



October 31, 2018

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

Re: Docket No. FDA-2018-N-3685 - International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; ADB-FUNINACA; FUB-AMB(MMB-FUBINACA_AMB-FUBINACA); ABD-CHMINACA; CUMYL-4CN-BINACA; Cyclopropyl Fentanyl; Methoxyacetyl Fentanyl, *Ortho*-Fluorofentanyl; *Para*-Fluoro Butyrfentanyl; *Para*-Methoxybutyrfentanyl; *N*-Ethylnorpentylone; Tramadol; Pregabalin; Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol; Stereoisomers of Tetrahydrocannabinol; 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 abuse potential, medical usefulness, and the impact of scheduling changes on the availability for medical use of drug 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 nearly 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 easing 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. 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.

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 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. 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 assist if you need additional clarification or information. Please contact Aaron Polacek at apolacek@michaeljfox.org. Thank you for the opportunity to provide comments.

Sincerely,



Ted Thompson, JD
Senior Vice President of Public Policy

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.