First Congressional Hearing on Cannabis Policy Reform

House Subcommittee debates and explores proposed legislation.

The U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health held its first legislative cannabis hearing on January 15, 2020. The 3.5-hour hearing included testimonials from congressional representatives and key witnesses from the National Institute on Drug Abuse (NIDA), the FDA and the Drug Enforcement Administration (DEA). Although no policy changes were enacted and no voting took place, subcommittee members debated and explored proposals to lessen restrictions in order to advance cannabis research. The congressional representatives discussed issues related to 6 bills that offer a range of solutions for federal cannabis policy reform (Table).[1]

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> *—Anna Eshoo, Chair, Subcommittee on Health*

Barriers to Cannabis Research

Anna Eshoo, Chair of the Subcommittee on Health, discussed the current catch-22 situation regarding cannabis research given the Schedule I classification of this agent. Researchers "can't conduct cannabis research until they show that cannabis has a medical use, but they can't show that cannabis has a medical use until they can conduct research," she said.[1]

Currently, the only provider of cannabis for FDA-approved clinical research is a government-authorized farm at the University of Mississippi. This supply has been criticized by scientists as lacking the properties and potency of commercially available cannabis, thereby limiting research.

The current supply "does not have the capacity to manufacture a broad array of cannabis-derived formulations for research or to supply these cannabis products for commercial development," said Nora Volkow, MD, Director of NIDA at the National Institutes of Health.[1] "Moreover, it is not clear how entities seeking to develop these products for commercial purposes would demonstrate equivalency between the University of Mississippi cannabis used in clinical trials and the drug product that would ultimately be approved by the FDA for marketing and sale."

DEA May Expand List of Growers

The DEA hopes to expand the number of registrants approved to grow cannabis for research purposes, and as of August 2019 has begun to review applications from other cannabis growers for use in federally authorized research.[2] The DEA anticipates that registering additional qualified marijuana growers will increase the variety of marijuana available for research purposes.[2]

Matthew J. Strait, Senior Policy Advisor, Diversion Control Division at the DEA outlined the agency's regulatory plans. "In

Table. Proposed Legislation for Cannabis Policy Reform

Bill	Resolution	Proposal
H.R. 171	Legitimate Use of Medicinal Marijuana Act	To provide for the legitimate use of medicinal marijuana in accordance with the laws of the various states; moves marijuana to Schedule I
H.R. 601	Medical Cannabis Research Act of 2019	To increase the number of manufacturers registered under the CSA to manufacture cannabis for legitimate research purposes, to authorize health care providers of the Department of Veterans Affairs to provide recommendations to veterans regarding participation in federally approved cannabis clinical trials, and for other purposes
H.R. 1151	Veterans Medical Marijuana Safe Harbor Act	To allow veterans to use, possess, or transport medical marijuana and to discuss the use of medical marijuana with a physician of the Department of Veterans Affairs as authorized by a state or Indian tribe, and for other purposes
H.R. 2843	Marijuana Freedom and Opportunity Act	To decriminalize marijuana, and for other purposes
H.R. 3797	Medical Marijuana Research Act of 2019	To amend the CSA to make marijuana accessible for use by qualified marijuana researchers for medical purposes, and for other purposes
H.R. 3884	Marijuana Opportunity Reinvestment and Expungement Act of 2019	To decriminalize and deschedule cannabis, to provide for reinvestment in certain persons adversely impacted by the War on Drugs, to provide for expungement of certain cannabis offenses, and for other purposes

CSA, Controlled Substances Act.

Source: Committee on Energy and Commerce.[1]

the near future, DEA intends to propose regulations that would govern persons seeking to become registered with DEA to grow marijuana as bulk manufacturers, consistent with applicable law, taking into account recent changes in the Controlled Substances Act [CSA]. At present, a notice of proposed rulemaking is under review by the Office of Management and Budget," he said.[1]

Next Steps

Dr. Volkow pointed out that obtaining or modifying a Schedule I registration for research can take up to 1 year and adding new substances to an existing registration is a lengthy process.[1] To remedy this situation, Dr. Volkow called for clarification of the CSA to allow "one individual to hold a Schedule I registration under which colleagues from the same institution may work even if those colleagues do not work directly for the registrant (eg, as members of their laboratory); that registered researchers may store, administer, and work with any substances for which they hold a researcher registration at multiple practice sites on a single contiguous campus; and that if a person is registered to conduct research with a controlled substance and applies to conduct research with a second controlled substance that is in the same schedule or in a schedule with a higher numerical designation, an inspection that was performed for purposes of the existing registration shall be sufficient to support the application."[1]

Dr. Volkow also noted that registered researchers do not need to obtain a separate manufacturing registration to create specific dosage formulations that are consistent with their research protocol. She added that this is particularly true when researchers need to create dosage formulations from cannabis products supplied through the NIDA Drug Supply Program.[1] She also called for changes to federal law restricting research supported by NIDA and other federal agencies on marketed cannabis products available through state marijuana dispensaries, resulting in a "significant gap in our understanding of their impact on health," Dr. Volkow said.[1]

Pathways for Nondrug CBD Products

The FDA is actively working to determine the safety and efficacy of nondrug products containing cannabidiol (CBD), including safe manufacturing processes, and is considering the possibility of establishing new legal pathways for the safe marketing of certain dietary supplements and/or food products containing CBD, explained Douglas Throckmorton, MD, Deputy Director for Regulatory Programs at the FDA's Center for Drug Evaluation and Research.[1]

References

1. Hearing before the Subcommittee on Health; Committee on Energy and Commerce. Cannabis policies for the new decade. January 15, 2020. https://energycommerce.house.gov/committee-activity/hearings/hearing-on-cannabis-policies-for-the-new-decade
2. Drug Enforcement Administration. Bulk manufacturer of controlled substances applications: bulk manufacturers of marihuana. *Fed Reg*. 2019;84(166):44920-44923. Docket No. DEA–392

The full Subcommittee on Health hearing of "Cannabis Policies for the New Decade" is available at https://energycommerce.house.gov/committee-activity/hearings/hearing-on-cannabis-policies-for-the-new-decade