MAPS AND MDMA RESEARCH IN THE UNITED STATES

Though the War on Drugs indiscriminately targets all uses of Schedule 1 drugs, including the therapeutic, scientific knowledge can serve to counteract exaggerated fears and provide a factual basis to support claims of benefits. Over the past several years, MAPS has funded pilot studies which generated the first scientific information about the effect of MDMA use on human serotonin levels, and about the no-effect levels and recovery rates for MDMA neurotoxicity in the primate. In addition, MAPS funded 28-day MDMA toxicity studies in the dog and rat which were used to open an FDA Drug Master File for MDMA.

MAPS currently devotes most of its energies to supporting the effort to conduct MDMA human safety and efficacy research. This priority was chosen for several reasons. First, we believe that MDMA is a uniquely valuable drug that many therapists would use, if it were legal, to treat patients suffering from a wide variety of debilitating emotional illnesses. Second, MDMA, by virtue of its popularity in the non-medical market, is attracting many millions of dollars of government research funds. The data from government studies, funded from public rather than private monies, can be appropriated by MAPS into its FDA application to make MDMA available by prescription. Furthermore, because MDMA is relatively short acting and gentle, it can be easily used within a psychiatric outpatient setting. This feature makes the adoption of the use of MDMA in psychiatric practice much more likely than the use of longer acting, more powerful psychedelic drugs such as LSD.

Last year, MAPS' main project was the international psychedelic research methodology conference held in November, 1990 in Bern, Switzerland and Prague, Czechoslovakia. (Note: proceedings of the conference available from MAPS). Some of the United States' main experts on MDMA neurotoxicity were at the conference and a dialogue was established that improves the chance of securing FDA approval for human studies with MDMA.

A research protocol is currently being developed by University of California at Irvine psychiatrists Drs. Charles Grob, Gary Bravo and James McQuade, in collaboration with MAPS. The study focuses on the use of MDMA-assisted psychotherapy in the treatment of pain, depression and anxiety in end-stage cancer patients. Since the protocol would be the first-ever FDA-approved human study with MDMA, we must focus more on safety and tolerance than on efficacy. We plan to administer MDMA to the patients four times over a period of six months, in conjunction with guided imagery and music. On the issue of safety, we will look at the effect of MDMA on the brain's serotonin system through the use of spinal taps and tryptophan challenge tests, and on the immune system and organ function through the use of blood and urine tests. Pharmacokinetic studies (the route and timing of the drug through the body) will also be conducted. Regarding efficacy, we will look at pain, depression, anxiety and quality of life through a variety of standardized tests.

The protocol was circulated for critique to over 25 experts around the country and is now being revised in response to the excellent comments that were received. We plan to submit a final draft of the protocol to the FDA by around the end of the year. The FDA is then required to respond within 30 days, either permitting or rejecting the study or requesting more information. If our extensive design work has been successful, and if we are lucky, permission will be granted sooner rather than later. ■

MAPS AND MDMA RESEARCH IN RUSSIA

A collaborative working relationship has been established between MAPS, psychiatrist Dr. Evgeny Krupitsky in St. Petersburg (Leningrad) and the psychiatrists working on the MDMA protocol here in the US. The catalyst for this working relationship was the presence of four psychiatrists and a translator from Moscow at the MAPS international psychedelic research methodology conference in Switzerland. Dr. Krupitsky writes that he has "discussed again the possibilities of MDMA research with Drs. Rzhankova and Dunaevsky from the Leningrad Institute of Oncology, Academy of Medical Sciences of the USSR. They informed me that maybe it will be possible to receive permission for this work from the Pharmacological Committee of the Ministry of Health, especially for the last draft of the protocol with the accent on the relief of pain, because