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Congress Holds Hearing on Current & Future Federal Cannabis Policies

On January 15, 2020, the House Energy & Commerce Committee, Subcommittee on Health held a hearing entitled "Cannabis Policies for the New Decade."

Government witnesses testified from:

- the Drug Enforcement Administration (DEA);
- the Food and Drug Administration's Center for Drug Evaluation and Research (FDA/CDER); and
- the National Institutes of Health's National Institute on Drug Abuse (NIH/NIDA).

Members also discussed six bills and expressed bi-partisan support for some sort of change to federal cannabis law: some Members proposed to re-schedule cannabis from Schedule I to Schedule II; other Members proposed to de-schedule cannabis; and all aimed to relax requirements to enable continued cannabis-related research. Specifically, the six bills discussed were as follows:

- **H.R. 171, the "Legitimate Use of Medicinal Marijuana Act,"** which would re-schedule marijuana from a Schedule I to Schedule II drug under the Controlled Substance Act (CSA).
- **H.R. 601, the "Medical Cannabis Research Act of 2019,"** which would expand access to research-grade cannabis for research purposes and allow the Department of Veterans Affairs to inform patients of, and allow them to participate in, cannabis clinical trials.
- **H.R. 1151, the "Veterans Medical Marijuana Safe Harbor Act,"** which would allow for veterans to use, possess, or transport medical marijuana; allow physicians to inform veterans about medical marijuana treatment programs; and provide for the Secretary of Veterans Affairs to study the effects of medical marijuana by veterans.

- **H.R. 2843, the "Marijuana Freedom and Opportunity Act,"** which would decriminalize marijuana at the federal level and provide for greater research on the medical benefits of marijuana.
- **H.R. 3797, the "Medical Marijuana Research Act of 2019,"** which would increase the supply of marijuana for research purposes in the NIDA Drug Supply Program and allow for certain researchers and manufactures to produce marijuana.
- **H.R. 3884, the "Marijuana Opportunity Reinvestment and Expungement (MORE) Act of 2019,"** which would decriminalize marijuana, expunge certain marijuana-related convictions, and create several cannabis-related programs.

CURRENT FEDERAL CANNABIS LAW

The most notable change in federal cannabis law occurred in 2018 when the Farm Bill carved out hemp, a type of cannabis with extremely low tetrahydrocannabinol (THC) levels, from the definition of "marihuana" under the Controlled Substance Act (CSA). Under the Farm Bill amendments, it is no longer a criminal offense under the CSA to possess or distribute hemp or hemp-derived products. However, the Farm Bill made no changes to the CSA's classification of marijuana or marijuana-derived products, and it did not affect FDA's authority over products that are intended for use as a food, dietary supplement, drug, or cosmetic, including cannabis-related products, and specifically hemp. As such, despite the removal of hemp from the CSA, there are still several legal roadblocks for companies hoping to manufacture and distribute FDA-regulated products like dietary supplements and food products that contain cannabidiol (CBD), even if the CBD is derived from hemp.

For example, Sections 301(ll) and 201(ff)(3) of the Food, Drug and Cosmetic Act (FD&C Act) prohibit food and dietary supplements from containing substances that have already been studied in, or approved as, drugs. Over the last several years, FDA has issued multiple Warning Letters asserting that conventional food and dietary supplements containing CBD violate the FD&C Act because CBD first gained recognition in the marketplace by being studied as a drug (Epidiolex).[1]

In addition, there are still impediments to studying the benefits of marijuana. Researchers investigating the medicinal benefits of marijuana must still comply with strict requirements set by FDA, NIDA, and DEA. These requirements often make it enormously difficult, and sometimes impossible, for researchers to carry out informative cannabis-related research. For example, current DEA requirement largely limit researchers to use cannabis sourced from only the NIDA's Drug Supply Program, essentially preventing researchers from studying the benefits of different, and possibly more medically-effective, cannabis strains.

At the January 15, 2020 hearing, FDA and Congress made clear that they are interested in addressing these roadblocks. The hearing similarly signaled a willingness among policymakers to create more legal pathways for the use and study of cannabis that could help pave the way for addressing FDA's prohibition of cannabis-related food products and dietary supplements. Toward that end, FDA announced a public meeting on cannabis for May 31, 2020 that will consider potential paths forward that would allow the use of CBD in dietary supplements and other foods. Additionally, we understand that FDA is currently drafting legislation on this issue for Congress to consider, which could be enacted as early as this year. And this week, Rep. Colin Peterson (D-MN), the Chairman of the House Agriculture Committee, introduced HR 5587, legislation that would give FDA the option to allow for the distribution of dietary supplements containing CBD. That legislation will be considered by the House Energy & Commerce and Agriculture Committees.

HEARING HIGHLIGHTS

More research is essential: Testifying witnesses and committee members all agreed that more research is needed on the medical benefits and societal risks of cannabis. Witnesses discussed the various consequences of current

impediments to cannabis research. FDA explained that current limitations on marijuana research have slowed product development and made it difficult for FDA and states to recognize potentially harmful products. NIDA also explained that, because of these limitations, there has been a rise in hospital visits involving issues of marijuana toxicity and marijuana-related psychosis.

The CSA is currently the biggest impediment to research: Representatives from FDA/CDER, DEA, and NIH/NIDA repeatedly acknowledged issues with the CSA's strict requirements for researchers of controlled substances and the need for a more diverse inventory of marijuana. Manufacturers' applications for access to research-approved marijuana are often delayed because the DEA is required to thoroughly vet these applications. Additionally, the current inventory of research-approved marijuana does not reflect marijuana products in the real world because current inventory does not include different cannabis strains that may differ in quality, potency, and other aspects.

There is some evidence of the medical benefits and risks of cannabis based on the current state of research: FDA and NIDA discussed the current state of evidence showing that cannabis may be effective in treating chronic pain and multiple sclerosis. Additionally, FDA discussed evidence showing that cannabis may effectively treat severe seizure disorders and noted that approved THC-based products effectively treat nausea and vomiting associated with chemotherapy. As far as the risks, a NIDA representative stated that there is clear evidence showing the impacts of cannabis on fetal development and childhood brain development. NIDA also explained that there is some evidence showing that marijuana increases risks of psychosis and suicide, but there is not enough evidence to establish a clear correlation between THC and these mental health issues.

The complete de-scheduling of marijuana may go too far; expanding research sources and streamlining access for research could be a way to balance concerns: Many committee members voiced concern over the two proposed bills that would remove marijuana from the CSA's controlled substance schedules completely. Issues included some unknown health effects or benefits (which research could address) and the potential proliferation of THC-impaired driving. These members suggested that providing greater flexibility for researchers should be the first legislative step. Witnesses offered alternatives to the complete de-scheduling of marijuana, such as an amendment to the CSA that would remove the requirement that researchers procure marijuana from a DEA registrant.

FDA is working on establishing a legal pathway for dietary supplements and food products containing CBD, but it will not do so anytime soon: FDA was unwilling to set a target date for a regulatory solution that would allow for the legal distribution and marketing of dietary supplements and food products containing CBD. FDA noted that such a rule requires a delicate weighing of the benefits and risks of cannabis. FDA is largely concerned with potential adverse events and the lack of a learned intermediary (e.g., licensed healthcare professionals, as in the case of prescription drug products) who can help patients understand the risks of these products. FDA stated that its ultimate priority for food and dietary supplements is establishing their safety, and the Agency needs to do more research to develop procedures that can ensure the safe use of CBD in food products and dietary supplements. In the meantime, FDA hopes that the industry will self-regulate and that increased interest in research will bring with it a push from the public to hold manufacturers more accountable.

WITNESSES AND TESTIMONY OVERVIEW

Matthew J. Strait, Senior Policy Advisor, Diversion Control Division, U.S. Drug Enforcement Administration: In his testimony, Mr. Strait provided an overview of the CSA's classification of "marijuana" in Schedule I, and the changes made by the 2018 Farm Bill. He also expressed DEA's commitment, "consistent with the CSA, to assisting the health care needs of patients and supporting research involving marijuana." Mr. Strait expressed that "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 priorities include the approval of Schedule I researchers consistent with the CSA and DEA regulations.

Douglas Throckmorton, M.D., Deputy Director of Regulatory Programs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration: Dr. Throckmorton discussed FDA's support for medical research efforts related to cannabis. In doing so, he provided: an overview of the cannabis clinical research process and FDA's specific recommendations for developing a human drug derived from cannabis (citing FDA's 2016 Guidance on botanical drug development); an overview of ongoing regular meetings and interactions with applicants for investigational new drug applications (INDs) and regular meetings with clinical researchers; and an overview of how FDA supports investigators through CDER's Small Business and Industry Assistance group. Dr. Throckmorton also identified liver injury, drug interactions, and male reproductive toxicity as potential risks of CBD exposure, and he expressed that FDA is actively researching the risks of cannabis associated with cumulative exposure, special populations, and animals.

Nora D. Volkow, Director, National Institute on Drug Abuse, U.S. National Institutes of Health: Dr. Volkow provided an overview of the adverse health effects and therapeutic potential of cannabis. Adverse health effects include growth restriction, lower birth weight, and preterm delivery with prenatal exposure; changes in the adolescent brain affecting attention, memory, emotions, and motivation; dependence in nearly 10% of people who use THC; the potential to trigger acute psychotic episodes; impaired driving; and the role of THC in recent cases of e-cigarette, or vaping, product use associated lung injury (EVALI). Potential therapeutic benefits include treatment of chronic pain, improving patient-reported spasticity symptoms in patients with multiple sclerosis, and the use of Epidiolex—the only FDA-approved drug containing CBD that is used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age or older. Dr. Volkow also described access challenges in cannabis research.

Q&A HIGHLIGHTS

To de-schedule or re-schedule? Much of the debate among the Members of Congress was focused on whether to de-schedule (e.g., remove marijuana from the CSA's controlled substance schedules entirely), re-schedule (e.g., move marijuana from Schedule I to a less-restricted Schedule), or leave marijuana in Schedule I. Rep. John Sarbanes (D-MD) described the issue as a "chicken and egg situation," where the decision to de- or re-schedule is difficult because of unknowns regarding long-term effects or benefits of cannabis, yet the path to discovery is limited because of marijuana's Schedule I status.

DEA's practices. Some Members sharply criticized DEA for lethargy and bureaucracy with processing registrations and applications related to cannabis research. Rep. Greg Walden (D-OR) and Rep. Kurt Schrader (R-OR) focused their questioning on DEA, asking whether DEA is prepared to handle the registration of private and public laboratories for hemp sampling and why only one facility in Mississippi is the "sole nexus of research for CBD products." Rep. Morgan Griffith (R-VA) decried the unfairness of DEA requiring starting over through the submission of new applications to conduct scientific and medical research when regulatory changes happen mid-review, rather than allowing for an amendment of applications. When asked if DEA would commit to allowing amendments to applications, the DEA witness expressed that DEA would allow for a full refund of a submitted application fee.

Addressing proliferation of CBD products without knowing health implications: target a mature industry. Rep. Cathy McMorris Rodgers (R-WA) specifically asked Dr. Throckmorton for his view regarding solutions to the issue posed by all sorts of CBD products being marketed and sold throughout the country without knowing health implications. Dr. Throckmorton expressed that there is not just one solution. He said that he personally believes that an important element is to encourage development of a mature industry using CBD products. He thinks that these products should be manufactured and sold by industry that is used to complying with manufacturing standards, as well as labeling and packaging standards. Dr. Throckmorton hopes that the recent increase in interest in doing research will result in a growth

of science-driven products with high manufacturing standards. Dr. Throckmorton also believes in creating a clear pathway for non-drug products.

Impaired driving. Rep. Larry Buschon (R-IN) expressed his view that law enforcement is not equipped to handle drivers who are impaired due to THC use. Unlike with alcohol, there is no reliable test and no current legal standard to apply. Rep. Buschon introduced a bill that would require the U.S. Department of Transportation to implement pilot programs to address this issue and to increase funding to provide for advanced field testing. Dr. Volkow explained that with alcohol, there is a reliable level for measuring impairment. THC's high half-life makes detection unpredictable. Sometimes, high levels remain in blood though there is no impairment, and other times impairment may be present though low levels of THC exist in blood.

Mass incarceration. Rep. Joe Kennedy (D-MA) and Rep. Bobby Rush (D-IL) explored the issue of mass incarceration, particularly among people of color, for crimes related to marijuana possession and distribution and the need for re-entry services and expungement of criminal records. Re-entry and expungement services include: job training, legal aid for civil and criminal cases (e.g., expungement of cannabis convictions), literacy and health education programs, and youth recreation or mentoring programs.

Product claims. There was a near consensus that there is a problem related to the proliferation of current health claims for CBD products. NIH expressed that relaxing the current stringent requirements to conduct cannabis research would help with this. FDA expressed that focusing on supporting new new drug applications (NDAs) is also a solution. FDA currently has about 40 inquiries from manufacturers hoping to develop drugs for CBD and hemp and currently there are so many variations of marijuana that having a standardized body of knowledge regarding risks and benefits are almost impossible without additional research.

IMPLICATIONS AND NEXT STEPS

We expect Members of Congress (1) to continue to put pressure on FDA to develop a pathway to market non-drug hemp-derived CBD products and (2) to continue to push Congress to develop a pathway itself (with input from FDA). FDA's unwillingness to set a target date for a regulatory or policy solution that would enable the legal distribution and marketing of dietary supplements and food products containing hemp-derived CBD suggests that Congressional pressure or even legislation may be necessary to expedite changes. Nonetheless, we expect that Congress and FDA will work together closely to develop the contours of the path forward, and that Congress will defer to FDA regarding any requirements that are needed to ensure that hemp-derived CBD products are safe.

Near-term de-scheduling of marijuana is unlikely; relaxation of research requirements is possible. No one disagreed that more research is needed. The CSA's current requirements hinder cannabis research. Accordingly, easing research access could be low-hanging fruit for Congress. This could take the form of amending the CSA to relax requirements for research through specific carveouts, and it may include relaxing registration requirements, permitting researchers to source cannabis outside of Schedule I-registered and approved facilities, and allowing for more strains to be researched.

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[1] FDA, Notice of Public Hearing, *Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds*, 84 Fed. Reg. 12,969, 12,970 (Apr. 3, 2019); *see, e.g.*, FDA Warning Letter to PotNetwork Holdings, Inc., March 28, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/potnetwork-holdings-inc-564030-03282019