October 11, 2016

The Honorable Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Acting Administrator Rosenberg,

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 4,100 physicians and other clinicians specializing in the treatment of addiction, I would like to commend the Drug Enforcement Administration (DEA) for its recent actions to facilitate research into the potential therapeutic effects of marijuana. Specifically, we applaud the proposal to approve additional marijuana growers to supply researchers and the development of an online application system for researchers to apply for Schedule I research registrations. We urge the DEA to act on these commitments as swiftly as possible. We also commend the DEA for the December 2015 policy change that waives certain regulatory requirements for researchers conducting Food and Drug Administration (FDA)-authorized clinical trials on cannabidiol, enabling them to modify or expand the scope of their studies more easily.

ASAM agrees with the DEA and the FDA that scientifically valid and well-controlled clinical trials conducted under investigational new drug applications are the proper way to research all potential new medicines, including marijuana and specific extractable or synthesizable cannabinoids such as tetrahydrocannabinol and cannabidiol. We also agree with the Department of Health and Human Services' (HHS) conclusion that more research is needed into marijuana's effects, including potential medical uses for marijuana and its derivatives.

To that end, ASAM recommends the DEA take further action within its statutory authority to facilitate marijuana research by reducing registration approval times and eliminating requirements not specified by the Controlled Substances Act (CSA). Specifically, the DEA can approve marijuana research registration applications more quickly by not waiting for Institutional Review Board (IRB) approval first. The CSA does not

4601 N. Park Avenue, Upper Arcade #101, Chevy Chase, MD 20815
Phone: 301.656.3920 | Fax: 301.656.3815
www.ASAM.org

require the DEA to wait for IRB approval to review and approve research registrations, yet it is our understanding that the DEA does so. Eliminating this wait time could speed up the process for researchers to begin their work.

Additionally, the DEA should not allow its field offices to impose more stringent restrictions than are included in the statute. Field offices, which have the authority to conduct site inspections, currently have the flexibility to impose additional restrictions on researchers, such as requiring a safe instead of a securely locked, substantially constructed cabinet as required by the law. Eliminating such additional requirements would surely reduce barriers to research.

ASAM also recommends the DEA conduct and publish an outcomes report examining the impact of these policy changes on the research application and approval process and documenting any continued challenges that scientists and medical professionals face in attempting to conduct clinical research using marijuana. The publication should include recommendations for changes that the DEA can make to its internal processes and procedures as well as changes that it can make via rulemaking to expedite marijuana research applications and facilitate scientific inquiry into potential therapeutic effects of marijuana and specific cannabinoid molecules.

Finally, ASAM requests the DEA to issue additional guidance for researchers in states where marijuana has been legislated for medical or recreational use to make the federal government's position on the use of marijuana for research purposes clear.

Sincerely,

R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM
President, American Society of Addiction Medicine