

MDMA-Assisted Psychotherapy Pilot Study in Switzerland

MDMA/PTSD research marks resumption of psychedelic therapy in Switzerland

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Peter Oehen, Rick Doblin, and Valerie Mojeiko working during a data monitoring visit in January 2006

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AFTER THE 1993 WITHDRAWAL of the licenses of five members of the Swiss Medical Association for Psycholytic Therapy (SAePT), who practiced MDMA- and LSD-assisted psychotherapy for 5 years with few restrictions, we had to accept that future applications for licenses would be limited to the context of scientific research. In 2003, the Ethics Committee rejected a

protocol developed by SAePT members to investigate the efficacy of psilocybin-assisted psychotherapy in recurrent depression.

In April 2005, my wife Verena Widmer and I visited MAPS President Rick Doblin, Ph.D., and MAPS-funded researchers John Halpern, M.D., and Michael Mithoefer, M.D., to discuss strategies to resume research into the therapeutic application of psychedelics in Switzerland. This meeting soon resulted in close cooperation between MAPS and SAePT, and in a short time we were able to adapt the MAPS standard protocol for MDMA/PTSD research to our study.

The proposed pilot study will investigate the safety and efficacy of MDMA-assisted psychotherapy in 12 patients with treatment-resistant post-traumatic stress disorder (PTSD), as in the ongoing MAPS-sponsored study led by Mithoefer. Based on the preliminary results from Mithoefer's study, we modified the design to include three experimental MDMA-sessions with 125mg MDMA, followed by a supplemental dose of 62.5mg after 2.5 hours. We also adjusted MAPS' protocol to use an active placebo consisting of 25mg MDMA, followed by a supplemental dose of 12.5mg MDMA.

As in the U.S. study, patients who receive the placebo can choose to participate in a second stage of the study, in which they go through the whole process again with a full dose of MDMA. Outcome measures will be the CAPS (Clinician Administered PTSD Scale) and the PDS (Posttraumatic Stress Diagnostic Scale), a self-report scale. Due to new findings and the absence of neurocognitive deterioration in MAPS' U.S. study, we consider these neurocognitive measures sufficient.

The protocol was submitted to the Ethics Committee in October 2005 and was approved on December 23, 2005. The application is now being reviewed by Swissmedic (the Swiss Drug Institute). Prior to the LSD conference in Basel, Switzerland, the first pre-study data monitoring visit took place at my psychiatric practice near Solothurn, Switzerland, where the study will be performed. During this meeting, we set up study procedures and Case Report Form protocol. At the time of this writing, another data monitoring visit is planned for early March. The last step will be to apply for a license from the BAG (Swiss Health Agency). We plan to begin recruiting subjects within a few months.

So far, the development of this study has proceeded rapidly, without major obstacles, thanks to the invaluable support of MAPS. Both MAPS and SAePT have pledged substantial contributions - together 2/3 of the \$150,000 study budget - but further efforts will now have to be undertaken to fund the study through donations. The LSD conference in Basel in honor of Albert Hofmann has helped to bring the subject of psychedelic drugs to a wider public audience and into the consciousness of the medical community. We hope that our research can be a contribution to helping psychedelic drugs get back to where they belong: in healing!