CANNRA

CANNABIS REGULATORS ASSOCIATION

Drug Enforcement Administration
Attn: Administrator Ann Milgram
Drug and Chemical Evaluation Section
8701 Morrissette Drive,
Springfield, Virginia 22152
nprm@dea.gov

RE: Request for Public Comment on the Proposed Rule Rescheduling Marijuana, Docket No. DEA-1362

Dear Administrator Milgram,

Thank you for the opportunity to comment on the Proposed Rule Rescheduling Marijuana, Docket No. DEA-1362. The Cannabis Regulators Association (CANNRA) is a nonpartisan association of government agencies involved in cannabis, cannabinoid, and hemp regulation across more than 45 states and U.S. territories. Our mission is to convene, educate, and support governments tasked with implementing cannabis and cannabinoid policy. We do not take a position on rescheduling, but rather are focused on the implementation of any new federal policy or position in U.S. states and territories.

Our U.S. membership includes states and territories who regulate medical cannabis programs, including all 38 states with programs providing comprehensive medical access, as well as states with regulated programs providing access to low-THC medical cannabis products. As referenced in the U.S. Health and Human Services (HHS) Basis for the Recommendation to Reschedule Marijuana,[1] these programs have more than 30,000 health care providers authorized to recommend the use of medical marijuana for more than 6 million patients, across a range of medical conditions. Many of these state programs have been in place for more than a decade, and many have medical advisory boards or review boards that have approved the list of qualifying medical conditions. Cannabis is rigorously regulated in these state programs with a goal of protecting patient safety and public health and preventing diversion.

Our public comment on the proposed rescheduling rule calls for additional guidance in six areas to support state and territorial regulators in being able to continue to keep consumers and patients safe:

> **1. Guidance is needed on how federal priorities, including enforcement priorities, will change under the proposed rescheduling.** As a body of regulators tasked by their governing jurisdictions with implementing both medical and adult use cannabis regulatory programs and hemp regulatory programs, our members are most interested in understanding how rescheduling marijuana will impact state-regulated markets and those engaged in state-regulated markets, including recommending clinicians, patients and consumers, and operators. The draft rule does not contain any federal guidance for states on this topic and does not elucidate any potential changes in the current federal-state dynamic. The 2013 U.S. Department of Justice (DOJ) Cole Memorandum[2] was rescinded in 2018 and has not been replaced by new guidance for states.[3] This, coupled with the proposed rescheduling, leaves state regulatory agencies in a position of having to speculate about the potential impacts of the rescheduling decision on those engaged with their state regulated market. For example, would state-regulated cannabis products (which are not FDA approved drugs) remain federally illegal under a new schedule? If so, would federal enforcement authorities or priorities change with rescheduling? <u>Accordingly, guidance is needed to clarify federal enforcement priorities so states and territories understand how rescheduling of marijuana may impact state regulated programs and the various participants in those programs.</u>

2. Guidance is needed on how federal agencies will engage with states and territories under the proposed rescheduling. With marijuana designated federally as a Schedule 1 substance, states and territories have been left on their own to make decisions in areas where they normally would have guidance, technical assistance, routine coordination with, and support from federal agencies. These decisions range from identifying which pesticides and additives are safe to use on cannabis and in cannabinoid products, to responding to events that may warrant recall and embargo procedures, to addressing matters related to energy and environment, to traffic safety policies, to small business support, and more. Resources in most state governmental agencies are dwarfed by the resources federal agencies have. While CANNRA has open lines of communication with many U.S. federal agencies, including through an information sharing agreement, federal agencies have historically had their hands tied in their ability to support CANNRA member states in even basic ways that protect public health and promote consumer safety. Deliberate coordination can only enhance the value of measures critical to protecting public health and safety. Guidance is needed to clarify how federal agencies can engage with states under the proposed rescheduling.

3. Guidance is needed on how state governments can interact with each other under the proposed rescheduling. Under the current federal Schedule 1 designation, a state-run reference lab cannot send a marijuana sample to a state-run reference lab in another state for analysis, confirmatory testing, or additional non-target analyte screening. Proficiency testing materials to assess the quality and accuracy of laboratory testing cannot be shared between states, severely limiting the value of this tool for determining quality and accuracy. Any rescheduling should be coupled with federal approval for state governments to coordinate the interstate exchange of specific cannabis-related materials for product safety and testing purposes.

In addition, it will be important for federal agencies to issue clear guidance about any allowance and requirements for interstate commerce under a new schedule, recognizing that states have developed their own requirements for the cultivation, processing, transportation, tracking, and sale of marijuana. Furthermore, guidance on the implications of rescheduling on the transportation of marijuana by aircraft or watercraft is warranted.

4. Guidance is needed on how research processes and protocols will change under the proposed rescheduling. CANNRA member regulators remain acutely interested in research that can help guide policy and, in particular, research that can be conducted with products currently available on the state-regulated marketplaces. Among other things, such research could help regulators in their efforts to understand the risks and benefits of different products on the market, which are important to informing state agency determinations on permitted and prohibited products, packaging and labeling requirements, testing requirements, and public education needs. Researchers and government officials lack clarity about what research processes and protocols will change in the proposed rescheduling and whether researchers will be permitted to use state-regulated products, with appropriate approval from FDA. There is also a lack of clarity on whether research entities, including universities, can engage in scientific research and related activities with marijuana without the threat of losing federal funding. Accordingly, federal guidance is needed on how research processes and protocols will change with rescheduling and what products can be used for research purposes.

5. Guidance is needed on how to regulate cannabinoids that appear in two different places on the schedule due to the federal legalization of hemp. Regulators face a reality now where the same 200mg delta-9 THC chocolate bar can be scheduled if the THC was derived from *Cannabis sativa* L with >0.3% delta-9 THC by dry weight (i.e., marijuana), or unscheduled if the delta-9 THC came from *Cannabis sativa* L with <=0.3% delta-9 THC by dry weight (i.e., hemp) – even when the chocolates are identical. This creates an extremely difficult regulatory environment, particularly when certain

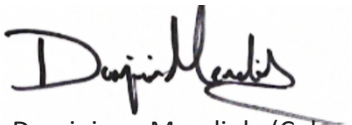
hemp-derived products in the market contain higher THC levels than those allowed under state-regulated cannabis (i.e., "marijuana") laws. Even detecting the source of the cannabinoid in a product can be challenging. CANNRA has communicated these regulatory challenges to Congress via testimony, letters, and a response to a Request for Information.[4–6] Regulators would benefit from federal clarity and guidance on how to assess and regulate the same molecules (often in the same quantity in finished products) differently based on whether they are from "hemp" or "marijuana."

6. Guidance is needed on how the proposed rescheduling will impact banking and finance directives and policies. CANNRA has sent prior letters to Congress describing the urgent need for banking reform and the challenges and safety risks to operating in a cash-only environment.[7,8] In addition, the financial health of state-regulated cannabis businesses is impacted by 280E and regulators are seeing an increase in the number of cannabis businesses that are going into receivership and surrendering their licenses. Some states (e.g., NJ, MI, CO, MO) have responded to this by passing legislation allowing licensed cannabis businesses to deduct any otherwise eligible disallowed expense at the state level, though 280E still applies federally. Many of our state regulator members are interested in understanding the financial and tax implications from rescheduling, where federal clarity and guidance can support their ability to provide clear and consistent messaging to state-regulated cannabis businesses. In addition, clear guidance is needed about the impact of rescheduling on bankruptcy filings by commercial medical and adult use marijuana businesses.

Guidance in these six areas is vital to the successful implementation of the final rule on rescheduling. Without it, state and territorial government agencies will be left to guess and hypothesize about federal-state dynamics and the potential impacts on state-regulated programs, the state populations affected by those programs, and the states in which those programs operate. CANNRA remains committed to supporting our members in successfully implementing whatever the final rule on rescheduling is, and respectfully calls on the DEA, the DOJ, and other engaged federal agencies to issue appropriate guidance to guide implementation. As a nonpartisan government association whose members are charged with administering state and territorial laws related to marijuana and cannabinoids, we are available to provide additional insight. Please contact us if we may be of assistance.

Respectfully,

Gillian Schauer, PhD, MPH
Executive Director
Cannabis Regulators Association



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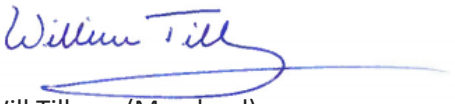
President
Cannabis Regulators Association



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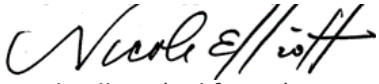

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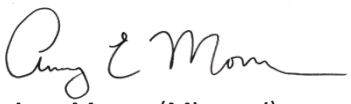
Board Member
Cannabis Regulators Association



Amy Moore (Missouri)
Board Member
Cannabis Regulators Association

Andrew Turnage (Georgia)
Board Member
Cannabis Regulators Association

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