mdma research news

Five subjects have now received at least one experimental treatment in our ongoing study of MDMA-assisted psychotherapy for veterans with chronic, treatment-resistant PTSD.

First Five Veterans Treated in US Study of MDMA-Assisted Psychotherapy for PTSD

Five subjects (out of 16) have now received at least one experimental treatment session in our ongoing U.S. Phase 2 Study of MDMA-assisted psychotherapy for veterans with chronic, treatment-resistant PTSD. Of these subjects, three have completed all three experimental treatment sessions in Stage 1 and one has completed the entire study. The long line of veterans now awaiting in-person screening for this study is both encouraging and saddening—encouraging because it means we will certainly have enough subjects for the study, saddening because there are so many people for whom conventional PTSD treatments have failed to provide sufficient relief. Female combat veterans and veterans living near Charleston, SC, are especially encouraged to apply for study participation (see **www.maps.org/vets**). Clinical Investigators and co-therapists Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N., will be hosting a workshop at Cartographie Psychedelica, our 25th Anniversary conference and celebration in Oakland from December 8-12. More information about these workshops will be available at **www.maps.org/25**.

MDMA-Assisted Psychotherapist Training Study Treats First Subject

On April 22, 2011, the first subject completed our therapist training protocol for MDMA-assisted psychotherapy for PTSD. Two additional subjects have been scheduled for later this year. This protocol is designed as a Phase 1 study of the psychological effects of MDMA in healthy volunteers, with subjects limited to people in MAPS' therapist training program. In addition to providing new information about the effects of MDMA-assisted psychotherapy in healthy volunteers, the study will enable us to train therapists to conduct future MDMA/PTSD studies. Clinical Investigators Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N., are leading the study, and Julie Holland, M.D., is the medical monitor.

FDA and Ethics Committee Approve US MDMA/PTSD Relapse Study Protocol

On June 9, 2011, our Institutional Review Board (IRB), or ethics committee, approved the protocol for our new "relapse study" of MDMA-assisted psychotherapy for PTSD. This study, which will take place in Charleston, SC, is limited to up to three subjects whose PTSD symptoms returned after participating in our flagship Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD. Over 80% of the subjects in our previous study no longer met criteria for PTSD two months after treatment. These benefits tended to persist over time until our long-term follow-up, conducted an average of 41 months after treatment. However, for several subjects symptoms did eventually return. This relapse study will attempt to determine whether a single additional open-label MDMA-assisted psychotherapy session along with several non-drug psychotherapy sessions can enable these subjects to once again be free of a PTSD diagnosis.

On June 14, Clinical Investigator and co-therapist Michael Mithoefer, M.D., submitted the protocol for the relapse study to the DEA, which must now conduct its own review before granting us the license to store and administer the MDMA. We anticipate that the DEA will approve the study soon, allowing us to schedule the study initiation and begin enrolling subjects.

Israeli MDMA/PTSD Study Initiated

On July 24, 2011, our new Israeli study of MDMA-assisted psychotherapy for PTSD was officially initiated. Representatives from Antaea Medical Services, Ltd., the clinical research organization that will be assisting MAPS with managing our Middle East studies, visited the site to finalize documents and provide training to the study staff. The study has all necessary clearances from Israeli regulatory bodies, including the Israeli Ministry of Health and an independent Ethics Committee. We have also submitted the protocol to the U.S. FDA, which is required because we are conducting the study under a U.S. Investigational New Drug application. We expect to begin enrolling Israeli subjects with chronic, treatment-resistant PTSD this fall.

Jordanian MDMA/PTSD Study Awaits Clearance from Jordanian FDA

On July 19, 2011, clinical research organization Antaea Medical Services, Ltd., made a presentation to the Jordanian Food and Drug Administration (JFDA) regarding safety procedures in our Jordanian protocol investigating MDMA-assisted psychotherapy for PTSD. JFDA officials had some questions about subject demographics, safety requirements, and our experience with previous studies, to which we responded in writing.

On July 30, we learned that the JFDA decided not to approve the study at this time, based in part on comments from an expert reviewer chosen by the JFDA. We anticipate receiving a further set of questions from JFDA soon, and we are hopeful this study will eventually be approved. Our supplier in Switzerland is ready to ship the MDMA to Jordan, so all we need is the final word from the JFDA and the permits for bringing the MDMA into Jordan. We will then be ready to initiate the study and begin recruiting and enrolling subjects.

Health Canada Reports on Inspection of MDMA/PTSD Study Pharmacy

On May 10, 2011, Health Canada inspected the Vancouver pharmacy that will be used to store and label the MDMA capsules for our upcoming Canadian study of MDMA-assisted psychotherapy for subjects with chronic, treatment-resistant PTSD. On July 6, 2011, we received a letter from Health Canada (dated June 17, 2011) requesting additional information about the site and about how we proposed to transfer the MDMA from the pharmacy to the treatment facility.

Canadian regulations require that the study pharmacy be adequately secure, and that the proper accountability procedures be in place. The information requested by Health Canada included clarifications about the address of the pharmacy, the security measures available at the site, the method of transportation of the MDMA between the pharmacy and the research site, and the format of the labels to be used on the capsules. Health Canada also requires that we include an alarm system at the site. We are currently preparing our reply, and anticipate these issues will be relatively easy to address. The final step before initiating the study will be to obtain the license to import the MDMA for the study into Canada from Switzerland (where another MAPS MDMA/PTSD study was recently completed).

MDMA-assisted psychotherapy treatment room, Charleston, SC

Swiss MDMA/PTSD Study Completed, Data Prepared for Publication

On June 1, 2011, our clinical research team closed and locked the database for our Swiss study of MDMA-assisted psychotherapy for PTSD, officially concluding the data collection portion of the study. The team is now assisting Clinical Investigator Peter Oehen, M.D., and co-author Ulrich Schneider, M.D. (former president of the International Society for Traumatic Stress Studies) in preparing a manuscript to be published in a peer-reviewed scientific journal. The quality inspection of the final data set from our Swiss ready revealed remarkably clean results, with a 0.04% error rate (far below the 0.5% required to pass). The locked database will also be used for our final report to the U.S. FDA.

MAPS Creates New Tools and Translations for International MDMA/PTSD Research

The international expansion of MAPS' MDMA-assisted psychotherapy studies makes it essential to keep our therapeutic approach consistent across study sites. In light of this challenge, MAPS has created a training manual to instruct the blinded independent raters involved in our studies of MDMA-assisted psychotherapy for PTSD in the reliable administration of the Clinician Administered PTSD Scale (CAPS). This manual and its accompanying video tutorials were adapted for MAPS' experimental methodology from training materials provided by the U.S. Veterans Administration, which created the CAPS.

The CAPS was one of the first diagnostic interviews developed specifically for PTSD. Because of the flexibility of the CAPS interview format, there can be differences between how interviewers use it to evaluate PTSD symptoms. By standardizing how these interviews are conducted and scored, we will obtain more consistent data and in doing so enable our research staff to conduct meta-analyses and compare data across sites—of major importance when conducting international clinical trials.

With our Israeli study being initiated and our Jordanian study seeking final government approval, MAPS has been working especially hard to make our research tools accessible to clinical researchers in the Middle East. We have now completed translations of the CAPS into Hebrew and Arabic, and we are working on back-translations to verify their accuracy and consistency. By sharing these translations freely with the Veteran Administration's National Center for PTSD, and with researchers throughout Israel and the Arab world, MAPS is promoting the development of effective PTSD treatments by fostering collaborations and comparisons between international research teams and across different cultures.

MARIJUANA RESEARCH NEWS

Study of Marijuana for Veterans with PTSD Gets FDA Go-Ahead; Awaits Response from NIDA/PHS

On April 28, 2011, the U.S. Food and Drug Administration accepted MAPS' protocol design for our study of marijuana for veterans with PTSD. Once again, the FDA has demonstrated its willingness to evaluate studies on the basis of scientific merit rather than political partisanship. Many U.S. veterans already use medical marijuana to deal with their symptoms of PTSD. The study would be the first clinical trial of smoked or vaporized marijuana for PTSD patients, comparing the safety and effectiveness of five strains for symptoms of PTSD in 50 U.S. veterans with chronic, treatment-resistant PTSD.

Although MAPS, the FDA, and an independent Institutional Review Board (IRB) are all satisfied with the protocol design, we cannot begin the study until it passes yet another review process with the National Institute on Drug Abuse and Public Health Service (NIDA/PHS). This redundant review has been required solely because NIDA has a monopoly on the supply of marijuana for research, and the agency must review the protocol before allowing us to purchase marijuana. Unfortunately for patients, NIDA's mission does not include exploring the potential beneficial uses of marijuana. Now NIDA and the PHS will decide if MAPS can obtain marijuana for 50 suffering veterans.

We submitted the protocol to be reviewed by NIDA/PHS on April 28, the same day we learned that the FDA had accepted it. On July 15, the Department of Health and Human Services (HHS) informed us that the review had been completed and that we should receive the report soon. At the time of this publication, we still had not received their response. The HHS notice came only days before an article about the study in *The New York Times* ("Marijuana May Be Studied for Combat Disorder," July 18, 2011) made MAPS' marijuana research national news. We're hopeful that the combination of the need for this research into marijuana for PTSD in veterans and the high media profile of our study will prompt HHS to issue a reasonable set of comments regarding our protocol.

In order to facilitate MAPS' privately-funded medical marijuana research, MAPS has been pressuring the federal government through hearings, lawsuits, and appeals for over a decade to allow us to grow our own marijuana exclusively for use in federally-reviewed research. Producing our own medical marijuana would mean not having to go through the redundant NIDA/PHS review. The DEA has thus far refused to accept its own Administrative Law Judge's recommendation that it would be in the public interest for Professor Lyle Craker of the University of Massachusetts, Amherst, to receive a license to grow marijuana for research regulated by the FDA.

MORE RESEARCH NEWS

Swiss LSD/End-of-Life Anxiety Study Treats Last Subject

On May 26, 2011, in a major milestone for psychedelic research, the 12th and last subject was treated in MAPS' Swiss study of LSD-assisted psychotherapy for anxiety associated with advanced-stage illness. We collected two-month follow-up data from this subject in July, bringing to an end the first clinical LSD study in a patient population in over 35 years. In 30 treatment sessions, not a single subject experienced a Serious Adverse Event (SAE), such as psychotic experiences, suicidal crises, flashbacks, or severe anxieties ("bad trips"). These safety results indicate that the risk of administering LSD in carefully controlled clinical settings is acceptably low, and that there is a promising future for LSD research.

According to Clinical Investigator Peter Gasser, M.D., all 12 patients reported benefits from the treatment, although the trend toward reductions in anxiety did not reach statistical significance. You can read more about the historical significance of this study in a recent article by award-winning writer and *MAPS Bulletin* guest editor David Jay Brown in the *Santa Cruz Patch* ("Landmark Clinical LSD Study Nears Completion," May 27, 2011).

New Study of Ibogaine Treatment for Addiction Planned for New Zealand

On August 30, 2011, Geoff Noller, Ph.D., Research Fellow in Psychological Medicine at the University of Otago, New Zealand, will submit the protocol for his new study of ibogaine treatment for addiction in New Zealand to an independent Institutional Review Board (IRB). MAPS has agreed to provide $15,000 for this study (out of a generous $25,000 grant from Matt and Kristi Bowden of Stargate International). Like our other observational ibogaine studies, this research will investigate the long-term effects of ibogaine therapy at up to three different independent clinics. This data may be used to make a case for a future clinical study and to evaluate differences in treatment approach and effectiveness between clinics. Since this is a non-clinical study, we will be able to begin enrolling subjects as soon as we have clearance from the IRB.

The remaining $10,000 of the Bowdens' contribution will be allocated to our ongoing ibogaine research program in Mexico. This study has now enrolled 28 out of 30 subjects. All subjects will be monitored for one year after ibogaine treatment, after which we will analyze the data and prepare it for publication.

MAPS Helps ACLU Successfully Challenge Harsh Ecstasy Sentencing Guidelines

On July 15, 2011, the American Civil Liberties Union, with scientific assistance from MAPS, won a major victory in a legal case challenging the federal sentencing guidelines for Ecstasy-related crimes. The defendant charged with distributing Ecstasy was sentenced to 26 months in prison, less than half the time recommended by current sentencing guidelines. The federal judge's willingness to downwardly depart from the sentencing guidelines was due to evidence presented by the ACLU demonstrating that the guidelines had been made in a time of irrational panic over the dangers of the drug—and highlighting the current scientific consensus that the risks of Ecstasy are substantially lower than presented a decade ago. Several expert witnesses testified when the guidelines were created (including MAPS Executive Director Rick Doblin, Ph.D., Richard Glen Boire, Julie Holland, M.D., Charles Grob, M.D., and David Nichols, Ph.D.), but their comments were ignored. MAPS contributed to the victory by educating ACLU lawyers about current evidence about the risks of recreational Ecstasy use and suggesting expert witnesses. The outcome of the trial indicates that the science of psychedelics can have real, positive implications for health, policy, and human rights. Learn more about this case at **www.maps.org/acluecstasy.**