



National
Multiple Sclerosis
Society

April 23, 2018

Leslie Kux
Associate Commissioner for Policy
Food and Drug Administration
Docket No. FDA-2018-N-1072

Ms. Kux,

The National Multiple Sclerosis Society appreciates the Food and Drug Administration's (FDA) request for organizations to provide input concerning the abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on the availability for medical use of cannabis and its extracts. We believe that the cannabis plant and its extracts have potential medical value for people living with multiple sclerosis (MS) and we request that you respond to the World Health Organization's (WHO) request for comments with arguments in favor of loosening international restrictions on cannabis research.

The Society supports the ability of people living with MS to make an informed choice about their treatments, including the use of medical cannabis, with their MS health care providers. Additionally, the Society supports advancing research to better understand the benefits and potential risks of cannabis and its derivatives as a treatment for MS symptoms.¹ Recognizing that additional research is still needed, we are evaluating ways we can remove the barriers to allowing research on medical cannabis at the federal level, which is complex due to government restrictions.

MS is a disorder of the central nervous system characterized by inflammation, demyelination and degenerative changes. Symptoms vary by individual and range from numbness or tingling, to walking difficulties, fatigue, dizziness, pain, depression, blindness and paralysis. People with MS may experience relapses and remissions of neurological symptoms or symptoms may progress over time. FDA-approved disease modifying therapies are effective at limiting the number of relapses and disease progression, however, they do not specifically treat MS symptoms. Optimal symptom management requires a comprehensive approach and medical cannabis is often used as a complementary therapy to manage MS symptoms, such as muscle spasms and spasticity.

The Society strongly believes that more research is needed to understand the interaction between cannabis and endogenous cannabis receptors and how that interaction affects the central nervous system. This is necessary for the scientific and medical communities to accurately gauge the potential benefits and risks of using cannabis to treat MS symptoms as well as other diseases and conditions of the central nervous system. Under current law, researchers must overcome a burdensome and restrictive application process administered by the Drug Enforcement Administration (DEA) and the Department of Justice (DOJ) to conduct research on medical cannabis. Furthermore, even if researchers are able to obtain the approval of the DEA and DOJ to conduct research with medical cannabis, the federal government restricts the number of entities licensed to grow the cannabis that must be used for these experiments. Restricting the supply of cannabis in this manner reduces the varieties of cannabis that can be researched and prevents researchers from exploring the full potential of the cannabis plant. This has a chilling effect on research and innovation,

¹ <https://www.nationalmssociety.org/Treating-MS/Complementary-Alternative-Medicines/Marijuana>



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preventing researchers from establishing a complete understanding of the therapeutic value that cannabis can provide to patients. Indeed, the Society has first-hand experience with these challenges. Despite making our interest in supporting high quality research in this area clear, the Society has only funded one research project in this area since 2000. This is due primarily to a paucity of qualified proposals caused by the significant restrictions researchers face. Additionally, these research barriers prevent the state and federal governments of the United States from crafting informed cannabis policy.

Due to the extent that it impedes research into the potential therapeutic benefits and risks of cannabis, the Society does not believe that it is appropriate for the United States or the international community to maintain Schedule I status for cannabis. A report² published by the National Academies of Sciences, Engineering, and Medicine in 2017 determined that “there is conclusive or substantial evidence that cannabis or cannabinoids are effective ... for the treatment of chronic pain in adults [and] improving patient-reported multiple sclerosis spasticity symptoms.” Furthermore, the report concluded that “there is moderate evidence that cannabis or cannabinoids are effective ... for improving short-term sleep outcomes in individuals with sleep disturbance associated with ... multiple sclerosis.” Given the strong association between cannabis and its interaction with multiple sclerosis symptoms, the fact that multiple sclerosis is a common qualifying condition for participation in state medical cannabis programs, and the inadequate scientific understanding that we have of the cannabis plant, we strongly urge the FDA to advocate for loosening international restrictions that govern the amounts and types of research that can be done on cannabis.

Thank you for providing us with the opportunity to comment on this issue that is very important to many people who are living with MS. If you have any questions or concerns, you can contact John Wylam in the Society’s Public Policy Office, at john.wylam@nmss.org.

Sincerely,

A handwritten signature in cursive script that reads "Bari Talente".

Bari Talente, Esq.
Executive Vice President of Advocacy

² National Academies of Sciences, Engineering, and Medicine. 2017. The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24625>.