RESEARCH AGENDA

mdma research: phases 1 and 2

THE TOP PRIORITY of MAPS in 1996 is to move beyond the study of the safety of MDMA and to begin to study MDMA's therapeutic potential. If this goal can be obtained in 1996, it will have taken eleven years from the time that the recreational use of MDMA was made illegal to the resumption of the scientific investigation of its therapeutic potential.

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The Phase 1 Safety Study

On May 18, 1994, Charles Grob, M.D. administered MDMA to the first subject in his Food and Drug Administration (FDA)-approved dose-escalating double-blind safety study. This marked the first time that MDMA had been legally administered in the United States since it was criminalized by the Drug Enforcement Administration (DEA) in 1985.

On November 27, 1995, Dr. Grob administered MDMA to the eighteenth and final subject in the study. This groundbreaking research has now been completed.During the first several months of 1996, Dr. Grob will focus on analyzing the wealth of information he gathered about many of the physiological and psychological effects of an escalating series of doses of MDMA. The study began with the administration of a barely perceptible dose of .25 mg/kg and rose to 2.5 mg/kg, an amount somewhat larger than the standard therapeutic (or recreational) dose. Upon completion of the data analysis, Dr. Grob will submit his findings to the FDA for review.

Though Dr. Grob's data analysis is not complete, the most significant side effect was blood pressure instability in two subjects. Another subject dropped out of the study because of panic anxiety but his adverse psychological reaction occurred during his placebo session and was not related to the administration of MDMA. This surprising event is yet another demonstration of the wisdom of using placebos in clinical research. It also suggests that a hospital room may be a less than ideal setting for psychedelic research, a conclusion that Rick Strassman, M.D. also drew from his psilocybin research project.

The Phase 2 Cancer Patient Study

After the FDA completes its review of the Phase 1 safety data, Dr. Grob plans to submit a Phase 2 protocol for FDA review. This Phase 2 study will gather preliminary data on the safety and efficacy of MDMA and guided imagery when used as an analgesic in cancer pain and as a psychotherapeutic adjunct for the treatment of anxiety and depression related to terminal illness. The study will also seek to determine the physiological effect of MDMA on the immune system as well as whether the combination of MDMA and guided imagery could be used as an effective tool to facilitate psychoneuroimmunological (mind/body) stimulation of the immune system.

The population of end-stage cancer patients was selected because of the desperate life circumstance they encounter, for which conventional psychotherapeutic and pain reduction treatments often offer limited relief. This patient population was also chosen because people not normally sympathetic with the medical use of psychedelics might be more open-minded if it can be demonstrated that MDMA can be of use if they or their loved ones were to find themselves in the unfortunate situation of having cancer, a disease that touches most people's lives directly or indirectly.

The Phase 2 pilot study will involve twelve subjects and should take approximately

one year to complete. MAPS has agreed to raise the entire cost of the Phase 2 study, estimated to be $70,000. MAPS has submitted several grant applications seeking funding for the study to foundations. Though several previous grant applications for this study have been rejected by other foundations, hope springs eternal. If foundations are not supportive, the study will be funded out of donations from MAPS members and the bequest of Eric Bass.

The Phase 2 PTSD Study

MAPS is also seeking to catalyze a pilot study into the use of MDMA in the treatment of post-traumatic stress disorder (PTSD). As has been noted, MDMA "helps reduce the fear-response to a perceived emotional threat," making it a very effective element in the treatment of people suffering the residual effects of past emotional trauma.

As long-term readers of the MAPS newsletter may recall, MAPS has been trying for several years to conduct an MDMA/ PTSD study at the Military Hospital in Managua, Nicaragua. Doctors at the hospital conducted a 20-patient pilot study in 1988 with promising results. In 1992, shortly after the FDA approved the first human study with MDMA in the United States, the Nicaraguan doctors contacted MAPS seeking protocol assistance and funding support for a follow-up study. MAPS obtained a grant of $28,000 for the Nicaraguan study from a foundation in England (our first and only foundation grant to date) and proceeded with high hopes for the project. Among other things, MAPS sent several experts in PTSD research to Managua to assist the Nicaraguan doctors in designing, implementing, and seeking approval for a more rigorously designed study. Unfortunately, little progress was made.

Meanwhile, in March 1995, Dr. Grob reached a point where he needed additional funding for his Phase 1 safety study. Rather than let Dr. Grob's research languish when MAPS had funds in the bank that weren't being used, MAPS obtained permission from the donor foundation to redirect $10,000 reserved for the Nicaraguan study to Dr. Grob's study. This redirection of resources left sufficient funding for a scaled-back but still important study in Nicaragua.

Despite a substantial amount of time and effort, it has still not proven possible to design an MDMA/PTSD study that could be implemented in Nicaragua and that would generate data that the FDA would consider reliable. The many crises that the country is undergoing and the overly stretched resources at the Military Hospital make it very difficult to conduct rigorous research. I must regretfully report that the Nicaraguan project has been cancelled, leaving slightly in excess of $12,000 still available for MDMA research.

MAPS is now trying to catalyze a PTSD study either in the United States or Israel where it will be much easier to design and implement a study that will be considered valid by the FDA. MAPS is budgeting $25,000 for this study, combining $12,000 remaining from the Nicaraguan project with an additional $13,000 from the bequest of Eric Bass. The crucial missing element is a physician willing to be the principle investigator on the study. I've put out some inquiries and have also been in contact with a company that specializes in conducting clinical trials under contract to pharmaceutical companies. I'm working to ensure that a MAPS-sponsored MDMA/PTSD study will begin before the year is out.•

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