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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

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*Submitted electronically to: https://www.regulations.gov/commenton/DEA-2024-0059-0001*

July 22, 2024

Drug Enforcement Administration
Attn: DEA Federal Register Representative/DPW
8701 Morissette Drive
Springfield, Virginia 22152

**RE: UC Comments in Response to the Notice of Proposed Rulemaking "Schedules of Controlled Substances: Rescheduling of Marijuana" (Docket No. DEA-1362)**

To Whom It May Concern:

I write on behalf of the University of California (UC) system with regard to the Notice of Proposed Rulemaking (NPRM) "Schedules of Controlled Substances: Rescheduling of Marijuana" (Docket No. DEA-1362) published in the *Federal Register* on May 21, 2024.

The UC system is comprised of ten campuses, six academic health centers, and three affiliated U.S. Department of Energy national laboratories. Specific to cannabis research, UC serves as the scientific frontrunner investigating and publishing impactful cannabis research in clinical, molecular-chemical, economic, societal, environmental, and agricultural disciplines. UC's notable cannabis research centers extend throughout the State of California[1, 2], including:

- UC Berkeley – Cannabis Research Center
- UC Irvine – Center for the Study of Cannabis
- UC Los Angeles – Center for Cannabis and Cannabinoids
- UC Merced – Nicotine and Cannabis Policy Center
- UC Riverside – Center for Cannabinoid Research
- UC San Francisco – Center for Tobacco Control Research and Education
- UC San Diego – Center for Medicinal Cannabis Research

[1] Forsyth AD, Kulik MC, Richmond McKnight T, Perkins AD, Balla A (2022) University of California Cannabis Research Workshop, May 2021: Meeting summary, *Cannabis and Cannabinoid Research* 7:2, 152–155, DOI: 10.1089/can.2021.0213.
[2] Kulik MC, Lee YO, Butsic V, Cermak TL, Cooper ZD, Corva D, Marcotte TD, Üsküp DK, Richmond McKnight T, Balla A (2024) California cannabis research briefing, April 2023: Meeting summary, *Cannabis and Cannabinoid Research* X:X, xxx–xxx, DOI: 10.1089/can.2024.0074.

UC appreciates the opportunity to submit comments in response to the NPRM. Our comments focus on aspects of the NPRM that impact institutions' ability to conduct cannabis research. While UC supports DEA moving forward with rescheduling marijuana, marijuana extracts, and naturally derived delta-9-THC from a schedule I to a schedule III substance as a step towards decreasing barriers to conducting research, we ask that the DEA consider the following in its rulemaking:

1. Take further immediate regulatory action to allow university researchers to work more closely with cannabis products available in state regulated markets;
2. Include synthetically derived delta-9-THC in the rulemaking and apply the eight-factor analysis to THC isomers, analogs, and other THC derivatives; and
3. Provide updated guidance on regulatory requirements for researchers.

Further details on each of these points appear below.

**1. Further regulatory action to allow university researchers to work more closely with cannabis products available in state regulated markets**

We are concerned the DEA's effort to reschedule marijuana, marijuana extracts, and naturally derived delta-9-THC from a schedule I to a schedule III solely would be insufficient to remove barriers that hinder researchers' ability to conduct studies with products available in states that have passed laws permitting medical and/or adult non-medical use of cannabis. This is because under a schedule III classification, marijuana products would still need to be obtained from DEA-registered distributor, which we are unsure would include cannabis produced and sold in state-sanctioned markets.

Researchers need access to real-world marijuana products currently available to the public. Without such access, scientific understanding of cannabis and its impacts in all spaces, from plant sciences to public health, continue to be stymied. The current inability for researchers to access state-permitted products that are widely available from state-regulated dispensaries is extremely detrimental to scientific efforts to understand both the health benefits and risks of these products and to fully assess their impact on public health. Dispensary cannabis products are available in an array of forms (plant, edibles, vaping liquid, topical), an option currently unavailable for research purposes when obtained through DEA-approved bulk marijuana manufacturers. The effects of these varying modes of delivery and potential interactions with other drugs is unknown and will continue to be unknown without action to allow researchers to obtain cannabis from local sources.

We ask that the DEA take additional steps to allow researchers to access cannabis products available in state regulated markets. We propose several ways in which DEA could take action to improve researchers' access to real-world cannabis products:

- Enact regulations that allow researchers to conduct research on cannabis products procured from any source legally operating in compliance with state laws. For example, DEA may specify in regulations that:

  > An institution of higher education, as defined in Section 101 of the federal Higher Education Act of 1965 (20 U.S.C. Sec. 1001), may access and possess marijuana, marijuana extracts, and naturally derived delta-9-tetrahydrocannabinol available in

states that have enacted medical use and adult non-medical use cannabis laws, for the purposes of conducting academic research.

- Develop guidance clarifying how institutions of higher education engaged in research may access cannabis products available to be sold directly to consumers and fresh plant materials from licensed cultivation sites.
- Develop a process in which state-legal sources may easily register with DEA to provide cannabis to researchers.

**2. Include synthetically derived delta-9-THC in the rulemaking and apply the eight-factor analysis to THC isomers, analogs, and other THC derivatives**

In the proposed rulemaking, DEA specifies the following:

> This proposal would not apply to synthetically derived THC, which is outside the CSA's definition of marijuana. Those tetrahydrocannabinols that can be derived only through a process of artificial synthesis (*e.g.,* delta-10-tetrahydrocannabinol) are excluded. HHS provided a recommendation only relating to "marijuana" as defined in the CSA. That definition is limited to the plant (other than the mature stalks and seeds) and derivatives of the plant. Therefore, synthetic THC will remain in schedule I.[3]

Experts in chemistry at UC agree that delta-9-THC, whether naturally derived or synthetically derived, is one and the same molecule. Therefore, drawing a line between naturally derived or synthetically derived delta-9-THC creates unnecessary confusion amidst an already complicated regulatory landscape when it comes to conducting research.

Rather than excluding synthetically derived delta-9-THC from the current rescheduling rulemaking, we urge DEA to classify delta-9-THC within the same schedule III classification regardless of whether it is naturally or synthetically derived. In addition, we urge DEA to assess THC isomers, analogs, and other THC derivatives utilizing the eight-factor analysis set forth in the NPRM. Whether these compounds are being produced synthetically from hemp-derived cannabidiol, made synthetically, or obtained by other means should lead to the same classification for a given compound.

As the NPRM notes, there are FDA-approved drugs that have previously been rescheduled from schedule I (e.g., Marinol® and Syndros®), suggesting that the eight-factor analysis has already been applied to evaluate synthetic delta-9-THC and resulted in a determination that schedule I classification was unwarranted. We suggest doing likewise here to determine if the same considerations under the eight-factor analysis apply to THCA, THC isomers not present or present in exceedingly low levels in cannabis (including delta-8-THC and delta-10-THC), and THC analogs and derivatives (including THCp and HHCs) regardless of their source. This approach promotes consistency in how natural and synthetic forms of THC are evaluated. It also facilitates the research necessary to generate the scientific data necessary to more comprehensively understand the pharmacology, health effects, and potential medical uses of a range of THC products.

[3] https://www.federalregister.gov/d/2024-11137/p-262

### 3. Provide updated guidance on regulatory requirements for researchers

Separate from the above asks, we strongly urge DEA to update its guidance documents regarding the conduct of research using marijuana to reflect the changes that will result from this rulemaking. Resources such as the DEA Researcher's Manual are useful aids to assist research personnel in determining agency requirements. However, the conduct of cannabis research frequently involves consideration of multiple agencies' regulations, including the interplay between state and federal requirements. DEA could greatly assist researchers in navigating their regulatory obligations by developing updated resources and training that explain DEA regulatory requirements as well as other federal agency requirements (e.g., FDA), and consider the interplay of federal and state regulations in this arena. Samples of completed forms, diagrams of registration/approval processes, and answers to frequently asked questions would be especially helpful.

One area in which clarification is necessary concerns the following statement set forth in the NPRM:

> If the transfer to schedule III is finalized, the regulatory controls applicable to schedule III controlled substances would apply, as appropriate, along with existing marijuana-specific requirements and any additional controls that might be implemented, including those that might be implemented to meet U.S. treaty obligations. If marijuana is transferred to schedule III, the manufacture, distribution, dispensing, and possession of marijuana would remain subject to the applicable criminal prohibitions of the CSA.[4]

Clarification on this point is necessary for research institutions to understand the full implications of rescheduling, including whether further regulatory action is necessary to ensure that academic researchers are allowed to access and possess, for research purposes, cannabis products sold in states that have passed adult use and medicinal laws.

In addition, we ask that DEA clarify how the schedule III classification will open doors to research utilizing fresh plant material from licensed growers to study a range of agricultural and environmental questions, including on plant breeding, pest management, pesticide use, water and fertilizer use, environmental aspects of cannabis agriculture including plant waste management such as composting or potential biochar conversion, and impacts of indoor cultivation, among others. Currently, agronomic, botanical, and environmental research is hindered by the lack of access to the growing plant, or to cultivation activities either in the field, indoor sites, or in a university setting. Researchers need access to such materials to inform vital marijuana related policy decisions made on the federal, state, and local levels.

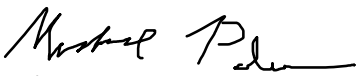
We welcome any opportunity to further discuss the comments of this letter. If you have any questions concerning our comments, please contact Agnes Balla at agnes.balla@ucop.edu.

[4] NPRM at p. 44597.

Sincerely,

Agnes Balla
Director
Research Policy Analysis and Coordination
University of California, Office of the President

These comments are shared among the undersigned Directors of UC cannabis research centers:



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