

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.