

Multidisciplinary Association for Psychedelic Studies

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Switzerland Leads the Way

Great News! Finally, somewhere in the world, psychotherapeutic research with MDMA is taking place. About two years ago, over 30 Swiss psychiatrists interested in psychedelic psychotherapy and research formed the Swiss Psycholytic Association in order to formally request legal permission to use MDMA in treatment and research. In June of 1988, Swiss officials in the Office of Pharmaceuticals and Narcotics, of the Department of Public Health of the Ministry of the Interior, granted permission to six of the Association's psychiatrists to treat patients and conduct research not only with MDMA but also with LSD, mescaline, DMT, and 2CB. Psychiatric patients suffering from reactive depression, addictive disorders, character neuroses, phobias, psychosomatic illness, obsessive-compulsive disorders, and anorexia nervosa are being treated with MDMA-assisted psychotherapy, with very positive initial reports from both psychiatrists and patients. The Swiss psychiatrists have been told they will be permitted to administer these drugs for the next year or two, but in order to continue their work beyond that time will be required to show scientific data supporting their view that the drugs are both safe and efficacious.

In May of 1989, I went to Switzerland to observe the Swiss experience with regulated psychedelic research as part of my work towards a Masters in Public Policy at Harvard's Kennedy School of Government. The report I wrote was submitted for critique to U.S. officials in the National Institute of Mental Health (NIMH), the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA). Being here at the Kennedy School learning to be a bureaucrat (or at least think like one!) has provided me with an insightful training in governmental decision making, and remarkable opportunities to engage the present drug policy officials in dialogue. The fact that hundreds of patients have been successfully treated with MDMA in Switzerland strengthens the circumstantial case for research into the therapeutic use of MDMA.

MDMA Research in the United States

In response to the estimated 400,000 doses of MDMA that are consumed in the United States every month (my estimate based on DEA seizures, and gossip), NIDA has decided to thoroughly evaluate the possible harm that may be caused by human use of MDMA. Eight university-based researchers are conducting NIDA-funded research on the neurological effects of MDMA and serotonin, while NIMH also has funded some basic neurotoxicity research.

One of NIDA's multi-year grants has gone to Dr. George Ricaurte of Johns Hopkins University for basic animal research. Dr. Ricaurte's primate study is investigating the mechanism by which damaged serotonin nerve terminals regenerate, and determining how long such regeneration takes, whether it will restore baseline levels, and whether

or not this degeneration has any practical significance or observable behavioral effects. Dr. Ricaurte's pilot study investigating the regeneration of serotonergic nerve terminals was partially supported by grants from MAPS.

NIDA is funding two studies of human users of MDMA. Dr. Marsha Rosenbaum is conducting a two year descriptive study of MDMA users, and assessing abuse potential. Nearing completion, preliminary reports note that "There appears to be minimal abuse in the population we have studied thus far. The most frequent use tends to occur during the first months following an initial experience. An abusive stage, if it occurs at all, tends to be brief."

NIDA's other human study is being conducted by Dr. Ricaurte, and involves 24 people whom have taken MDMA over 20 times volunteering to undergo three and a half days of hospital tests having their brain waves computer monitored during two nights of sleep, being given a complete series of neurological tests, a spinal tap, blood tests, a tryptophan challenge test, a pain sensitivity test, and various non-invasive puzzles and memory tests. MDMA users will be compared with a group of non-drug users and a group of MDMA naive drug users. Dr. Ricaurte's pilot studies of MDMA users at Stanford and Yale, which demonstrated the feasibility of the project, were partially supported by grants from MAPS. In addition, many of the volunteers for the study were referred by MAPS.

A Call for Volunteers

Before studies evaluating possible benefits from MDMA, the FDA requires that MDMA's risks be carefully evaluated. Dr. Ricaurte's study of MDMA users will lead to the FDA's ability to make more informed assessments concerning the risks of MDMA, replacing fear with facts. Subjects will have all expenses covered to Baltimore, and be given a fee of \$400. If you or anyone you know is interested in volunteering, you can write or call me for more details. Though not the ideal vacation, it is fascinating to learn how one measures on all these various tests. It is a also very valuable contribution towards helping clarify our national policy towards MDMA. Due to confidentiality, identities of participants will not be disclosed. Even the Director of NIDA has no inherent right to see medical files.

Preliminary Findings

When a primate is given a single oral dose of 2.5 mg/kg, which is higher than the standard therapeutic dose, there is no neurotoxicity at all. MAPS has contributed seed money to Dr. Ricaurte for a study in which an oral dose of 2.5 mg/kg of MDMA will be given once every two weeks week for four months, for a total of eight administrations. The study will help to determine the neurotoxic risk of multiple doses of 2.5 mg/kg, a dose pattern more similar to the average therapeutic or recreational than a single dose. This study will be concluded in late 1989.

Degenerated serotonergic nerve terminals experience regeneration. Dr. Ricaurte demonstrated that ten weeks after exposure to very large doses, primates that had 80-90% reductions in their serotonin levels has recovered roughly half their lost nerve terminals. Currently underway is another study by Dr. Ricaurte, partially assisted by MAPS, which is investigating whether serotonergic nerve terminals will exhibit total recovery after a period of 40 weeks. This study will also be completed in late 1989.

Serotonergic nerve terminal degeneration, even in the range of 80-90% , seems not to result in behavioral or functional consequences. After over 7 millions doses of MDMA have been taken in the United States there are still no cases in the literature of any individual experiencing symptoms of MDMA related neurotoxicity. Nor are there any published studies demonstrated that a relationship between repeated high doses of MDMA and long term behavioral effects. Dr. Thomas Insel's NIMH study found that even large doses to newborn rats had no long term behavioral effect. The only time that behavioral effects were noted occurred when MDMA was given in large amounts to pregnant rats, with the newborns exhibiting some abnormal behavior.

International Interest in MDMA Research

Several senior psychiatrists in the USSR have expressed an interest in learning about MDMA research. MAPS has offered to coordinate a conference to be held in Moscow in the summer or fall of 1989, and to raise funds to cover the expenses. Dr. Lester Grinspoon of Harvard Medical School, Dr. George Ricaurte, and Dr. Jorg Roth (research coordinator for the Swiss psychiatrists) all the intended speakers. It may actually be possible to arrange for collaborative studies in Moscow before FDA permission is granted for U.S. research.

MAPS has recently arranged for a donation of \$12,000 to Dr. Joseph Zohar, an Israeli researcher at Ben Gurion University. Dr. Zohar is seeking permission from the Israeli government to investigate the use of MDMA in the treatment of patients suffering from obsessive-compulsive disorders. Dr. Thomas Insel of NIMH has previously worked with Dr. Zohar researching treatments for obsessive-compulsive disorders , and will be reviewing the progress of the research .

The Swiss Neurotoxicity Collaborative Research Project

The human neurotoxicity experiment in the United States is scientifically complicated by the difficulty of creating control groups that exactly match the MDMA using group in all respects except the use of MDMA. Serotonin levels vary over 300% in the normal population, and personality ,diet and other factors play major roles in the variance. An ideal study design would have subjects acting as their own control, being tested at two points in time with administration of MDMA occurring between tests. This type of study is not permitted yet in the United States but is possible in Switzerland. In order to gather necessary data, the psychiatrists of the Swiss Psycholytic Association volunteered to collaborate with Dr. Ricaurte on a neurotoxicity study, even though the Swiss government has not specifically requested the study. Swiss subjects will donate spinal fluid before and after multiple treatment with MDMA, permitting the establishment of pre-MDMA levels. Sample analysis will be conducted by Dr. Ricaurte.

The Funding of Scientific Studies- An Appeal for Donations

Medical use of MDMA may prove very beneficial to many U.S. citizens, yet unless scientific studies are conducted this potential will remain unrealized. Since scientific studies require financial support, this MAPS report is both informational and an appeal for tax deductible donations from individuals who care about this research.

Donors can make restricted gifts to the project of their choice, or simply make donations to the *general fund*.

Supporting the Swiss collaborative neurotoxicity study can be accomplished for \$10,000. MAPS has offered to try and raise \$400 for each of the 25 subjects, who all will be receiving two spinal taps. NIDA is paying U.S. subjects \$400 for one spinal tap and three days of other tests. It seemed considerate to offer something to the Swiss subjects, who are conducting this specific study more for our benefit than theirs. The Swiss doctors have volunteered their time collecting the spinal fluid and Dr. Ricaurte has offered to cover costs of conducting the analysis of spinal fluid out of his current laboratory budget.

The seminar in Moscow can be fully supported for \$10,000. The three physicians and myself who will attend will receive no remuneration, and incur estimated travel costs of \$2,500 each. This project is important both as a small citizen-sponsored bridge between two nations very cautiously allowing the cold war to thaw and as a method of furthering the possibilities for legal MDMA research in the USSR and the United States. There would be nothing quite like an MDMA gap to motivate U.S. officials to permit MDMA research. What better sort of competition could there be than on healing technologies?

In the United States, one additional control group would be very helpful in Dr. Ricaurte's neurotoxicity study at Johns Hopkins. In addition to testing a group of MDMA users who had tried MDMA over 20 times, another group of subjects who had only used MDMA 2-7 times would help determine whether users of small amounts of MDMA were significantly different from frequent users of MDMA, or from non-drug users or non-MDMA drug users. This additional control group would ideally have 24 subjects, just like the other groups. Estimated expenses of \$435 and a \$400 fee suggest that a total of about \$20,000 is needed to bring this extra control group into being. Dr. Ricaurte could cover the cost of lab fees and experimenters' time from out of current budgets.

Progress- No More Animal Studies

It is important to note that no future donations will be used for animal studies. Some people have felt uncomfortable giving funds to MAPS to support animal studies, preferring human studies. I have previously thought that additional animal studies were essential to secure FDA permission, and now think that enough animal data either has been gathered, or is currently underway. I have recently made contact with several animal rights groups including the Humane Society, the Anti-Vivisection League, and People for the Ethical Treatment of Animals, and have asked their help in lobbying the FDA for permission to move into human studies.

Looking Ahead

Legal MDMA psychotherapy research is possible. We can work to heal the national trauma of drug abuse and drug wars by listening to the concerns of the drug abuse officials, learning their language, conducting research and seeking mutually acceptable solutions. MAPS will continue to develop scientific data for decisionmakers.

Another MAPS report will come out in the early fall outlining the progress made and the state of affairs. Once school starts again I will be rather quiet until Christmas vacation, sending out a short report around the New Year.