

MDMA-Assisted Psychotherapy Pilot Study in Switzerland: On the Verge of Initiation



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On June 14, 2006, the Swiss MAPS-sponsored MDMA/PTSD pilot study passed its final major regulatory hurdle: licensing from BAG (*Bundesamt für Gesundheit*, the Swiss equivalent to DEA). The license is necessary for myself, the Principal Investigator, to administer MDMA, a Schedule I drug. It is also required for the manufacturer to be able to handle the substance, conduct quality analysis, and encapsulate and randomize the MDMA. Furthermore, the license was necessary to export MDMA from the same batch for the MAPS-sponsored Israeli MDMA/PTSD study in Tel Aviv. In early August, the MDMA was successfully exported to Israel after the Swiss export permit and the Israeli import permit were approved.

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In a recent development, we are now also planning to collaborate with the Psychiatric University Hospital in Zürich. Prospective subjects will be asked to participate in the ongoing study "Psychophysiology of PTSD: A Comprehensive Parameter Study," conducted by Franz Vollenweider, M.D., a renowned MDMA researcher. Prevailing evidence suggests that PTSD patients suffer from deficits in early information processing, such as deficits in "gating," or filtering, internal and external sensory stimuli. Two experimental paradigms designed to assess gating are pre-pulse inhibition (PPI) of the acoustic startle response and suppression of the P50 event-related potential. The neurophysiological correlates of PPI and P50 suppression, as well as the interdependency of these gating measures, will be explored using electroencephalographic (EEG) measures in combination with ERP (evoked response potential) technique. These neurophysiologic parameters will be measured in a novel combination before and after the MDMA-assisted psychotherapy. This will allow the researchers to locate and map the corresponding areas of the brain more

precisely than was possible before. We also hope that this additional neurophysiologic data will document the efficacy of MDMA-assisted psychotherapy. The amendment of our protocol is currently awaiting approval from an Ethics Committee, the Swiss IRB equivalent.

Since the protocol is being amended, recruitment of the first patient—who is already waiting to enter the screening process—will be delayed for several weeks. At the time of this writing, we are planning to initiate the study in September 2006.

From the moment my wife Verena Widmer and I first met with Rick Doblin, Ph.D., and Michael Mithoefer, M.D., in April 2005 to discuss the possibility of a Swiss MDMA study, it has taken less than a year and a half to develop the protocol and guide it through the scientific and governmental approval process. Considering the controversial nature of MDMA-assisted psychotherapy research, this relatively rapid pace has only been possible with MAPS' know-how, and the support and advice I have received from the medical and scientific community here in Switzerland. •