ences between teams. During this seminar, inner experiences would be catalyzed by holotropic breathwork rather than MDMA.

By creating this formal training program, therapists will be able to undergo two personal experiences with MDMA in a controlled, therapeutic setting. We'll encourage therapists to work on their own issues so they can be as supportive as possible for their research subjects. The goal of the program is for trainees to understand how to collaborate with research participants in creating a set and setting that maximizes the effects of MDMA-assisted therapy and how to deal with emotional and physiological problems that might arise during treatment.

We are presently searching for measures to evaluate the effectiveness of the training program on the trainees. With this data, MAPS will then be able to select from among the training program participants those most likely to successfully conduct the Phase 3 multi-site studies evaluating the safety and efficacy of MDMA-assisted therapy.

Since MDMA is a controlled substance, the only way that MAPS can legally conduct a training program that includes trainees having personal experiences with MDMA is under the auspices of an FDA-approved clinical study. This is a situation for which we know of no precedent. In several months, MAPS will request a meeting with FDA staff to discuss the most appropriate contexts for moving forward. •

1. Ruse J, Jerome L, Mithoefer M, Doblin R (2005). MDMA-Assisted Psychotherapy for the Treatment of Posttraumatic Stress Disorder (PTSD): A Treatment Manual Draft. MAPS

Update: **LSD-Assisted Psychotherapy** in Persons Suffering from Anxiety Associated with Advanced-Stage Life-Threatening Illness: A Phase 2, Double-Blind, Placebo-Controlled Dose-Response Pilot Study

Peter Gasser, MD, pgasser@gmx.net

ON MARCH 19, 2007, during a long phone call with the president of the Ethics Committee (EC) (the Swiss equivalent to an institutional review board), which is responsible for the approval of my proposed MAPS-sponsored study, she announced that the committee had granted conditional approval.

So we have reached a milestone. I am convinced that the approval by the EC is the most difficult step in the entire approval process. Ethical decisions are judgments. Four years ago I was a member of a group of researchers from the Swiss Medical Society for Psycholytic Therapy (SaePT) that had a frustrating experience with a psilocybin/depression project that was not allowed to proceed following rejection by the EC.

During the recent EC meeting, although the committee was critical and posed detailed questions, in general they were not overcome by prejudice. In the end, the committee was convinced that the potential benefits of LSD-assisted therapy outweigh the risks.

Now, how to continue? First, before receiving unconditional approval, I have to wait for the written report of the EC and fulfill their requirements. Then, I will submit my papers to Swissmedic (Swiss Food and Drug Administration equivalent) and finally to the BAG (Swiss Drug Enforcement Administration equivalent). After all three of these groups grant approval, I will have full regulatory approval for the study.

In the end, the committee was convinced that the potential benefits of LSD-assisted therapy outweigh the risks.

I am happy and relieved to have reached this step. I'd like to thank everybody who supported me until now. As a researcher in private practice I depend on a network of people who are able to support this work. I'd like to thank Rick Doblin for his enthusiasm and financial support; Ilsa Jerome for busy and patient support in scientific literature research; Valerie Mojeiko, Amy Emerson, and Josh Sonstroem for their methodological support; John Halpern and Matt Bagott for permission to use their protocols; Rudolf Brenneisen for his support in accessing and handling the LSD; and, finally, I thank Albert Hofmann for the opportunity to consult with him about this study.

This was a big step in the right direction, although it's still a long climb to the mountain top. I'll keep you up to date! •