



July 12, 2024

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

RE: Schedules of Controlled Substances: Rescheduling of Marijuana (Docket No. DEA-1362; A.G. Order No. 5931-2024)

To Whom It May Concern:

The AAMC (Association of American Medical Colleges) and COGR write to offer comments in response to the Drug Enforcement Administration’s (DEA) notice of proposed rulemaking “[Schedules of Controlled Substances: Rescheduling of Marijuana](#),” published in the [Federal Register on May 21, 2024](#)¹ (NPRM). We appreciate the opportunity to submit comments in response to the NPRM. Many of our member institutions conduct cannabis-related research that is essential to answering questions regarding cannabis’ safety, effectiveness, and side effects in humans and animals. Our comments focus on aspects of the NPRM that impact institutions’ ability to conduct this important research and are informed by the input and expertise from our member institutions.

AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America’s medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

COGR is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. We focus on the impact of federal regulations, policies, and practices on the performance of research conducted at our member institutions, and we advocate for sound, efficient, and effective regulation that safeguards research and minimizes administrative and cost burdens.

We support the proposed rescheduling of marijuana, marijuana extracts, and naturally derived delta-9-THC from schedule I under the Controlled Substances Act of 1970 (CSA) to schedule III (“Rescheduling”). As we emphasized in our October 2022 letter to the NIH in

¹ 89 F.R. 44597.

response to the request for information on Investigators' Interests in and Barriers to Research Studies on the Health Effects of Cannabis and its Constituents, "cannabis' status as a Class I controlled substance poses significant and often insurmountable barriers to [...] research, including research on cannabis and cannabis products available in states where cannabis has been legalized for medicinal and/or recreational use. We also express concerns for the administrative and compliance requirements (e.g., registration process for a Class I controlled substance) which diverts time away from conducting this critical research."² The Rescheduling aligns with and is supported by the scientific and medical determinations in the August 2023 Department of Health and Human Services (HHS) rescheduling recommendation letter cited in the NPRM.³ Further, the Rescheduling will facilitate researchers' ability to conduct research using marijuana, as compliance with schedule III security requirements is less burdensome than those associated with schedule I substances, while still requiring responsible storage and security protocols.

We also urge DEA to reconsider its proposal to exclude synthetic THC from the scope of the rulemaking so that both naturally and synthetically derived delta-9-THC can be analyzed under the CSA's eight-factor analysis. The NPRM excludes synthetic THC from its scope based on the following reasoning:

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.

Distinguishing between naturally occurring and synthetic THC is extremely difficult and frequently involves laborious and expensive chemical analysis methods such as chiral chromatography (trefoil chiral chromatography) or nuclear magnetic resonance spectroscopy. Given the significant similarity between naturally occurring and synthetic THC, while noting that there may also be important differences, we urge DEA to separately consider both synthetic THC and "marijuana" under the eight-factor analysis set forth in the NPRM.

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 some synthetic THC products 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 both naturally occurring THC in marijuana and to synthetic forms of THC. This approach promotes consistency in how natural and synthetic forms of THC are evaluated. Further, if rescheduling of synthetic THC is warranted, it brings the added benefit of facilitating the research necessary to generate the scientific data

² AAMC COGR Response to NIH Request for Information (RFI): Investigators' Interests in and Barriers to Research Studies on the Health Effects of Cannabis and its Constituents (NOT-AT-22-026) https://www.cogr.edu/sites/default/files/AAMC%20COGR%20Response%20to%20NIH%20Cannabis%20RFI_10.15.22_%20final%20letter%20PDF.pdf (October 15, 2022).

³ NPRM at p. 44599.

necessary to fully understand the pharmacology, health effects, and potential medical uses of both categories of THC.

Once the Rescheduling is complete, we strongly recommend that DEA quickly update its guidance documents regarding the conduct of research using marijuana to reflect the changes as a result of this rulemaking. Resources such as the [DEA Researcher Manual](#) are useful aids to assist research personnel in identifying and complying with 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 applicable regulatory obligations by developing updated resources and training that explain DEA regulatory requirements, reference 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

We encourage the DEA to clarify what is meant by “existing marijuana-specific requirements” and “additional controls.” Institutions conducting research in this area need to understand the impact that Rescheduling will have on researchers' ability to access marijuana products that are available in states that have adopted laws permitting medical and/or adult non-medical use of marijuana and marijuana extracts (“State Permitted Marijuana Products”). The current inability for researchers (particularly those conducting federally funded research) to access State Permitted Marijuana Products that are widely available via state-regulated dispensaries is extremely detrimental to scientific efforts to understand the health benefits and/or risks presented by these products and fully assess their impact on public health. 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 State Permitted Marijuana Products for research purposes.

We thank DEA for the opportunity to offer these comments on the NPRM. AAMC, COGR and their member institutions strongly believe that the proposed Rescheduling will promote the

⁴ NPRM at p. 44597,

conduct of important scientific research and is therefore in the public interest.

Please do not hesitate to contact either of us at hpierce@aamc.org or kwest@cogr.edu or Daria Grayer, MA, JD, Director of Policy and Regulations at AAMC (dgrayer@aamc.org).if you have any questions regarding this transmittal.

Sincerely,



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cc: David J. Skorton, MD, AAMC President and Chief Executive Officer
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