



Sue Sisley, M.D.

# Clinical Trial Update: Marijuana for PTSD in U.S. Veterans

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AFTER NEARLY SEVEN YEARS NAVIGATING barriers to cannabis research, the Multidisciplinary Association for Psychedelic Studies (MAPS)-sponsored clinical trial of cannabis for veterans with treatment-resistant posttraumatic stress disorder is nearly underway. We have already received over 400 requests from U.S. military veterans to volunteer at the Arizona site to be screened for the study. We have begun phone screenings and hope to enroll our first patient in November.

At least 76 veterans will be enrolled in total, and we expect that 38 will be recruited at each of two study sites. I will serve as Site Principal Investigator (PI) at the Scottsdale Research Institute in Phoenix, and my colleague Ryan Vandrey, Ph.D., will be the Site PI at Johns Hopkins University in Baltimore. Marcel Bonn-Miller, Ph.D., of the University of Pennsylvania is leading the study as the Coordinating PI. Additionally, Paula Riggs, M.D., an addiction specialist at the University of Colorado's Anschutz Medical Campus, will oversee data integrity for the study.

The study is being funded by a \$2.156 million grant from the Colorado Department of Public Health and Environment, awarded to MAPS by the State of Colorado's Medical Marijuana Scientific Advisory Council in December 2014. Funds for the grant came from fees collected on state medical marijuana licenses. The grant is the first government funding that MAPS has received.

This pilot study will gather preliminary evidence of the safety and efficacy of four potencies of smoked marijuana to manage chronic, treatment-resistant posttraumatic stress disorder (PTSD) among 76 veterans. The objectives of this study are to evaluate whether i) smoking whole plant marijuana attenuates PTSD symptoms, ii) to compare the efficacy of varying ratios of THC and CBD to placebo using standard clinical measures, and to iii) collect safety data. If the trial is successful, MAPS intends to develop future studies and seek use of smoked botanical marijuana as a federally approved prescription drug.

We will be exploring the effectiveness of four varieties of marijuana on PTSD symptoms in this trial: (1) High THC/Low CBD, (2) High CBD/Low THC, (3) High THC/High CBD, and placebo. The precise ratios and potencies will be determined after we complete a final round of quality assurance testing on the marijuana we received from the National Institute on Drug Abuse (NIDA).

We have organized a stellar team to conduct this research, including the addition of former MAPS Clinical Research Associate Ben Shechet as our new Study Coordinator. We aim to collect impeccable data that will meet the highest possible standards for publication in peer-reviewed journals. We anticipate being able to submit results for publication in approximately three years. In the meantime, we will strive to guarantee that the study's methods and conduct represent a pillar of scientific integrity.

We are most grateful to the many veteran service organizations who have helped us reach this point. Veterans from around the U.S. have stood side-by-side with us as we have overcome all of the obstacles that have presented themselves along the way. We had to secure many regulatory approvals for this trial, including the Public Health Service (PHS), Food and Drug Administration (FDA), local and federal Drug Enforcement Administration (DEA) offices, three Institutional Review Boards (IRBs), the NIDA, and a number of additional security measures. We began developing the protocol in 2010; it has taken nearly seven years to obtain all of these approvals, to allow us to place the order of the study drug with NIDA.

After such a long wait, it was very exciting to receive our supply of marijuana for the study this past August. We are conducting multiple rounds of external quality assurance testing to characterize the product provided by the NIDA. We are hopeful that this process will be done in time to begin enrollment this November.

We thank you for your support and determination in helping us to see this groundbreaking study through its development process. We look forward to seeing and sharing the results with you when they become available. 🌿

*Sue Sisley, M.D., is an Arizona-based physician practicing Internal Medicine and Psychiatry. She works as Medical Director for medical cannabis license holders in 11 different US states/territories, enabling her to collect data on patient's response to state-level, lab-tested cannabis. Sue serves as Site Principal Investigator for the only FDA-approved randomized controlled trial in the world examining safety/efficacy of whole plant marijuana in combat veterans with treatment-resistant post traumatic stress disorder PTSD. She is on faculty at Colorado State University, and has been a Member of Nevada ILAC Medical Cannabis Commission for the past 2 years.*