



March 14, 2019

Mr. James R. Hunter
Center for Drug Evaluation and Research
Controlled Substance Staff
Food and Drug Administration
10903 New Hampshire Ave
Bldg. 51, Rm. 5150
Silver Spring, MD 20339-0002

Re: Docket No. FDA-2019-N-0767 – International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Cannabis and Cannabis Resin; Dronabinol (*delta*-9-tetrahydrocannabinol); Tetrahydrocannabinol (Isomer of *delta*-9-tetrahydrocannabinol); Extracts and Tinctures of Cannabis; Cannabidiol Preparations; Preparations Produced Either by Chemical Synthesis or as Preparation of Cannabis; Request for Comments

Dear Mr. Hunter:

Thank you for the opportunity to submit comments on the U.S. Food and Drug Administration's notice concerning recommendations to impose manufacturing and distributing restrictions under international treaties on certain substances, including cannabis. The Michael J. Fox Foundation for Parkinson's Research (MJFF) advocates on behalf of the Parkinson's disease community, including researchers, patients, and families, and is committed to exploring new treatment options for those living with the disease. This includes conducting research on cannabis and its component cannabinoids to determine potential therapeutic use.

As the world's largest nonprofit funder of Parkinson's disease (PD) research, MJFF is dedicated to accelerating a cure for Parkinson's and developing improved therapies for those living with the disease today. In providing more than \$800 million in research to date, the Foundation has fundamentally altered the trajectory of progress toward a cure. It is estimated that more than 1 million people in the United States have PD, with an annual economic burden of at least \$26 billion. Currently, there is no therapy to slow, stop, or reverse the progression of PD, nor is there a cure.

MJFF requests and supports the elimination of barriers to conduct medical research to determine if cannabis or any of its component compounds may or may not safely and effectively help patients manage their symptoms associated with Parkinson's. In addition, MJFF supports the scheduling of cannabis and its component compounds to be at a level that will not restrict its access to medical research, and allows for optimal opportunities to conduct research to determine any medical benefit or therapeutic use. To date, little systematic research has been conducted to assess whether cannabis can modify the progression of PD or provide symptomatic relief for patients living with PD, resulting in insufficient evidence for the safety and efficacy of the

plants and its constituent pounds in PD. This insufficient evidence is due to the limited medical research on cannabis in PD, among other diseases.

With the legalization of medical and recreational cannabis in many states throughout the United States, PD patients are already utilizing cannabis and cannabis products in attempts to ease the symptoms of the disease that are not ameliorated by currently approved medications. However, lack of systematic research on cannabis in PD due to legal restrictions has led to desperate patients using cannabis products based purely on anecdotal evidence. Current restrictions on cannabis are preventing basic safety research on “over-the counter” products that are extremely easy for PD patients to acquire and use.

While research on cannabis has given insufficient evidence on its potential benefit for PD patients, there are completed clinical trials that provide promising signals for why more research is necessary. PD patients have indicated an improved quality of life¹, an improvement in pain and sleep², decreased psychosis³, limited symptoms of REM sleep behavior disorder⁴, and improvements in dyskinesia⁵ while taking cannabis or purified component compounds such as cannabidiol. A complete interpretation of this clinical research data is difficult, due to a lack of standardized doses, variable concentrations of cannabinoids and other compounds in different strains of plant, and small study sizes in the design of cannabis research. Additionally, the recent U.S. Food and Drug Administration approval of an effective cannabidiol-based drug for epilepsy provides a template for advancing cannabis research for PD.

Current U.S. regulations surrounding cannabis block comprehensive medical research on the drug. Because of its federal classification as a Schedule I drug, coupled with the low quantity produced by the sole federally-approved growing site, researchers do not have the proper materials to conduct the necessary research and face time-consuming administrative hurdles in initiating and performing their intended studies. MJFF supports access to a wide range of scientific resources to encourage urgently needed discoveries to unlock new therapies and treatments to cure PD.

Continued research into cannabis and PD is critical for supporting patients living with the disease and future generations who may be affected by PD. The Michael J. Fox Foundation is available to

¹ Chagas, M., Zuardi A., Tumas, V., Pena-Pereira, M., Sobreira, E., Bergamaschi, M., dos Santos, A., Teixeira, A., Hallak, J., Crippa, J. Effects of Cannabidiol in the Treatment of Patients with Parkinson's Disease: An Exploratory Double-Blind Trial. *Journal of Psychopharmacology*. November 2014, 28 (11). 1088-1098.

² Lotan, I., Treves, T., Roditi, Y., Djaldetti, R. Cannabis Treatment for Motor and Non-Motor Symptoms of Parkinson Disease: An Open-Label Observational Study. *Clinical Neuropharmacology*. March-April 2014, 37(2). 41-44.

³ Zuardi, A., Crippa, J., Hallak, J., Pinto, J., Chagas, M., Rodrigues, G., Dursun, S., Tumas, V. Cannabidiol for the Treatment of Psychosis in Parkinson's Disease. *Journal of Psychopharmacology*. November 2009, 23(8). 979-983.

⁴ Chagas, M., Eckeli, A., Zuardi, A., Pena-Pereira, M., Sobreira-Neto, M., Sobreira, E., Camilo, M., Bergamaschi, M., Schenck, C., Hallak, J., Tumas, V., Crippa, J. Cannabidiol Can Improve Complex Sleep-Related Behaviors Associated with Rapid Eye Movement Sleep Behavior Disorder in Parkinson's Disease Patients: A Case Series. *Journal of Clinical Pharmacy and Therapeutics*. October 2014, 39(5). 564-566.

⁵ Sieradzan, K., Fox, S., Hill, M., Dick, J., Crossman, A., Brotchie, J. Cannabinoids Reduce Levodopa-Induced Dyskinesia in Parkinson's Disease: A Pilot Study. *Neurology*. December 2001, 57(11). 2108-2111.



THE MICHAEL J. FOX FOUNDATION
FOR PARKINSON'S RESEARCH

assist if you need additional clarification or information. Please contact Aaron Polacek at 202-638-4101 ext. 252 or by email at apolacek@michaeljfox.org. Thank you for the opportunity to provide input on this issue.

Sincerely,

Ted Thompson, JD
Senior Vice President of Public Policy