New Marijuana-for-PTSD Protocol Close to Complete

MAPS is preparing a marijuana/PTSD pilot study in veterans of war to be conducted by Principal Investigator Sue Sisley, M.D. in Arizona. The protocol is close to being submitted to the FDA after having been reviewed, critiqued, and revised by several outside experts. The study is being developed in response to anecdotal reports of marijuana being used to alleviate PTSD symptoms. At present, there is no published data from a randomized, placebo-controlled, double-blind study of the risks and benefits of marijuana for chronic PTSD sufferers.

Forty subjects will be randomly allocated to one of four treatment groups. Each subject will be provided with two rolled cigarettes daily, each weighing 0.9 grams, the standard-size marijuana cigarette provided by the National Institute on Drug Abuse (NIDA). The cigarettes will contain either (1) 2% D9-tetrahydrocannabinol (THC), (2) 6% THC, (3) 6% THC and 6% cannabidiol (CBD), or (4) 12% THC. The subjects who receive 2% THC will serve as the low-dose/active placebo group; while an ideal placebo would not contain any potentially therapeutic action, previous research has shown completely inactive marijuana is rarely effective at producing an effective double-blind. Marijuana will be self-administered daily on an outpatient basis for four weeks, followed by two weeks of none. Within each treatment group, five of 10 subjects will smoke marijuana cigarettes; the other five are assigned to use a vaporizer.

In this groundbreaking study, marijuana will be used as a pharmacological medicine without associated psychotherapy. The primary outcome variable measuring the severity of PTSD will be the Clinician Administered PTSD Scale (CAPS), required by FDA and the European Medicines Agency (EMEA).

At present, NIDA does not produce any marijuana with significant levels of CBD. We are specifically requesting NIDA produce such a strain for this study. NIDA has previously indicated that it could provide any marijuana strains requested by researchers. Should NIDA be unable to provide marijuana with CBD due to NIDA’s monopoly on the supply of marijuana for FDA-regulated research we would have no other sources of supply and would be forced to eliminate the 6% THC/6% CBD group from the protocol.

Swiss LSD/Life-Threatening Illness Study Amended and Progressing

On May 4, 2010, Peter Gasser, M.D. submitted an amendment to our Swiss LSD-assisted psychotherapy for the treatment of anxiety associated with life-threatening illness study to his Ethics Committee (EC). The EC met on May 25 and approved the amendment. The amendment includes audio and video recording of the treatment sessions for later analysis, adds interim data analysis in order to get a sense of the safety and effectiveness of treatments before the study is over, and makes the protocol more flexible to meet the needs of the study population, which are people with advanced-stage cancer or other life-threatening diseases. Often these subjects have difficulties leaving home because of pain. As a result, we expanded some of the timelines from the former version of the protocol in order to be more flexible with the subjects.

On June 22, 2010, the eighth subject out of twelve received LSD in the subject’s first experimental session. Dr. Gasser is in the recruitment process for the remaining subjects. Additionally, we added a new clinical study assistant to the staff, Katharina Kirchner, M.A., of Switzerland.

MAPS Intensifies Campaign for Craker’s Marijuana Production License

MAPS has hired Chris Chiles and Stephen Morseman to coordinate a campaign to obtain a DEA license for Professor Lyle Craker of UMass Amherst to grow marijuana under contract to MAPS, and end the National Institute on Drug Abuse (NIDA) monopoly over the supply of marijuana available to the research community. Chiles and Morseman are attempting to have the issue brought up at the Senate Judiciary Committee’s confirmation hearing for the new DEA Administrator. President Barack Obama has nominated DEA Deputy Administrator Michele Leonhart, but she is a holdover from President Bush and her track record does not bode well for medical marijuana and marijuana research.

On February 12, 2007, DEA Administrative Law Judge (ALJ) Mary Ellen Bittner ruled it is in the public interest for the DEA to license Craker. However, on January 12, 2009, Leonhart rejected this recommendation. On January 30, 2009, Craker’s lawyers at the American Civil Liberties Union (ACLU) filed a Motion to Reconsider. The DEA has not responded. The ACLU has filed nine status updates (every 60 days) with the U.S. Court of Appeals, First Circuit, in case the DEA conclusively rejects the ALJ recommendation and a legal appeal is needed.

The goal of MAPS’ campaign is to pressure three key senators—Senators Patrick Leahy (D-Vermont), Sheldon Whitehouse (D-Rhode Island) and Al Franken (D-Minnesota)—to ask Leonhart during the confirmation hearing to grant Craker’s motion and accept the administrative law judge’s recommendation to end the federal monopoly on the supply of marijuana for federally regulated research. MAPS members are encouraged to contact these senators, using our sample letter and phone script available at: www.maps.org/mmj/campaign

We Won the Guidestar/Great Nonprofits Nationwide Health Campaign! Mainstream Medical Acceptance Increases

On July 1, 2010, we won the Guidestar/Great Nonprofits Nationwide Health Campaign 2010, a one-month contest to collect the most reviews by an organization’s supporters on the Great Nonprofits website. We have received a price of $5,000 along with increased credibility and visibility. On August 5, 2010, Guidestar sent an email out to more than one million people announcing our victory, which means many more people have become aware of us.

The success indicates our increasing mainstream acceptance as a health care related organization. More than 115 organizations entered the contest. Six hundred and three MAPS supporters submitted reviews between June 1 and June 30, while the two runner-ups had fewer than half our number of reviews. This is testimony to the strength of our community. As we strive to mainstream psychedelics as therapeutic medicines, we know our supporters are willing to provide us with the resources we need. Each small victory like this brings us closer to historic achievements.