*Submitted Electronically*

July 22, 2024

The Honorable Anne Milgram
Administrator
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Schedules of Controlled Substances: Rescheduling of Marijuana (Docket No. DEA-1362)

Dear Administrator Milgram:

LeadingAge appreciates the opportunity to provide comments to the Drug Enforcement Administration (DEA) regarding the proposal to reschedule marijuana to a Schedule III controlled substance.

In its notice of proposed rulemaking (NPRM), DEA provides a summary of the determinations made by the U.S. Department of Health and Human Services (HHS) with respect to the eight factors that the Controlled Substances Act (CSA) requires the Department of Justice (DOJ) to consider when determining if a drug should be controlled and, if so, under what schedule. DEA also shares in the NPRM certain information about its own analysis, and notes that additional data and other information are necessary to support DEA in making a final determination.

For the reasons set forth below, LeadingAge supports the proposed rescheduling, and we call on DEA to provide additional detail addressing various uncertainties that would arise if the proposal were finalized.

We note first that, if DEA's proposal is finalized, researchers would face less strict regulatory controls in researching marijuana as a Schedule III controlled substance, which may in turn promote further research on marijuana.[1]

We believe such additional research would be beneficial given the widespread emergence of state approved medical marijuana programs, among other reasons. As noted in the NPRM, since 1996 thirty-eight states, the District of Columbia, and four Federal Territories have legalized the use of medical marijuana by individuals whose health care practitioners have recommended that they use marijuana to treat certain health conditions.[2] In its August 2023 recommendations to DEA, HHS noted that more than 30,000 licensed health care practitioners across forty-three U.S. jurisdictions are authorized to recommend the medical use of marijuana for more than six million registered patients for at least fifteen medical conditions. For several jurisdictions, HHS further notes, these programs have been in

[1] Congressional Research Service, Department of Health and Human Services Recommendation to Reschedule Marijuana: Implications for Federal Policy (September 13, 2023)
[2] 89 FR 44597, 44600. Also, while not directly relevant in the context of the DEA's NPRM, the National Conference of State Legislatures (NCSL) identifies that twenty-four states, two territories and the District of Columbia have legalized small amounts of cannabis for adult recreational use. NCSL Report: Cannabis Overview (https://www.ncsl.org/civil-and-criminal-justice/cannabis-overview) (accessed July 21, 2024)

place for several years, and include features that actively monitor medical use and product quality characteristics of marijuana dispensed. Owing in part to the emergence of these state programs, among other factors, use of cannabis has notably increased among older adults nationally in recent years.

In a comment submitted to this Docket, for example, the American Academy of Hospice and Palliative Medicine shared its perspective about the potential benefit of more widespread research on the management of and clinical uses for marijuana:

> *Physicians and patients would be able to benefit from more rigorous evidence on appropriate dosing, frequency, and route of administration of marijuana products. …. Research could also provide evidence on the risks of marijuana use, including the risk for misuse or abuse as well as on risks of interactions with other medications, most notably with emerging cancer therapies, that could impact patient safety and medication effectiveness.*

Further, the NRPM makes clear that any drugs containing a substance within the CSA's definition of "marijuana" would remain subject to the applicable prohibitions in the Federal Food, Drug, and Cosmetic Act.[3] Based on our understanding that transferring marijuana from Schedule I would create additional opportunities for research, rescheduling may also support the development of clinically tested and validated pharmaceutical products for treatment of certain conditions.

Second, we believe the proposed rescheduling may, in some ways, begin to address the misalignment between federal and state policy concerning medical marijuana. According to guidance from the U.S. Department of Housing and Urban Development, for example, the use of medical marijuana is illegal under federal law even if it is permitted under state law.[4] This creates unnecessary housing access barriers for older adults with chronic medical conditions who may benefit from accessing medical marijuana through a state established program. Also, it furthers exacerbates health inequities between older adults based on income and, due to the overrepresentation of racial minorities in HUD-assisted housing, based on race, households with low incomes living in federally subsidized housing cannot benefit from certain treatments that other, non-housing assisted older adults can legally access under state-established medical marijuana programs.

In offering these comments, we recognize that there is significant uncertainty about specific impacts reclassification to Schedule III would have, and we believe detailed implementation guidance would be essential. The following are examples of questions that the NPRM does not address, but where clear DOJ/DEA guidance will be needed if the proposed rescheduling of marijuana is finalized:

- While we assume research opportunities will expand if the proposal is finalized, there will be questions about how research processes and protocols would change following rescheduling. For

[3] 89 FR 44621. See also Congressional Research Service, Legal Consequences of Rescheduling Marijuana (Updated May 1, 2024) ("With respect to medical marijuana, a key difference between placement in Schedule I and Schedule III is that substances in Schedule III have an accepted medical use and may lawfully be dispensed by prescription, while substances in Schedule I cannot. However, prescription drugs must be approved by the Food and Drug Administration (FDA).")

[4] Memorandum from Benjamin T. Metcalf, HUD Deputy Assistant Director for Multifamily Housing Programs, Use of Marijuana in Multifamily Assisted Housing (https://www.hud.gov/sites/documents/USEOFMARIJINMFASSISTPROPTY.PDF)

example, could research be conducted with products currently available through State-regulated marketplaces? If so, what FDA or DEA requirements would apply?

- What will the impact be on state-regulated cannabis products, which are not FDA approved drugs? Based on the NRPM's confirmation that the Food Drug and Cosmetic Act will continue to apply (see note 3 above), is it correct that these products would remain federally illegal under a transfer to Schedule III? If so, guidance confirming federal enforcement priorities is needed to understand how rescheduling of marijuana may impact state regulated medical marijuana programs and those who are participating in those programs.

- DEA states that, concurrent with this rulemaking, it will consider "marijuana-specific controls" that would be necessary to meet U.S. treaty obligations in the event that marijuana is rescheduled to Schedule III, and that it will seek to finalize such regulations as soon as possible. The NPRM does not provide additional information about what such controls would be, however, and we request that DEA provide opportunity for stakeholder analysis and feedback on these issues.

LeadingAge is committed to supporting our members in navigating any final rule on rescheduling, and we respectfully request that DOJ, DEA and HHS issue appropriate guidance to inform implementation, whether as part of, or concurrently with, a rule that finalizes DEA's proposal.

Thank you for your consideration, and please contact me (jlips@leadingage.org) if we can answer any questions or provide additional information.

Sincerely,

*Jonathan Lips*

Jonathan Lips
Vice President, Legal Affairs

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*LeadingAge represents more than 5,400 nonprofit aging services providers and other mission-driven organizations serving older adults that touch millions of lives every day. Alongside our members and 36 partners in 41 states, we use advocacy, education, applied research, and community-building to make America a better place to grow old. Our membership encompasses the entire continuum of aging services, including skilled nursing, assisted living, memory care, affordable housing, retirement communities, adult day programs, community-based services, hospice, and home-based care. We bring together the most inventive minds in the field to lead and innovate solutions that support older adults wherever they call home.*