

MAPS' Proposed Israeli MDMA/PTSD Pilot Study

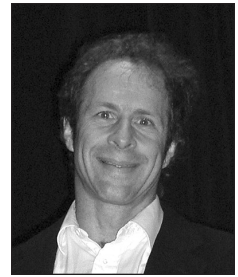
MAPS' effort to sponsor research in Israel into the use of MDMA-assisted psychotherapy in subjects with war and terrorism-related posttraumatic stress disorder (PTSD) began in 1998, when I first met with Israel psychiatrist Dr. Moshe Kotler. At that time, MDMA/PTSD research had not yet begun in the United States (that would take six more years) nor had the MAPS-sponsored MDMA/PTSD dose-response study in Spain been approved (that would take about two more years). Three MAPS-sponsored scientific conferences in Israel later (September 1999, *MAPS Bulletin* online archives Volume 9, Number 3; November 2002, archives Volume 13, Number 1; and March 2005, see page 4), and after FDA had approved two MAPS-sponsored MDMA-assisted psychotherapy studies (Dr. Mithoefer's MDMA/PTSD study, approved in February 2004, and Dr. Halpern's MDMA/cancer anxiety study, approved in December 2004), the Israeli research team felt that the time had arrived to submit the protocol for review.

On May 3, 2005, MAPS donated \$5,000 to the Medical Research Fund at Beer Yaakov Mental Health Center, to cover costs and professional time associated with the review of the protocol by the local and national ethics committees. An additional \$5,000 will be donated after the protocol has been approved by both the ethics committees, to cover costs associated with the review of the protocol by the Ministry of Health. Once the study becomes fully approved, we have budgeted \$75,000, from funds we still need to raise.

On June 6, 2005, the ethics committee at Beer Yaakov Mental Health Center, where the study will take place, approved the protocol. They subsequently passed the protocol on to the national ethics committee for its review. We expect to hear from them around the end of the summer. If approved, the protocol will then be submitted to the Ministry of Health. We're hoping we will have all the approvals required to begin the study before the end of this year.

The Israeli protocol differs from Dr. Mithoefer's US MDMA/PTSD study in several respects. This study focuses specifically on people who have developed PTSD as a result of war or terrorism, while Dr. Mithoefer's study includes victims of rape and sexual assault as well. Instead of an inactive placebo, we're proposing the use of low-dose MDMA as an active placebo that should be more effective at creating uncertainty as to which dose was received. We're also proposing that subjects receive a supplemen-

Rick Doblin, Ph.D.



tal dose of half the initial dose, to be administered about 2 1/2 hours after the initial dose. This will extend the period of the peak therapeutic effects into a plateau lasting for several more hours, enabling the subjects and therapists to do additional emotional work. We're going to keep the model of a male/female co-therapist team and use the same primary outcome measure, the Clinician Administered PTSD Scale (CAPS).

MAPS' long-term goals are to obtain permission from the FDA as well as the European Medicines Agency for the use of MDMA-assisted psychotherapy by prescription, in specially-licensed clinics by specially trained and licensed therapists. Our strategy to achieve this goal is to conduct pilot studies and one of the two required large-scale Phase III studies in the US, while also having pilot studies and the other of the two required large-scale Phase III studies conducted in Europe. We hope to develop studies in Israel, Spain, Switzerland and elsewhere, perhaps even Palestine. Around 300 subjects would be enrolled in the US studies and a similar number in those around the world.

Though it may seem surprising, much credit for the progress that we have made so far in the review process is due to the Israeli Anti-Drug Authority. We arranged a meeting at their office the day

before our scientific conference to discuss in detail the purpose of the initial pilot study and our longer-term plans. In particular, the chief scientist of the Authority, Dr. Rachel Bar-Hamburger, attended the conference and spoke to the media expressing support for the study. See page 11 for some of her comments.

We look forward to continuing to work closely with all the Israeli regulators to shepherd this study through the approval process. We're eager to reach the point where we are able to actually gather data about whether MDMA-assisted psychotherapy can indeed play a role in reducing the terrible amount of trauma suffered by many people in Israel and Palestine.

We're trying to channel the healing potential of MDMA into studies that not only treat individuals suffering from the debilitating trauma of violent conflict but also, in a form of preventative medicine, address larger social patterns of fear, hatred, and division.