempt from” specified statutory and regulatory provisions governing the labeling, approval, and clinical trials of drugs. [21 U.S.C. 360bbb-0a\(b\)](#).² Such exemptions are contingent, however, on compliance with regulations that forbid promoting, commercially distributing, or test marketing investigational drugs. *Id.* (requiring compliance with [21 CFR 312.7](#)). Importantly, the RTT expressly stated that it was not intended to “establish a new entitlement” or a “positive right” in any individual. Pub. L. No. 115-176, § 3(1), 132 Stat. at 1374. Rather, the law “only expands the scope of individual liberty and agency among patients, in limited circumstances.” *Id.* § 3(3). Thus, it was understood that this new access to investigational drugs would be “consistent with, and . . . act as an alternative pathway alongside, existing expanded access policies” of the Food and Drug Administration. *Id.* § 3(4).

The CSA and the FDCA are separate regulatory schemes with separate protocols and restrictions. “Any person or organization that produces or distributes prescription drugs that are also controlled substances must comply with the requirements of both the FDCA and the CSA.” [AIMS, PLLC v. Garland, 24 F.4th 1249, 1254 \(9th Cir. 2022\) \(AIMS I\)](#).³ The RTT expressly amended the FDCA, not the CSA, and it did not provide any exemptions from the CSA or its implementing regulations. *See AIMS, PLLC v. DEA*, 128 F.4th 1133, 1144 (9th Cir. 2025) (*AIMS II*) (“The CSA and its related regulations are not included in the RTT Act’s enumerated exemptions; the RTT Act does not mention the CSA at all.”). And as the Ninth Circuit observed in *AIMS I*, the RTT “did not give the DEA authority to waive CSA requirements.” 24 F.4th at 1261. Therefore, the CSA’s requirements to manufacture, distribute, dispense, prescribe, or otherwise handle schedule I controlled substances—including any eligible investigational drugs containing psilocybin or psilocin—remain in effect, such as appropriately registering with DEA, complying with applicable labeling and packaging requirements, issuing any prescription or order for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, and maintaining

² Under the RTT, an “eligible investigational drug” is defined as a drug that (1) has not been approved or licensed by the U.S. Food and Drug Administration (FDA) for sale in the United States for any use; (2) has been the subject of a completed Phase 1 clinical trial; (3) is either the subject of an NDA filed with FDA (meaning that clinical trials have been completed) or is the subject of an active IND and is currently under investigation in a clinical trial; and (4) is under active development or production and has not been discontinued by the manufacturer or placed on a clinical hold by FDA. 21 U.S.C. 360bbb-0a(a)(2). An “eligible patient” is someone who has (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 eligible investigational drug” (as certified by a physician); and (3) provided written informed consent regarding the drug in question. *Id.* § 360bbb-0a(a)(1).

³ *Accord Epic Sys. Corp. v. Lewis*, 584 U.S. 497, 510 (2018) (because there is a “strong presumption that repeals by implication are disfavored,” courts presume that “Congress will specifically address preexisting law when it wishes to suspend its normal operations in a later statute” (quotation marks and brackets omitted)); *Fed. Comm’n Comm’n v. NextWave Pers. Comm’n, Inc.*, 537 U.S. 293, 304 (2003) (“When two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.” (brackets and quotation marks omitted)); *Morton v. Mancari*, 417 U.S. 535, 549 (1974) (quoting *Posadas v. National City Bank*, 296 U.S. 497, 503 (1936)) (“repeals by implication are not favored”); *see also Whitman v. American Trucking Ass’n*, 531 U.S. 457, 468 (2001) (stating that Congress “does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions”).

required records and reports.

I trust this letter adequately addresses your inquiry. For information regarding DEA's Diversion Control Division, please visit <https://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,

Cheri Oz
Assistant Administrator
Diversion Control Division