



Department of Justice

STATEMENT OF THE U.S. DEPARTMENT OF JUSTICE

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BEFORE THE

**HOUSE ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES**

**FOR A HEARING ENTITLED
CANNABIS POLICY – FOR THE NEW DECADE**

PRESENTED

JANUARY 15, 2020

**Statement of the Department of Justice
Before the United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health**
For a Hearing Entitled “Cannabis Policy – For the New Decade”
January 15, 2020

Chairman Eshoo, Ranking Member Burgess, and distinguished members of the Subcommittee, as the Senior Policy Advisor of the Diversion Control Division, Drug Enforcement Administration (DEA), within the Department of Justice (Department), I am integrally involved in the Department’s efforts to expand access to research with controlled substances. The Diversion Control Division is charged with the responsibility 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. I appreciate the opportunity to share with you an update on the actions that DEA has taken as well as those that are intended to be undertaken in the near future with the goal of improving access to marihuana to meet the research needs of the United States.

Much like our partners at the Department of Health and Human Services (HHS), the Department and DEA fully support research into the effects of marihuana and the potential medical utility of its chemical constituents. In the last few years, the Department and DEA, in close collaboration with HHS and the Office of National Drug Control Policy (ONDCP), have made great strides in improving research with marijuana and its constituent parts. For example:

- In December 2015, DEA announced to all existing schedule I researchers that it was easing the requirements for obtaining a modification of their existing registration for those who wished to conduct research with cannabidiol (CBD), an effort directly aimed at improving research on the substance which ultimately contributed to the subsequent approval by Food and Drug Administration (FDA) of Epidiolex for use in the treatment of certain childhood epilepsy syndromes.¹
- In early 2018, DEA announced that it had developed and implemented an online portal for researchers to safely and securely submit their qualifications, research protocol and institutional approvals for a proposed schedule I research registration thereby streamlining the acquisition of information necessary to process each application. Presently, the average time it takes for DEA and the FDA to review/approve an application is 52 days.
- Between 2017 and 2020, DEA increased the aggregate production quota² for marihuana by 575 percent from 472 kg in 2017 to 3,200 kg in 2020. The increase has directly supported the National Institute on Drug Abuse’s (NIDA) provision of various strains of marihuana to researchers in the United States.

¹ See <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuananamarijuana-treat-rare-severe-forms>

² The “aggregate production quota” for schedule I and II controlled substances.

- Over the last 5 years, there has been a 155 percent increase in the number of active researchers registered with DEA to conduct research with marihuana, marihuana extracts and marihuana derivatives (from 237 in November 2014 to 605 in October 2019).
- At present, more research is conducted on marihuana, marihuana extracts, and marihuana derivatives than any other Schedule I substance in the United States. More than 70 percent of DEA's total Schedule I research registrant population (605 of 829 as of December 2019) conducts research on these substances.

As detailed below, to further expand medical and scientific research, the Department and DEA are taking a number of actions to increase the number of registered marihuana manufacturers (or growers), consistent with applicable law, to meet a demonstrated need for different varieties.

The Controlled Substances Act and Marihuana

Under the Controlled Substances Act (CSA), every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. § 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. § 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308. Substances in Schedule I are those that 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. 21 U.S.C. § 812(b)(1).

Congress specifically placed “marihuana” in Schedule I of the CSA in 1970³ and defined “marihuana” as all parts of the plant Cannabis sativa L., with certain exceptions for the parts of the plant that are not the source of cannabinoids. Among the parts of the cannabis plant included in the definition of marihuana are: the flowering tops, the leaves, viable seeds, and the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. 21 U.S.C. § 812(c) Schedule I; 21 U.S.C. § 802(16); 21 C.F.R. § 1308.11(d).

The Agriculture Improvement Act of 2018 (Pub.L. 115-334, referred to as the AIA) was signed into law on December 20, 2018. It provided a new statutory definition of “hemp” and amended the definition of “marihuana” under the CSA. The AIA modified the definition by adding that the “term ‘marihuana’ does not include hemp, as defined in section 1639o of Title 7.” 21 U.S.C. § 802(16)(B). Furthermore, the AIA added a definition of “hemp” to 7 U.S.C. 1639o, which reads as follows:

The term “hemp” means the plant Cannabis sativa L. and any part of the plant including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis.

³ Controlled Substances Act, Section 100 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub.L. 91-513 Oct. 27, 1970.

The CSA and the Federal Food, Drug, and Cosmetic Act (FDCA) contain provisions that are specifically designed to allow for both clinical research with, and treatment uses of, investigational drugs containing controlled substances, provided certain steps are taken to protect the rights, safety, and welfare of human subjects. The FDA drug approval process, as established and modified by Congress, ensures that safe and effective new medicines are available as soon as possible for the largest numbers of patients; DEA and the Department stand committed to assist our federal partners in this process.

Current Statutory Framework Governing the Registration of Certain Individuals Handling Marihuana under the CSA

Under the CSA, DEA is responsible for registering growers who can produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions for such research.⁴ The University of Mississippi (UMiss) has, for several decades, applied for and received a registration from DEA to grow marihuana. This work is performed pursuant to a contractual agreement with NIDA for the production of research-grade marihuana for federally-approved research.⁵ Presently, there are no other DEA-registered bulk manufacturers of marihuana authorized to cultivate marihuana for research purposes. The DEA is actively taking steps to expand the program, which should result in additional registered growers and a larger, more diverse variety of marihuana for research.

The CSA requires all individuals who wish to perform research with marihuana to register with DEA. In those instances, DEA's role is to ensure that proper safeguards are in place to prevent diversion (e.g., security and recordkeeping), while HHS (delegated to FDA) is charged with determining the qualifications and competency of the researcher as well as reviewing the merits of the protocol.⁶ Those who wish to perform research with marihuana (or any schedule I controlled substance) must submit certain information to assist DEA and HHS with their respective roles:

1. Information about the Investigator – name, address, curriculum vitae and institutional affiliation
2. Information about the Research Project – Purpose, description of the research (i.e., protocol), the location for the research and security
3. Authority – Document approval by the research institution

Importantly, the applicant also provides information about the name of the substance under investigation, the amount required and the proposed source of supply.⁷ With regard to this provision, DEA and HHS work in concert to ensure that the source of the schedule I controlled substance is from a DEA registrant to ensure that the substance was produced in accordance with state, federal, and international law. Furthermore, as coincident activity a DEA registered schedule I researcher, may import marijuana for research purposes so long as the activity is

⁴ 21 U.S.C. 823(a)(1). <https://www.deadiversion.usdoj.gov/21cfr/21usc/823.htm>

⁵ NIDA has established procedures governing the process for providing marihuana to non-federally approved researchers as well.

⁶ 21 U.S.C. 823(f). <https://www.deadiversion.usdoj.gov/21cfr/21usc/823.htm>

⁷ 21 CFR 1301.18

consistent with their protocol and from a legitimate source as authorized through the regulated importation process.

DEA has never denied an application to conduct bona fide research with marihuana from a researcher who has received a favorable recommendation from HHS. As of December 12, 2019, there were 605 DEA-registered schedule I researchers authorized to conduct research with marihuana, marihuana extracts and/or tetrahydrocannabinols in the United States.

DEA's August 2016 Policy Statement and Subsequent Efforts to Expand the Number of Registrants to Grow Marihuana

In August 2016, after consultations with both FDA and NIDA, and following the denial of two petitions from former Governors to reschedule marihuana,⁸ DEA published a policy statement in the Federal Register (81 FR 53846) ("2016 Policy Statement"). The 2016 Policy Statement addressed applications by persons seeking to become registered under the CSA to grow marihuana (i.e., manufacture) in order to supply DEA-registered researchers in the United States for bona fide research.

Since publication of the 2016 Policy Statement, the Department of Justice has subsequently engaged in a review of the Policy Statement and the proposed changes, and determined that adjustments to DEA's policies and procedures may be necessary under applicable U.S. law to be consistent with certain treaty functions. As DEA explained in its August 2019 letter to each of the then-33 pending applicants who sought authority to grow marihuana, given that the size of the applicant pool is unprecedented in DEA's experience, the agency has determined that adjustments to its policies and practices with respect to the marihuana growers program are necessary to fairly evaluate the applicants under the factors outlined in 21 U.S.C. 823(a), including 823(a)(1), which requires that DEA "limit the ... bulk manufacture of [Schedule I and II] 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."

In addition, since publication of the 2016 Policy Statement, the Department of Justice, in consultation with other federal agencies, has been engaged in a policy review process to ensure that the marihuana growers program is consistent with applicable laws and treaties. That review process remains ongoing; however, had progressed to the point where DEA was able to issue a notice of applications on August 27, 2019, (84 FR 44920).

In August 2019, DEA acknowledged that the as a result of the AIA, some who applied for a registration pursuant to the 2016 Policy Statement for the purpose of growing cannabis that contains no more than 0.3 percent delta-9-tetrahydrocannabinols on a dry weight basis, including cannabis that contains cannabidiol and falls below the delta-9-tetrahydrocannabinol threshold, no longer need to register for the DEA for that purpose. Accordingly, those applicants were allowed to withdraw their application and were eligible to receive a refund from DEA for fees paid at the time of their application.

⁸ 81 FR 53687

In the near future, DEA intends to propose regulations that would govern persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, consistent with applicable law, taking into account recent changes in the Controlled Substances Act. At present, a notice of proposed rulemaking is under review by the Office of Management and Budget.

Throughout this process, DEA and the Department remain committed to supporting research opportunities and these advancements are in effort to register more marihuana manufacturers, and expand the amount and type of marijuana grown for research purposes.

Conclusion

The Diversion Control Division within DEA is charged with preventing the diversion of legitimate sourced controlled substances while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs. We are steadfast in our effort to fulfill that mission, and to work with our partners to improve this process.

DEA is committed, consistent with the CSA, to assisting the health care needs of patients and supporting research involving marihuana. DEA shares the view that medical decisions should be based on science and adherence to the established drug approval process which ensures that only safe and effective drugs are approved to be available in the United States. DEA continues to make the approval of schedule I researchers a top priority and we look forward to continuing our efforts with our interagency partners to expand research efforts for all controlled substances, including marihuana.

Thank you for the opportunity to testify today and we look forward to continuing to work with Congress on this important topic.