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BY FIRST-CLASS AND FEDEX MAIL

Drug Enforcement Administration, Attn: Administrator
Hon. Anne Milgram
Docket No. DEA–1362
8701 Morrissette Drive,
Springfield, Virginia 22152

RE: Request for Hearing on the Proposed Rule Rescheduling Marijuana, Docket No. DEA–1362

Dear Administrator Milgram:

Smart Approaches to Marijuana (SAM) hereby requests a hearing on the Proposed Rule that would reschedule marijuana from Schedule I to Schedule III under the Controlled Substances Act. *See* 89 Fed. Reg. 44,597 (May 21, 2024), Docket No. DEA-1362 ("NPRM"). SAM is a bipartisan alliance of organizations and individuals dedicated to a health-first approach to marijuana policy. It is comprised of medical doctors, lawmakers, treatment providers, preventionists, teachers, law enforcement officers and others who seek a middle road between incarceration and legalization. SAM's mission is to equip policymakers with commonsense proposals, based in reputable science, to promote public health and decrease marijuana use and its consequences. SAM opposes the removal of cannabis from Schedule I.

SAM is an interested person who would be adversely affected or aggrieved by the agency's action if marijuana were rescheduled. *See* 21 C.F.R. §§ 1300.01(b), 1308.44. Moving marijuana to Schedule III will negatively affect SAM by reducing restrictions on access to marijuana and thereby requiring SAM to divert resources and expend additional funds on new and different lines of effort to protect those most at risk—including at-risk youth—from the harms produced by more ready access to this psycho-active substance. A sweeping change in the regulatory environment would require SAM to divert resources from its current advocacy and informational efforts and expend resources on entirely different projects. The NPRM also requests expert testimony that SAM is uniquely situated to coordinate and provide to the agency. SAM's interest in this proceeding is also directly analogous to the interests of other public interest and professional associations whose requests for a hearing on the record during past attempts to reschedule marijuana were granted. *See, e.g.*, *NORML v. DEA*, 559 F.2d 735, 742 (D.C. Cir. 1977) (noting

that "NORML and the American Public Health Association" successfully requested a hearing on rescheduling cannabis).[1]

As the most significant relaxation of restrictions on a psychoactive substance in the history of the CSA, the Proposed Rule deserves full consideration through a hearing on the record. In the NPRM, DEA went out of its way to request "additional information" and "expert opinions" on a host of complex subjects. SAM requests a hearing to present evidence on the subjects identified by DEA, including but not limited to, the following:

1. *Marijuana's actual or relative potential for abuse.*—SAM believes that the assessment of marijuana's actual or relative potential for abuse in the Proposed Rule is flawed. At a hearing, SAM would present evidence bearing upon several points demonstrating that marijuana has a higher actual rate of abuse and higher potential for abuse than acknowledged in the analysis presented by HHS. Among other things, SAM would present evidence from the Drug Abuse Warning Network (DAWN) related to adverse outcomes from the use of marijuana; evidence from the National Survey on Drug Use and Health (NSDUH) bearing upon the development of substance use disorder among users of marijuana; and evidence from other relevant studies and data sets.

2. *Marijuana's risk to public health.*—The Proposed Rule, relying on HHS's analysis, asserts that marijuana presents a lower public health risk profile in comparison to "most other comparator drugs." 89 Fed. Reg. at 44,601. But HHS did not compare marijuana against all Schedule I drugs; rather, it compared marijuana to a limited, hand-picked list of other controlled and noncontrolled substances (*e.g.*, heroin, alcohol, cocaine). HHS also omitted entirely any comparison with Schedule I hallucinogens. At a hearing, SAM would present evidence from expert witnesses to provide a more balanced analysis of the public health risks posed by marijuana.

The Proposed Rule also fails to consider research demonstrating that marijuana plays a causal role in the development of psychosis, including schizophrenia, in certain individuals. At the hearing, SAM would produce evidence concerning this link.

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[1] SAM respectfully notes that administrative law judges (ALJs) at DEA are almost certainly inferior officers under the Constitution. As a result, their appointment by the Administrator is inconsistent with the Appointments Clause of Article II. *See, e.g.*, *Lucia v. SEC*, 585 U.S. 237 (2018). SAM raises this issue to make clear that, by requesting a hearing as permitted by 21 U.S.C. § 811(a) and 21 C.F.R. § 1308.44, SAM does not consent to a hearing before an ALJ who has not been appointed in a manner consistent with the requirements of the Appointments Clause, and SAM expressly preserves its right to challenge the outcome of any hearing on the ground that the ALJ was not properly appointed.

Additionally, HHS elides the significant danger of marijuana-impaired driving by ignoring the *rate* of self-reported impaired driving by users of marijuana (which is far higher than the rate of impaired driving among users of other substances, including alcohol). At a hearing, SAM would provide evidence on this and related points.

The Proposed Rule also downplays the unique risks that marijuana poses to youth and adolescents. At a hearing, SAM would provide expert testimony showing that cannabis use harms adolescent brain development, diminishes learning, and inhibits mental processing speed. This evidence is critical because this aspect of the public health risks posed by marijuana appears to have been ignored by HHS.

SAM would also provide evidence related to the health risks of marijuana use during pregnancy.

3. *The redefinition of "Currently Accepted Medical Use."*— To change marijuana's designation as a Schedule I substance, HHS had to change the standard for determining "currently accepted medical use." The new test uses only two factors under which a substance has an accepted medical use, namely (i) if licensed healthcare providers have widespread current experience with medical use of the drug and (ii) if that medical use has "some credible scientific support." Memorandum for the Commissioner, FDA, from the Assistant Secretary for Health, HHS, Re: Part 1 Analysis at 1-2 (July 17, 2023) (HHS Memo). Under this new test, HHS concluded that marijuana has a currently accepted medical use for "anorexia related to a medical condition; nausea and vomiting (e.g., chemotherapy-induced), and pain." *Id.* at 29.

At a hearing, SAM would present testimony showing that marijuana does not satisfy the second factor of the new test because there is not credible scientific support that marijuana can be used to treat anorexia, chemotherapy-induced vomiting, or pain.

4. *Marijuana's history or pattern of abuse*.—HHS found that marijuana has a potential for abuse less than the drugs or other substances in schedules I and II, and the DEA requested additional evidence related to this point. *See, e.g.*, 89 Fed. Reg. at 44,603 (requesting "additional data" on marijuana's actual or potential for abuse). At a hearing, SAM would present testimony showing that marijuana's history and pattern of abuse is much more like that of Schedule I substances than Schedule III substances.

All notices to be sent pursuant to the proceeding should be addressed to:

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Respectfully submitted,

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CC: Hearing Clerk/OALJ
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