

Switzerland

On June 24, after a one-year hiatus, official governmental permission was given to four Swiss psychiatrists to resume work with 100 patients previously treated with LSD, MDMA, or 2CB. Switzerland is once again the only country in the world where psychiatrists have legal permission to treat patients with these substances. As you may recall, permission was withdrawn as a result of a tragic situation in France when a woman died after taking the African psychedelic root ibogaine. When the autopsy results were finally released by the Swiss and French authorities there was no evidence MDMA, LSD or 2CB was involved.

Treating new patients will require a rigorous research context and a separate permit. Several Swiss doctors are currently discussing protocol designs with consultants recommended by the Swiss government. Approval for treating new patients is expected by October, 1991. Human pharmacokinetic studies of MDMA are being planned at Berne University to take place in late 1991.

Soviet Union

MAPS was contacted by Dr. Yevgeny Krupitsky, a psychiatrist in Leningrad who works as director of a government research team into the treatment of substance abusers. Yevgeny has successfully incorporated Ketamine into the inpatient treatment of alcoholics and is interested in initiating an effort to conduct MDMA research in Leningrad. MAPS arranged a visit for Yevgeny to Baltimore, where he met with Drs. Charlie Grob, Richard Yensen, Donna Dryer, Al Kurland, and myself. We reviewed the LSD and MDMA protocols and discussed research collaboration.

Mexico

MAPS member Dr. Jim Prescott has begun to collaborate with Drs. Grob, Bravo and I along with Dr. Fernandez, a Mexican physician, on the design of a protocol to investigate MDMA-assisted psychotherapy in the treatment of young women with breast cancer. This protocol will be submitted for approval to the Mexican health authorities, possibly before the end of 1991.

**MAPS
Organizational
News**

MAPS recently received a generous donation of \$10,000. The donors said their gift will be annual *"as long as there is a need for such an organization and as long as MAPS continues to be effective... I trust this long-term pledge will help you in planning your budget as well as encouraging others to be charitable."* Since last year's MAPS budget was \$45,500, there is still a need for donations of any size.

The largest single item in last years MAPS budget, \$26,000, was devoted to the Swiss conference. The remainder supported part of Dr. Krupitsky's travels in the US, a study examining the Swiss use of psychedelics, several small meetings to discuss the design of the MDMA protocol, the production and mailing of the MAPS newsletters and video, and office expenses, copies, and phones. No salaries were paid. This year's expenditures will focus on protocol development, support for any hearings called by the FDA to discuss the protocol and, hopefully, the experiment itself.

The MDMA protocol in progress involves one experimental group and two matched control groups. The subjects will be terminal cancer patients with an estimated remaining life span of less than four years and more than six months. The volunteers will be patients suffering from clinically diagnosed anxiety and depression who are in significant physical pain. The experimental group will receive four MDMA-assisted psychotherapy treatment sessions and one session with an inactive placebo. The setting will be relaxed with the patient listening to music with eyes closed, intermittently interacting with the therapists. One control group will receive no MDMA but will receive five music therapy sessions lasting the same length of time as the MDMA-assisted psychotherapy sessions. The other control group will be a no-treatment group. These patients will be encouraged to seek treatment from whomever they choose. All subjects will be evaluated and followed up in an identical manner.

The protocol is not designed as a double blind study. In part this is because following such a methodology would have required administering stressful spinal taps and tryptophan challenge tests even to seriously ill subjects who did not receive MDMA. In addition, the double-blind probably would not fool either the patients or physicians about who received either the placebo or the MDMA.

The protocol now has five separate sections:

A) For the investigation of neurotoxic risk to the serotonin system, volunteers will be administered both a spinal tap and a tryptophan challenge test. Drs. George Ricaurte and Lewis Seiden have been asked to review this aspect of the protocol to ensure that our methodology will be state of the art.

B) Research into the effect of MDMA on the immune system will be conducted as part of the risk analysis and also in order to determine whether positive cathartic experiences are associated with improved functioning of the immune system. This research will help determine if imagery work conducted under the influence of MDMA can assist in a holistic approach to the treatment of cancer. Information will also be gathered about the risk of MDMA-assisted psychotherapy in AIDS patients, where some preliminary reports suggest that productive psychotherapeutic work can be conducted.

Preliminary contacts have been made with officials of the Fetzer Foundation and with Dr. George Gellert, a researcher funded by the Fetzer Foundation to investigate the survival rates of some patients in Dr. Bernie Siegel's Exceptional Cancer Patients program. Dr. Gellert has met several times with Charles Grob and is interested in assisting with protocol design. If all goes well, this aspect of the protocol may help to attract some financial support and will provide excellent data on the remarkable mind/body interaction that MDMA can facilitate.

C) Another aspect of the protocol involves the investigation of the effect of MDMA-assisted psychotherapy on physical pain. We will monitor amounts of pain-killing anesthetic drugs needed and will also conduct a series of pain sensitivity tests before, during and after the sessions.

D) An attempt will be made to describe the effect of MDMA on the psychological functioning of the volunteers during the acute period of MDMA's action. We are hypothesizing that MDMA may be an effective adjunct to psychotherapy due to its ability to strengthen the therapeutic alliance, deepen the experience of emotion, reduce anxiety and fear, and promote a heightened sensitivity for non-habitual thinking. We will try to measure some of these concepts through non-intrusive ratings of tape and possibly video recordings of the sessions, scored by independent raters. We will also try to gather some direct information through short questionnaires and tests. David Lukoff, co-author of an excellent review of psychedelic research in the late 1990 issue of the *Journal of Transpersonal Psychology*, has already helped suggest some tests. Additional consultants will soon be contacted.

E) We will also seek to determine if volunteers experience a lifting of the anxiety and depression related to their terminal status. We will be using a variety of standard measures to evaluate psychotherapy outcome, quality of life, and an index of spirituality.

The MDMA Protocol – proposed methodology of the experiment

Personal Note:
If anyone has any suggestions for the design of any portion of the protocol, please contact me. I will be out of touch travelling from August 7-September 5, visiting Israel, Egypt, Germany and Switzerland. I will respond to all calls or letters beginning about September 5th.