MDMA research update

Phase 1 Safety Study

United States: The MDMA safety studies (Phase 1) being conducted by Dr. Charles Grob at Harbor-UCLA Hospital in Los Angeles are proceeding at an expeditious pace. As readers of the last MAPS newsletter may recall, on May 18, 1994, Dr. Grob administered the first legal dose of MDMA since it was placed om Schedule 1 in 1985. Dr. Grob is conducting the only FDA-approved human study in which MDMA is administered to volunteer subjects. Supporting Dr. Grob's MDMA research is one of MAPS' top priorities.

By the end of November, Dr. Grob had completed the administration of MDMA to six subjects, each of whom participated in three experimental sessions. Two of the sessions involved the administration of MDMA (in two different doses) while one session involved the administration of an inactive placebo. The experiment was conducted in a double-blind manner such that neither the experimental team nor the subject knew ahead of time whether the test dose would be a placebo or one of the two different doses of MDMA.

During the experimental sessions, the subjects' vital signs are measured. In addition, blood is drawn for later analysis, and psychological and physiological tests are administered. Additional tests are administered several weeks before the first experimental session and several weeks after the last session. Dr. Grob's experiment uses a randomized dose-escalating design. The first group of six subjects was divided into three pairs. The first pair of subjects received one administration each of .25 mg/kg of MDMA, .5 mg/kg or placebo, with the order of the dosing randomly determined. The second pair received one administration each of .5mg/kg, .75 mg/kg or placebo. The third pair received .75 mg/kg, 1 mg/kg or placebo. These doses are all well below the therapeutic dose range of 1.50 to 2.25 mg /kg.

The FDA has required Dr. Grob to submit the data from his first six patients for official review before proceeding to administer larger doses to additional subjects. Dr. Grob is now in the final stages of analyzing his data and will soon be submitting a report to the FDA for its first safety review. Nothing unusual was noticed in the first six subjects, so we anticipate that Dr. Grob will be granted permission by the FDA to enroll an additional six subjects in his experiment.

The doses of MDMA that will be administered to the second set of six subjects will range from 1 mg/kg and 1.25 mg/kg, to 1.25 mg/kg and 1.5 mg/kg, up to 1.5 mg/kg and 1.75 mg/kg. Dr. Grob will need to submit another report to the FDA containing the data from this second set of six subjects before receiving permission to enroll the third and final set of subjects in this experiment. If all goes as anticipated, the doses to be administered to the final set of six subjects will range from 1.75 mg/kg and 2 mg/kg, to 2 mg/kg and 2.25 mg/kg, up to 2.25 mg/kg and 2.5 mg/kg. Once the final set of six subjects has been evaluated, the data from the entire experiment will be reviewed by the FDA.

Over the last several months, Dr. Grob has also used high-tech brain imaging techniques (MRI and SPECT) to evaluate brain functioning in several frequent MDMA users. This research is ongoing and it is still too early to evaluate the data.

We anticipate that by Fall, 1995, Dr. Grob will be given permission by the FDA to proceed into an efficacy study (Phase 2) designed to evaluate the potential of MDMA and guided imagery to reduce physical pain and psychological distress and stimulate the immune system in cancer patients. MAPS has been actively seeking to raise funds for this Phase 2 project and has developed some promising leads. ■

Post-Traumatic Stress Disorder Study

Nicaragua: The MAPS-sponsored project into the use of MDMA in the treatment of soldiers and civilians suffering from Post-Traumatic Stress Disorder (PTSD) is still in the design phase. In August, MAPS arranged for two experts in PTSD research to travel to Nicaragua to give a series of lectures on research design. Attending the lectures was the Nicaraguan research team at the Military Hospital in Managua led by Dr. Manuel Marin Madriz. As a result of the information presented in the lectures, Dr. Madriz has been working to redesign the protocol and to standardize diagnostic, treatment, and evaluative procedures. Though this project is proceeding more slowly than anticipated, the end result will be that any data gathered will have a greater impact due to the incorporation of more rigorous scientific standards for data collection. ■