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

of the large amount of substances with high addictive potential (narcotics) that are tested and used in oncology for the relief of pain. I can't give any guarantee, but we hope it will be successful."

A comparable study in Russia would be much less expensive than one in the US, even though researchers in the US will donate much of their time to the experiment. Dr. Krupitsky writes that "the cost for one patient may be about $700 - $1,000." Research in Russia is of value to MAPS because the FDA will accept one efficacy study from abroad into the MAPS MDMA Drug Master File. This means that international collaboration, particularly in countries like Russia with experienced researchers and relatively low salaries, is definitely the way to get the most out of MAPS' scarce resources.

There will be some differences between the protocols in the US and in Russia due to different political pressures and research objectives. Dr. Krupitsky reports that the use of spinal taps would make it more difficult to gain approval for the study in Russia, since spinal taps are strictly limited to people with certain indications. We need to use spinal taps in the US because of official concern over neurotoxicity. Ironically, a Swiss Institutional Review Board (IRB) also rejected the use of spinal taps in MDMA research, which they felt posed more risk to the patients than the possibility of MDMA neurotoxicity. In addition, Dr. Krupitsky proposes that the Russian control group receive "logical therapy", much like what we call "cognitive therapy", rather than guided imagery and music (without MDMA) as in the US plan. ■

MAPS AND RESEARCH WITH PSYCHEDELICS OTHER THAN MDMA

Though MAPS will continue to concentrate its resources on MDMA research, it will also broaden its vision. The field of psychedelic research is so interdependent that progress with one drug in one country can effect researchers interested in another drug in another country. Conversely, problems with one drug can hinder research with other drugs. For example, the tragic and still puzzling death of a patient in France who had been treated with ibogaine halted all therapeutic use of MDMA, LSD and 2-CB in Switzerland for over a year. Their use was only recently permitted to resume.

As part of the broader MAPS agenda, this issue of the MAPS newsletter contains a discussion of DMT research by Dr. Rick Strassman and a request for donations to help him write a book on DMT. In addition, Dr. John Morgan writes about research with ibogaine. When the FDA-approved LSD protocol has secured Institutional Review Board approval, MAPS will then seek funds for LSD research. This newsletter also discusses developments regarding the medical use of marijuana. ■

MEDICAL MARIJUANA... SYMBOLIC VICTORIES

The last MAPS newsletter reported on the scientific findings and astonishing publicity received by the publication in the *Annals of Internal Medicine* and the *Journal of Clinical Oncology* of a study conducted by MAPS President and then Harvard Kennedy School of Government student Rick Doblin and faculty member Mark Kleiman. The study, reported in the *New York Times*, on *NBC National News*, and elsewhere, found widespread support among oncologists for the medical use of marijuana to reduce nausea and vomiting in cancer patients. Though the DEA still opposes the medical use of marijuana and the FDA says it does not have enough data to support claims of marijuana's safety and efficacy, there have been some new symbolic victories.

On October 30,1991, a symbolic bill in favor of the medical use of marijuana was endorsed 7-1 by the Cambridge City Council. On November 6th, 1991, Dale Gieringer, Coordinator, California NORML reports that, "San Francisco voters overwhelmingly endorsed Proposition P, supporting legalized prescription use of medical marijuana. Final returns showed Proposition P with 79.5% yes votes, more than any other ballot proposition including one affirming the city's support for the First Amendment. Proposition P received the endorsement of all of the city's newspapers, as well as the Democratic Central Committee and the leading mayoral candidates. It was opposed by the Partnership for a Drug-Free America, the Chamber of Commerce, and the Republican Party. Proposition P puts the city of record as favoring legalized medical use of marijuana on prescription, but does not alter current state or federal restrictions."

In San Francisco, de facto legalization of home-grown marijuana by patients in medical treatment may result. Nationally, a non-profit like MAPS needs to be organized to work with the FDA. ■