United States Government Accountability Office

Report to Congressional Committees

May 2024

DRUG CONTROL

DEA Should Improve its Religious Exemptions Petition Process for Psilocybin (Mushrooms) and Other Controlled Substances

GAO-24-106630

GAO Highlights

Highlights of GAO-24-106630, a report to congressional committees

May 2024

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DEA Should Improve its Religious Exemptions Petition Process for Psilocybin (Mushrooms) and Other Controlled Substances

Why GAO Did This Study

DEA is responsible for investigating and enforcing violations of the Controlled Substances Act; overseeing, and coordinating with the Food and Drug Administration (FDA), on the process to study controlled substances; and reviewing petitions for religious exemptions to the Controlled Substances Act. Historically, psilocybin has been used in Indigenous cultures for spiritual ceremonies. Some states have taken steps to legalize the adult use of psilocybin or establish programs to study psilocybin for therapeutic applications.

The Joint Explanatory Statement accompanying the Consolidated Appropriations Act, 2023, includes a provision for GAO to review the use of psilocybin. Among other objectives, this report addresses (1) what federal data show on psilocybin's enforcement; and (2) reported barriers to the legal access and use of psilocybin for religious practices under the Religious Freedom Restoration Act.

GAO analyzed data from DEA related to enforcement and religious exemption processes, and interviewed officials at professional associations, DEA, FDA, research institutions, selected attorney and associated advocacy groups; and officials from two states that legalized psilocybin use.

What GAO Recommends

GAO is making four recommendations to DEA, including that DEA should establish timeframes to make determinations on completed religious exemption petitions under the Religious Freedom Restoration Act. DEA concurred with each of the recommendations.

View GAO-24-106630. For more information, contact Triana McNeil at (202) 512-8777 or McNeilt@gao.gov.

What GAO Found

Psilocybin is a naturally occurring hallucinogenic substance found in certain types of mushrooms. Generally, it is a federal crime for any person to possess, manufacture or distribute this controlled substance. However, numbers of investigations and seizures for psilocybin are small compared to other Schedule I controlled substances. During fiscal years 2018 through 2023, psilocybin cases (identified as the harshest or primary drug of concern) represented less than 1 percent of all cases the Drug Enforcement Administration (DEA) investigated and closed. Over the same period, psilocybin accounted for about 2 percent of all the U.S. Customs and Border Protection's drug seizures.

Depiction of Various Forms of Psilocybin (Mushrooms)

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Selected stakeholders reported several barriers to the legal access and use of psilocybin for religious practices under the Religious Freedom Restoration Act. For example, DEA established a process for parties to petition for a religious exemption from the Controlled Substances Act to use controlled substances for religious purposes. However, DEA's guidance does not inform petitioners on its timeframes to make determinations on completed petitions. DEA officials stated the agency is aware of public concerns on the need to better understand its policies and processes that impact the petitions for religious exemptions. In 2019, DEA initiated a draft notice of proposed rulemaking related to its process for petitioning for religious exemptions. Four years later, in February 2023, the final draft notice was submitted to DEA's Office of the Administrator, according to DEA officials; but there is no timeframe for issuance of the notice or final regulations.

Over an 8-year period—from fiscal year 2016 through January 2024—DEA reported that 24 petitioners requested a religious exemption for various controlled substances. As of January 2024, DEA reported that none of these petitions had been granted an exemption and of the 6 for psilocybin, three were withdrawn and three were pending a DEA determination. The three pending religious exemption petitions related to psilocybin ranged from about 8 months to over 3 years from the date of receipt. DEA's information also showed instances where finalized actions regarding exemption petitions related to other controlled substances have been pending a determination for an extensive period—one almost 5 years and one almost 8 years.

Including timeframes to make determinations about religious exemption petitions in DEA's guidance will provide better transparency about the agency's process.

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Abbreviations

BIA	Bureau of Indian Affairs
CBP	U.S. Customs and Border Protections
DOJ	Department of Justice
DEA	Drug Enforcement Administration
DMT	Dimethyltryptamine
EOUSA	Executive Office for United States Attorneys
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
IND	Investigational New Drug
LSD	lysergic acid diethylamide
MDMA	3,4-methylenedioxymethamphetamine
ONDCP	Office of National Drug Control Policy
USPIS	U.S. Postal Inspection Service

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
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May 30, 2024

Congressional Committees

Psilocybin is a naturally occurring hallucinogenic substance found in certain types of mushrooms in South America, Mexico, and the United States. Psilocybin is a Schedule I controlled substance under the Controlled Substances Act, as amended,[1] meaning that it has a high potential for abuse, no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the substance under medical supervision.[2] In addition, as a Schedule I controlled substance, generally it is a federal crime for any person to knowingly or intentionally possess, manufacture, distribute, or dispense psilocybin under federal law.[3]

However, some states and localities have taken steps to legalize, decriminalize or deprioritize the personal use or possession of psilocybin under state or local law.[4] Alternatively, other states have established initiatives supporting psilocybin-based research or pilot programs administering psilocybin services in a limited capacity. Some medical researchers are exploring how psilocybin may be used as an alternative

[1]Pub. L. No. 91-513, 84 Stat. 1242. The Controlled Substances Act classifies all federally controlled substances into categories known as schedules depending upon, among other things, the drug's likelihood for abuse or dependence, and whether the drug has an accepted medical use. These schedules range from I through V – with Schedule I having the greatest restrictions. Schedule I substances are those that have been found by the federal government to have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

[2]21 U.S.C. § 812(c), Schedule I (c)(15) and 21 U.S.C. § 812(b)(1).

[3]21 U.S.C. §§ 841, 844.

[4]We defined "deprioritize" generally as instances where states or localities have passed laws reducing the criminal penalties associated with the personal use or possession of psilocybin from a felony to a lesser crime or fine; stating that non-commercial planting, cultivating, transporting, or possession of psilocybin is among law enforcement's lowest enforcement priorities; or preventing public funds from being used to enforce criminal laws related to the personal use or possession of psilocybin. A state or local entity's alteration of its laws or priorities with respect to a particular substance has no effect on the legal status under federal law. Generally, possession or distribution of a Schedule I controlled substance continues to violate the Controlled Substances Act even if a state no longer imposes separate penalties for that conduct.

psychedelic treatment to provide relief to individuals with certain conditions, such as depressive disorders and addictions. Reportedly, psilocybin has historically been used ritualistically as a psychedelic or hallucinogenic agent in Indigenous cultures for religious and spiritual ceremonies.

Within the Department of Justice (DOJ), the Drug Enforcement Administration (DEA) is the primary federal law enforcement agency responsible for investigating and enforcing potential violations of the Controlled Substances Act. DEA reported that the use of psilocybin is associated with negative physical and psychological consequences—effects are similar to other hallucinogens, such as mescaline and lysergic acid diethylamide (LSD).[5] According to DEA, the physical effects may include nausea, vomiting, muscle weakness, drowsiness, and lack of coordination. The psychological consequences of psilocybin use may include hallucinations, the inability to discern fantasy from reality. DEA officials also stated that the psychological consequences may include fear, paranoia, anxiety, and depression that may last for days, weeks, or years after use. In addition, suicide, suicide ideation, and suicidal attempts have been reported after psilocybin use, according to DEA officials.

Some medical researchers have found that applications of psilocybin may provide therapeutic options for neuropsychiatric conditions, like depression and anxiety, often in conjunction with psychotherapy. Some researchers are examining psilocybin use for post-traumatic stress disorder, substance use disorders, pain, and eating disorders, among other things. Federal authorization to conduct a study involving a Schedule I controlled substance is required for individuals or entities.

In addition, psilocybin has reportedly been used historically for certain religious and spiritual ceremonies. Federal law requires a heightened level of scrutiny for government actions that substantially burden an

[5]Hallucinogens are drugs that alter awareness of perception, thoughts, and feelings. Psilocybin, mescaline, and LSD are all psychedelic hallucinogens, often just called psychedelics, which means “mind-manifesting.” These substances share a similar mechanism of action, which involves activating receptors for the brain chemical serotonin. Mescaline is a psychedelic hallucinogen obtained from the small, spineless cactus Peyote, the San Pedro cactus, Peruvian torch cactus, and other mescaline-containing cacti. LSD is a synthetic hallucinogen originally derived from ergot fungus.

individual's religious exercise.[6] Pursuant to this federal law, DEA has a process to evaluate whether the enforcement of the Controlled Substances Act substantially burdens the religious exercise of an individual or entity based upon a petition for a religious exemption to the Controlled Substances Act. Concerns have been raised by numerous stakeholders regarding the timeliness of DEA determinations for religious exemptions as well as clarity on the type of information petitioners should provide to support petitions.

The Joint Explanatory Statement accompanying the Consolidated Appropriations Act, 2023,[7] incorporates House Report 117-395, which includes a provision for GAO to report to Congress on the barriers to tribal, state, and local governments that incorporate psilocybin products, including for therapeutic use and religious, indigenous, or spiritual practices. This report addresses: (1) What federal data show about psilocybin's enforcement under the Controlled Substances Act; (2) The processes to obtain federal authorization to conduct research with psilocybin; and stakeholders' perspectives on them; and (3) The process and reported barriers that exist in the legal access and use of psilocybin for religious practices under the Religious Freedom Restoration Act of 1993.

To address our first objective, we analyzed enforcement data from DEA's CONCORDE/IMPACT Case Management System (CONCORDE System) to identify the number of closed and open investigations related to Schedule I controlled substances (including psilocybin) for each fiscal year—2018 through 2023.[8] DEA identifies an investigation as closed when all investigative and prosecutorial related activities are completed. According to DEA officials, the CONCORDE System cannot account for all closed and open investigations involving psilocybin because the

[6]Religious Freedom Restoration Act of 1993, Pub. L. No. 103-141, 107 Stat. 1488.

[7]Pub. L. No. 117-328, 136 Stat. 4459.

[8]According to DEA officials, the CONCORDE System is used to record and track DEA's criminal investigations.

system only tracks investigations by the "harshest" controlled substance involved in a seizure.[9]

We also analyzed data from DEA's National Forensic Laboratory Information System, which is comprised of data voluntarily reported by forensic laboratories on the results of its testing and analysis conducted on substances seized through federal, state, and local law enforcement operations. We also analyzed the U.S. Customs and Border Protection's (CBP) seizure data related to Schedule I controlled substances (including psilocybin) for each fiscal year—2018 through 2023. We assessed the reliability of DEA and CBP data by reviewing existing information and documentation about the data and the system that produced them and determined that they were sufficiently reliable for our purposes of presenting enforcement trends over time.

To address our second objective, we identified and analyzed DEA's policies and procedures, and other documentation that outlined the process new and existing researchers use to apply for federal authorization to conduct research with Schedule I controlled substances—including psilocybin. We interviewed DEA and Food and Drug Administration (FDA) officials to identify their perspectives on improvements needed, if any, to the federal authorization process related to conducting research with Schedule I controlled substances—including psilocybin. We also interviewed a non-generalizable sample of researchers to represent a range of perspectives on the process used to obtain federal authorization to conduct research with psilocybin and other Schedule I controlled substances, and the extent to which the process could be improved, if any.[10]

To address our third objective, we reviewed federal law and court cases involving the Religious Freedom Restoration Act; and assessed DEA's policies and procedures, and other documentation that outlined the agency's process for reviewing religious exemption petitions from the

[9]For example, DEA officials stated that if a DEA investigation involves a seizure with two controlled substances (i.e., heroin and psilocybin) the CONCORDE System may only identify heroin, because heroin may be considered to be the "harshest" controlled substance, or primary drug of concern in this instance based upon the judgment of DEA officials.

[10]We selected four organizations that represent a range of perspectives and expertise in the research community, including advocacy organizations, research institutions, and medical researchers.

Controlled Substances Act under the Religious Freedom Restoration Act. We also analyzed DEA's information on the number of petitions filed and processing status (i.e., approved, denied, withdrawn, or pending) for applicants who submitted petitions to use psilocybin and other controlled substances for religious practices for fiscal year 2016 through January 2024. We interviewed DEA officials to identify their perspectives on the agency's process to review petitions for a religious exemption.

We also interviewed a non-generalizable sample of nine individuals from law firms and advocacy organizations selected to represent a range of perspectives on the process and reported barriers, if any, that exist in the legal access to and use of psilocybin for religious, Indigenous, or spiritual practices under the Religious Freedom Restoration Act. In addition, we attempted to meet with officials representing various Tribal Nations to obtain their perspectives on DEA's petition process for the use of psilocybin for religious or spiritual purposes. A representative from one of the eleven Tribal Nations we contacted responded to our request and stated the Tribe has no history of psilocybin use for religious, Indigenous, spiritual or any other practices.

To address all three objectives, we attended the 2023 Psychedelic Science Conference, held in Denver, Colorado and met with stakeholder representatives from diverse groups that represented various government, medical, spiritual, tribal, and other psychedelic related organizations. We also attended panel discussions and presentations that focused on the policy and legislation, clinical research, the Religious Freedom Restoration Act, and Indigenous and historical uses of psilocybin.

To obtain various perspectives on psilocybin use, we selected and interviewed six of the conference participants (i.e., attorneys, researchers, and faculty researchers) who were identified and considered as knowledgeable on the legal and therapeutic aspects of psilocybin use. Based upon a review of states' laws related to psilocybin, we identified Oregon and Colorado as the two states that had legalized the adult use of psilocybin under state laws as of July 2023 and interviewed relevant and knowledgeable program officials from Oregon and Colorado to obtain their perspectives on state legalization of psilocybin—including the challenges experienced with implementing their recently passed psilocybin laws.

For background purposes to report on scientific research indicating potential uses for psilocybin, we conducted a literature review identifying

sources published from January 2013 through August 2023 that related to the applications of psilocybin therapy. GAO then identified any sources that provided or cited evidence regarding psilocybin's efficacy to treat medical and mental health conditions and reviewed the methodology of the studies and the outcomes.

We conducted this performance audit from February 2023 to May 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Federal and State Psilocybin Laws

Psilocybin is a naturally occurring hallucinogenic substance found in certain types of mushrooms. Psilocybin is a controlled substance under federal law and is classified as a Schedule I controlled substance—the most restrictive of categories of controlled substances by the federal government. The Controlled Substances Act, as amended, does not allow Schedule I controlled substances, including psilocybin, to be dispensed with a prescription,[11] and generally provides federal sanctions for the unauthorized possession, manufacture, distribution, or dispensing of such controlled substances.[12]

For a number of years, the 50 states generally had uniform drug control laws or similar provisions that mirrored the Controlled Substances Act, making their violation a state criminal offense. However, since 2017, despite the federal government's prohibition on psilocybin, a few states and localities have legalized, decriminalized, or deprioritized psilocybin use under state or local law. According to Department of the Interior's Bureau of Indian Affairs officials, based on their knowledge, no federally

[11]See 21 U.S.C. § 829.

[12]Generally, the Controlled Substances Act, as amended, allows for the limited use of Schedule I drugs in the context of a government approved research project. 21 U.S.C. §§ 823(g)(2)(A), 841, 844.

recognized Indian Tribes have legalized the use of psilocybin for religious or spiritual purposes.[13]

Legalization. As of July 2023, two states—Colorado and Oregon—passed state laws generally legalizing the adult use of psilocybin. In November 2020, Oregon passed a state ballot initiative, also known as the Oregon Psilocybin Services Act, to permit persons licensed, controlled, and regulated by the state to legally manufacture psilocybin products and provide psilocybin services to persons 21 years of age and older, subject to state law; and establish a comprehensive regulatory framework concerning psilocybin products and psilocybin services under state law, after a two-year program development period.[14] On December 31, 2022, Oregon adopted final administrative rules for the regulated framework codified in Oregon law, in Oregon Revised Statutes Chapter 475A. Beginning January 2, 2023, Oregon began reviewing applications for licensure, issuing licenses, and regulating licensees.

In 2022, Colorado passed a state ballot initiative to generally decriminalize the personal use and possession of certain hallucinogenic and entheogenic plants and fungi, including psilocybin. In addition, the initiative provided for the establishment of a natural medicine services program for the supervised administration of these substances, a regulatory framework for the growth, distribution, and sale of these substances, and a natural medicine advisory board to promulgate rules and implement the regulated access program. In May 2023, Colorado passed an act concerning natural medicine (referred to as the Natural Medicine Regulation and Legalization), which sets the regulatory framework for a natural medicine program in Colorado. In addition, the Act generally decriminalizes the possession, consumption, cultivation, manufacture, and sharing of natural medicine or natural medicine product

[13]As of January 2024, there were 574 federally recognized Indian Tribes in the United States. The Indian Tribes in the U.S. vary greatly in terms of culture, language, population size, land base, location, and economic status. These Tribal Nations are distinct political entities whose inherent sovereignty predates the United States and is reflected in the government-to-government relationship between Tribal Nations and the federal government. Tribal Nations are subject to federal law, but as sovereign entities, they operate under their own constitutions, enact their own laws, and provide services to their citizens.

[14]2021 Or. Laws Ch. 1 (B.M. 109). Or. Rev. St. §§ 475A.210-722.

for the purpose of personal use without remuneration for persons 21 years of age and older.[15]

See appendices I and II, for additional information on the legalization and regulation of psilocybin in Oregon and Colorado.

Deprioritization. The District of Columbia has not legalized or decriminalized the use of psilocybin,[16] but under the D.C. Code, generally, the Metropolitan Police Department is to make the investigation and arrest of persons 18 years of age or older for non-commercial planting, cultivating, purchasing, transporting, distributing, or possessing certain entheogenic plants and fungi, including psilocybin, as among its lowest enforcement priorities—as of March 2021.[17] In addition, pursuant to D.C. Code § 48-921.53, "[t]he people of the District of Columbia call upon the Attorney General of the District of Columbia and the United States Attorney for the District of Columbia to cease prosecution of residents of the District of Columbia for non-commercial planting, non-commercial cultivating, purchasing, transporting, distributing, engaging in practices with, and/or possessing entheogenic plants and fungi as defined in [D.C. Code] § 48-921.52."

State-level initiatives. Some states have not decriminalized, deprioritized, or legalized psilocybin but have state laws establishing state-level pilot research programs and studies. For example, Connecticut required the Department of Mental Health and Addiction Services to establish, within available appropriations, a psychedelic-assisted therapy pilot program,[18] to be administered by a medical school in the state by January 1, 2023.[19] In addition, Maryland established the Post-Traumatic Stress Disorder and Traumatic Brain Injury Alternative Therapies Fund to

[15]2023 Colo. Legis. Serv. Ch. 249.

[16]D.C. Code § 48-902.04(3)(R).

[17]D.C. Code § 48-921.52. Generally, the term "entheogenic plant and fungus" means any plant or fungus of any species in which there is naturally occurring any of the following substances in any form, which would cause such plant or fungus to be described as a Schedule I controlled substance under D.C. Code § 48-902.04(3): ibogaine, dimethyltryptamine (DMT), mescaline, psilocybin, or psilocyn.

[18]The pilot program is required to provide qualified patients with 3,4-Methylenedioxymethamphetamine (MDMA)-assisted or psilocybin-assisted therapy as part of a research program approved by FDA pursuant to 21 C.F.R. pt. 312.

[19]Conn. Gen. Stat. § 17a-484g.

study the use of and provide cost-free access to alternative therapies, including the use of psilocybin, for post-traumatic stress disorder and traumatic brain injuries in veterans.[20] For an overview of some of the characteristics of selected states with legislation establishing a pilot program or study of psilocybin for therapeutic use, see appendix III.

Local-level decriminalization/deprioritization. Some localities and a municipal government have allowed for use of psilocybin even though the respective state has not decriminalized or deprioritized enforcement of psilocybin. For example, in June 2019, the City Council in Oakland, California, voted unanimously to decriminalize the adult use and possession of psilocybin and other entheogenic, or psychoactive, plants, and fungi. As a result, the city's funds are not allowed to be used to enforce laws criminalizing such substances—the Alameda County District Attorney stopped prosecuting people who have been apprehended for use or possession of such substances.

Even though some states and localities have taken steps to legalize, decriminalize, or deprioritize the personal use or possession of psilocybin, the Controlled Substances Act generally provides federal sanctions for the unauthorized possession, manufacture, distribution, or dispensing of Schedule I controlled substances, including psilocybin.[21] In addition, pursuant to federal law, it is generally unlawful to knowingly open, lease, rent, use, or maintain any place for the purpose of manufacturing, distributing, or using any controlled substance.[22]

Federal Roles and Responsibilities Enforcing the Controlled Substances Act

DEA is the primary federal law enforcement agency responsible for conducting criminal and regulatory investigations of potential violations of the Controlled Substances Act and works to disrupt and dismantle the leadership, command, control, and financial infrastructure of major drug-trafficking organizations. DEA uses a multifaceted approach that includes:

- investigating narcotics cases and preparing them for prosecution;

[20]Md. Code Ann. Health-Gen. § 24-2102. Pursuant to Md. Code Ann. Health-Gen. § 24-2101(b), "'alternative therapies' includes hyperbaric oxygen therapy and psychedelics including 3,4—Methylenedioxymethamphetamine (MDMA), psilocybin, and ketamine." Pursuant to Md. Code Ann. Health-Gen. § 24-2101(d), "veteran" means a former member of the following entities who was discharged from active duty: the armed forces of the United States; a reserve component of the armed forces of the United States; or the National Guard of any state.

[21]21 U.S.C. §§ 841, 844.

[22]21 U.S.C. § 856.

- managing a national drug intelligence program to collect, analyze, and disseminate drug intelligence;
- enforcing counternarcotics laws involving the diversion of legally produced substances for illegal purposes; and
- coordinating with and leveraging the resources of international, federal, state, and local partners.

DEA is also responsible for investigating and enforcing potential violations of the Controlled Substances Act in Indian country.[23] The Federal Bureau of Investigation (FBI) also investigates cases related to violations of the Controlled Substances Act.[24] DEA coordinates and collaborates with state and local law enforcement agencies to implement or enforce the Act by sharing information and partnering in investigations and enforcement actions. DEA also manages and reviews petitions seeking religious exemptions from the Controlled Substances Act under the Religious Freedom Restoration Act to permit the use of controlled substances, including psilocybin. Within DEA, the Diversion Control Division's Diversion Regulatory Section and the Import/Export Section are the two main components that carry out this process.

In addition to DEA and FBI, several other federal departments and agencies are involved in efforts to address controlled substances, including psilocybin, in the United States. Appendix IV provides some examples of the key federal agencies involved in these efforts.

The DEA is the principal agency that oversees the process for researchers to apply for authorization to study Schedule I controlled

[23]Pursuant to 18 U.S.C. § 1151, the term "Indian country" generally means "(a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation, (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state, and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same." Generally, DEA's jurisdiction for narcotics investigations in Indian country is based on the Controlled Substances Act, 21 U.S.C. §§ 801-971, which applies throughout the United States, including in Indian country.

[24]Under 28 C.F.R. § 0.85, the FBI has the authority to investigate violations of the laws, including the criminal drug laws, of the United States and collect evidence in cases in which the United States is or may be a party in interest, except in cases in which such responsibility is by statute or otherwise exclusively assigned to another investigative agency.

substances. However, FDA also has responsibilities in this process, which we discuss in more detail later in the report.

Federal Process to Obtain Permission to Study Psilocybin

Individuals or entities interested in working with Schedule I controlled substances, such as psilocybin, must meet DEA requirements for registration, ordering, recordkeeping, inventory, storage, and disposal of the controlled substances. Such individuals or entities include manufacturers, distributors, researchers, practitioners, and pharmacists. An individual or entity's registration lasts between 1 and 3 years. Separate registrations are required for each place of business where a controlled substance is involved in a study, manufactured, distributed, imported, exported, or dispensed.

Registrants are to follow guidelines related to recordkeeping and reporting of the inventory and distribution of the controlled substances they have been approved to study. Additionally, they are subject to DEA inspection of the place of business, and they must implement controls to guard against theft or diversion of controlled substances. Specifically, nonpractitioners-such as researchers-must follow certain requirements when storing controlled substances and have adequate security measures to provide effective controls and procedures to guard against theft and diversion of controlled substances.

Generally, the Attorney General may deny, suspend, or revoke a registration for a practitioner to conduct research with Schedule I controlled substances upon a finding that the registrant has:

1. materially falsified any application;
2. been convicted of a felony relating to a controlled substance or certain chemicals;
3. had a state license or registration suspended, revoked, or denied by a competent state authority, or has had a suspension, revocation, or denial of a registration recommended by a competent state authority;
4. committed acts which would render the registration inconsistent with the public interest; or

5. been excluded (or directed to be excluded) from participation in certain federal health care programs.[25]

In 2021, we reported an interagency workgroup, that was facilitated by the Office of National Drug Control Policy (ONDCP) and included DEA, had developed recommendations to enact legislation to accomplish several goals, including: requiring the Attorney General and the Secretary of Health and Human Services conduct a review of the process for obtaining or modifying a research registration under the Controlled Substances Act to identify redundancies, inefficiencies, or burdens on persons seeking registrations that can be reduced while ensuring public safety; and subsequently requiring the Attorney General and the Secretary of Health and Human Services to issue joint guidance clarifying the registration process, among other recommendations.[26]

Federal Pathways Permitting Religious, Spiritual, or Medical Use of Controlled Substances

Various pathways allow for individuals or organizations to apply for exemptions which would allow for the religious or spiritual use, in limited circumstances, of psilocybin, or the use of controlled substances for medical advances, research, and treatment.

Religious Exemptions. Generally, the Religious Freedom Restoration Act provides for an individual or entity the opportunity for judicial review of government action that substantially burdens a person's religious exercise. The Act provides that the "[g]overnment shall not substantially burden a person's exercise of religion" unless the Government can demonstrate "that application of the burden to the person is in furtherance

[25]21 U.S.C. §§ 823(g)(2)(A), 824(a).

[26]The workgroup recommendations also addressed allowing registered researchers to store, administer, and otherwise work with any substances for which they hold a researcher registration at multiple practice sites on a single contiguous campus. GAO, *Synthetic Opioids: Considerations for the Class-Wide Scheduling of Fentanyl-Related Substances,* GAO-21-499 (Washington, D.C. Apr. 2021).

of a compelling governmental interest and is the least restrictive means of furthering that compelling governmental interest."[27]

Generally, a person claiming that the government has placed a substantial burden on the person's practice of religion for purposes of the Religious Freedom Restoration Act must establish that the government action: (1) substantially burdens; (2) a religious belief, not just a philosophy or way of life; (3) which belief is sincerely held. Once the person has demonstrated that the government has burdened the person's exercise of religion, the government must demonstrate the government action being challenged furthers a compelling governmental interest by the least restrictive means.

In general, the Religious Freedom Restoration Act provides for a heightened standard of review for government actions, including rules of general applicability, that "substantially burden" a person's religious exercise. Typically, this burden exists when an individual must choose between refraining from following the individual's religious beliefs to avoid facing legal penalties from the government or following the individual's religious beliefs and foregoing the receipt of a government benefit. A person whose religious exercise has been burdened in violation of the Religious Freedom Restoration Act may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government.[28] This includes actions taken by the federal government pursuant to the Controlled Substances Act.[29] For example, an individual

[27]Pub. L. No. 103-141, § 3, 107 Stat. 1488, 1488-89 (codified at 42 U.S.C. § 2000bb-1). The Religious Freedom Restoration Act was enacted in response to a 1990 Supreme Court case, *Employment Division v. Smith*, 494 U.S. 872 (1990), where the Court held, in part, that generally applicable, religion-neutral criminal laws that have the effect of burdening a particular religious practice need not be justified, under the free exercise of religion clause, by a compelling governmental interest. In this case, two drug rehabilitation counselors, both of whom were members of the Native American Church, were fired from their jobs with a private corporation in Oregon because they had ingested peyote, a hallucinogenic drug, for sacramental purposes at a ceremony of the Church. The counselors applied to the Employment Division of Oregon's Department of Human Resources for unemployment compensation, but the department's Employment Appeals Board ultimately denied their applications on the ground that the counselors had been discharged for misconduct connected with work. Section 2 of the Religious Freedom Restoration Act, Pub. L. No. 103-141, § 2, 107 Stat, 1488 specifically addressed the Supreme Court's holding in *Employment Division v. Smith*, 494 U.S. 872 (1990) with the purposes of the Act to restore the compelling interest test and to guarantee its application in all cases where free exercise of religion is substantially burdened.

[28]42 U.S.C. § 2000bb-1(c).

[29]Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal**,** 546 U.S. 418 (2006).

or entity may bring a suit to prohibit the federal government from enforcing the Controlled Substances Act to ban the use of a controlled substance in religious ceremonies under the Religious Freedom Restoration Act. In addition, an individual or entity prosecuted under the Controlled Substances Act may raise as a defense to such prosecution that the federal government has placed a substantial burden on the individual or entity's practice of religion for purposes of the Religious Freedom Restoration Act.

In order to reconcile and balance the interests of the Controlled Substances Act and Religious Freedom Restoration Act, in 2009, DEA first promulgated a guidance document establishing a procedure for seeking religious exemptions from the Controlled Substances Act from DEA. In November 2020, this guidance was updated and provides a process for individuals or entities to petition for an exemption from the Controlled Substances Act to use certain controlled substances for religious circumstances.[30] We discuss DEA's establishment of a process to review religious exemptions to the Controlled Substances Act under the Religious Freedom Restoration Act later in the report.

Clinical Trials. The development and approval of a new drug is a complex and costly process that can take several years. Typically, the drug development process involves a number of stages, including basic research,[31] drug discovery,[32] preclinical research,[33] clinical trials, and

[30]According to DEA officials, DEA's Diversion Regulatory Section and the Import/Export Section are the two components within DEA's Diversion Control Division that process Religious Freedom Restoration Act applications for the use of psilocybin. The Diversion Regulatory Section typically coordinates with the Office of Chief Counsel, DEA field offices, and any other Diversion Control Division sections where information can be gained to further assist with the processing of petitions under the Religious Freedom Restoration Act.

[31]Basic research may involve the scientific investigation of the molecular, cellular, or biological mechanisms of a disease that lays the foundation for the development of new drugs.

[32]Drug discovery may involve the screening of thousands of compounds in the laboratory to identify promising candidates to treat the disease.

[33]Preclinical research may involve laboratory and animal testing to further narrow the list of compounds and answer basic questions about safety and proof of concept.

review and approval.[34] Clinical trials involve the testing of the drug in human volunteers for safety and efficacy which is conducted in phases. Clinical trials are usually conducted in phases that build on one another, though the phases may overlap. Phase one trials generally test the safety of a drug with a small group of healthy volunteers (usually fewer than 100) to determine the drug's initial safety profile and find the highest dose of the new drug or treatment that can be given safely without causing severe side effects. If the drug does not show unacceptable toxicity in phase one clinical trials, phase two clinical trials are conducted in a larger group of volunteers (usually dozens to hundreds) to assess the drug's safety and effectiveness for a particular disease or condition and determine common short-term side effects and risks.

In phase two clinical trials, generally some volunteers receive the drug and others receive a control, such as a placebo. If there is evidence that the drug is effective in phase two clinical trials, phase three clinical trials are conducted to gather additional information on the drug's safety and effectiveness in several thousand volunteers. According to GAO's review of the National Institutes of Health's clinicaltrials.gov database, current research is investigating the effects of psilocybin on conditions such as depression, anxiety, headaches, fibromyalgia and other pain, substance use (including alcohol, tobacco, and opioids), eating disorders, obsessive-compulsive disorder, and post-traumatic stress disorder, among other things.[35]

Access to Investigational Drugs. Patients who are unable to participate in clinical trials may seek access to investigational drugs through two pathways: (1) expanded access and (2) the Right to Try Act.[36] Under either pathway, patients may only access the investigational drug if the drug sponsor agrees to provide access. Expanded access is the use of an investigational drug outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there

[34]Review and approval involve the FDA conducting a regulatory review and approval of the drug for marketing and sales in the United States if it is found to be safe and effective for its intended use.

[35]The National Institutes of Health's National Library of Medicine manages ClinicalTrials.gov, a website and online database of clinical research studies from around the world, including psilocybin-related clinical trials. The purpose of ClinicalTrials.gov is to provide information about clinical research studies to the public, researchers, and health care professionals. We reviewed the data including summaries and conditions studied for 139 clinical trials, as of September 18, 2023.

[36]Investigational drugs have not yet been approved by FDA.

are no comparable or alternative satisfactory options.[37] Requests for expanded access must be reviewed by FDA and an Institutional Review Board. Patients diagnosed with life-threatening diseases or conditions who have exhausted approved treatment options may also be able to access investigational drugs through the Right to Try Act.[38] Unlike expanded access, the Right to Try Act does not require FDA or an institutional review board to review individual requests. The treating physician is responsible for requesting access to the investigational drug and for obtaining informed consent from the patient. FDA's role in implementing this Act is limited to receiving and posting certain information submitted to the agency.

Breakthrough Therapies. Breakthrough therapy designation was established by the Food and Drug Administration Safety and Innovation Act and is a process designed to expedite the development and review of drugs intended to treat a serious or life-threatening disease or condition.[39] A sponsor of a drug may request FDA to designate the drug as a breakthrough therapy.[40] Not later than 60 calendar days after the receipt of a sponsor's request, FDA is required to determine whether the drug that is the subject of the request is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.[41] If FDA finds that the drug meets these criteria, FDA is required to designate the drug as a breakthrough therapy and take appropriate actions to expedite the development and review of the application for approval of such drug.[42] Two entities reported that FDA has granted breakthrough therapy designations: COMPASS Pathways for its psilocybin therapy treating treatment-resistant

[37]See 21 U.S.C. § 360bbb and 21 C.F.R. Part 312, Subpart I (2023).

[38]Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, Pub. L. No. 115-176, 132 Stat. 1372 (2018) (codified at 21 U.S.C. § 360bbb-0a).

[39]Pub. L. No. 112-144, § 902, 126 Stat. 993, 1086-88 (2012).

[40]21 U.S.C. § 356(a)(2).

[41]21 U.S.C. § 356(a)(1), (a)(3)(A).

[42]21 U.S.C. § 356(a)(3)(A).

depression and Usona Institute for its psilocybin program treating major depressive disorder.[43]

Psilocybin Investigations, Forensic Laboratory Reports, and Seizures Are Few Relative to Other Schedule I Drugs

DEA Closed 24 Criminal Investigations in Which Psilocybin Was the Harshest Drug Involved During Fiscal Years 2018 through 2023

Over a 6-year period—fiscal years 2018 through 2023—the DEA closed a total of 24 investigations where psilocybin was the harshest drug involved, which represents less than one percent of closed investigations involving all Schedule I controlled substances, according to DEA officials.[44] DEA officials added that because its data management system only records the drug involved in an investigation that is designated as the harshest, psilocybin may be involved in other DEA investigations but may be underreported due to the presence of harsher drugs, such as heroin or methamphetamine.[45] According to DEA officials, as of July 2023, the agency had 609 open investigations involving Schedule I controlled substances and psilocybin was the harshest drug in 16 of the investigations—representing about three percent of the total open

[43]Compass Pathways is a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. The company studies investigational psilocybin therapy (also known as psilocybin treatment), administered with psychological support, as a treatment for certain mental health conditions. The Usona Institute is a medical research organization dedicated to supporting and conducting basic, pre-clinical and clinical research to further the scientific understanding and therapeutic application of consciousness-expanding medicines.

[44]DEA considers closed investigations to include cases where DEA has concluded all investigation and prosecutorial related activities.

[45]According to DEA officials, the harshest drugs include controlled substances considered to pose more serious public health and safety threats.

investigations.[46] DEA officials said the agency usually focuses its investigative resources on controlled substances related cases that involve high-level drug trafficking organizations or are considered significant to the agency's enforcement efforts. Table 1 identifies the number of DEA closed investigations involving Schedule I controlled substances (including psilocybin) for each fiscal year—2018 through 2023.

Table 1: Drug Enforcement Administration's Closed Investigations Involving Schedule I Controlled Substances for Each Fiscal Year—2018 through 2023

Schedule I controlled substances[a]	Drug Enforcement Agency: Closed Investigations by Fiscal Year (FY)						
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	Total closed investigations
Psilocybin	3	2	1	4	8	6	**24**
All other Schedule I controlled substances	1,602	2,587	2,526	2,721	2,582	1,847	**13,865**
Total closed investigations	**1,605**	**2,589**	**2,527**	**2,725**	**2,590**	**1,853**	**13.889**

Source: GAO analysis of DEA's enforcement data. | GAO-24-106630

Note: According to DEA officials, DEA tracks its investigations by one drug type—typically the drug involved in the investigation that is considered the harshest by the agency.

[a]The Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1242, places all federally controlled substances in one of five "schedules" depending, among other things, on the drug's likelihood for abuse or dependence, and whether the drug has an accepted medical use. These schedules range from I through V – with Schedule I having the greatest restrictions. Schedule I controlled substances are those that have been found to have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

Psilocybin-Related Reports Voluntarily Reported by Laboratories Increased but Were Less than One Percent of Overall Drug Reports from 2018 through 2022

[46]According to DEA officials, the FBI has not initiated investigations exclusively related to psilocybin during fiscal years 2018 through 2023; however, it has encountered psilocybin in numerous investigations during the time period.

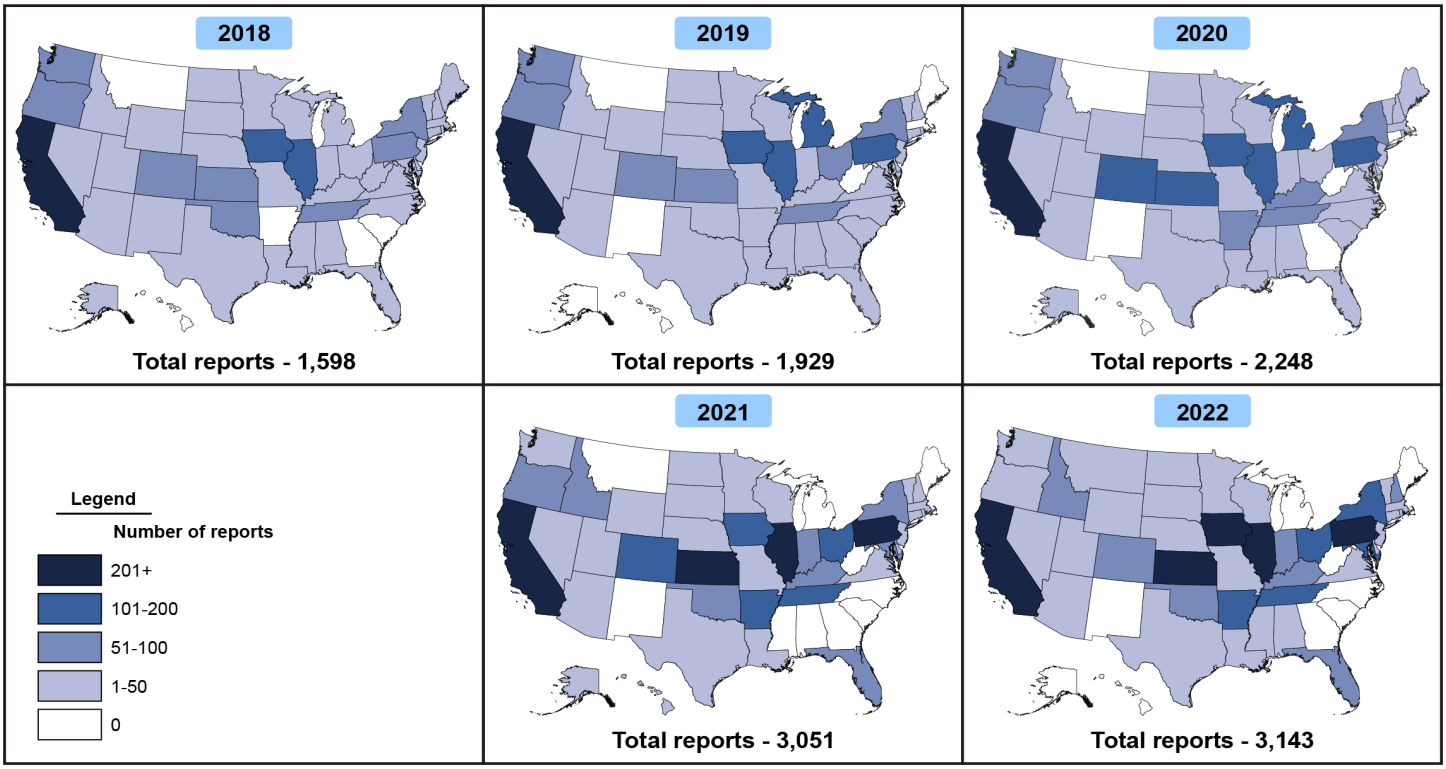
According to our analysis of DEA's National Forensic Laboratory Information System drug component data,[47] the number of psilocybin-related reports (reports of psilocybin; psilocin, another Schedule I controlled substance derived from certain types of psychedelic mushrooms; and a combination of psilocybin and psilocin) increased from 1,598 in calendar year 2018 to 3,143 in calendar year 2022.[48] This represented less than one percent of the total annual reports for each of the calendar years from 2018 through 2022. During this period, California, Illinois, Kansas, and Pennsylvania saw the largest increase in the number of psilocybin-related reports.

DEA's National Forensic Laboratory Information System systematically collects drug identification results and associated information from drug reports submitted to and analyzed by federal, state, and local forensic laboratories. The laboratory system includes voluntary participation from 50 state systems and 111 local or municipal laboratories, representing a total of 286 individual laboratories. DEA data include results for drug reports submitted by DEA agents, other federal law enforcement agencies, and select local police agencies. In addition to drug reports from DEA, reports from seven CBP laboratories are also included. According to DEA officials, the forensic laboratories exist to support investigations and court cases. Figure 1 identifies the number of psilocybin-related drugs voluntarily reported by forensic laboratories in the various states for calendar years 2018 through 2022.

[47]The data in DEA's National Forensic Laboratory Information System is made up of data reported by forensic laboratories that voluntarily report the results of forensic testing and analysis conducted on substances seized by law enforcement operations. The term "report" is used to represent an item or exhibit that was secured in law enforcement operations and positively identified by a forensic laboratory to contain a particular substance, such as psilocybin.

[48]According to DEA officials, the data presented are sums of reports of psilocybin, psilocin, and psilocin and/or psilocybin. Psilocin (or "psilocyn") is a schedule I controlled substance found in psychedelic mushrooms. 21 U.S.C. § 812(c), Schedule I (c)(16).

Figure 1: Number of Psilocybin-Related Reports Voluntarily-Reported by Forensic Laboratories by State, Calendar Years 2018 through 2022



Source: GAO analysis of Drug Enforcement Administration's National Forensic Laboratory Information System Data. | GAO-24-106630

Note: The term "report" is used to represent an item or exhibit that was secured in law enforcement operations and positively identified by a forensic laboratory to contain a particular substance, such as psilocybin, psilocin, and psilocybin and/or psilocin. Psilocin (or "psilocyn") is a Schedule I controlled substance found in psychedelic mushrooms. 21 U.S.C. § 812(c), Schedule I (c)(16).

Federal Prosecution Data Do Not Track Psilocybin

For fiscal years 2018 through 2023, Executive Office for United States Attorneys (EOUSA) officials stated that it is unable to identify the number of cases prosecuted by U.S. Attorneys' offices related to psilocybin under the Controlled Substances Act, including cases for simple possession, manufacturing, distributing, or dispensing of psilocybin, because this drug type is not specifically identified in CaseView or other database systems the U.S. Attorneys' offices use to manage cases.[49] However, according to EOUSA officials, the inability to identify these types of cases does not

[49]CaseView is the case management system for the U.S. Attorneys' offices.

mean that DOJ has not and does not prosecute Controlled Substances Act violations related to psilocybin.

CBP Seizures Involving Psilocybin Accounted for About 2 Percent of the Agency's Total Drug Seizures During Fiscal Years 2018 through 2023

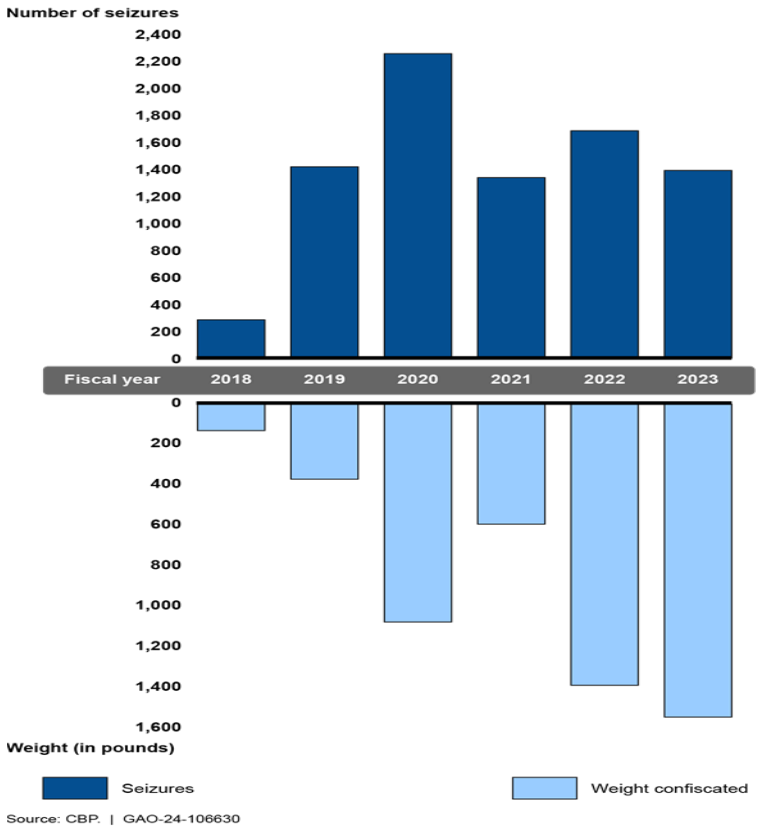
DHS's CBP reported the seizure of 49 different drug types—representing a total of 371,088 drug seizures—over the last 6-years (fiscal years 2018 through September 18, 2023). During this period, psilocybin accounted for 8,349 drug seizures—representing about 2 percent of the total seizures reported by CBP. Another Schedule I controlled substance that is classified as a hallucinogen, LSD,[50] accounted for 13,489 drug seizures—representing 4 percent of the total seizures reported by CBP during the same period. CBP's drug seizures most often involved marijuana[51] (80,583 seizures—representing about 22 percent of CBP's total seizures) during the 6-year time frame.

During fiscal years 2018 through September 18, 2023, CBP's seizure data show that the number and weight of its drug seizures involving psilocybin generally increased—accounting for about a 400 percent increase in the number of psilocybin seizures and over a 1,000 percent increase in the weight (in pounds) of the seizures. Over this six-year period, CBP's Chicago Field Office location accounted for about 37 percent (3,081), which is the CBP field office with the largest number of the seizures related to psilocybin. Figure 2 identifies the number and weight of CBP's drug seizures involving psilocybin for each fiscal year—2018 through September 18, 2023.

[50]21 U.S.C. § 812(c), Schedule I (c)(9).

[51]21 U.S.C. § 812(c), Schedule I (c)(10) (referred to as "marihuana").

Figure 2: Number and Weight of U.S. Customs and Border Protection's Drug Seizures Involving Psilocybin for Each Fiscal Year, 2018 through September 18, 2023



Source: CBP. | GAO-24-106630

Application Process to Conduct Psilocybin Research and Stakeholders' Perspectives

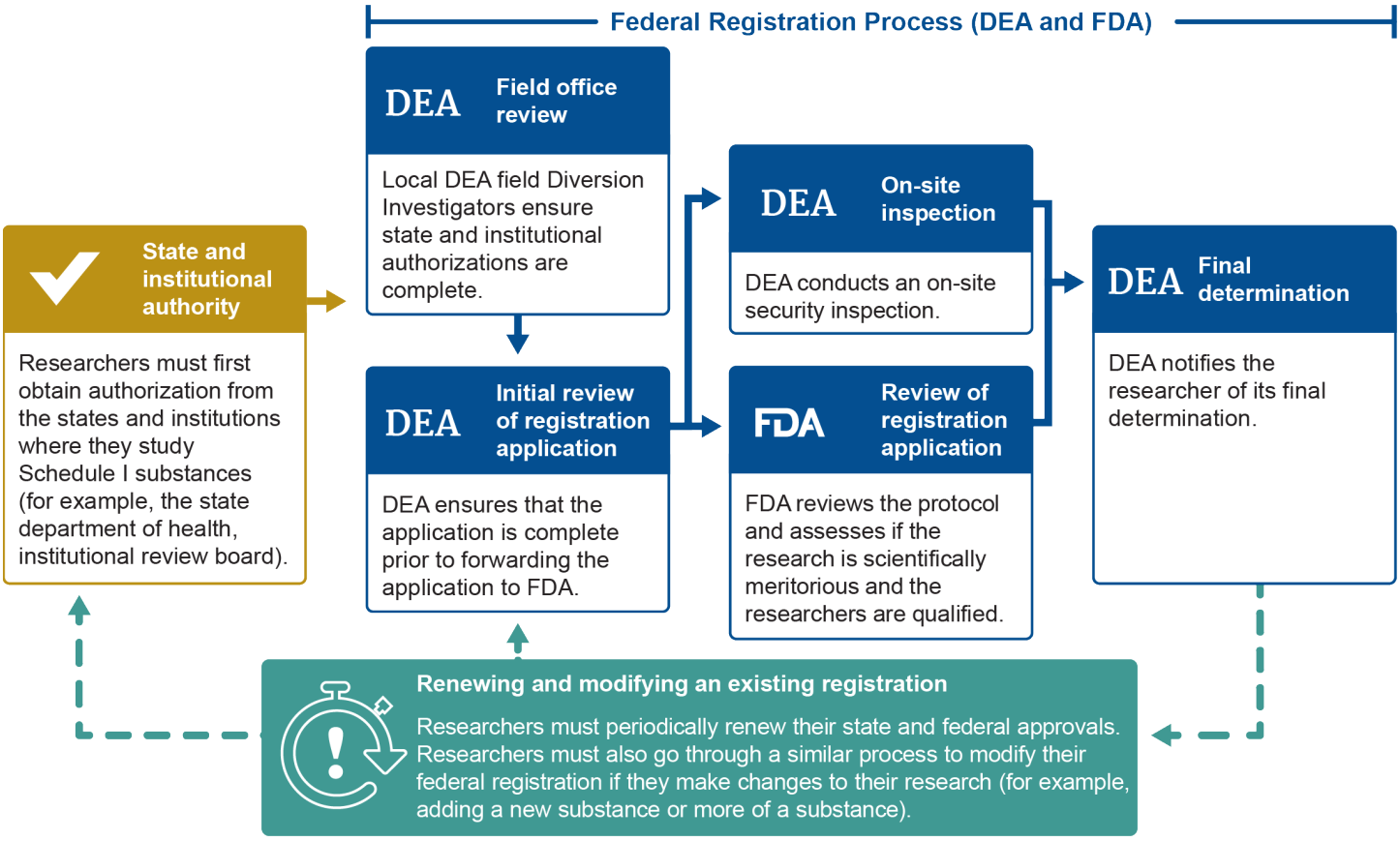
To conduct research involving psilocybin, researchers must (1) obtain approvals from their respective states and institutions, (2) be registered with DEA to conduct research with schedule I controlled substances and be authorized to carry out a specific research protocol involving psilocybin,[52] and (3) if the research involves human subjects (clinical trials), submit to FDA an investigational new drug (IND) application, which must be in effect at the time the research is being conducted.[53] In 2022, DEA updated its Researcher's Manual, which provides guidance for new and current research registrants who intend to conduct research with

[52]21 U.S.C. § 823(g)(2); 21 C.F.R. §§ 1301.18, 1308.32.

[53]21 U.S.C. § 355(i); 21 C.F.R. Part 312 (2023).

Schedule I controlled substances, such as psilocybin.[54] The guidance outlines DEA's requirements for researchers related to registration, ordering, recordkeeping, inventory, storage, and disposal of controlled substances. Based on the guidance, a researcher's registration must be renewed annually. Figure 3 provides an overview of the process to obtain authorization to conduct research on Schedule I controlled substances.

Figure 3: The Process to Obtain Authorization to Conduct Research on Schedule I Controlled Substances



DEA Drug Enforcement Administration **FDA** Food and Drug Administration

Source: GAO analysis of DEA and FDA information; agency logos courtesy of respective agencies; GAO adaptation of AtScene/stock.adobe.com illustration (clock); GAO (icon). | GAO-24-106630

[54]DOJ, Drug Enforcement Administration, Diversion Control Division, *Researcher's Manual: An Informational Outline of the Controlled Substances Act* (Revised 2022) DEA-DC-057, EO-DEA217 (Springfield, VA.: June 15, 2022).

State and institutional authorization. Before applying for DEA registration, researchers must obtain authorization from their sponsoring institution and the state in which the institution is registered with the DEA. Specific requirements vary by state and institution, and applicants may contact their local diversion field office on clarification on state laws and regulations before completing their application, according to DEA's research manual.

Initial DEA review of registration application. After obtaining the necessary state and institutional authorization, a researcher must apply to receive a registration from DEA. DEA's Registration and Program Support Section receives registration applications and DEA's Drug and Chemical Evaluation Section reviews the applications for completeness. Applications are to include information such as the researcher's professional curriculum vitae, substances being studied and their amounts, and the location(s) where the research will take place.

FDA review of investigational new drug application. Before obtaining a DEA registration, researchers who intend to conduct investigations involving human subjects (clinical trials) are required to submit an IND application to FDA.[55] During this time, FDA has an opportunity to review. Generally, an IND application goes into effect 30 days after it has been submitted, unless FDA issues a clinical hold to delay the proposed trial. During this time, FDA has an opportunity to review the application to ensure the safety and rights of trial participants.

FDA review of registration application and DEA onsite inspection. Once DEA completes its initial review to ensure the application is complete, it sends the application to FDA for review and determination on whether applicants are qualified and the research protocol has scientific merit.[56] Simultaneously, DEA's field offices conduct an on-site inspection of research facilities for security of the controlled substances and a background inspection of the researcher and individuals handling the controlled substances.

DEA final review and determination. Following FDA advisement to DEA on the research protocol merits and investigator qualifications, the diversion investigator assigned to the registration application can make the final determination to approve or deny the application. Once the on-

[55]21 U.S.C. § 355(i); 21 C.F.R. Part 312 (2023).

[56]21 U.S.C. § 823(g)(2); 21 C.F.R. § 1308.32.

site inspection and all related matters are complete, DEA notifies the researcher of its final determination.

DEA uses the Registrant Information Consolidated System to review applications requesting authority to conduct Schedule I-based research and manages DEA's research registrant data for those approved to work with controlled substances.[57] Based on DEA's data, in fiscal year 2018, the new registrations approved for psilocybin studies represented about 3 percent (4 out of 153 approvals) of the new research registrations for all Schedule I controlled substances. In fiscal year 2022, the new registrations approved for psilocybin studies increased to about 29 percent (39 out of 134 approvals) of the new research registrations for all Schedule I controlled substances. See table 2 for additional information on DEA's new research registration approvals for each fiscal year—2018 through 2023.

Table 2: Drug Enforcement Administration's (DEA) New Research Registrations for Each Fiscal Year—2018 through 2023

New research registrations	Number of DEA's New Research Registrations by Fiscal Year (FY)					
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023 (partial)[a]
Psilocybin approvals	4	11	16	26	39	28
Total Schedule I drug approvals	**153**	**189**	**113**	**120**	**134**	**71**

Source: Data from DEA's Registrant Information Consolidated System. | GAO-24-106630

Note: The new research registrations approvals for the psilocybin category are a subset of the category for the total new research registrations for Schedule I drug approvals.

[a]The fiscal year 2023 data represent the period covering October 1 through March 31. The data for the remaining fiscal years represent the period covering October 1 through September 30.

Based on DEA's data, in fiscal year 2018, the active registrations for psilocybin studies represented about 5 percent (32 out of 693 approvals) of the active research registrations for all Schedule I drugs. In fiscal year 2022, the active registrations approved for psilocybin studies increased to

[57]The Registrant Information Consolidated System is a database that consolidates several of DEA's internal systems, each with its own uniquely different functions, that DEA uses to manage all registrant actions and information records. In addition, the system allows DEA field divisions to know when registrants are being investigated at the national level to avoid duplicate efforts.

about 18 percent (148 out of 819 approvals) of the active research registrations for all Schedule I controlled substances. See table 3 for additional information on DEA's active approved research registrations for each fiscal year—2018 through 2023.

Table 3: Drug Enforcement Administration's (DEA) Active Approved Research Registrations for Each Fiscal Year—2018 through 2023

Active approved research registrations	Number of DEA's Active Research Registrations by Fiscal Year (FY)					
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023 (partial)[a]
Psilocybin registrations	32	47	65	100	148	181
All Schedule I drug registrations	693	820	832	804	819	842

Source: Data from DEA's Registrant Information Consolidated System. | GAO-24-106630

Note: The active research registrations approvals for the psilocybin category are a subset of the category for the total active research registrations for Schedule I drug approvals.

[a]The fiscal year 2023 data represent the period covering October 1 through March 31. The data for the remaining fiscal years represent the period covering October 1 through September 30.

Selected stakeholders we interviewed provided feedback on DEA's process for authorizing research to study a Schedule I controlled substance.[58] We also obtained comments from DEA officials regarding some of the concerns shared by these stakeholders.

License requirements. According to a selected stakeholder from a large university, they must obtain a DEA license for each building included in a psilocybin-related study. The stakeholder said that these steps are redundant and time consuming for a registrant with one study across multiple buildings. By regulation, a separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured,

[58]We interviewed four stakeholder organizations representing two universities and two research institutes that sponsor psilocybin-based research. We selected these stakeholders based on the literature reviews we conducted, and comments received from individuals regarded as knowledgeable and considered to have a high-level of experience in psilocybin-based clinical research.

distributed, imported, exported, or dispensed by a person.[59] DEA officials explained that this requirement is intended to prevent diversion as the transport of a controlled substance from one location to another can be a security risk.[60]

Time requirements. According to a selected stakeholder who represented an organization involved in psilocybin-related research, the DEA registration process has detailed requirements that take up staff time and lead to delays without adding significantly to preventing the misuse of a controlled substance. DEA officials stated the longest delay in processing an application is typically when waiting for an applicant to provide all the necessary information to complete their application package. The officials added that the research protocols (i.e., Institutional Review Board, Institutional Animal Care and Use Committee approval documentation, investigational new drug application, drug amount/quantity/source, security, and storage specifications) are all documents and information that the researchers should have in place before applying for a DEA registration. The DEA officials said the application package does not require new or novel information; rather, it simply requires the transmission of information the researchers should already have or know. DEA cannot transmit the application package to FDA for review until all the necessary information is obtained. According to DEA officials, DEA staff work with researchers to gather all the necessary documentation to assure compliance with the Controlled Substances Act.

DEA headquarters communication. According to a selected researcher who represented an organization involved in psilocybin-related research, researchers' communication with DEA headquarters is challenging unless working with a specific point of contact. For example, some emails sent to DEA headquarters' general email inboxes either bounce back or go unanswered. DEA officials noted that it could not speak to all the agency's general email inboxes but described the inbox for Schedule I

[59]21 C.F.R. § 1301.12(a).

[60]According to DEA, many problems associated with drug abuse are the result of legitimately made controlled substances being diverted from their lawful purpose into illicit drug traffic. DEA's Diversion Control Division is tasked to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

research inquiries as being regularly monitored, and that its messages are swiftly responded to by staff.

DEA not communicating with sponsors. One selected stakeholder operating as a sponsor of psilocybin-based research explained that DEA's refusal to communicate directly with sponsors prolonged the challenges one of their researchers had been experiencing. In this instance, the researcher had questions regarding DEA Form 222 but had not received support from DEA, leaving the researcher to approach their sponsor for guidance which forced the two parties to spend time screen-sharing to trouble-shoot the issue.[61]

DEA officials explained that all agency communications be made directly with research registrants due to privacy concerns. The DEA referenced that research registrants may provide explicit permission for DEA to communicate with an approved party, like a sponsor. According to DEA officials, sponsors and contractors who represent sponsors are not registrants. DEA staff do work with sponsors in general terms to help them prepare for large, multi-site studies to assure the approval process goes as smoothly as possible. The DEA officials stated that when dealing with specific registrations and applications, communications are directed to the researcher. In addition, researchers can seek clarification and help through their assigned diversion investigator and the DPEScheduleIResearch@dea.gov mailbox.

The same selected stakeholders we spoke with also provided general perspectives on the process to obtain federal authorization to conduct research with a Schedule I controlled substance.

Working with FDA. One selected stakeholder described FDA as being very involved and communicative throughout the process, while characterizing FDA's involvement as friendly and helpful. Additionally, this selected stakeholder noted that the requirements set by FDA were relevant to the safety of research participants and appeared to be appropriate for such research to take place. According to DEA officials, this comment may be relevant to the IND application review process, which is different from the Schedule I research review process. FDA's controlled substances personnel do not communicate directly with

[61]DEA's Office of Diversion Control will accept requests from distributors that require a large volume of Order Forms (DEA Form 222)—the forms are used for the distribution of a Schedule I or II controlled substance.

researchers, instead communicating back to DEA to address any concerns.

Local DEA offices. Another selected researcher highlighted their local DEA office as being very responsive and accessible, which has enabled them to receive timely responses to questions throughout the process.

Inventory record-keeping requirements. One selected stakeholder stated that the federal requirements set for the record-keeping of its inventory were not too burdensome as they are considered standard requirements for research laboratories to uphold. With respect to researchers, generally, each person registered or authorized to dispense or conduct research with controlled substances is required by regulation to include in the inventory a complete and accurate record of all controlled substances on hand on the date the inventory is taken. For example, this inventory is required to include for each controlled substance in finished form, the name of the substance; each finished form of the substance; the number of units or volume of each finished form in each commercial container; and the number of commercial containers of each such finished form.[62]

Aspects of DEA's Religious Freedom Restoration Act Exemption Review Process Are Unclear to Petitioners

DEA Established a Petition for Religious Exemption to Meet Legal Requirements

DEA established a process for individuals and entities to apply for religious exemption to the Controlled Substances Act under the Religious Freedom Restoration Act in response to a Supreme Court case. The Supreme Court held that government action taken pursuant to the

[62]21 C.F.R. § 1304.11.

DEA Established a Process for Applying for Religious Exemption to the Controlled Substances Act Under the Religious Freedom Restoration Act in Response to a Supreme Court Case

Gonzales v. O Centro – Compelling Interest Test

In O Centro, a religious sect brought suit, seeking to preliminarily enjoin the federal government from enforcing the Controlled Substances Act to ban the sect's use of hoasca (or ayahuasca), a tea containing a Schedule I controlled substance, dimethyltryptamine (DMT), in religious ceremonies. After U.S. Customs inspectors seized a hoasca shipment to the religious sect and threatened prosecution, the sect filed a suit for declaratory and injunctive relief, alleging that applying the Controlled Substances Act to the sect's sacramental hoasca use violated the Religious Freedom Restoration Act. The federal government conceded that the challenged application would substantially burden a sincere exercise of religion but argued that this burden did not violate the Religious Freedom Restoration Act because applying the Controlled Substances Act was the least restrictive means of advancing three compelling governmental interests and does not allow exceptions.

Source: Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418 (2006). | GAO-24-106630

Controlled Substances Act is subject to the Religious Freedom Restoration Act. Under the Religious Freedom Restoration Act, the federal government may not substantially burden a person's exercise of religion, even if the burden results from a rule of general applicability.[63]

The only exception recognized by the statute requires the government to satisfy the compelling interest test. This means the government must show that the application of the burden to the person is in furtherance of a compelling governmental interest and is the least restrictive means of furthering that compelling governmental interest.[64] A person whose religious exercise has been burdened in violation of the statute may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government.[65]

The Controlled Substances Act generally prohibits the unauthorized handling of controlled substances. Thus, for individuals and entities who want to engage in the use, manufacture, importation, or dispensing of controlled substances for religious purposes or ceremonies, the Controlled Substances Act may conflict with the Religious Freedom Restoration Act. This is because, as held by the Supreme Court, the Religious Freedom Restoration Act prohibits DEA from burdening an individual's free exercise of sincerely held religious beliefs through action taken pursuant to the Controlled Substances Act unless DEA can demonstrate that the burden advances a compelling governmental interest and is carried out with the least restrictive means.[66]

[63]42 U.S.C. § 2000bb-1(a).

[64]42 U.S.C. § 2000bb-1(a)-(b).

[65]42 U.S.C. § 2000bb-1(c).

[66]Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418 (2006).

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The Supreme Court indicated that under the more focused inquiry required by the Religious Freedom Restoration Act and the compelling interest test, the government's mere invocation of the general characteristics of Schedule I substances, as set forth in the Controlled Substances Act, was not sufficient. Rather, the Supreme Court indicated that the Religious Freedom Restoration Act and its strict scrutiny test required the federal "[g]overnment to demonstrate that the compelling interest test is satisfied through application of the challenged law 'to the person'—the particular claimant whose sincere exercise of religion is being substantially burdened."

Source: Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418 (2006). | GAO-24-106630

According to DEA, it recognized that the Supreme Court decision required DEA to engage in a case-by-case analysis of religious exemptions to the Controlled Substances Act in order to strike sensible balances of interests based on desired religious uses of controlled substances. [67] As such, DEA first promulgated a guidance document in 2009 to establish a procedure for seeking religious exemptions from the Controlled Substances Act pursuant to the Religious Freedom Restoration Act. This guidance, entitled *Guidance Regarding Petitions for Religious Exemption from the Controlled Substances Act Pursuant to the Religious Freedom Restoration Act (Revised)*, was most recently updated in November 2020.[68]

DEA's guidance generally sets forth a process for obtaining a religious exemption for the use of controlled substances. Parties requesting religious exemptions from the Controlled Substances Act must submit a petition in writing or email to DEA's Diversion Control Division. The guidance indicates that a petition may include both a written statement and supporting documents and a petitioner should provide as much information as the petitioner deems necessary to demonstrate that application of the Controlled Substances Act to the party's activity would (1) be a substantial burden on (2) the petitioner's sincere (3) religious exercise. The guidance also indicates the record should include detailed information about, among other things, (1) the nature of the religion; (2) each specific religious practice that involves the manufacture, distribution, dispensing, importation, exportation, use or possession of a controlled substance; (3) the specific controlled substance that the party wishes to use; and (4) the amounts, conditions, and locations of its anticipated manufacture, distribution, dispensing, importation, exportation, use or possession. In addition, the guidance provides that the petitioner may submit any and all information they believe to be relevant to DEA's

[67]In Soul Quest Church of Mother Earth, Inc. v. Attorney General, No. 22-110722, 2023 WL 8714320 (11th Cir. 2023), the Eleventh Circuit Court of Appeals found that "[t]he DEA's religious exemption process and the accompanying Religious Freedom Restoration Act Guidelines were a direct response to the Supreme Court's warning in O Centro that [the Religious Freedom Restoration Act] may warrant accommodations to the Controlled Substances Act," and "[t]herefore, it was entirely appropriate that the DEA seek to reconcile the two statutes and that the agency consider [individuals'] rights under [the Religious Freedom Restoration Act] when implementing the Controlled Substances Act."

[68]DEA, *Guidance Regarding Petitions for Religious Exemption from the Controlled Substances Act Pursuant to the Religious Freedom Restoration Act (Revised).* Accessed November 16, 2023.

Court of Appeals for the Eleventh Circuit Recognition of DEA's Process for Religious Exemptions to the Controlled Substances Act under the Religious Freedom Restoration Act

Soul Quest Church of Mother Earth, Inc. – Appeal

In December 2023, the Eleventh Circuit Court of Appeals, in response to an appeal filed by Soul Quest Church of Mother Earth, Inc. ("Soul Quest") seeking to legally use and handle a sacramental tea known as ayahuasca, described the two-step process for obtaining a religious exemption for the use of controlled substances from DEA's guidance. The court said that the petition was the first step, a prerequisite to obtaining a permission to handle a controlled substance. The court further stated that even if the DEA granted a petition, a petitioner must continue to refrain from engaging in any activity prohibited under the Controlled Substances Act or its regulations until the petitioner has applied for and received a Certificate of Registration. The court also noted that the Controlled Substances Act and its attendant regulations permit a waiver of Controlled Substances Act provisions, including registration, as a potential alternative route to lawful use of controlled substances.

Source: Soul Quest Church of Mother Earth, Inc. v. Attorney General, No. 22-110722, 2023 WL 8714320 (11th Cir. 2023). | GAO-24-106630

determination under the Religious Freedom Restoration Act and the Controlled Substances Act.

In a recent decision, the Court of Appeals for the Eleventh Circuit held that this "petition [is] the first step, a prerequisite to obtaining permission to handle a controlled substance."[69] In accordance with that holding, should the petition be granted, the second step under the guidance is for the petitioner to apply for and receive a DEA Certificate of Registration.[70] The guidance directs that no petitioner may engage in any activity prohibited under the Controlled Substances Act or its regulations unless the petition has been granted and the petitioner has applied for and received a DEA Certificate of Registration.

This means that even a petitioner whose petition for a religious exemption from the Controlled Substances Act is granted remains bound by all applicable laws and Controlled Substances Act regulations governing registration, labeling and packaging, quotas, recordkeeping and reporting, security and storage, and periodic inspections, among other things.[71] The guidance states that a petitioner seeking exemption from these Controlled Substances Act regulations may petition under 21 C.F.R. § 1307.03, and the "petition must separately address each regulation from which the petitioner seeks exemption and provide a statement of the reasons for each exemption sought."[72] The regulation provides for those petitions to be submitted to DEA's Office of Diversion

[69]Soul Quest Church of Mother Earth, Inc. v Attorney General, No. 22-110722, 2023 WL 8714320 (11th Cir. 2023).

[70]Generally, pursuant to 21 U.S.C. § 823(a), DEA considers whether the requested registration is consistent with the public interest. In evaluating the public interest, DEA generally considers various factors, including: (1) the need to maintain effective control against diversion of the controlled substances into non-legitimate channels; (2) the applicant's compliance with applicable state and local law regarding use of the controlled substance; (3) whether the applicant has any prior convictions relating to controlled-substance manufacture, distribution, or dispensing; (4) the applicant's past experience in manufacturing controlled substances; and (5) other factors that may be relevant to and consistent with the public health and safety.

[71]See 21 C.F.R. pts. 1300-1316.

[72]21 C.F.R. § 1307.03. See also 21 U.S.C. § 822(d) (permitting the Attorney General, by regulation, to waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety).

Court of Appeals for the Eleventh Circuit Recognition of DEA's Process for Religious Exemptions to the Controlled Substances Act under the Religious Freedom Restoration Act

In the case of Soul Quest, the court found that Soul Quest did not seek a waiver of any provision, and that DEA classified Soul Quest as an applicant for registration, deeming its petition for exemption to be commensurate with an application for registration. DEA denied Soul Quest's petition. DEA found that Soul Quest's promotion of ayahuasca to the public for self-help and therapeutic reasons was not a sincere exercise of religion under the Religious Freedom Restoration Act. In addition, DEA determined that even assuming Soul Quest had proven the sincerity of its religious belief and that Controlled Substances Act enforcement would be a substantial burden on its religious exercise, Soul Quest's religious practices could not be accommodated in a manner that would allow DEA to preserve its compelling interests in public health and safety and in preventing the illegal diversion of ayahuasca. The court found that DEA's denial of Soul Quest's petition for religious exemption to the Controlled Substances Act was a denial at the first step of the two-step process; however, the court also said that because this denial precluded Soul Quest from applying for registration, it was also a decision made under the Controlled Substances Act. In addition, the court found that DEA discussed whether Soul Quest's handling of ayahuasca was consistent with public health and safety and whether the church maintained effective controls against diversion, which are relevant to the Controlled Substances Act's registration process. As such, the court held that "DEA's final decision adjudicated both [the church's Religious Freedom Restoration Act] right and its ultimate right to a Certificate of Registration under the [Controlled Substances Act]."

Source: Soul Quest Church of Mother Earth, Inc. v. Attorney General, No. 22-110722, 2023 WL 8714320 (11th Cir. 2023). | GAO-24-106630

Control.

According to DEA officials, in 2019, DEA initiated the drafting of a notice of proposed rulemaking related to DEA's process for petitioning for religious exemptions to the Controlled Substances Act under the Religious Freedom Restoration Act. According to DEA, the draft notice was developed and drafted by DEA's Diversion Control Division and the Office of Chief Counsel. In addition, the notice of proposed rulemaking is listed on the Fall 2023 Unified Agenda of Regulatory and Deregulatory Actions as a DEA priority. According to the Unified Agenda, DEA proposes to amend its regulations to accommodate religious entities who seek to apply for a DEA registration based on the terms of the Religious Freedom Restoration Act. Additionally, DEA also proposes regulatory amendments to incorporate and accommodate religious entities under the regulatory framework and proposes certain related, but generally applicable changes to regulatory definitions, application procedures, and hearing procedures. However, DEA has no estimated timeline for issuing the notice of proposed rulemaking, according to DEA officials.

DEA Has a Process to Review Petitions and Conduct Investigations

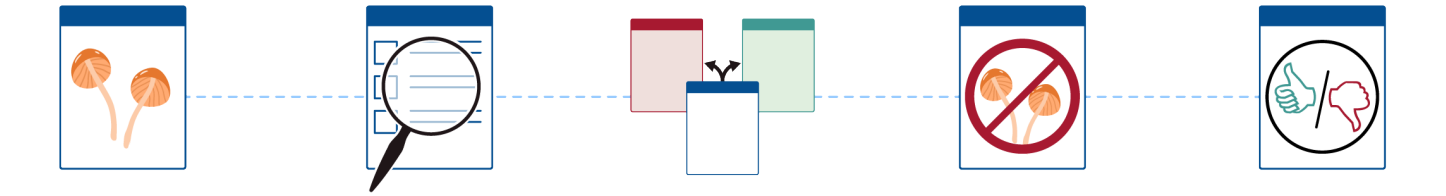
DEA's assessment process for petitions submitted under the Religious Freedom Restoration Act is applied across all petitions to include the use of an internal tracking system to identify where each petition is in the review process, according to DEA. Further, DEA indicated that it ensures that all petitions are handled using consistent procedures, which are outlined in the guidance posted on the Diversion Control Division website.

According to DEA officials, DEA also is responsible for conducting on-site visits and interviews which, according to DEA officials, also serve an educational purpose to inform the petitioner about DEA's regulatory requirements. In addition, DEA investigates a petitioner's past conduct, as it may indicate the ability to properly handle controlled substances.

According to DEA, following the on-site visits and interviews with the petitioner, a field report is submitted. DEA's Diversion Control Division reviews the petition in its entirety and all information provided by the field office. According to DEA officials, these reviews are to be done on a case-by-case basis, and the facts and information pertaining to the Religious Freedom Restoration Act petition will be assessed in light of public health and welfare interest factors, as well as religious sincerity considerations. If necessary, the Diversion Control Division may direct the field to request further information from the petitioner, or to conduct additional interviews or investigations with the petitioner or related third-parties. As a result of this review, the Diversion Control Division is to make a decision to grant or deny the petition.

According to DEA officials, the agency's processing times for religious exemption petitions may vary greatly based on various factors. For example, DEA officials stated that common issues with these petitions may include unsuccessful attempts to locate a petitioner, insufficient information to determine whether a religious belief is sincerely held, unsafe practices that may threaten the public health and safety, prior criminal convictions, and inability of a petitioner to meet reasonable/minimum security requirements to prevent the diversion of controlled substances. Figure 4 provides an overview of the process to obtain a Religious Freedom Restoration Act exemption to the Controlled Substances Act to permit the use of controlled substances.

Figure 4: Drug Enforcement Administration's Religious Freedom Restoration Act Review Process



1. Petition is submitted

An individual or religious organization submits a petition to the Drug Enforcement Administration requesting a religious exemption to the Controlled Substances Actfor use of a controlled substance under the Religious Freedom Restoration Act.

2. Petition is reviewed

Drug Enforcement Administration headquarters reviews the petition for completeness. The local field office overseeing the petitioner's jurisdiction is notified and is tasked with conducting a field investigation into the petitioner.

3. DEA accepts or returns petition

Petitions that are found to be complete are accepted, and those found lacking critical information or to be incomplete are returned to the petitioner. The Drug Enforcement Administration is required to communicate either decision to the petitioner pursuant to DEA guidance.

4. Full evaluation of accepted petition

While the Drug Enforcement Administration conducts a full evaluation, a petitioner requesting a religious exemption from the Controlled Substances Act is required to abide by the Act and its regulations for the duration of the evaluation according to DEA guidance.

5. DEA makes a determination

The petition is either granted or denied. Determinations are provided in writing and are often accompanied by a statement of reasons behind the decision. A statement of reasons is not included if a previous denial is cited, or the denial is considered self-explanatory.

Source: GAO analysis of DEA documentation; GAO (icons), Myuren/adobestock.com. | GAO-24-106630

Petition is submitted. A petitioner submits a petition for a religious exemption from the Controlled Substances Act under the Religious Freedom Restoration Act that would permit the use of controlled substances. The guidance indicates that a petition may include both a written statement and supporting documents and a petitioner should provide as much information as the petitioner deems necessary to demonstrate that application of the Controlled Substances Act to the party's activity would (1) be a substantial burden on (2) the petitioner's sincere (3) religious exercise. According to the guidance, the petition is to be submitted in writing or email to the Assistant Administrator, Diversion Control Division, DEA. In addition, the petition must be signed by the petitioner, who must declare under penalty of perjury that the information provided therein is true and correct.

Petition is reviewed. According to DEA, DEA's Diversion Regulatory Section reviews the petition, checking for the following information:

- the nature of the religion (e.g., its history, belief system, structure, practice, membership policies, rituals, holidays, organization, leadership, etc.);

- each specific religious practice that involves the manufacture, distribution, dispensing, importation, exportation, use or possession of a controlled substance;
- the specific controlled substance that the party wishes to use; and
- the amounts, conditions, and locations of its anticipated manufacture, distribution, dispensing, importation, exportation, use or possession.

DEA accepts or returns petition. According to DEA guidance, if a petition is found to be incomplete or have insufficient information, it will be returned with a statement of the reason explaining why it was not accepted. The petitioner may correct and resubmit a deficient petition. It is the petitioner's responsibility to provide DEA with accurate contact information. If a petitioner does not respond to a request for additional information within 60 days from the date of DEA's request, the petition will be considered to be withdrawn, according to the guidance.

Full evaluation of accepted petition. The DEA guidance indicates that the petitioner must not engage in any activity prohibited under the Controlled Substances Act or its regulations during the review period. Two attorneys we spoke with said that included petitioners refraining from any religious sacraments that involve the controlled substance referenced in the petition.

DEA makes a determination. Once the full evaluation has been completed, including all submissions in response to any requests for additional information, the Assistant Administrator of the Diversion Control Division will provide the petitioner with a written response on the outcome, according to DEA. According to DEA guidance, the written response is a final determination under 21 U.S.C. § 877 and as such can then be reviewed in the United States Court of Appeals for the District of Columbia or for the circuit in which the principal place of business is located. Under that statutory provision, the petitioner has thirty days after notice of the decision to file their petition for review.

Aspects of Process and Timeframes for Review of Petitions Were Unclear to Selected Stakeholders

A select group of nine individuals from law firms and advocacy organizations told us the DEA's religious freedom exemption review process is difficult to navigate and lacks clear guidance in some

instances.[73] Specifically, they found challenges with burdensome requirements, lack of clarity and communication related to processing time, and general lack of faith in the DEA's review process. See appendix V for additional perspectives we obtained related to the challenges and barriers that exist in the legal access and use of psilocybin for religious practices under the Religious Freedom Restoration Act.

Burden of DEA requirements for Religious Freedom Restoration Act exemptions. According to three of nine selected stakeholders, the amount of information required throughout the Religious Freedom Restoration Act petition process can be overly burdensome. For example, a stakeholder told us that they do not know how much and what type of information DEA would consider to be proof of religious sincerity. Such a requirement can be especially true for those petitioners who come from cultures where psilocybin has been used for generations and do not maintain documentation to prove their use of psilocybin is sincere, according to stakeholders.

In adjudicating a petition that was made public pursuant to litigation, DEA applied the "compelling interest test" from the Religious Freedom Restoration Act and the Supreme Court case *O Centro*. DEA further applied the case law interpreting it, in addition to relying upon its investigation of the petitioner. This is consistent with internal DEA guidance we reviewed that draws upon relevant factors from case law related to the Religious Freedom Restoration Act to be considered in making a threshold determination under the Act, as well as the various kinds of information that investigators should seek to collect. However, DEA's guidance does not provide the standard the agency will use to assess "religious sincerity" or other aspects of the application. DEA officials told us the agency continuously reevaluates certain areas to prevent any unnecessary burden on the petitioner and its internal processes.

Lack of clarity and communication. According to five of nine selected stakeholders we spoke with, DEA's Religious Freedom Restoration Act guidance and lack of communication make the process to obtain a religious exemption to the Controlled Substances Act under the Religious Freedom Restoration Act confusing. For example, the DEA guidance requires petitioners to provide documentation on a belief system,

[73]We selected nine individuals from law firms and advocacy organizations that represent a range of perspectives on the barriers, if any, that exist in the legal access to and use of psilocybin for religious, indigenous, or spiritual practices under the Religious Freedom Restoration Act.

structure, and practice, but the guidance does not explicitly state what type of documentation would sufficiently address this requirement. And while the guidance provides a petition process for a "religious exemption" from the Controlled Substance Act, it states that successful petitioners remain bound by all applicable laws and Controlled Substances Act regulations without indicating that petitioners may have additional claims under the Religious Freedom Restoration Act for exemptions from those regulations.[74]

Additionally, stakeholders shared that DEA does not answer petitioners' questions after a petition has been submitted, leaving petitioners unaware of their petition's status, potentially for years. The lack of petition review updates and expected dates for processing outcomes in the DEA's guidance were specifically cited as challenges in the DEA's processing of petitions. Such status updates may involve DEA determining a petition as having insufficient information. DEA officials stated that generally local field offices are the primary point of contact for petitioners, unless specific circumstances are in place requiring input from DEA's Office of Chief Counsel. Officials added that a petitioner may communicate with their local DEA field office to receive an update on the processing status of their petition at any time. However, DEA's guidance does not identify local DEA offices as a point of contact for petitioners. Additionally, DEA officials noted that they are aware of public comments on the need to better understand DEA's policies and processes that impact their petitions. In response, DEA stated it has conducted an assessment resulting in possible resolutions to address these needs.[75]

Processing timelines for petitions. Five of nine selected stakeholders highlighted that the absence of a clear benchmark for processing has enabled the petitioning process to become a lengthy procedure. Another selected stakeholder further illustrated this by describing the processing period as an activity lasting for an undetermined time. Over an 8-year period—fiscal year 2016 through January 2024—DEA reported that 24 petitioners requested a religious exemption from the Controlled Substances Act under the Religious Freedom Restoration Act. As of January 2024, DEA's information indicated that none of these petitioners

[74]As noted above, DEA's guidance states that a petitioner seeking exemption from Controlled Substances Act regulations may petition under 21 C.F.R. § 1307.03.

[75]DEA's possible resolutions include but are not limited to, streamlining internal processes, regulatory drafting, and revision of online guidance and additional investigative guides to field investigators.

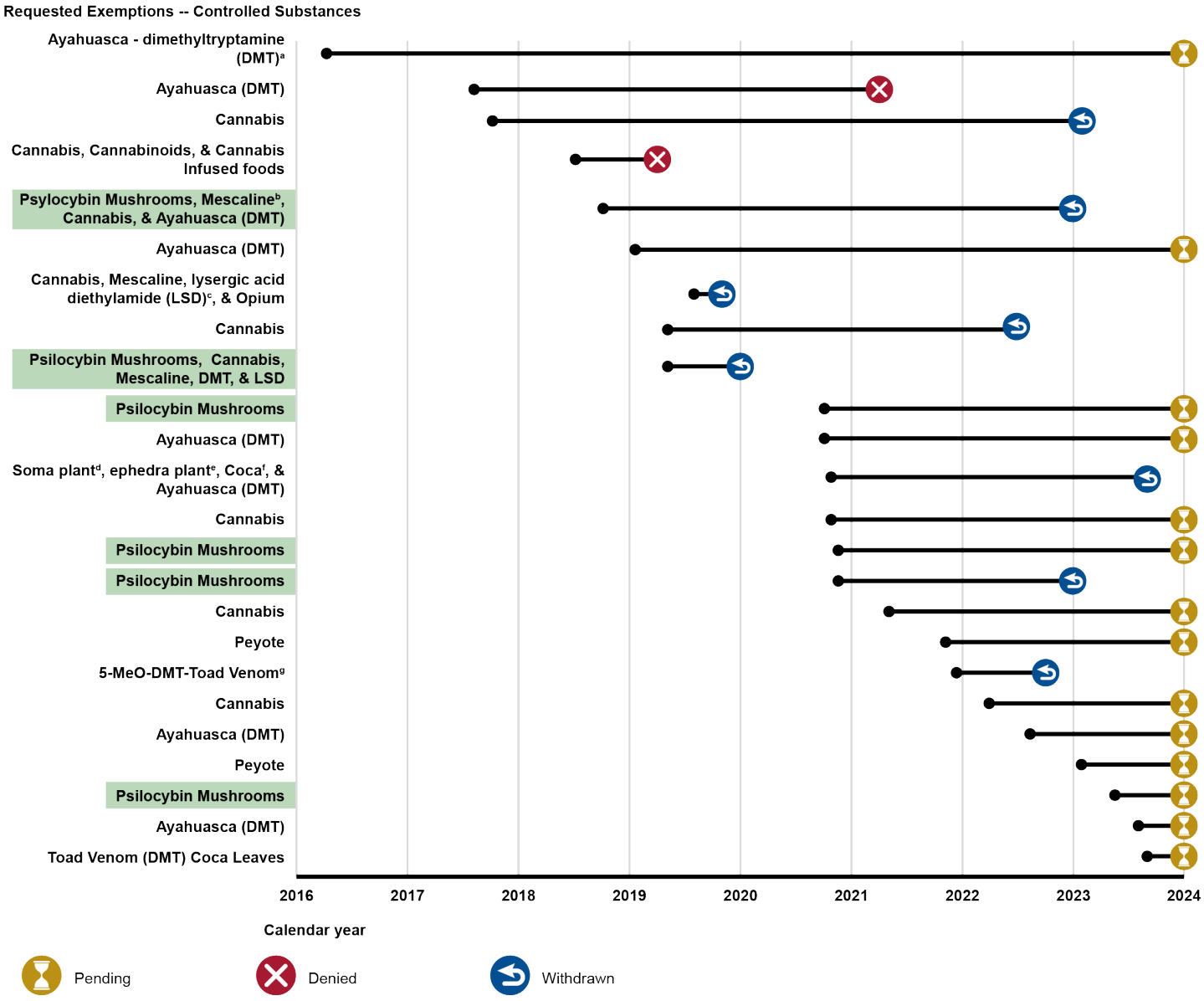
were granted a religious exemption. Specifically, based on DEA's information, two of the 24 petitioners were denied a religious exemption.[76]

There are also 14 petitioners that are pending a determination related to a religious exemption and 8 petitioners that withdrew from consideration, according to DEA's information. Of the 24 petitioners requesting a religious exemption, DEA reported that 6 petitioners requested a religious exemption related to psilocybin—three withdrawing and three pending a determination from DEA. Based on DEA's information, the "date of receipt" to "date of action(s)" for petitioners that withdrew their requests related to psilocybin ranged from about 7 months to over 4 years. Additionally, petitioners' exemption requests related to psilocybin that are pending a DEA determination ranged from about 8 months to over 3 years from the date of receipt. Over the 8-year period, based on DEA's information, we identified instances where DEA's finalized actions regarding petitions related to other controlled substances have been pending a DEA determination for an extensive period—one almost 5 years and one almost 8 years.[77] Figure 5 identifies DEA's processing time(s)—"date of receipt" to "date of action"—for each of the 24 petitioners that requested a religious exemption from the Controlled Substances Act under the Religious Freedom Restoration Act, fiscal year 2016 through January 2024.

[76]Based on DEA's information, one petitioner was denied a religious exemption after nearly 9 months, while the other petitioner was denied a religious exemption after more than 3 years.

[77]Based on DEA's guidance, the agency's final determination or action regarding a petition for a religious exemption is categorized as either granted (approved), or denied.

Figure 5: DEA's Processing Times for Religious Exemptions from the Controlled Substances Act, Fiscal Year 2016 through January 2024



Source: GAO analysis of DEA information. | GAO-24-106630

Note: The DEA processing times information presented reflects the fiscal year 2016 through January 2024 time frame.

[a]Ayahuasca is a tea containing a Schedule I controlled substance, dimethyltryptamine (DMT). DMT is a hallucinogen that is found in a number of plant materials and can be extracted or synthetically produced.

[b]Mescaline is the active hallucinogen ingredient in peyote—a small, spineless cactus. Mescaline is a Schedule I controlled substance.

[c]Lysergic acid diethylamide (LSD) is a potent hallucinogen that has a high potential for abuse and currently has no accepted medical use in treatment in the United States. LSD is a Schedule I controlled substance.

[d]Soma plant contains a psychoactive stimulant similar to ephedra used to produce a hallucinogenic stimulant drink made from the juice of the plant.

[e]Ephedra plant species grow as low, shrubby plants and considered a stimulant. Certain ephedra plant species contain ephedrine or pseudoephedrine which are precursor chemicals that may be used to produce methamphetamine and amphetamine. Ephedrine and pseudoephedrine are scheduled listed chemical products pursuant to 21 U.S.C. § 802(45). Methamphetamine is a Schedule II controlled substance and amphetamine is a Schedule III controlled substance.

[f]Coca is a common name for cocaine and is derived from coca leaves. Cocaine is a stimulant drug and a Schedule II controlled substance.

[g]5-MeO-DMT-Toad Venom is a hallucinogenic substance found in the secretion from the parotoid glands of the Bufo alvarius toad. 5-MeO-DMT is a Schedule I controlled substance pursuant to 21 C.F.R. § 1308.11(d)(15).

In 2017, petitioners from the Soul Quest Church requested a religious exemption from the Controlled Substances Act. After three years without a response from DEA, the petitioner, Soul Quest, filed a complaint against the DEA in federal district court and an accompanying motion seeking declaratory and injunctive relief. Soul Quest claimed that through the DEA's failure to respond to its petition, the agency violated Soul Quest's right to the free exercise of religion and its rights under the Religious Freedom Restoration Act. According to the Eleventh Circuit decision, shortly afterward, DEA responded to Soul Quest with an undated letter confirming receipt of the petition.

DOJ and Soul Quest seemingly reached an agreement on the procedures for handling Soul Quest's exemption request. In June 2020, the DOJ sent a follow-up letter memorializing their discussions. Soul Quest agreed to stay its litigation against the DEA and to withdraw its motion for a preliminary injunction. In return, the DEA committed to responding to Soul Quest within 14 days of receiving the information it had requested in its previous communication (an undated letter confirming receipt of Soul Quest's petition). In addition, the agency committed to providing Soul Quest with a final decision on its petition within 75 days after the completion of the factfinding process.

DEA officials acknowledged its long processing times for Religious Freedom Restoration Act petitions and explained that it had put in place processes aimed at reducing processing times, while still assessing other

areas in which processing can be streamlined.[78] Further, the agency stated that it had established timelines for specific stages throughout the process,[79] and continually considers the implementation of additional timelines. Lastly, officials pointed out that DEA's necessity to request additional information from petitioners can create delays in the petition's processing timeline.

Belief that DEA will not grant religious exemptions. According to five of nine selected stakeholders, DEA is unlikely to grant a petition for religious exemption for psilocybin use. Selected stakeholders cited reasons such as DEA's record of granting zero exemptions for protected psychedelic use through the petitioning process, and DEA having to assess the sincerity of non-western religious beliefs. Selected stakeholders we spoke to also stated that the absence of processing timelines and processing updates on the part of DEA have enabled the agency to withhold determinations from applicants following their submission. As a result, clients of these stakeholders have opted to withdraw their submitted petitions, sue DEA to receive a determination, or continue their psilocybin-based practices without going through the petitioning process.

DEA officials explained that its processing of Religious Freedom Restoration Act petitions does not vary based on the controlled substance(s) being requested. According to DEA officials, the agency did not approve or deny any petitions related to psilocybin. As stated above, information provided by DEA shows that from fiscal year 2016 through January 2024, no exemptions for any controlled substances were granted, only two exemptions were denied, and eight exemptions were withdrawn. DEA added that the agency has no records suggesting these exemptions were withdrawn by petitioners based on DEA denying the use of psilocybin or other controlled substances for religious purposes.

DEA has posted on its Diversion Control Division website the agency's guidance which generally outlines how petitions will be processed by the agency; however, this guidance does not include key information that

[78]These processes included (1) ensuring consistent procedures in the handling of petition, (2) synchronizing related processes with key offices (i.e., DEA local field office, Office of Chief Counsel, and Diversion Control Division), and (3) providing specialized training and streamlined guidance to all local field offices handling such Religious Freedom Restoration Act-related petitions.

[79]DEA did not name the stages in which timelines are in place for, nor were any benchmarks shared for these timelines.

clearly defines the types of information DEA requires of petitioners to evaluate religious sincerity, nor the standards or relevant factors that DEA will consider in making a threshold determination on evaluating a petition for an exemption from the Controlled Substances Act under the Religious Freedom Restoration Act. DEA officials stated the guidance is meant to clearly outline the Religious Freedom Restoration Act process and requirements for petitioners, and to ensure messaging is consistent.

In addition, DEA's guidance lacks established reporting time frames for DEA to respond to petitioners regarding decisions, as well as information on a communication process for providing updates to petitioners on the status of the exemption petition review. As a result, stakeholders and petitioners have limited transparency and may continue experiencing long petition review times without any mechanisms in place to obtain status updates from DEA. In addition, it is unclear when or if the notice of proposed rulemaking will be finalized.

Standards for Internal Control in the Federal Government requires management to implement control activities through policies and effectively communicate externally to support the internal control system.[80] It is important that an organization's management document the internal control responsibilities of the organization and the operational processes, objectives, control activity and operating effectiveness of each organizational unit in its policies. These policies may further define day-to-day procedures and include the timing of when a control activity occurs and any follow-up or corrective actions to be performed.[81] Also, management should externally communicate the necessary quality information to achieve the entity's objectives. This includes communicating with and obtaining quality information from external parties using established reporting lines. Open two-way external reporting lines allow for this form of communication. Established reporting lines to communicate quality information externally may help entities achieve their objectives and address related risks.[82]

[80]Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved. See GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: Sept. 2014).

[81]GAO-14-704G, pg. 44, Control Activities, Principle 12, Implement Control Activities, pg. 56.

[82]GAO-14-704G, pg. 58, Information and Communication, Principle 15—Communicate Externally, pg. 62.

According to DEA officials, the agency's notice of proposed rulemaking related to DEA's process to petition for religious exemptions to the Controlled Substances Act under the Religious Freedom Restoration Act was being reviewed by the Office of the Administrator. It is unclear when the notice of proposed rulemaking will be published, whether any regulations will ultimately be finalized, and the extent to which, if any, these regulations will address the concerns identified in our report. According to DEA, the agency had no estimated timeline for issuing the notice of proposed rulemaking due to the multi-step interagency review process. Better clarifying its process to petitioners and establishing a process to provide regular updates to petitioners on the status of its reviews will help ensure that petitions include the information DEA needs to appropriately adjudicate Religious Freedom Restoration Act rights. Additionally, it will ensure that petitioners who are required by DEA guidance to refrain from any use of a controlled substance have more information on the amount of time they can expect to receive a decision on their petition from DEA.

Conclusions

DEA established a process for parties that wish to petition for an exemption from the Controlled Substances Act under the Religious Freedom Restoration Act to use certain controlled substances for religious or spiritual purposes. DEA also provides guidance on its website that outlines how petitions will be processed by the agency. However, this publicly available guidance does not include information that clearly defines the types of information DEA requires of petitioners to evaluate their religious sincerity, nor the standards or relevant factors that DEA will consider in making a threshold determination on evaluating a petition. This guidance also does not inform petitioners of review processing timeframes for a petition for an exemption from the Controlled Substances Act. In addition, the guidance lacks information for petitioners to be able to inquire about the status of any petitions that have been submitted. As a result, stakeholders and petitioners have limited transparency and may continue experiencing long petition review times without any mechanisms in place to obtain status updates from DEA. DEA officials stated that its website guidance is meant to clearly outline the Religious Freedom Restoration Act process and requirements for petitioners, and to ensure messaging is consistent.

DEA initiated a draft notice of proposed rulemaking related to DEA's process for petitioning for religious exemptions from the Controlled Substances Act under the Religious Freedom Restoration Act in 2019. The draft notice was submitted to DEA's Office of the Administrator and is being reviewed by the office, according to DEA officials. However,

DEA officials stated that the agency has no estimated timeline for issuing the notice of proposed rulemaking. Therefore, it is unclear whether any regulations will be finalized and when that may occur. In addition, it is unclear the extent to which the notice of proposed rulemaking and any corresponding regulations will address the concerns identified in our report. Providing clearer guidance on the information that petitioners should provide to address the relevant factors in DEA's determination of religious sincerity and the standard DEA will use to assess religious sincerity, better clarifying its exemption petition process timeframes to petitioners, and establishing a process to provide regular updates to petitioners on the status of its reviews will help ensure that petitions include the information DEA needs to appropriately adjudicate Religious Freedom Restoration Act rights. Clearer guidance could also strengthen the quality of reviews, increase the trust among stakeholders and petitioners, provide transparency in the process, and clarify and identify DEA's standard petition review processing times for exemptions from the Controlled Substances Act.

Recommendations for Executive Action

We are making the following four recommendations to DEA:

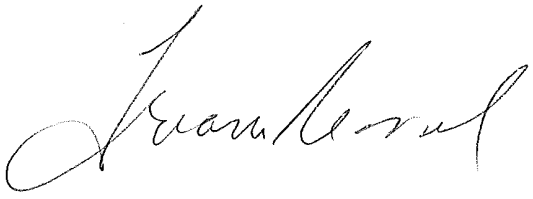
- The DEA Administrator should more clearly communicate the types of information that Religious Freedom Restoration Act petitioners should provide to allow DEA to evaluate petitions for religious sincerity. (Recommendation 1)
- The DEA Administrator should more clearly communicate the standards and relevant factors to Religious Freedom Restoration Act petitioners in making a determination related to religious sincerity. (Recommendation 2)
- The DEA Administrator should establish timeframes for DEA to make determinations on completed religious exemption petitions to provide Religious Freedom Restoration Act petitioners with DEA's final determinations. (Recommendation 3)
- The DEA Administrator should provide Religious Freedom Restoration Act petitioners with information for petitioners to be able to receive updates on the agency's progress related to exemption reviews. (Recommendation 4)

Agency Comments and Our Evaluation

We provided a draft of this report to DHS, DOJ, DOI, and HHS for review and comment. DOJ agreed with our 4 recommendations to the DEA Administrator. DOJ did not provide written comments. DOJ and HHS provided technical comments, which we incorporated as appropriate. DHS and DOI had no comments.

We are sending copies of this report to appropriate congressional committees, the Secretary of Health and Human Services, the Attorney General, Secretary of Interior, and Secretary of Homeland Security. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-8777 or mcneilt@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix VI.



Triana McNeil
Director, Homeland Security and Justice

List of Committees

The Honorable Jeanne Shaheen
Chair
The Honorable Jerry Moran, Ranking Member
Subcommittee on Commerce, Justice, Science, and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Hal Rogers
Chairman
The Honorable Matt Cartwright
Ranking Member
Subcommittee on Commerce, Justice, Science, and Related Agencies
Committee on Appropriations
House of Representatives

Appendix I: State of Oregon's Legalization of Psilocybin

In 2017, Oregon generally reduced the penalties for knowingly or intentionally possessing a Schedule I controlled substance, including psilocybin, from a Class B felony (which generally has a maximum term of imprisonment of 10 years and a fine not to exceed $250,000)[1] to a Class A misdemeanor (which generally has a maximum term of imprisonment of 364 days and a fine not to exceed $6,250).[2] Subsequently, in 2020, Oregon passed a state ballot initiative which generally reduced the penalties for knowingly or intentionally possessing a Schedule I controlled substance, including psilocybin, from a Class A misdemeanor to a Class E violation, which became effective in 2021.[3] A person subject to the penalty for a Class E violation may, in lieu of the fine,[4] complete a Behavioral Health Resource Network screening by a certified addiction peer support or wellness specialists or other qualified persons, or any other equivalent or more intensive treatment contact, within 45 days of when the person receives the citation for the Class E violation. Upon verification of the screening, the court shall dismiss the citation.[5]

In April 2024, Oregon passed legislation that generally repeals the Class E violation that previously applied to possession of small amounts of a controlled substance, and replaces it with a new misdemeanor crime of

[1]2017 Or. Laws Ch. 706. Or. Rev. Stat. §§ 161.605(2), 161.625(1)(c) (2016).

[2]Or. Rev. Stat. § 475.752(3)(a) (2017). With respect to psilocybin, pursuant to Or. Rev. Stat. § 475.752(7) (2017), unlawful possession of a controlled substance in Schedule I is a Class B felony if: (a) The person possesses a usable quantity of the controlled substance and: (A) At the time of the possession, the person has a prior felony conviction; (B) At the time of the possession, the person has two or more prior convictions for unlawful possession of a usable quantity of a controlled substance; or (C) The possession is a commercial drug offense under ORS 475.900 (1)(b); or (b) The person possesses twelve grams or more of a mixture or substance containing a detectable amount of psilocybin. Or. Rev. Stat. § 161.615(1) (maximum term of imprisonment for Class A misdemeanor). Or. Rev. Stat. § 161.615(1)(a) (maximum fine for Class A misdemeanor).

[3]2021 Or. Laws Ch. 2 (B.M. 110). Or. Rev. Stat. § 475.752. Pursuant to Or. Rev. Stat. § 475.752(7), unlawful possession of a controlled substance in Schedule I is a Class A misdemeanor if the person possesses twelve grams or more of a mixture or substance containing a detectable amount of psilocybin or a Class B felony if the possession is a commercial drug offense under Or. Rev. Stat. § 475.900(1)(b); or the person possesses a substantial quantity (sixty grams or more of a mixture or substance containing a detectable amount of psilocybin) under Or. Rev. Stat. § 475.900(2)(b).

[4]Pursuant to Or. Rev. Stat. § 153.018(2)(e), the maximum fine for a violation committed by an individual is $100 for a Class E violation.

[5]Or. Rev. Stat. § 153.062.

unlawful possession of a controlled substance, effective September 1, 2024.[6]

In addition, in November 2020, Oregon passed a separate state ballot initiative, also known as the Oregon Psilocybin Services Act, to permit persons licensed, controlled, and regulated by the state to legally manufacture psilocybin products and provide psilocybin services to persons 21 years of age and older, subject to state law; and establish a comprehensive regulatory framework concerning psilocybin products and psilocybin services under state law, after a two-year program development period.[7] According to the legislative findings of the Oregon Psilocybin Services Act, the State of Oregon has one of the highest prevalence rates of mental illness among adults in the nation.[8] An estimated one in every five adults in Oregon is coping with a mental health condition.[9] In addition, the 2019-2021 governor's budget proposed spending over $2.8 billion on mental health and behavioral health programs.[10] The legislative findings also reported that "studies conducted by nationally and internationally recognized medical institutions indicated that psilocybin has shown efficacy, tolerability, and safety in the treatment of a variety of mental health conditions, including but not limited to addiction, depression, anxiety disorders, and end-of-life psychological distress."[11]

Some of the purposes of the Act are to educate the people of Oregon about the safety and efficacy of psilocybin in treating mental health conditions; reduce the prevalence of mental illness among adults in the state, and to improve the physical, mental, and social well-being of all people in the state; and to develop a long-term strategic plan for ensuring that psilocybin services will become and remain a safe, accessible and

[6]2024 Or. HB 4002.

[7]2021 Or. Laws Ch. 1 (B.M. 109). Or. Rev. St. §§ 475A.210-.722.

[8]Or. Rev. Stat. § 475A.200(1).

[9]Or. Rev. Stat. § 475A.200(2).

[10]Or. Rev. Stat. § 475A.200(4).

[11]Or. Rev. Stat. § 475A.200(5).

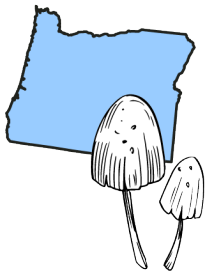
affordable therapeutic option for all persons 21 years of age and older in Oregon for whom psilocybin may be appropriate.[12]

The Oregon Health Authority licenses and regulates the manufacturing, transportation, delivery, sale, and purchase of psilocybin products and the provision of psilocybin services. Although Oregon has generally legalized or decriminalized the manufacture, sale, and use of psilocybin under certain circumstances, the federal Controlled Substances Act provides federal sanctions for the possession, manufacture, distribution, and dispensing of Schedule I controlled substances, including psilocybin, except in limited circumstances.[13] Figure 6 provides an overview of the legislative and administrative components involved in the state's legalization of psilocybin.

[12]Or. Rev. Stat. § 475A.205(1)(a)-(c).

[13]21 U.S.C. §§ 841, 844.

Figure 6: Overview of State of Oregon's Legislative and Administrative Components Involved Legalizing Psilocybin



State of Oregon:

Oregon Psilocybin Services Act

The Oregon Psilocybin Services Act was primarily codified in Oregon Revised Statutes, Title 37, Chapter 475A and generally directs the Oregon Health Authority (OHA) to license and regulate psilocybin products and the provision of psilocybin services.

By law, "psilocybin services[a]" means services provided to a client before, during, and after the client's consumption of a psilocybin product, including: a preparation session[b]; an administration session[c]; and an integration session[d]. The sale of psilocybin products and the provision of psilocybin services are available for individuals aged 21 and over and do not require a prescription or medical referral.

The Oregon Psilocybin Services (OPS) Section, within the Oregon Health Authority Public Health Division's Center for Health Protection, implements the Oregon Psilocybin Services Act. The Oregon Health Authority is responsible for licensing and regulating the manufacturing, transportation, delivery, sale, and purchase of psilocybin products and the provision of psilocybin services.

The Act established the Oregon Psilocybin Advisory Board to provide advice to the Oregon Health Authority with respect to the administration of Oregon's psilocybin program, including, but not limited to, making recommendations to the authority on available medical, psychological, and scientific studies, research, and other information relating to the safety and efficacy of psilocybin in treating mental health conditions, including but not limited to addiction, depression, anxiety disorders, and end-of-life psychological distress; making recommendations to the authority on the requirements, specifications and guidelines for providing psilocybin services to a client; and making recommendations to the authority on the education and training that psilocybin service facilitators must complete and on the examinations that psilocybin service facilitators must pass.[e]

The OPS Section began accepting applications for licensure on January 2, 2023. According to Oregon officials, psilocybin service centers began to open their doors to clients in the summer of 2023.

Source: GAO analysis of the State of Oregon Psilocybin Services Act. | GAO-24-106630

[a]Or. Rev. Stat. § 475A.220(16).

[b]Pursuant to Or. Rev. Stat. § 475A.220(9), a preparation session "means a meeting between a client and a psilocybin service facilitator that must occur before the client participates in an administration session."

[c]Pursuant to Or. Rev. Stat. § 475A.220(1), an administration session "means a session held at a psilocybin service center at which a client purchases, consumes, and experiences the effects of a psilocybin product under the supervision of a psilocybin service facilitator."

[d]Pursuant to Or. Rev. Stat. § 475A.220(3), an integration session "means a meeting between a client and a psilocybin service facilitator that may occur after the client completes an administration session."

[e]Or. Rev. Stat. § 475A.230.

In December 2022, the Oregon Health Authority adopted rules to regulate the production of psilocybin products and the provision of psilocybin services in Oregon. The following describes some of the features of Oregon's regulatory system.

Licensing. The Oregon Health Authority has established four types of psilocybin licenses that allow licensees to conduct specific tasks, including a manufacturer license,[14] a facilitator license,[15] a psilocybin service center operator license,[16] and a laboratory license.[17] Generally, an applicant for a license must apply to the Oregon Health Authority in the form required by the authority by rule, showing the name and address of the applicant, location of the premises that is to be operated under the license and other pertinent information required by the authority.[18] An applicant for a facility license need not show the location of any premises.[19] In addition, generally, a licensee must be 21 years of age or older and pass a criminal background check.

By law, generally, an individual who performs work for or on behalf of a licensee must have a valid permit issued by the Oregon Health Authority

[14]Or. Rev. Stat. § 475A.290. Pursuant to Or. Rev. Stat. § 475A.220(7), "'[m]anufacture' means the manufacture, planting, cultivation, growing, harvesting, production, preparation, propagation, compounding, conversion or processing of a psilocybin product, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the psilocybin product or labeling or relabeling of its container."

[15]Or. Rev. Stat. § 475A.325. Generally, a facilitator provides services to a client during a preparation, administration, or integration session.

[16]Or. Rev. Stat. § 475A.305. Pursuant to Or. Rev. Stat. § 475A.498, a client may purchase, possess, and consume a psilocybin product only at a psilocybin service center and only under the supervision of a psilocybin service facilitator.

[17]Or. Rev. Stat. § 475A.594. A laboratory that conducts testing of psilocybin products must be accredited by the Oregon Environmental Laboratory Accreditation Program.

[18]Or. Rev. Stat. § 475A.245(1).

[19]Or. Rev. Stat. § 475A.245(4).

if the individual participates in certain psilocybin-related activities, such as the provision of psilocybin services at the premises for which a license has been issued; the possession, manufacturing, securing or selling of psilocybin products at the premises for which the license has been issued; the recording of the possession, manufacturing, securing or selling of psilocybin products at the premises for which the license has been issued; or the verification of any document for the sale or provision of a psilocybin product to another person.[20] In addition, a licensee must verify that an individual has a valid permit from the Oregon Health Authority before allowing the individual to perform any of the previous work described.[21] Figure 7 identifies the number and status of licenses and work permits submitted to the Oregon Health Authority, as of December 4, 2023.

Figure 7: Oregon Psilocybin Services Applications for Licenses and Worker Permits, as of December 4, 2023

Application type	Submitted[a]	Approved[b]
Manufacturer	21	7
Facilitator	249	183
Service center operator	35	19
Testing labratory	3	2
Worker permit	594	382

Source: GAO's analysis of the state of Oregon's psilocybin services data. | GAO-24-106630

[a]Submitted is considered as an application that is submitted through the Training program, Licensing, and Compliance (TLC) system or by mail.

[b]Approved is considered as an application that is approved, and fees are paid and cleared.

Facility security measures. Oregon regulations require certain security measures for facilities. A service center, manufacturer or laboratory licensee is responsible for the security of all psilocybin products on the licensed premises or in transit from the licensed premises, including providing adequate safeguards against theft or diversion of psilocybin products. Licensees must ensure that all limited access areas of a

[20]Or. Rev. Stat. § 475A.480(1).

[21]Or. Rev. Stat. § 475A.480(2).

licensed premises are accessible only to licensee representatives and other personnel authorized to be present. During hours when the licensee is not operating, the licensee must ensure that all points of ingress and egress to and from indoor areas of the licensed premises are securely locked.[22] A service center, manufacturer or laboratory must have a fully operational security alarm system on the licensed premises, activated at all times when the licensed premises is closed for business. In addition, licensees must make all information related to security alarm systems, monitoring and alarm activity available to the Oregon Health Authority, upon request.[23] A licensed premises must have a fully operational video surveillance recording system.[24] The regulations specify that the video surveillance equipment, must at a minimum, consist of digital or network video recorders, cameras capable of meeting certain coverage requirements of the licensed premises, video monitors, digital archiving devices, a minimum of one monitor on the premises capable of viewing video, and interface devices such as a mouse or keyboard, if required to operate the system. In addition, the equipment must have the capability of producing and printing a still photograph from any camera image and have sufficient battery backup to support a minimum of one hour of recording time in the event of a power outage. A service center, manufacturer or laboratory licensee must have cameras that continuously record, 24 hours a day, using cameras that record at a minimum resolution of 1280 x 720 pixels and record at 10 frames per second (fps) in all areas where psilocybin products are produced or stored on the licensed premises and psilocybin waste may be present on the licensed premises, and all points of entry or exit to these areas and the indoor areas of the licensed premises.[25]

Verification of age. Pursuant to regulation, prior to completing the sale of a psilocybin product or providing psilocybin services to a client, a service center licensee representative and a facilitator must verify that the client has a valid, unexpired government-issued photo identification and must verify that the client is 21 years of age or older by viewing a particular type of government-issued client's identification, such as a passport,

[22]Or. Admin. R. 333-333-4550.

[23]Or. Admin. R. 333-333-4600.

[24]Or. Admin. R. 333-333-4620.

[25]Or. Admin. R. 333-333-4650.

driver's license, or identification card issued by a federally recognized Indian tribe with photo, name and date of birth.[26]

Product tracking. A service center, manufacturer or laboratory licensee must use the psilocybin tracking system as an inventory and record keeping system, have a psilocybin tracking system account activated and functional within five business days of being licensed, and maintain an active psilocybin tracking system account while licensed.[27] Each service center, manufacturer and laboratory licensee must have at least one licensee who is a psilocybin tracking system administrator. A licensee may authorize additional licensees or licensee representatives to obtain psilocybin tracking system administrator accounts. Generally, to obtain a psilocybin tracking system administrator account, a license holder must attend and successfully complete all required psilocybin tracking system training. The Oregon Health Authority may also require additional ongoing, continuing education for individual administrators to retain his or her psilocybin tracking system administrator account.

Preparation, Administration, and Integration Sessions with Clients. Prior to a client being able to purchase and consume a psilocybin product, a facilitator must complete a preparation session with each client who will participate in an administration session at least twenty-four hours but no more than 90 days prior to the commencement of the client's first administration session with the facilitator. For every client who will participate in an administration session, a facilitator must receive a completed client information form, complete a transportation plan in coordination with the client,[28] and coordinate with the client to complete a safety and support plan. Additionally, a facilitator must review certain documents with a client during the preparation session, such as the required informed consent document, the client bill of rights, and the product information document for any products that may be consumed during an administration session.[29] Administration sessions must be conducted by a facilitator and may only take place within a service center's designated administration area. Generally, a facilitator must always be present during administration sessions and is required to

[26]Or. Admin. R. 333-333-4490.

[27]Or. Admin. R. 333-333-8200.

[28]By regulation, the transportation plan may not approve a client to operate a motor vehicle, bicycle, or other form of self-operated transportation following the administration session.

[29]Or. Rev. Stat. § 333-333-5000.

continuously monitor any client participating in the administration session. Continuous monitoring means that a facilitator must maintain visual and audio contact with clients and monitor clients for signs of physical or emotional distress. Video monitoring or other equipment may not be used to satisfy the requirement to continuously monitor clients. In addition to a facilitator conducting the administration session, at least one licensee representative of a service center license must be present on the licensed premises at all times when an administration session is taking place at a service center. If the additional licensee representative required to be present also holds a facilitator licensee, they are prohibited from transferring, selling or otherwise handling any psilocybin product while they are facilitating a preparation, administration or integration session. Facilitators must also ensure that a back-up facilitator is available to assist in case of unforeseen circumstances that prevent the primary facilitator from completing the session. Back up facilitators must be able to reach the licensed premises within a reasonable period of time. In addition, a service center is limited in the number of clients it may have for administrative sessions at one time. A service center may not host administrative sessions for more than 100 clients at any given time regardless of whether the clients are participating in separate individual or group administration sessions.[30] Client-facilitator ratios are required for group administration sessions depending on the dosage of psilocybin consumed. In addition, group administration sessions may not exceed a total of 25 clients, or the service center's maximum occupancy, regardless of the number of facilitators present.

[30]Or. Rev. Stat. § 333-333-5200.

Appendix II: State of Colorado's Legalization of Psilocybin

In November 2022, the voters of Colorado approved a citizen-initiated measure, the Natural Medicine Health Act of 2022, related to the use of certain plants and fungi, including psilocybin, for people 21 years of age and older. Within the legislative declaration of the Act, the voters of Colorado stated that the state's "current approach to mental health has failed to fulfill its promise. Coloradans deserve more tools to address mental health issues, including approaches such as natural medicines that are grounded in treatment, recovery health, and wellness rather than criminalization, stigma, suffering, and punishment."[1] In addition, according to the Act, "Coloradans are experiencing problematic mental health issues, including but not limited to suicidality, addiction, depression, and anxiety."[2] The legislative declaration of the Act also stated "an extensive and growing body of research is advancing to support the efficacy of natural medicines combined with psychotherapy as treatment for depression, anxiety, substance use disorders, end-of-life distress and other conditions."[3]

The purpose of the Natural Medicine Health Act of 2022 is to establish a new, compassionate, and effective approach to natural medicines by adopting a public health and harm reduction approach to natural medicines by removing criminal penalties for personal use for adults 21 years of age and older; developing and promoting public education related to the use of natural medicines and appropriate training for first responders; and establishing regulated access by adults twenty-one years of age and older to natural medicines that show promise in improving well-being, life satisfaction, and overall health.[4] In May 2023, Colorado passed an act concerning natural medicine referred to as the Natural Medicine Regulation and Legalization, which repealed and reenacted, with amendments, portions of the citizen-initiated measure. This act sets the regulatory framework for a regulated natural medicine program in Colorado.[5]

Under the law, the Director of the Colorado Division of Professions and Occupations (Director) within the Colorado Department of Regulatory Agencies has the power and duties to promulgate rules related to the

[1]Colo. Rev. Stat. § 12-170-102(1)(a).

[2]Colo. Rev. Stat. § 12-170-102(1)(b).

[3]Colo. Rev. Stat. § 12-170-102(1)(c)-(d).

[4]Colo. Rev. Stat. § 12-170-102(j).

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[5]2023 Colo. Legis. Serv. Ch. 249.

requirements for the safe provision of regulated natural medicine, regulated natural medicine product, and natural medicine services to a participant.[6] For example, this includes promulgating rules related to the parameters for a preparation session,[7] administration session,[8] and integration session, for a participant to consume and experience the effects of a regulated natural medicine or product, such as psilocybin, at a licensed facility.[9] In addition, generally this includes promulgating rules on the requirements for the licensing of facilitators, practice of facilitation, and professional conduct of facilitators, including the form and procedures for applying for a new license, renewing or reinstating a license; and the educational and experiential requirements and qualifications for an individual to become a facilitator, including education and training on participant safety, drug interactions, contraindications, mental health and state, physical health and state, social and cultural considerations, preparation, administration, integration, and ethics.[10] Colorado also established a state licensing authority for the purpose of regulating and licensing the cultivation, manufacturing, testing, storage, distribution, transport, transfer, and dispensation of natural medicine or natural medicine product by and between natural medicine licensees.[11]

The Director is required to establish the federally recognized American tribes and Indigenous community working group for the purpose of engaging and creating a dialogue to identify issues related to the commercialization of natural medicine, natural medicine product, and

[6]Colo. Rev. Stat. § 12-170-105.

[7]Colo. Rev. Stat. § 12-170-104(16). A preparation session means a meeting between a participant and facilitator that occurs before an administration session, but does not mean an initial consultation, an inquiry, or a response about natural medicine services.

[8]Colo. Rev. Stat. § 12-170-104(1). An "administration session' means a session conducted at a healing center, or another allowed location…during which a participant consumes and experiences the effects of regulated natural medicine or regulated natural medicine product under the supervision of a facilitator."

[9]Colo. Rev. Stat. § 12-170-104(10). An "integration session' means a meeting between a participant and facilitator that occurs after the completion of an administration session."

[10]Colo. Rev. Stat. § 12-170-105(1)(a)(II).

[11]Colo. Rev. Stat. § 44-50-201.

natural medicine services for tribal and Indigenous people, communities, cultures, and religions.[12]

Colorado also created the Natural Medicine Advisory Board (Board).[13] This Board's duties include, but are not limited to, examining issues related to natural medicine and natural medicine product, and making recommendations to the Director and the executive director of the state licensing authority. In addition, the Board is responsible for making recommendations to the Director and state licensing authority related to the addition of other types of natural medicine, including ibogaine, dimethyltryptamine and mescaline. These recommendations are to be based on available medical, psychological, and scientific studies, research, and other information related to the safety and efficacy of each natural medicine, with prioritization on the consideration of the addition of ibogaine.[14]

Generally, Colorado has legalized and decriminalized the personal use of natural medicines and natural medicine products, including psilocybin, under certain circumstances. Under Colorado law, unless expressly limited by the law, a person who, for the purpose of personal use and without remuneration, possesses, consumes, shares, cultivates, or manufactures natural medicine or natural medicine product, does not violate state law, or county, municipality, or city and county ordinance, rule, or resolution.[15] However, there are activities that are prohibited under Colorado law. For example, a person who is under 21 years of age who knowingly possesses or consumes natural medicine or natural medicine product commits a drug petty offense. Upon conviction, the

[12]Colo. Rev. Stat. § 12-170-107. In general, this community working group is required to study a number of issues, including, but not limited to avoiding the misappropriation and exploitation of the federally recognized American tribes and Indigenous people, communities, cultures, and religions; avoiding the excessive commercialization of natural medicine, natural medicine product, and natural medicine services; conservation issues associated with the legalization and regulation of natural medicines; and best practices and open communication to build trust and understanding between the certain entities for the purpose of avoiding unnecessary burdens and criminalization of traditional tribal and Indigenous uses of natural medicine.

[13]Colo. Rev. Stat. § 12-170-106.

[14]Colo. Rev. Stat. § 12-170-106(5)(f).

[15]Colo. Rev. Stat. § 18-18-434(5)(a). Pursuant to Colo. Rev. Stat. §§ 18-18-102(31) and 12-170-104(19), "'remuneration' means anything of value, including money, real property, tangible and intangible personal property, contract rights, choses in action, services, and any rights of use or employment or promises or agreements connected therewith."

person is subject to a fine of not more than $100 or not more than 4 hours of substance use education or counseling. A second or subsequent conviction for this violation is subject to a fine of not more than $100, not more than 4 hours of substance use education or counseling, and not more than 24 hours of useful public service.[16] It is also unlawful for a person to openly and publicly display or consume natural medicine or natural medicine product. Under the law, this is a drug petty offense and, upon conviction, the person is subject to a fine of not more than $100 and not more than 24 hours of useful public service.[17] A person who knowingly cultivates natural medicine that cumulatively exceeds an area of more than 12 feet wide by 12 feet long in one or more cultivation areas on private property, or knowingly allows such cultivation on private property that the person owns, occupies, or controls, commits a drug petty offense, and upon conviction, is subject to a fine of not more than $1,000.[18] In addition, it is a drug felony for a person who is not licensed under the law to knowingly manufacture natural medicine product using an inherently hazardous substance or for a person who owns, manages, operates, or otherwise controls the use of a property to allow a person to do so.[19]

As of July 2023, Colorado's regulatory framework is currently under development and expected to begin accepting healing center applications by the end of calendar year 2024. Although Colorado has generally taken steps to legalize and decriminalize psilocybin, the federal Controlled Substances Act provides federal sanctions for the possession, manufacture, distribution, and dispensing of Schedule I controlled substances, including psilocybin, except in limited circumstances.[20] Figure 8 provides an overview of the legislative and administrative components involved in the state's legalization of psilocybin.

[16]Colo. Rev. Stat. § 18-18-434(1).

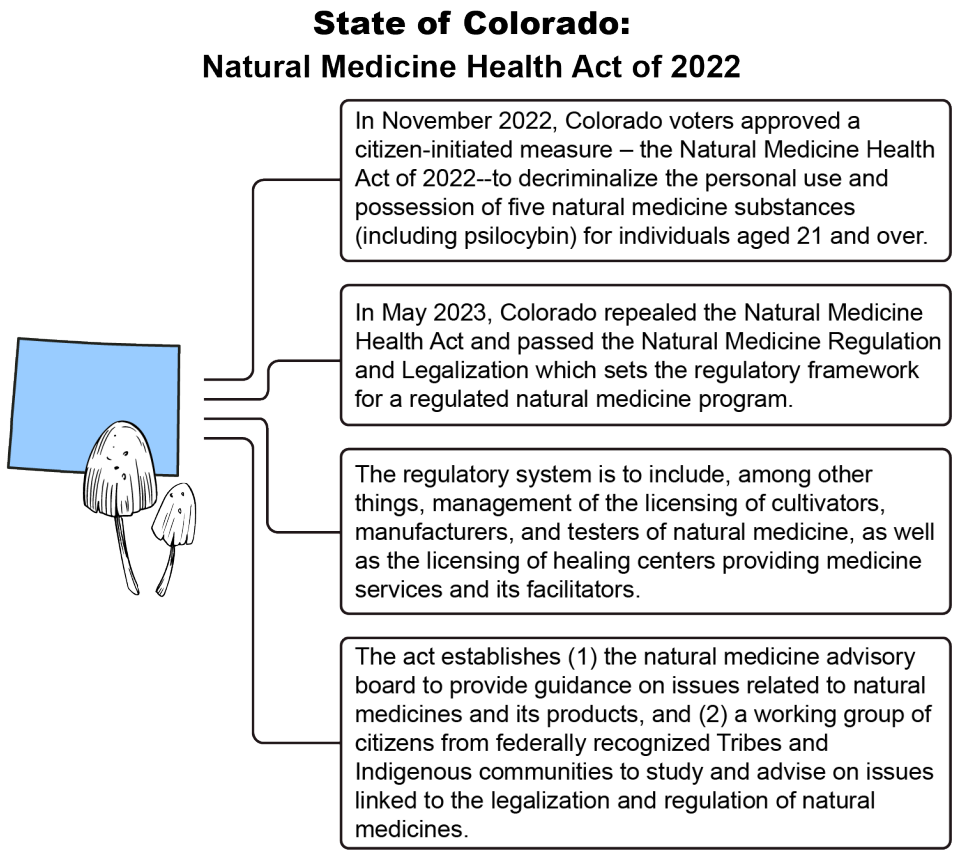
[17]Colo. Rev. Stat. § 18-18-434(2).

[18]Colo. Rev. Stat. § 18-18-434(3)(a).

[19]Colo. Rev. Stat. § 18-18-434(4).

[20]21 U.S.C. §§ 841, 844.

Figure 8: Overview of State of Colorado's Legislative and Administrative Components Involved Legalizing Psilocybin



Source: GAO analysis of the State of Colorado Natural Medicine Health Act of 2022. | GAO-24-106630

Appendix III: Selected States with Initiatives Focusing on Psilocybin

Some states have passed state laws establishing state-level pilot or research programs. For example, in Connecticut, the Department of Mental Health and Addiction Services was required to establish, within available appropriations, a psychedelic-assisted therapy pilot program, to be administered by a medical school in Connecticut, no later than January 1, 2023.[1] In addition, Maryland established the Post-Traumatic Stress Disorder and Traumatic Brain Injury Alternative Therapies Fund for the purpose of supporting the Maryland Department of Health in studying the effectiveness of and improving access to alternative therapies for post-traumatic stress disorder and traumatic brain injuries in veterans.[2] Table 4 provides a description of selected states with state laws related to pilot programs for psilocybin services or studies of psilocybin for therapeutic use.[3]

Table 4: Descriptions of the Selected States Initiatives Focusing on Psilocybin Related Therapies and Treatments

Selected States	Characteristics of Selected States Psilocybin-Based Initiatives
Arizona	In Arizona, the Director of the Arizona Department of Health Services is required to provide from monies appropriated, competitive research grants for whole mushroom psilocybin phase one, two, and three clinical trials that are capable of approval by the U.S. Food and Drug Administration (FDA) to evaluate the effects of whole mushroom psilocybin on treating conditions such as post-traumatic stress disorder, symptoms associated with long COVID-19, symptoms associated with end-of-life distress, depression, substance use disorder and addiction disorders, chronic pain, and eating disorders.[a]
Connecticut	In Connecticut, the Department of Mental Health and Addiction Services was required to establish, within available appropriations, a psychedelic-assisted therapy pilot program, to be administered by a medical school in Connecticut, no later than January 1, 2023. The pilot program is required to provide qualified patients with 3,4-methylenedioxymethamphetamine (MDMA)-assisted or psilocybin-assisted therapy as part of a research program approved by FDA.[b]

[1]Conn. Gen Stat. § 17a-484g.

[2]Md. Code Ann., Health-Gen. § 24-2102.

[3]We reviewed the controlled substances laws of the 50 States and Washington, D.C., related to psilocybin to provide information related to the criminalization, deprioritization, decriminalization, or legalization of the use, possession, manufacture, and/or sale of psilocybin. During our research, we identified states that have passed state laws establishing state-level pilot research programs or studies of the therapeutic use of psilocybin. We randomly selected several of these programs to provide an overview of some of the characteristics of these programs.

Maryland	Maryland established the Post-Traumatic Stress Disorder and Traumatic Brain Injury Alternative Therapies Fund for the purpose of supporting the Maryland Department of Health in studying the effectiveness of and improving access to alternative therapies for post-traumatic stress disorder and traumatic brain injuries in veterans. “Alternative therapies” includes hyperbaric oxygen therapy and psychedelics including 3,4-Methylenedioxymethamphetamine (MDMA), psilocybin, and ketamine.[c] Generally, the Fund may be used only for studying the use of alternative therapies for veterans with post-traumatic stress disorder and traumatic brain injuries; providing cost-free access to alternative therapies for veterans with post-traumatic stress disorder and traumatic brain injuries; administrative expenses of the Maryland Department of Health; and the Department’s periodic consultation with certain entities, such as the Department of Veterans Affairs, The Johns Hopkins University, the University of Maryland, and Walter Reed National Military Medical Center.[d]
Washington	In Washington, subject to amounts appropriated, a psilocybin therapy services pilot program is established within, and administered by, the University of Washington’s Department of Psychiatry and Behavioral Sciences. No later than January 1, 2025, the University of Washington’s Department of Psychiatry and Behavioral Sciences must implement a psilocybin therapy pilot program that generally, must offer psilocybin therapy services through pathways approved by FDA, to populations including first responders and veterans who are: 21 years of age or older; and experiencing post-traumatic stress disorder, mood disorders, or substance use disorders. Generally, the pilot program must offer psilocybin therapy services facilitated by a licensed advanced social worker, independent clinical social worker, or mental health counselor; a licensed physician; or a licensed psychiatric advanced registered nurse practitioner. In addition, the pilot program must ensure psilocybin therapy services are safe, accessible, and affordable.[e]

Source: GAO’s analysis of the some of the characteristics of selected states with legislation establishing a pilot program or study of psilocybin for therapeutic use. | GAO-24-106630

[a]2023 Ariz. Legis. Serv. Ch. 139, § 6 (Ariz. Rev. Stat. 36-132 note).

[b]Conn. Gen Stat. § 17a-484g.

[c]Md. Code Ann., Health-Gen. § 24-2101.

[d]Md. Code Ann., Health-Gen. § 24-2102.

[e]Wash. Rev. Code § 19.410.010.

Appendix IV: Key Federal Agencies Involved in Combating the Illegal Use, Manufacture, Distribution, and Transport of Controlled Substances, Including Psilocybin

As previously noted, the Drug Enforcement Administration (DEA) investigates and enforces potential violations of the Controlled Substances Act. The Federal Bureau of Investigation (FBI) also investigates cases related to violations of the Controlled Substances Act.[1] DEA coordinates and collaborates with state and local law enforcement agencies to implement or enforce the Act by sharing information and partnering in investigations and enforcement actions. DEA also manages and reviews petitions seeking religious exemptions from the Controlled Substances Act under the Religious Freedom Restoration Act to permit the use of controlled substances, including psilocybin. Within DEA, the Diversion Control Division's Diversion Regulatory Section and the Import/Export Section are the two main components that carry out this process. In addition to DEA and FBI, several other federal departments and agencies are involved in efforts to address controlled substances, including psilocybin, in the United States. Table 5 provides some examples of the key federal agencies involved in these efforts.

Table 5: Examples of Key Federal Agencies Involved in Combating the Illegal Use, Manufacture, Distribution, and Transport of Controlled Substances, Including Psilocybin

Federal Agency	Tasks
Department of Justice	
Drug Enforcement Administration (DEA)	Enforces the controlled substances laws and regulations of the United States. Coordinates with the Food and Drug Administration to review DEA registration applications requesting authorization to conduct research with a Schedule I controlled substance. Completes on-site inspections of the research facilities associated with DEA registration applicants. Develops guidance, policies, procedures, and other documentation that outlines DEA's process for reviewing religious exemption petitions from the Controlled Substances Act under the Religious Freedom Restoration Act. Accepts and reviews petitions seeking exemptions under the Religious Freedom Restoration Act to permit the use of controlled substances, including psilocybin.
Executive Office for United States Attorneys (EOUSA)	Provides executive and administrative support for the U.S. Attorney's offices across the United States.

[1]Under 28 C.F.R. § 0.85, the FBI has the authority to investigate violations of the laws, including the criminal drug laws, of the United States and collect evidence in cases in which the United States is or may be a party in interest, except in cases in which such responsibility is by statute or otherwise exclusively assigned to another investigative agency.

U.S. Attorneys' Offices	Enforce federal laws throughout the country, including drug trafficking and production offenses. U.S. Attorneys serve as the nation's principal litigators and conduct most of the trial work in which the United States is a party, including prosecuting drug cases. There are 93 U.S. Attorneys located in districts throughout the United States and its territories.
Executive Office of The President	
Office of National Drug Control Policy (ONDCP)	Leads and coordinates the federal government's drug policy. ONDCP's primary functions include: (1) developing and overseeing the implementation of the National Drug Control Strategy, (2) developing and overseeing the implementation of the National Drug Control Budget, and (3) administering programs to address overdoses, disrupt drug trafficking, and support community-led efforts to reduce youth substance use disorder.
Health and Human Services	
Food and Drug Administration (FDA)	Coordinates with DEA to review DEA registration applications requesting authorization to conduct research with a Schedule I controlled substance. Protects public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. Coordinates with DEA on scheduling drugs under the Controlled Substances Act. May authorize the use of experimental drugs in emergency situations that do not allow time for prior submission of an Investigational New Drug application if done in accordance with 21 C.F.R. pt. 312, subpt. I. Collaborates with the U.S. Customs and Border Protection (CBP) and Immigration and Customs Enforcement's Homeland Security Investigations to prevent the importation of unapproved drugs and investigates their distribution. Inspects registered facilities that manufacture drugs approved for marketing in the United States.
Department of Homeland Security	
U.S. Customs and Border Protection (CBP)	Responsible for securing the United States borders—protecting against terrorist threats and to prevent the illegal entry of inadmissible persons and contraband, while also facilitating lawful travel, trade, and immigration.
U.S. Immigration and Customs Enforcement	Enforces federal laws governing border control, customs, trade, and immigration. Homeland Security Investigations investigates the illegal movement of goods into and out of the United States, including narcotics. Collaborates with FDA and CBP to prevent the importation of unapproved drugs and investigates their distribution.
Department of the Interior	
Bureau of Indian Affairs (BIA)	Responsible for controlling the use of psilocybin on Tribal Nation lands. Tribal Nations are subject to federal law, but as sovereign entities, they operate under their own constitutions, enact their own laws, and provide services to their citizens. At the time of this review, the Bureau of Indian Affairs officials stated that no federally recognized Indian tribes have legalized the use of psilocybin for religious or spiritual practices.[a]

United States Postal Service	
U.S. Postal Inspection Service (USPIS)	Protects against and prevents criminal attacks to postal employees, customers, infrastructure, and the U.S. Mail. Enforces laws that defend the nation's mail system from illegal or dangerous use. As the federal law enforcement arm of the U.S. Postal Service, investigates cases and prepares them for court along with U.S. Attorneys, other law enforcement, and local prosecutors.

Source: GAO analysis of agency documents. | GAO-24-106630

[a]In August 2023, we attempted to meet with officials representing selected Tribal Nations throughout the United States to obtain their perspectives on the legalization of psilocybin for religious or spiritual purposes. A majority of the Tribal Nations were not responsive; however, we spoke with a representative from one Tribal Nation and the representative stated that the Tribe has no history of psilocybin use for religious, Indigenous, spiritual or any other practices.

Appendix V: Additional Perspectives Related to Challenges and Barriers Obtaining Exemptions

Along with the stakeholders' perspectives mentioned earlier in the report, we obtained additional perspectives related to the challenges and barriers that exist in the legal access and use of psilocybin for religious practices under the Religious Freedom and Restoration Act. As stated earlier, we interviewed a non-generalizable sample of nine individuals from law firms and advocacy organizations selected to represent a range of perspectives on the barriers, if any, that exist in the legal access to and use of psilocybin for religious, Indigenous, or spiritual practices under the Religious Freedom Restoration Act. In addition, we attempted to meet with officials representing various Tribal Nations to obtain their perspectives on the petitioning for the use of psilocybin for religious or spiritual purposes. A representative from one of the eleven Tribal Nations we contacted responded to our request and stated the Tribe has no history of psilocybin use for religious, Indigenous, spiritual or any other practices. We also interviewed DEA officials to identify their perspectives on the agency's process to review petitions for a religious exemption. Table 6 provides an overview of the additional perspectives we obtained related to the challenges and barriers that exist in the legal access and use of psilocybin for religious practices under the Religious Freedom and Restoration Act.

Table 6: Additional Perspectives Related to Challenges and Barriers Obtaining Exemptions

Category	Perspectives of Challenges and Barriers Obtaining Exemptions
Fear of Drug Enforcement Administration (DEA) prosecution	According to four of nine selected stakeholders, some citizens of Tribal Nations fear that DEA will investigate and prosecute them for having used psilocybin for spiritual practices such as coming of age ceremonies and introducing religious chiefs prior to submitting their Religious Freedom Restoration Act petition. This fear stems from preexisting emotional and mental trauma from racial persecution, according to select stakeholders. Additionally, other selected stakeholders shared that members of religious communities also had concerns regarding prosecution by acknowledging any previous unlawful or illegal conduct with psilocybin. DEA's guidance indicates that "[t]he petition must be signed by the petitioner, who must declare under penalty of perjury that the information provided therein is true and correct See 28 U.S.C. § 1746."[a] DEA officials noted that entities and individuals submitting a petition under the Religious Freedom Restoration Act remain subject to the Controlled Substances Act and its regulations. DEA described the collection of information as an important component of its investigation to understand a petitioner's ability to properly handle a controlled substance. DEA stated that it does not use information about a petitioner's use of a controlled substance in granting or denying a petition, and that it does not use this information to threaten civil or criminal sanctions against a petitioner during the review process, however this information is not included in the public guidance.

Legal costs of the Religious Freedom Restoration Act exemption process	According to two of nine selected stakeholders, petitioners incur legal costs from attorneys who assist the petitioner to navigate the complex DEA process. Individuals or organizations may not be able to afford these costs. Facing the prospect of retaining an attorney for a process that may take years, we were told by stakeholders that this could discourage petitioners from applying for religious exemption. According to DEA officials, each petition is unique and calls for a case-specific review and agency decision as to whether, and under what conditions, a religious exemption under the Religious Freedom Restoration Act should be granted.
Prohibition of ceremonial use of psilocybin during petition process	DEA's guidance requires petitioners to abstain from sacramental ceremonies involving controlled substances as petitions undergo review by the DEA. According to four of nine selected stakeholders, this requirement is burdensome to petitioners and becomes amplified by the absence of a clear processing timeframe.[b] DEA officials stated that as a Schedule I controlled substance, unless a substance has specifically been exempted under federal law, any person engaging in activities with any controlled substance must acquire a DEA registration. Pursuant to 21 U.S.C. § 823(a), the Attorney General generally is required to register an applicant to manufacture controlled substances in Schedule I if the Attorney General determines that such registration is consistent with the public interest and with United States obligations. In determining the public interest, one of the factors to be considered is the maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes. Similarly, pursuant to 21 U.S.C. § 823(b), the Attorney General generally is required to register an applicant to distribute a controlled substance in Schedule I unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, one of the factors to be considered is the maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels. Under 21 U.S.C. § 822(d), the Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if the Attorney General finds it consistent with the public health and safety. While DEA initiated the drafting of a notice of proposed rulemaking related to DEA's process for petitioning for religious exemptions to the Controlled Substances Act under the Religious Freedom Restoration Act in 2019 and it is under review, DEA has no estimated timeline for issuing the notice of proposed rulemaking due to the multi-step interagency review process, according to DEA officials.

Source: GAO analysis of perspectives provided by selected attorney and advocacy organization stakeholders. | GAO-24-106630

[a]Pursuant to 18 U.S.C. § 1621(2), whoever in any declaration, certificate, verification, or statement under penalty of perjury as permitted under 28 U.S.C. § 1746, willfully subscribes as true any material matter which he does not believe to be true; is guilty of perjury and shall, except as otherwise expressly provided by law, be fined under this title or imprisoned not more than five years, or both. This section is applicable whether the statement or subscription is made within or without the United States.

[b]As described in a decision by the Court of Appeals for the Eleventh Circuit, in 2017, a church requested a religious exemption from the Controlled Substances Act permitting them to import, possess, and distribute plants containing DMT to make ayahuasca. The DEA initially did not respond to Soul Quest's petition. After three years with no response from the DEA, Soul Quest filed a complaint against the DEA in federal district court and an accompanying motion seeking declaratory and injunctive relief. Soul Quest claimed that through the DEA's failure to respond to its petition, the agency violated its right to the free exercise of religion and its rights under the Religious Freedom Restoration Act. Soul Quest also filed a motion for a preliminary injunction, seeking an order

prohibiting the DEA from arresting, prosecuting, or threatening Soul Quest or its members for importing, distributing, or ingesting the sacramental tea. According to the decision, this action apparently got the DEA's attention because, soon after, the DEA responded to Soul Quest with an undated letter confirming receipt of the petition. DEA denied that request on April 16, 2021, advising petitioners that the decision constituted a final determination of petitioners' exemption request under 21 U.S.C. § 877. Soul Quest Church of Mother Earth, Inc. v. Attorney General, No. 22-110722, 2023 WL 8714320 (11th Cir. 2023).

Appendix VI: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments:

In addition to the contact named above, Frederick T. Lyles, Jr. (Assistant Director), Katrina Taylor (Analyst in Charge), Janet Temko-Blinder, Caroline Christopher, Billy Commons, Benjamin Crossley, Michele Fejfar, Geovana Mendoza, Kevin Reeves, and Candace Strickland made key contributions to the report. Also contributing to the report were Tyler Autry, Wendy Dye, Susan Hsu, and Gabriel Jimenez.

Related Products

High-Risk Series: Efforts Made to Achieve Progress Need to be Maintained and Expanded to Fully Address All Areas, GAO-23-106203. Washington, D.C.: April 20, 2023.

Drug Control: Office of National Drug Control Policy Met Some Strategy Requirements but Needs a Performance Evaluation Plan, GAO-23-105508. Washington, D.C.: December 19, 2022.

Drug Policy: Preliminary Observations on the 2022 National Drug Control Strategy, GAO-22-106087, Washington, D.C.: June 15, 2022.

Drug Control Grants: ONDCP Should Document Its Process for Identifying Duplication, Overlap, and Fragmentation, GAO-22-104666, Washington, D.C.: December 8, 2021.

Synthetic Opioids: Considerations for the Class-Wide Scheduling of Fentanyl-Related Substances, GAO-21-499. Washington, D.C.: April 12, 2021.

High-Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas, GAO-21-119SP. Washington, D.C.: March 2, 2021.

Substance Use Disorder: Reliable Data Needed for Substance Abuse Prevention and Treatment Block Grant Program, GAO-21-58. Washington, D.C.: December 14, 2020.

Drug Misuse: Agencies Have Not Fully Identified How Grants That Can Support Drug Prevention Education Programs Contribute to National Goals, GAO-21-96. Washington, D.C.: November 18, 2020.

Prescription Drug Monitoring Programs: Views on Usefulness and Challenges of Programs, GAO-21-22. Washington, D.C.: October 1, 2020.

Bureau of Prisons: Improved Planning Would Help BOP Evaluate and Manage Its Portfolio of Drug Education and Treatment Programs, GAO-20-423, Washington, D.C.: May 26, 2020.

Workforce Innovation and Opportunity Act: Additional DOL Actions Needed to Help States and Employers Address Substance Use Disorder, GAO-20-337, Washington, D.C.: May 21, 2020.

Drug Misuse: Sustained National Efforts Are Necessary for Prevention, Response, and Recovery, GAO-20-474. Washington, D.C.: March 26, 2020.

Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders, GAO-20-118. Washington, D.C.: January 29, 2020.

Opioid Use Disorder: Barriers to Medicaid Beneficiaries' Access to Treatment Medications, GAO-20-233. Washington, D.C.: January 24, 2020.

Drug Control: The Office of National Drug Control Policy Should Develop Key Planning Elements to Meet Statutory Requirements, GAO-20-124. Washington, D.C.: December 18, 2019.

Veterans Health Care: Services for Substance Use Disorders, and Efforts to Address Access Issues in Rural Areas, GAO-20-35. Washington, D.C.: December 2, 2019.

Drug Policy: Preliminary Observations on the 2019 National Drug Control Strategy, GAO-19-370T. Washington, D.C.: March 7, 2019.

Drug Control: DOD Should Improve Its Oversight of the National Guard Counterdrug Program, GAO-19-27. Washington, D.C.: January 17, 2019.

Colombia: U.S. Counternarcotics Assistance Achieved Some Positive Results, but State Needs to Review the Overall U.S. Approach, GAO-19-106. Washington, D.C.: December 12, 2018.

Illegal Marijuana: Opportunities Exist to Improve Oversight of State and Local Eradication Efforts, GAO-19-9. Washington, D.C.: November 14, 2018.

Opioid Crisis: Status of Public Health Emergency Authorities, GAO-18-685R. Washington, D.C.: September 26, 2018.

Prescription Opioids: Medicare Needs Better Information to Reduce the Risk of Harm to Beneficiaries, GAO-18-585T. Washington, D.C.: May 29, 2018.

VA Health Care: Progress Made Towards Improving Opioid Safety, but Further Efforts to Assess Progress and Reduce Risk Are Needed, GAO-18-380. Washington, D.C.: May 29, 2018.

Illicit Opioids: Office of National Drug Control Policy and Other Agencies Need to Better Assess Strategic Efforts, GAO-18-569T. Washington, D.C.: May 17, 2018.

Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess their Efforts, GAO-18-205. Washington, D.C.: March 29, 2018.

Substance Use Disorder: Information on Recovery Housing Prevalence, Selected States' Oversight, and Funding, GAO-18-315. Washington, D.C.: March 22, 2018.

Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment, GAO-18-44. Washington, D.C.: October 31, 2017.

Counternarcotics: Overview of U.S. Efforts in the Western Hemisphere, GAO-18-10. Washington, D.C.: October 13, 2017.

Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs, GAO-18-25. Washington, D.C.: October 12, 2017.

Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm, GAO-18-15. Washington, D.C.: October 6, 2017.

Drug Control Policy: Information on Status of Federal Efforts and Key Issues for Preventing Illicit Drug Use, GAO-17-766T. Washington, D.C.: July 26, 2017.

Drug-Free Communities Support Program: Agencies Have Strengthened Collaboration but Could Enhance Grantee Compliance and Performance Monitoring, GAO-17-120. Washington, D.C.: February 7, 2017.

State Marijuana Legalization: DOJ Should Document Its Approach to Monitoring the Effects of Legalization, GAO-16-1. Washington, D.C.: December 30, 2015.

Office of National Drug Control Policy: Office Could Better Identify Opportunities to Increase Program Coordination, GAO-13-333. Washington, D.C.: March 26, 2013.

ONDCP Media Campaign: Contractor's National Evaluation Did Not Find That the Youth Anti-Drug Media Campaign Was Effective in Reducing Youth Drug Use, GAO-06-818. Washington, D.C.: August 25, 2006.

Marijuana: Early Experiences with Four States' Laws That Allow Use for Medical Purposes, GAO-03-189. Washington, D.C.: November 1, 2002.

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