We Begin! — The First FDA-Approved Study of the Effects of MDMA on Human Volunteers

ALL THE NECESSARY permissions, approvals, sign-offs, shipping forms, and scientific protocols are in place for the first ever FDA-approved human research with MDMA. Around New Years' Day, 1994, Dr. Charles Grob's pharmacy at Harbor UCLA Medical Center will receive a supply of legal MDMA from Dr. David Nichols of the Department of Medicinal Chemistry at Purdue University. Dr. Nichols, who under DEA license also manufactured Dr. Rick Strassman's DMT and psilocybin, originally made MDMA for research purposes in 1985. At the time, we weren't sure if we would ever be able to administer the MDMA to humans instead of just to research animals. Though it took eight long years to reach this point, it was well worth the effort.

Dr. Grob's original FDA-approved protocol involved the administration of two doses of MDMA and one dose of placebo to six people, along with a limited variety of physiological and psychological tests. However, in the intervening time between FDA-approval and all the other required approvals, Dr. Grob developed a collaboration with Russell Poland, Ph.D., a fellow UCLA faculty member who is an expert in the assessment of the effect of drugs on brain neurochemistry. As a consequence, the phase one study has been substantially expanded to clarify more exhaustively MDMA's physiological effects. MDMA pharmacokinetic studies will also be added to the study, as will fenfluramine challenge tests designed to probe the function of the subjects' serotonin system. Since serotonin is involved with the regulation of sleep, special sleep EEG studies will be conducted. Subjects in the study will also receive high-tech brain scans (Magnetic Resonance Imaging) and computer-enhanced analysis of brain wave patterns (SPECT). These tests will permit a more thorough evaluation of MDMA's short and long term effects on the serotonin system and its functional correlates. MAPS' donation of $2,700 towards the expenses of this study will cover the cost of these scans for two subjects.

Seekng Government Funding

Drs. Grob and Poland are also interested in conducting a separate study similar in design to Dr. George Ricaurte and Dr. Una McCann's multi-year investigation of the physiological and psychological differences between a group of MDMA users and a group of matched controls. Drs. Grob and Poland will thankfully substitute high-tech brain scans for spinal taps. Due to the substantially increased complexity and cost of Dr. Grob and Poland's Phase 1 MDMA study, and also to their plan to conduct another study involving matched controls, they are planning to apply to the National Institute on Drug Abuse (NIDA) for a grant for their MDMA research. The grant application is due February 1,1994 with the awards being announced about December, 1994. From now until February 1, Drs. Grob and Poland will be testing several subjects so as to gather preliminary pilot data to support their grant application.

MAPS' donation ($2,000 of which was raised from the conference commemorating the 50th anniversary of LSD and the remaining $700 from membership donations) will be used to help gather pilot data for the NIDA grant application. In this way, MAPS is using its relatively limited resources strategically, allowing Drs. Grob and Poland to use a small donation from MAPS in ways which enhance their efforts to secure a large grant from NIDA. This strategy has worked well in the past when MAPS offered some early assistance to Dr. Ricaurte so that he could gather preliminary MDMA neurotoxicity data from primates and MDMA users who volunteered for spinal taps. With the help of skilled researchers and a little luck, the strategy has an excellent chance of working again.

the phase one study has been substantially expanded

From February 1, 1994 until about the end of the year, when NIDA is supposed to decide whether or not to support their enlarged study, Drs. Grob and Poland will proceed with their Phase 1 study as far as their funds allow. In other words, donations are still needed to facilitate this project. (If interested in volunteering for the experiment, call Carla Edwards at Harbor UCLA Medical Center: (310) 222-1663. Subjects from southern California preferred; the study requires subjects to go the lab from 7–10 different days and/or nights.)

MDMA Cancer Study

It is our hope that enough basic Phase 1 safety data will be gathered by the fall of 1994 so that the FDA will permit Dr. Grob to initiate the Phase 2 study of the efficacy of MDMA in the reduction of pain and distress in terminal cancer patients. This MDMA study will focus on one of the most important areas of research in modern medicine, namely the mind-body connection. Dr. Grob and co-researchers will seek to determine whether MDMA-assisted psychotherapy and guided imagery can help patients reduce their sensitivity to pain and lessen the number of deadening narcotic painkillers they need, stimulate their immune system to fight their cancer, and help people deal more effectively with the emotions surrounding terminal illness. ■