

July 22, 2024

Drug Enforcement Agency (DEA)
U.S. Department of Justice (DOJ)
Attn: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Schedules of Controlled Substances: Rescheduling of Marijuana (<u>Docket No. DEA-1362</u>; A.G. Order No. 5931-2024)

Dear DEA Representative:

The American Pharmacists Association (APhA) is pleased to submit comments on the "Schedules of Controlled Substances: Rescheduling of Marijuana," Notice of proposed rulemaking (NPRM).

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists, scientists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA supports regulatory changes to facilitate clinical research related to the clinical efficacy and safety associated with the use of cannabis and its various components. Additionally, APhA encourages health care provider education and pharmacist participation in furnishing cannabis and its components. Pharmacists are experts in medication therapy and improving health outcomes and having the pharmacy profession involved in education for patients presents a range of benefits, including proper dosing, monitoring, and counseling of patients.

VII. Determination of Appropriate Schedule for Marijuana

The Attorney General is proposing to reschedule marijuana in schedule III and solicits comments on preliminary findings related to its abuse potential, whether it has a currently accepted medical use (CAMU), and its safety/dependence potential. HHS concluded that marijuana has a CAMU, specifically for the treatment of anorexia related to medical conditions (cancer or epilepsy), nausea and vomiting, and pain. APhA supports the findings of the CAMU

test, and strongly encourages health care providers to be involved in the clinical efficacy, safety, and management of patients using cannabis and its various components. If moved to schedule III, marijuana will likely be more incorporated into patients' medication regimens. APhA believes this will require health care provider collaboration. Patients using medical marijuana are typically indicated for other conditions such as cancer or epilepsy, accordingly, having an engaged health care team, including a pharmacist, working with the patient to review drugdrug and drug-disease interactions and make modifications as needed is paramount.

Pharmacists have extensive knowledge of scheduled medications as most pharmacies store and dispense scheduled II-V medications. Pharmacists are also trained to be experts in medication use. Pharmacists will collect and document information in the pharmacy patient profile about patient use of marijuana and its various components and provide appropriate patient counseling if it moves to schedule III.

IX. Requirements for Handling Marijuana and Other Applicable Controls

DOJ is also seeking comments on the practical consequences of rescheduling marijuana into schedule III under the relevant statutory frameworks. If transferred to schedule III, regulatory controls applicable to other schedule III substances would apply, along with existing marijuana-specific requirements.

Despite certain products already being accessible to consumers in the states, federal regulations limit researchers' ability to study cannabis and cannabis-derived products. APhA believes rescheduling marijuana to schedule III will improve research opportunities. Marijuana will be less burdensome to obtain and study. Marijuana's current schedule I classification imposes strict regulatory requirements that make it difficult for researchers and scientists to obtain it for study. For example, researchers must possess a Schedule I research registration from DEA to conduct research on marijuana. Researchers who wish to receive a grant from the National Institutes of Health (NIH) that can only be supplied by the University of Mississippi. A move to schedule III could allow for more DEA-approved suppliers of marijuana which will provide a more consistent research supply for scientists.

Rescheduling marijuana to schedule III will allow researchers to more easily secure federal funding for studies. Schedule I status limits the availability of federal grants for marijuana research due to the perceived risks and regulatory burdens.

Conclusion

Thank you again for allowing APhA the opportunity to comment on the proposed schedule transfer of marijuana. APhA believes the transition of marijuana to schedule III would accelerate the research of new medical uses for marijuana and potentially advance safer and more effective therapeutic uses. APhA is committed to working with the DEA and other relevant parties to ensure patients continue to receive safe and effective medications as

medication schedules change. If you have any questions or need any additional information, please contact APhA at mbaxter@aphanet.org.

Sincerely,

Michael Baxter

Vice President, Government Affairs

Michael Baxter