of the method. Fortunately, the entire program was not rigorously analytical since on the middle day, we scheduled a Holotropic Breathwork session to give the group an experience of a non-ordinary state of consciousness and to provide experiential, emotional release.

Overall, the effort to teach made it even clearer that we ourselves have a lot to learn. Nevertheless, creating our first formal educational program for teaching the principles and practices of psychedelic psychotherapy, specifically MDMA-assisted psychotherapy for PTSD, was a milestone that took over two decades to attain and signifies a maturing movement.

I am excited to announce that on August 11, we received accreditation to provide continuing medical education credits at our conference in April 2010—a conference that will undoubtedly mark another milestone in our educational path.

In order for MAPS to continue to expand our research and educational activities, we need your support. Come join with us as we move beyond the renaissance, to the deeper integrations ahead.

Rick Doblin, PhD, MAPS President
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MAPS Conference: Psychedelic Science in the 21st Century

From April 15 to April 18, 2010, MAPS will be hosting "Psychedelic Science in the Twenty-First Century," an international psychedelic conference in the San Francisco Bay Area. We will have continuing medical education (CME) credits available for psychiatrists, other physicians, psychologists, social workers and nurses. The conference will also be open to the general public. There will be two tracks of presentations at the conference: the CME track will have leading researchers presenting their evidence-based findings from numerous studies that have recently, or are currently, taking place around the world, while the second track will have psychologists, artists, and other culturally intriguing presenters from the psychedelic community. There will be a special banquet on Saturday evening to honor the lifetime achievements of psychedelic luminaries Alexander "Sasha" and Ann Shulgin.

Confirmed speakers include: Stanislav Grof, MD; Alexander "Sasha" Shulgin MD; Ann Shulgin; Alex and Allyson Grey; Andrew Weil, MD; Michael Mithoefer, MD; Ann Mithoefer, BSN; Charles Grob, MD; Alicia Danforth, PhD candidate; David Nichols, PhD; Franz Vollenweider, MD; Torsten Passie, MD, PhD; Matt Baggott, PhD candidate; Jose Carlos Bouso, PhD candidate; Peter Gasser, MD; Julie Holland, MD; Sergio Marchevsky, MD; Francisco Moreno, MD; Peter Oehen, MD; Jordi Riba, MD; Michele Weitz, BA; John Harrison, PsyD candidate; Jeffery Kamlet, MD; Clare Wilkins; June May Ruse, PhD; Ingrid Pacey, MD; Rick Doblin, PhD; Valerie Mojeiko; Amanda Feilding; Ben Sessa, MD; Caroline "Mountain Girl" Garcia; and others.

Taking place at a lovely Holiday Inn (formerly a Hilton) near San Jose International Airport, the conference will start with a reception on Thursday evening and will have three days of programming through Sunday afternoon. The hotel was chosen for its reasonable prices and close proximity to the airport and public transit. Registration information will be available soon. To be placed on a registration list, please send an email to: conference2010@maps.org.

This will be a remarkable event that will be even more remarkable if you join us!

Therapist Training Protocol Leads to Positive Teleconference with FDA

On June 22, 2009, MAPS submitted a protocol to FDA requesting permission to administer a single MDMA-assisted psychotherapy session to therapists as part of their training to conduct MAPS' MDMA/PTSD research. On July 23, Rick Doblin, PhD, Michael Mithoefer, MD, and MAPS Clinical Program Manager Amy Emerson had a productive and positive teleconference with six members of FDA's Division of Psychiatry Products. The FDA officials made a series of suggestions about how, from their perspective, we could improve the protocol. They suggested that we write the protocol so that it would more closely resemble a Phase 1 safety study in normal (healthy) volunteers. The revised protocol will include more measures of the psychological effects of MDMA on healthy participants. We plan to submit the revised protocol in mid-August and should learn by mid-September if it's approved.

We learned that we could provide much in the way of educational experiences during our recent therapist training seminar that took place in Austria, with therapists from seven different countries. Nevertheless, we also believe it will benefit therapists who will be administering MDMA to patients to achieve a personal or subjective understanding of MDMA's effects when administered within a therapeutic setting. The only way such an MDMA experience can be legally provided to therapists is through an FDA protocol designed to gather safety information on the effects of MDMA. The protocol requires potential participants to have first successfully completed a non-drug therapist training program where they will watch video tapes and review our treatment manual. We believe this protocol will significantly enhance our ability to train therapists to work more effectively on our MDMA/PTSD studies.

While many people may doubt the feasibility of asking the FDA to approve the administration of a Schedule 1 drug to therapists in order to better understand the effects of that drug, we have thus far been greatly encouraged by FDA's suggestions and handling of this project. The FDA has so far shown us that developing MDMA into a prescription medicine is a matter of science, not of politics. As

long as we continue to operate with the highest standards of research and data collection and to follow the guidelines set forth by the FDA and the European Medicines Agency (EMEA), it will be the results of the research (and not ideology) that determines whether or not MDMA is approved as a prescription medicine.

MAPS Prepares for New MDMA/PTSD Study with War Veterans

MAPS is preparing a follow-up study to our US pilot study of MDMA-assisted psychotherapy for the treatment of PTSD, conducted under the direction of MAPS-sponsored researchers Michael Mithoefer, MD, and Ann Mithoefer, BSN. This new study will enroll eight US veterans with PTSD from the wars in Iraq or Afghanistan.

There are three purposes for conducting this study. The first purpose is to see if veterans respond any differently than those who suffer PTSD from sexual assault, sexual abuse, or victims of crime. Veterans made up a small minority of subjects in the Mithoefers' previous study (out of 21 subjects, only two were veterans). The EMEA has published guidelines for PTSD research that call for studies with homogenous subpopulations of people who suffer from PTSD from different causes. This is to determine if the same therapy can be administered across these subpopulations. It is possible that people with PTSD from different causes will require different therapeutic protocols for MDMA–assisted psychotherapy, or that some subpopulations could be unresponsive to MDMA-assisted psychotherapy. If people with PTSD from different causes are found to respond well to similarly designed protocols, then we can include all of these subpopulations in the larger Phase 3 multi-site studies. If we find that the treatments are different, we will have to take this into consideration when designing the Phase 3 studies.

The second purpose of this new study in veterans will be to gather methodological information about how different doses of MDMA succeed in creating an effective double-blind study. The researchers and subjects in our pilot study were often able to accurately guess when asked whether subjects had received an active dose of MDMA or an inactive placebo. The new study of veterans involves administering doses of 125 mg, 75 mg, or 25 mg (with four of the subjects randomized to receive 125 mg, two to 75 mg and two to 25 mg). We will see if the use of these three doses can be a successful double-blind study. We will also look to see if people who receive the higher doses showed a larger therapeutic effect than people who receive the lower doses.

The third and final purpose of the study is to enroll some subjects previously excluded for risk factors such as hepatitis C and hypertension. There is not strong evidence that MDMA poses greater risks to people with these health conditions, but we excluded these factors from our first pilot study in order to proceed cautiously and please our Institutional Review Board (IRB). The new protocol will involve special pre- and post-screening and monitoring plans to evaluate whether MDMA can be safely administered to people with previously excluded risk factors. If we can safely enroll these subjects, then recruitment into our Phase 3 studies will be faster since fewer subjects will be excluded for risk factors.

This protocol will be submitted to the FDA in September. After it is submitted and approved by the FDA, it will be submitted to our IRB. We hope to have the first subject enrolled before the end of November 2009.

On March 4, 2009, MAPS' MDMA/PTSD research was featured on military.com, a popular military website (read the full text of this article on the MAPS website: www.maps.org/media). Since then, numerous war veterans who wish to be in the study have contacted us. However, it is not clear whether all of them will pass the screening process and some may no longer be interested in participating by the time the study gets started. If you know, or are yourself, a war veteran suffering from PTSD who would be interested in participating in a study in Charleston, South Carolina, please contact MAPS at: askmaps@maps.org.

MAPS Podcasts

Have you heard a MAPS podcast recently? We are producing new podcasts regularly now and you can hear them on our website or by subscribing on iTunes.

12th and Final Patient Enrolled in Swiss MDMA Study

MAPS' Swiss MDMA/PTSD study has enrolled the 12th and final subject. Nine patients have completed the study; the 10th and 11th are currently in the treatment process. We estimate that the final treatments will take place between three and six months from now, depending upon whether the last subject gets placebo or MDMA. If a subject gets a placebo session, they will later have the option to participate in Stage 2, where they will go through the entire treatment process again but will receive the full dose of MDMA. This is called an "open -label" study. In this way, these subjects serve as their own controls, as well as being part of a matched control group.

The Swiss project is our second study of MDMA-assisted psychotherapy for the treatment of PTSD. While the Clinician Administered PTSD Scale (CAPS) scores in the Swiss research have not dropped as dramatically as they had in our US pilot study, a preliminary analysis suggests that we are likely to obtain statistically significant results. The completion of this study will be yet another major accomplishment for MAPS and for our supporters.

The Swiss study differed from our US pilot study in several ways. Instead of using an inactive placebo as we had in the US study, we used a low-dose active placebo of 25 mg of MDMA, followed by a 12.5 mg booster dose. The population in the Swiss study also differed from our US study in that the majority of subjects had PTSD resulting from accidents and natural causes, rather than from sexual or physical assault. The Swiss study is also smaller than our US study, which enrolled 21 subjects.