



MEMORANDUM

January 10, 2020

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on “Cannabis Policies for the New Decade”

On Wednesday, January 15, 2020, at 10 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building, the Subcommittee on Health will hold a legislative hearing entitled, “Cannabis Policies for the New Decade.”

I. BACKGROUND

A. The Controlled Substances Act and Cannabis Research

The Controlled Substances Act (CSA) regulates the manufacture, possession, use, importation, and distribution of certain drugs, substances, and precursor chemicals.¹ The CSA includes five schedules in which controlled substances must be classified. Among the items regulated under Schedule I of the CSA, which is the most stringently regulated, are parts of the cannabis plant, defined as “marihuana” in statute.² Chemical constituents of cannabis, or cannabinoids, are also regulated under the CSA. This includes tetrahydrocannabinols, including delta-9-tetrahydrocannabinol, commonly referred to as THC.³

Although THC remains classified as a Schedule I substance, the Food and Drug Administration (FDA) has approved three synthetic cannabis-related drugs for therapeutic use: Marinol, Syndros, and Cesamet. Marinol and Syndros were approved for treating weight loss in AIDS patients, while all three were approved for treating nausea associated with cancer

¹ P.L. 91-513, as amended.

² 21 U.S.C. § 802 (16)(A) defines “marihuana” as all parts of the plant *Cannabis sativa L.*, whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, alt, derivative, mixture, or preparation of such plant, its seeds or resin. This definition excludes hemp, as defined in section 297A of the Agricultural Marketing Act of 1946. It also excludes the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

³ See note 1.

chemotherapy.⁴

Researchers seeking to investigate cannabinoids must work through certain protocols with FDA, the National Institute on Drug Abuse (NIDA), and the Drug Enforcement Administration (DEA). Due to its inclusion on the list of Schedule I, researchers who wish to study cannabis or THC must fulfill a number of additional requirements, including: obtaining a separate DEA registration for Schedule I substances; meeting production quota limitations; and fulfilling security specifications, among other protocols.⁵ The United States is also restricted by cannabis policies set out by three United Nations drug control treaties that set international standards for cannabis and THC aimed at reducing abuse of these substances.⁶ In addition to the waiting periods caused by these protocols, researchers at institutions of higher education have expressed frustration over difficulties they have experienced in carrying out cannabis research.⁷ In addition, provisions contained within the Drug Free Schools and Campuses Act that prohibit marijuana possession, use, or distribution by students, staff, and faculty may put federal funding for the entity at risk.⁸

To improve access to research on cannabis, DEA announced its intent in August 2019, to move forward with its review of pending applications from entities applying to manufacture marijuana for research.⁹ Currently, cannabis research must use cannabis products sourced through the NIDA's Drug Supply Program single DEA licensee: the University of Mississippi.¹⁰ This requirement prevents researchers from studying cannabis products used in commercial development and purchasing strains of cannabis from other sources, such as from widely used state dispensaries.

B. Changes to Cannabis Policy in the 2018 Farm Bill

The 2018 Farm Bill removed hemp, which includes low-THC derivatives of cannabis, such as cannabidiol (CBD) products from the definition of marijuana in the CSA. The bill expanded the definition of hemp to include “the plant *Cannabis sativa L.* and any part of that

⁴ Food and Drug Administration, *FDA and Cannabis: Research and Drug Approval Process* (www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process) (accessed January 6, 2020).

⁵ 21 U.S.C. § 823; 21 U.S.C. §826; 21 C.F.R. §1301.72; 21 C.F.R. §1301.18.

⁶ United Nations General Assembly, 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961; United Nations Convention on Psychotropic Substances, 1971; United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

⁷ *Risk of Losing Federal Funding Reason Why Medical Marijuana Research Won't Happen*, The Lantern (August 23, 2017).

⁸ P.L. 101-226; Illinois Higher Education Center, *Marijuana and The Drug Free Schools and Campuses* (November 2015) (www.eiu.edu/ihec/Marijuana%20and%20DFSCA.pdf).

⁹ Drug Enforcement Administration, *DEA announces steps necessary to improve access to marijuana research* (www.dea.gov/press-releases/2019/08/26/dea-announces-steps-necessary-improve-access-marijuana-research) (accessed January 6, 2020).

¹⁰ National Institute on Drug Abuse, *NIDA's Role in Providing Marijuana for Research* (www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research) (accessed January 6, 2020).

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 percent on a dry weight basis”, while also amending the CSA to specify that the terms ‘marihuana’ and ‘tetrahydrocannabinols’, which are currently included in Schedule I, do not include hemp, as defined under the Agricultural Marketing Act as amended under the 2018 Farm Bill.¹¹ FDA Principal Deputy Commissioner Amy Abernethy stated in congressional testimony that, “The passage of the 2018 Farm Bill has led to the misperception that all products made from or containing hemp, including those made with CBD, are now legal to sell in interstate commerce.”¹²

Currently, it is unlawful under the Federal Food, Drug, and Cosmetic Act (FFDCA) to market CBD in food or as a dietary supplement. FDA, however, has approved Epidiolex – a drug product with the active ingredient CBD, which is indicated to treat seizures for patients with Lennox-Gastaut syndrome or Dravet syndrome.^{13,14} Last year, FDA issued warning letters to various companies who marketed unapproved drugs or made false health claims about its products, including 15 letters to companies that were marketing CBD to treat diseases or for therapeutic uses in humans and/or animals.¹⁵ FDA continues to work through public feedback from its July 2019 hearing and public docket to regulate CBD products.^{16,17} Although FDA acknowledged that rulemaking may take three to five years to complete, the agency is exploring options to find a more timely solution.¹⁸

¹¹ P.L. 115-334 § 10113 and 12619.

¹² Senate Committee on Agriculture, Nutrition, and Forestry, Testimony of Amy Abernethy, Principal Deputy Commissioner, Food and Drug Administration, *Hearing on Hemp Production and the 2018 Farm Bill*, 116th Cong. (July 25, 2019).

¹³ See note 4.

¹⁴ Food and Drug Administration, *What You Need to Know (And What We’re Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD* (www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis) (accessed January 6, 2020).

¹⁵ Food and Drug Administration, *Warning Letters 2019* (www.fda.gov/drugs/warning-letters-and-notice-violation-letters-pharmaceutical-companies/warning-letters-2019) (accessed January 6, 2020); Food and Drug Administration. *FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns*. (www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details) (accessed January 8, 2020); Food and Drug Administration. *Warning Letters and Test Results for Cannabidiol-Related Products* (www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products).

¹⁶ Food and Drug Administration, *Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing*, (www.fda.gov/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds) (accessed January 6, 2020).

¹⁷ Food and Drug Administration, *Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments*, (www.regulations.gov/docket?D=FDA-2019-N-1482) (accessed January 6, 2020).

¹⁸ See note 12.

C. Petitions to Reschedule Marijuana

Over the years, DEA received several petitions to reschedule cannabis. A private citizen from New Mexico and two governors filed respective petitions in 2009 and 2011, to reclassify cannabis from its current Schedule I status. On August 12 2016, DEA denied both petitions citing a review by FDA and NIDA that stated, based on legal standards in the CSA, cannabis “remains a schedule I controlled substance because it does not meet the criteria for currently accepted medical use in treatment in the United States, there is a lack of accepted safety for its use under medical supervision, and it has a high potential for abuse.”¹⁹

D. Cannabis and Public Health

A 2018 survey from the Substance Abuse and Mental Health Administration (SAMHSA) found that marijuana is the most commonly used illicit drug in the United States.²⁰ Data also shows that perceived risk of marijuana use among teens has been declining over the past decade.²¹ In August 2019, the Surgeon General issued an advisory about the potential harms of using marijuana products on developing brains.²² FDA also strongly advised the American public against using cannabis or cannabis-derived products during pregnancy or while breastfeeding.²³

Given some of the changing landscape and public perceptions around cannabis, a recent report by the National Academies of Sciences, Engineering, and Medicine warned that the “lack of aggregated knowledge is a significant impediment not only to the scientific understanding of cannabis but also to the advancement of public policy and the Nation’s overall public health.”²⁴

¹⁹ Drug Enforcement Administration, *DEA Announces Actions Related To Marijuana And Industrial Hemp* (www.dea.gov/press-releases/2016/08/11/dea-announces-actions-related-marijuana-and-industrial-hemp) (accessed January 6, 2020).

²⁰ Substance Abuse and Mental Health Services Administration, Substance Abuse Center for Behavioral Health Statistics and Quality, *Results from the 2018 National Survey on Drug Use and Health* (www.samhsa.gov/data/report/2018-nsduh-detailed-tables).

²¹ National Institutes on Drug Abuse. *2019 Monitoring the Future Survey* (<https://www.drugabuse.gov/related-topics/trends-statistics/monitoring-future>) (accessed January 6, 2020).

²² Health and Human Services. *U.S. Surgeon General’s Advisory: Marijuana Use and the Developing Brain* (www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html).

²³ Food and Drug Administration. *What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding* (www.fda.gov/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding).

²⁴ National Academies of Sciences, Engineering, and Medicine 2017. *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*.

II. LEGISLATION

A. **H.R. 171, the “Legitimate Use of Medicinal Marijuana Act”**

H.R. 171, the “Legitimate Use of Medicinal Marijuana Act” or “LUMMA”, introduced by Rep. Griffith (R-VA), transfers marijuana from Schedule I to Schedule II of the CSA. It also specifies that no provision of the CSA or the FFDCA shall prohibit or restrict activities related to medical marijuana that comply with a state's medical marijuana law. The bill does not affect any federal, state, or local law that regulates or prohibits smoking in public.

B. **H.R. 601, the “Medical Cannabis Research Act of 2019”**

H.R. 601, the “Medical Cannabis Research Act of 2019”, introduced by Rep. Gaetz (R-FL), requires the Attorney General to assess the supply of research grade cannabis and directs the Attorney General to increase the number of federally registered cannabis manufacturers for research purposes. The bill also allows Department of Veterans Affairs health providers to provide information to veterans about federally-approved cannabis clinical trials, and to participate in such trials if registered under the CSA.

C. **H.R. 1151, the “Veterans Medical Marijuana Safe Harbor Act”**

H.R. 1151, the “Veterans Medical Marijuana Safe Harbor Act”, was introduced by Rep. Lee (D-CA). The bill amends the CSA to include a safe harbor provision for veterans to use, possess, or transport medical marijuana. The bill would also allow physicians to discuss medical marijuana treatment with veterans and allows physicians to recommend a veteran participate in medical marijuana treatment programs approved by State or tribal laws. The bill also directs the Secretary of Veterans Affairs to conduct a study on the effects of medical marijuana on veterans in pain.

D. **H.R. 2843, the “Marijuana Freedom and Opportunity Act”**

H.R. 2843, the “Marijuana Freedom and Opportunity Act”, introduced by Rep. Jeffries (D-NY), decriminalizes marijuana by removing marijuana and THC from the list of Schedule I substances. The bill includes directives to conduct research on the impact of marijuana on the brain, the efficacy of medicinal marijuana, identification of additional medical benefits and uses of cannabis, and support highway safety research. The bill requires Alcohol and Tobacco Tax and Trade Bureau to promulgate regulations that require restrictions on advertising and promotion of marijuana products. The bill also includes a grant program for States and local governments for marijuana conviction expungement programs.

E. **H.R. 3797, the “Medical Marijuana Research Act of 2019”**

H.R. 3797, the “Medical Marijuana Research Act of 2019”, introduced by Rep. Blumenauer (D-OR), would direct the Secretary of Health and Human Services (HHS) to ensure a supply of marijuana for research purposes through the NIDA Drug Supply Program. Among other provisions, the bill directs NIDA and HHS to act on marijuana research registration

applications within 30 days prior to supplying marijuana through the NIDA Drug Supply Program. The bill directs FDA to issue guidelines on the production of marijuana and to encourage authorized researchers and manufacturers to produce marijuana, in coordination with the law. The bill gives researchers who are approved for Schedules II through V the authorization to conduct research on marijuana. The bill also streamlines the protocol for researchers to receive an application approval from the Attorney General. The bill prevents HHS from reinstating an additional review processes related to marijuana research.

F. H.R. 3884, the “Marijuana Opportunity Reinvestment and Expungement Act of 2019” or the “MORE Act of 2019”

H.R. 3884, the “Marijuana Opportunity Reinvestment and Expungement Act of 2019” or the “MORE Act of 2019”, introduced by Rep. Nadler (D-NY), would remove marijuana and THC from the list of Schedule I drugs. The bill directs the Attorney General to finalize rulemaking to remove marijuana and THC from the schedules of controlled substances and deem the drug or substance that does not meet the requirements for inclusion in any schedule. The bill directs the Bureau of Labor Statistics to compile public data on the demographics of the cannabis industry.

The bill also creates an Opportunity Trust Fund at the Treasury to support new programs, including: the establishment of a Cannabis Justice Office within the Department of Justice Office of Justice Programs; and a Community Reinvestment Program that offers job training, reentry services, legal aid for civil and criminal cases, including expungement of cannabis convictions, literacy and health education programs, and youth recreation or mentoring programs. The bill includes authorities for the Small Business Administration to support services for cannabis-related businesses. The bill further includes a provision related to the expungement of arrests, convictions, or adjudication related to federal cannabis offenses.

III. WITNESSES

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