



Department of Justice

STATEMENT OF

**JOSEPH T. RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
DRUG ENFORCEMENT ADMINISTRATION**

BEFORE THE

**CAUCUS ON INTERNATIONAL NARCOTICS CONTROL
UNITED STATES SENATE**

FOR A HEARING CONCERNING

**CANNABIDIOL: BARRIERS TO RESEARCH AND POTENTIAL
MEDICAL BENEFITS**

PRESENTED

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Statement of Joseph T. Rannazzisi
Deputy Assistant Administrator
Drug Enforcement Administration
Before the Caucus on International Narcotics Control
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Good morning Chairman Grassley, Co-Chairman Feinstein, and distinguished Members of the Caucus. I am pleased to speak with you about Drug Enforcement Administration (DEA) regulatory oversight of cannabidiol (CBD) and products containing CBD, and the requirements necessary to conduct research on CBD.

I. Introduction

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 placed “marihuana” in Schedule I of the CSA 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 marijuana 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). CBD derived from the cannabis plant is controlled under Schedule I of the CSA because it is a naturally occurring constituent of marijuana. While there is ongoing research into potential medical uses of CBD, at this time CBD has no currently accepted medical use in the United States.

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, provided certain steps are taken to protect the rights, safety, and welfare of human subjects. The Food and Drug Administration’s (FDA) drug approval process, as established by Congress, represents the best way to ensure that safe and effective new medicines are available as soon as possible for the largest numbers of patients.

Currently, there are a number of researchers around the country who are looking into the possible medicinal benefits of CBD. Because no drug products containing CBD are approved for marketing under the FDCA, those wishing to conduct a clinical investigation involving CBD under the FDCA must submit an Investigational New Drug application to the FDA, which must be in effect before any human subject may be enrolled in such investigations.

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

DEA will also work with HHS to evaluate CBD under section 201 (a) – (c) of the Controlled Substances Act (21 U.S.C. 811(a-c)). To accomplish this, DEA will initiate the review of CBD and request a scientific and medical evaluation and scheduling recommendation for CBD from HHS. Please be advised, although CBD products are currently being evaluated under Investigational New Drug Applications, additional scientific studies may need to be initiated and conducted to assess CBD's abuse liability. Scheduling recommendations are evidence-based, and DEA will provide any assistance necessary to assist HHS in its collection of information critical to its scientific and medical evaluation and formulation of a recommendation.

II. Current regulations applicable to research involving Schedule I substances

As you know, both DEA and the FDA have statutory roles related to the oversight of research with Schedule I controlled substances such as CBD. DEA understands the importance of supporting the efficient scientific assessment of marijuana and its constituents such as CBD in connection with new drug development. DOJ and DEA are fully committed to supporting lawful research involving marijuana and CBD by ensuring compliance with the Controlled Substances Act and the Single Convention on Narcotic Drugs. DEA will continue to review the relevant regulations to ensure they are consistent with supporting lawful research. If this review

determines that amending the existing regulations governing the Schedule I researcher registration process is necessary to accomplish these goals, DEA would initiate the process to do so. DEA will also continue to work with HHS to streamline the Schedule I Researcher registration process and identify new opportunities for improvement.

A. Registration

The CSA requires:

Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title.

21 U.S.C. § 823(f).

Section 823(f) provides, in essence, that where a practitioner seeks to conduct research with a Schedule I controlled substance, the respective roles of the agencies are as follows: (1) FDA determines whether the research protocol is scientifically meritorious; and (2) DEA determines whether appropriate safeguards are in place to prevent the diversion of controlled substances and whether the registration would be consistent with 21 U.S.C. § 824(a).

In practice, the researcher submits a research protocol with his or her registration application, which DEA forwards to HHS for review. Once HHS determines that the researcher is qualified and the research protocol is scientifically meritorious, DEA will grant the registration, provided the researcher will have in place effective controls against the diversion of controlled substances, and the circumstances do not warrant a denial pursuant to 21 U.S.C. 824(a) (e.g., the applicant has not materially falsified the application, the applicant has not been convicted of a controlled substance-related felony).

To date, DEA has not denied any research application that has met the CSA requirements. In fact, the number of authorized Schedule I researchers, including CBD researchers, continues to grow.¹ Between November 2014 and today, the number of researchers

¹ As of November 17, 2014, there were approximately 237 active Schedule I researchers registered with DEA. Of those 237, 166 were approved to perform bona fide research with marijuana, marijuana extracts, and marijuana

approved to conduct research with CBD on human subjects has increased from 16 to 41. As of June 4, 2015, there are 399 active researchers registered with the DEA to conduct bona fide research with Schedule I controlled substances. Of these 399 Schedule I researchers, 265 active researchers are registered with DEA to conduct bona fide research with marijuana and marijuana extracts that include CBD, and 41 researchers are approved to conduct research with CBD on human subjects. Each of these 41 researchers is approved to conduct or supervise an investigation with at least one study subject if not more with synthetic or plant-derived CBD. This is a significant increase when compared to November 17, 2014, when 16 researchers were approved to conduct research with CBD on human subjects. In furtherance of our ongoing efforts to support CBD research, DEA will continue its policy of expediting these applications.

B. Amended Schedule I Protocols

Under current DEA regulations, when a researcher who is in the midst of an ongoing, approved study seeks to increase the quantity of the Schedule I controlled substance being used for the research, the researcher must submit to DEA an amendment to the approved protocol. 21 C.F.R. § 1301.18(c). “Upon return of the receipt, the registrant shall be authorized to purchase the additional quantity of the controlled substance or substances specified in the request.” *Id.* DEA forwards this information to HHS, and HHS “shall approve or deny the request as an amendment to the protocol.” *Id.* Submission of an amendment does not stop research with the previously approved protocol, which remains active. The researcher may continue to conduct research pursuant to the previously approved protocol.

DEA’s role in the process is to ensure that there is accurate accounting and security for the increase in material. From a diversion control standpoint, DEA needs to be informed of any changes in the quantity of Schedule I drug to ensure that there continue to be effective procedures to guard against diversion of all such controlled substance material. Further, in some instances, the Schedule I drug that is used in the clinical trial is imported. In such cases, where the researcher seeks to use more material than indicated in the original protocol, 21 C.F.R. § 1301.18(c) allows the increased amounts to be legitimately used in research, thereby providing the basis for allowing the increased amount to be imported pursuant to 21 U.S.C. § 952(a)(2)(C) (authorizing the import of Schedule I substances if in limited quantities for research uses).

derivatives such as CBD and cannabinol. Of these, 16 researchers were approved to conduct research with CBD on human subjects, and 7 researchers were pending approval to conduct such research. As of February 25, 2015, there were 372 active researchers registered with the DEA to conduct bona fide research with Schedule I controlled substances. Of these 372 researchers, 247 active researchers were registered to conduct bona fide research with marijuana and marijuana extracts that include CBD. As of June 4, 2015, there were 399 active researchers registered with the DEA to conduct bona fide research with Schedule I controlled substances; of these 399 researchers, 265 active researchers were registered to conduct bona fide research with marijuana and marijuana extracts.

The quantity changes might impact the scientific merit of the research; therefore, the regulations require the researcher to provide to DEA and FDA notice of the additional quantities of controlled substances that the researcher wishes to procure. FDA reviews the proposed increase in quantity to ensure that the protocol remains scientifically sound and meritorious, and safe for human research subjects.

C. Supplemental Schedule I Protocols

If an approved researcher intends to deviate from the previously approved research protocol other than in the quantity of controlled substance (e.g., if a researcher were to seek to expand the subject group to include pediatric patients, to include patients with different diagnoses or suffering from life-threatening ailments, or to change the method of delivery of the drug), the researcher must submit a supplemental protocol to DEA. DEA forwards the supplemental protocol to FDA for review and approval. These types of changes might raise significant new questions concerning the scientific merits of the protocol. Close review is important because material deviations in the research protocol could potentially alter the scientific merit of the research and have impacts on the health and safety of the human research subjects. For this reason, protocol changes noted in 21 C.F.R. § 1301.18(d) – unlike the quantity changes in 21 C.F.R. § 1301.18(c) – are reviewed in the same manner as an original protocol. The Schedule I researcher may continue research using the previously approved protocol until DEA and FDA take the final action regarding the supplemental protocol.

D. Processing Timeframes

It is important to act expeditiously on applications for Schedule I research. The timeframes for DEA's and FDA's processing of Schedule I research applications are specified in the regulations. DEA forwards complete Schedule I research protocols to the FDA within seven days of receipt; FDA notifies DEA of its determination regarding the merits of the protocol within 30 days; and DEA issues a certificate within 10 days of receiving the FDA's notice. 21 C.F.R. 1301.32(c). It should be noted that although many clinical researchers may be subject to a standardized protocol, thereby streamlining the process, some researchers must also meet institutional and State requirements prior to approval. DEA works closely with researchers to assist with the expeditious completion of their protocol submission and registration application.

III. Conclusion

The CSA allows for bona fide research with Schedule I controlled substances, provided that FDA has determined the researcher to be qualified and competent and the research protocol to be meritorious. Researchers who meet these criteria, as well as the other criteria set forth in the CSA, may obtain a registration to conduct research with a Schedule I controlled substance.

DEA is committed, consistent with the CSA and the FDCA, to assisting the health care needs of patients and supporting research involving CBD. DEA shares the view that medical decisions should be based on science and adherence to established drug approval processes. Accordingly, DEA will continue to make the review and approval of Schedule I researchers a top priority, and will make every effort to ensure that research continues where CSA requirements are met.

I look forward to taking your questions.