Multidisciplinary Association for Psychedelic Studies (MAPS)
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CLINICAL TRIAL FACT SHEET

MARIJUANA FOR SYMPTOMS OF PTSD IN U.S. VETERANS

Study Title: A Placebo-Controlled, Triple-Blind, Randomized Crossover Pilot Study of the Safety and Efficacy of Four Different Potencies of Smoked Marijuana in 76 Veterans with Chronic, Treatment-Resistant Posttraumatic Stress Disorder (PTSD)

Study Sponsor: MAPS, a 501(c)(3) nonprofit research organization

Coordinating Principal Investigator: Marcel Bonn-Miller, Ph.D.
Site Principal Investigator: Sue Sisley, M.D.
Senior Scientific Advisor: Paula Riggs, M.D.

Study Summary:

- In this groundbreaking **randomized, triple-blind, placebo-controlled** study, marijuana is being tested as a pharmacological agent to manage PTSD symptoms in 76 US military veterans.

- This is the **first controlled clinical trial** testing the therapeutic potential of marijuana for treating PTSD, and is essential for understanding potential risks and therapeutic benefits of marijuana for PTSD patients.

- **Results will provide** physicians, patients, scientists, and regulators with critical knowledge regarding whether marijuana benefits individuals with PTSD, whether adverse consequences occur, and the impact of the chemical composition of marijuana, specifically Δ-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), on clinical outcomes.

- The study is assessing the **safety and efficacy of four types of smoked marijuana** to manage chronic, treatment-resistant PTSD symptoms in an outpatient setting.

- The **study protocol** consists of an initial two-week screening period, followed by Stage 1 (three weeks of marijuana self-administration followed by a two-week period of marijuana abstinence), followed by Stage 2 (identical to Stage 1 with a different type of marijuana).

- Participants must be **adult military veterans** with chronic, treatment-resistant PTSD. Study volunteers will complete 17 outpatient study visits over 12 weeks. Eligibility is determined by medical evaluation. Participants must be able to visit

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the research site at the Scottsdale Research Institute in Phoenix, Arizona, for all scheduled visits.

- The **primary outcome measure** for the study is the Clinician-Administered PTSD Scale (CAPS-5), a semi-structured interview used in the majority of clinical trials for PTSD. Other measures will include the PTSD Checklist (PCL-5), Inventory of Depression and Anxiety (IDAS), Insomnia Severity Index (ISI), the Inventory of Psychosocial Functioning (IPF), and others.

- This study is examining the safety and efficacy of **four potencies** of whole plant marijuana. Placebo (<1% CBD/<1% THC), High THC (<1% CBD/12% THC), High CBD (12% CBD/<1% THC), and balanced (9% CBD/9% THC).

- The marijuana for the study was provided to MAPS by the **National Institute on Drug Abuse (NIDA)**. NIDA was able to provide three of the four varieties of marijuana requested, with the exception of the balanced 12%/12% variety, of which NIDA was only able to provide 9%/9%. The study sponsor accepts the marijuana provided by NIDA for the trial, however the marijuana provided by NIDA will not be acceptable for future Phase 3 trials. *See below for complete statement on the adequacy of the marijuana provided for the study.*

- The study is funded by a $2.156 million grant from the **Colorado Department of Public Health and Environment (CDPHE)** to MAPS.

- Since its founding in 1986, MAPS has raised over $47 million for psychedelic therapy and medical marijuana research and education. MAPS is working to evaluate the safety and efficacy of botanical marijuana as a prescription medicine for specific medical uses approved by the FDA.

- More information, including a complete study timeline, is available here.

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STATEMENT ON THE ADEQUACY OF MARIJUANA PROVIDED BY NIDA FOR PHASE 2 CLINICAL TRIALS FOR PTSD IN VETERANS (March 17, 2017)

As of July 18, 2018, 69 participants have received marijuana (cannabis) provided by the National Institute on Drug Abuse (NIDA) in an ongoing Phase 2 clinical trial sponsored by the non-profit Multidisciplinary Association for Psychedelic Studies (MAPS) at the Scottsdale Research Institute (SRI) in Phoenix, Ariz. MAPS is committed to sponsoring rigorous clinical research to develop cannabis into a prescription medicine through the Food and Drug Administration (FDA).

MAPS is testing the safety and efficacy of four different potencies of smoked NIDA cannabis to manage symptoms of chronic, treatment-resistant post-traumatic stress disorder (PTSD) in 76 veterans in a placebo-controlled clinical trial. Prior to initiating enrollment in the study, laboratory testing of the NIDA cannabis was conducted over five months. To maintain transparency to the public and to ensure the reporting of accurate information, MAPS has released the results of the five rounds of secondary analytical testing of the chemical composition of NIDA cannabis (see below).

All six batches of cannabis tested negative for harmful microbes, mycotoxins, pesticides, arsenic, cadmium, and mercury. Two batches tested negative for lead. Four batches tested positive for low levels of lead. Based on exposure limits set by the World Health Organization (WHO) Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues, the International Programme on Chemical Safety, the American Herbal Pharmacopoeia's Cannabis Inflorescence monograph, and the study protocol, the amount of possible lead exposure from NIDA cannabis was found to be well within the guidelines provided, and thus was considered safe for use in this clinical trial.

All test results were reviewed by an independent Institutional Review Board (IRB). Based on the NIDA-provided document Microbiology Safety Testing of Cannabis (Cannabis Safety Institute, May 2015) as well as test results that showed absence of harmful microbes and mycotoxins, and subsequent consultation with plant experts, MAPS concluded that the cannabis is safe for use in this clinical trial based on exposure limits and dispensation procedures specified by the amended study protocol. Only physically healthy participants who are not immunocompromised and without allergies or past adverse reactions to marijuana will be enrolled in this study. To our knowledge, there is no known case of NIDA cannabis contamination which interfered with a clinical trial or was the cause of an adverse event in a patient enrolled in the study.

Of the six batches tested, only one batch differed significantly from the potency information provided by NIDA in the certificate of analysis. It is believed the discrepancy in test results is due to homogenization issues as well as the analytical

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sampling technique used with the fine particulate nature of the specific batch. For this reason, treatment outcomes from a range of potencies will be reported from relevant cannabis treatment groups at the end of the trial.

Release specifications for NIDA cannabis, such as pass/fail or upper limits guidance for impurities, have not been set. NIDA is currently working with the FDA to identify appropriate tests and limits for marijuana used in Investigational New Drug (IND) studies. Despite the absence of federal guidance on quality, NIDA states that their cannabis is within the acceptable range of quality according to several common sets of guidelines for microbial contamination of dietary supplements. Two independent Schedule I-licensed and ISO17025 accredited analytical laboratories tested samples of cannabis provided by NIDA.

MAPS had initially planned to store the packaged cannabis at refrigerated temperatures prior to dispensing to participants. However, refrigerated storage was reported to exacerbate mold growth. Total Yeast and Mold (TYM) testing was conducted to determine appropriate storage conditions and dispensation procedures for study cannabis. Though many legal medical marijuana states have set varying acceptable levels of TYM, there is no agreement on whether TYM should be a required test. After review of testing, dispensation procedures were revised to limit likelihood of yeast and mold growth.

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