



# MAPS

NEWSLETTER OF THE MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

*thank you!*

*Thank you to Dan King of Austin, Texas for his generous donation of computer equipment for the MAPS office. Dan sent a Macintosh 2ci with a 20 inch monitor. This equipment makes it possible to work more efficiently with the database, word processing, and graphics programs which we use.*

*On another note of thanks, National Medical Marijuana Day was enhanced by the anonymous donation of 1,000 floppy discs imprinted with a design to commemorate the event. The artwork was provided by the ever-helpful graphics designer who volunteers his efforts in the layout of the MAPS Bulletin/Newsletter. ♦*

## INTERNET UPDATE

An email-based fileserver is being compiled to make individual MAPS articles available free via email. To check out this option, send email to the address: [Majordomo@server.blueline.com](mailto:Majordomo@server.blueline.com) with <index maps> in the message. The subject line is irrelevant. For a list of commands for file retrieval, send the message <help>. The World Wide Web site which features the MAPS back issues has a new URL. It is: <http://www.blueline.com/passenger-deck/maps>. An alternate URL is: <http://www.maps.org>. We continue to work towards making MAPS resources available in user-friendly formats. Please send comments and questions to [st.maps@cybernetics.net](mailto:st.maps@cybernetics.net) ♦

## BUILDING TOWARDS CLINICAL TRIALS

**T**HE FIELD OF PSYCHEDELIC RESEARCH is at a critical turning point. Currently, basic physiological and psychological safety studies (Phase 1) are underway with MDMA, DMT, psilocybin and ibogaine. Within the next year, it may be possible to begin research into the therapeutic efficacy (Phase 2) of several of these psychedelic drugs as well as LSD and marijuana. Research on the horizon includes studies into the use of MDMA in the treatment of pain and distress in cancer patients, MDMA in the treatment of Post Traumatic Stress Disorder, ibogaine in the treatment of substance abusers, LSD in the treatment of substance abusers, psilocybin in the psychological treatment of AIDS and cancer patients, and marijuana in the treatment of the AIDS Wasting Syndrome.

While the field of psychedelic research looks exceptionally promising, support for free scientific inquiry must not be taken for granted. The challenge for researchers, and for MAPS, is to demonstrate as quickly as possible that this line of research carries benefits for the average American. Positive results from efficacy studies can do just that, if we have the regulatory approval, time and resources needed to conduct the research.

In the last several months, MAPS has increased its membership by over 100 people. If we can continue this rate of growth for the next year, MAPS will reach the point where it is of sufficient size to support its organizational expenses. In order to help MAPS grow and be more effective, we'd like to encourage you to renew your annual membership if it is time to do so, and to consider giving gift memberships to friends, family, or institutions. Special grants for research projects are also needed.

The field of psychedelic research made great progress in 1994, in part because of the partnership between MAPS members and staff and several excellent and devoted researchers. Thank you for your continued support and participation. Even more dramatic progress can take place in 1995. ■

## MAPS EXPERIMENTS WITH NEW FORMAT

MAPS is experimenting with a new form of communicating with its members. This mailing contains a simple newsletter containing brief updates about the projects that MAPS is currently funding, as well as news about other psychedelic research projects. Unlike recent issues of the newsletter, it contains no lengthy articles. The newsletter is designed for you to read quickly and get a basic overview of MAPS' activities. The next issue of the MAPS newsletter will be called a Bulletin instead of a newsletter, to reflect the inclusion of longer and/or more scholarly articles, as well as book reports and news updates. We hope that by alternating newsletters and bulletins, we can provide you with more frequent and timely reports on MAPS' activities, as well as periodic overviews of the entire field of psychedelic research. ■

# MDMA research update

## Phase 1 Safety Study

### United States:

The MDMA safety studies (Phase 1) being conducted by Dr. Charles Grob at

Harbor-UCLA Hospital in Los Angeles are proceeding at an expeditious pace. As readers of the last MAPS newsletter may recall, on May 18, 1994, Dr. Grob administered the first legal dose of MDMA since it was placed on Schedule 1 in 1985.

Dr. Grob is conducting the only FDA-approved human study in which MDMA is administered to volunteer subjects.

Supporting Dr. Grob's MDMA research is one of MAPS' top priorities.

By the end of November, Dr. Grob had completed the administration of MDMA to six subjects, each of whom participated in three experimental sessions. Two of the sessions involved the administration of MDMA (in two different doses) while one session involved the administration of an inactive placebo. The experiment was conducted in a double-blind manner such that neither the experimental team nor the subject knew ahead of time whether the test dose would be a placebo or one of the two different doses of MDMA.

During the experimental sessions, the subjects' vital signs are measured. In addition, blood is drawn for later analysis, and psychological and physiological tests are administered. Additional tests are administered several weeks before the first experimental session and several weeks after the last session. Dr. Grob's experiment uses a randomized dose-escalating design. The first group of six subjects was divided into three pairs. The first pair of subjects received one administration each of .25 mg/kg of MDMA, .5 mg/kg or placebo, with the order of the dosing randomly determined. The second pair received one administration each of .5mg/kg, .75 mg/kg or placebo. The third pair received .75 mg/kg, 1 mg/kg or placebo. These doses are all well below the therapeutic dose range of 1.50 to 2.25 mg /kg.

The FDA has required Dr. Grob to submit the data from his first six patients for official review before proceeding to administer larger doses to additional subjects. Dr. Grob is now in the final stages of analyzing his data and will soon be submitting a report to the FDA for its first safety review. Nothing unusual was noticed in the first six subjects, so we anticipate that Dr. Grob will be granted permission by the FDA to enroll an additional six subjects in his experiment.

The doses of MDMA that will be administered to the second set of six subjects will range from 1 mg/kg and 1.25 mg/kg, to 1.25 mg/kg and 1.5 mg/kg, up to 1.5 mg/kg and

1.75 mg/kg. Dr. Grob will need to submit another report to the FDA containing the data from this second set of six subjects before receiving permission to enroll the third and final set of subjects in this experiment. If all goes as anticipated, the doses to be administered to the final set of six subjects will range from 1.75 mg/kg and 2 mg/kg, to 2 mg/kg and 2.25 mg/kg, up to 2.25 mg/kg and 2.5 mg/kg. Once the final set of six subjects has been evaluated, the data from the entire experiment will be reviewed by the FDA.

Over the last several months, Dr. Grob has also used high-tech brain imaging techniques (MRI and SPECT) to evaluate brain functioning in several frequent MDMA users. This research is ongoing and it is still too early to evaluate the data.

We anticipate that by Fall, 1995, Dr. Grob will be given permission by the FDA to proceed into an efficacy study (Phase 2) designed to evaluate the potential of MDMA and guided imagery to reduce physical pain and psychological distress and stimulate the immune system in cancer patients. MAPS has been actively seeking to raise funds for this Phase 2 project and has developed some promising leads. ■

## Post-Traumatic Stress Disorder Study

### Nicaragua:

The MAPS-sponsored project into the use of MDMA in the treatment of soldiers and civilians suffering

from Post-Traumatic Stress Disorder (PTSD) is still in the design phase. In August, MAPS arranged for two experts in PTSD research to travel to Nicaragua to give a series of lectures on research design. Attending the lectures was the Nicaraguan research team at the Military Hospital in Managua led by Dr. Manuel Marin Madriz. As a result of the information presented in the lectures, Dr. Madriz has been working to redesign the protocol and to standardize diagnostic, treatment, and evaluative procedures. Though this project is proceeding more slowly than anticipated, the end result will be that any data gathered will have a greater impact due to the incorporation of more rigorous scientific standards for data collection. ■

# Marijuana research update

## AIDS Wasting Syndrome Study

A substantial amount of MAPS' staff time and effort has been spent in an effort to secure governmental approval for Dr. Donald Abrams' study designed to compare the use of smoked marijuana versus the oral THC capsule in the treatment of weight loss associated with the AIDS wasting syndrome. If and when it begins, this study will become the first experiment in over a decade to evaluate the clinical use of marijuana in human subjects.

The last MAPS newsletter contained an article reporting in substantial detail on MAPS' efforts in support of Dr. Abrams' study. In that article, the various regulatory roadblocks preventing the initiation of the study were detailed and a series of possible strategies to overcome those obstacles were outlined. Shortly after the newsletter was mailed out, however, a new and totally unexpected development took place.

The last MAPS newsletter reported that the main problem preventing the study from going forward was Dr. Abrams' difficulty in obtaining an approved source of marijuana for the study. Attempts to import marijuana from a firm in the Netherlands which had legal permission to grow it had been rejected by the Drug Enforcement Administration (DEA). Since the only legal domestic source of marijuana was the National Institute on Drug Abuse (NIDA), and MAPS had previously been told that it did not have the higher potencies of marijuana that the FDA required us to use in the experiment, we were temporarily stymied. Alternative options considered were to continue to seek a Permit to Import, to try to raise funds to contract privately with NIDA's marijuana grower at the University of Mississippi, to try to use confiscated supplies, or to try to start a non-profit domestic marijuana growing operation. Unfortunately, non of these options seemed likely to succeed.

Fortuitously, a new option entered the equation when we learned that NIDA does have very limited but sufficient quantities of higher potency marijuana. This higher potency marijuana had been grown at NIDA's marijuana farm for the first time during the 1993 harvest, and was sitting on a shelf in a warehouse with no competing requests for its use. Though the quantities NIDA had in stock were relatively small and the potency wasn't quite as high as the variety which MAPS had tried to import (NIDA's supply was 7.57% THC while we wanted to import marijuana with 10% THC), NIDA's marijuana was more than sufficient for Dr. Abrams' pilot study.

In August, 1994, after it became clear that domestic supplies were indeed available, Dr. Abrams made a formal request to NIDA for the marijuana necessary for his study.

We assumed that since FDA had approved the study, NIDA's agreement to donate its marijuana would naturally and quickly follow. It seemed unthinkable that the Administration could justify refusing to reschedule marijuana because of a lack of scientific evidence, and at the same time refuse to permit research. Hope for easy access to NIDA's marijuana supply proved to be wishful thinking. Since obtaining a supply of marijuana assures that the study will take place, opposition to this research effort has intensified. As a result, MAPS sought help in trying to influence NIDA's decisionmaking process. Support for Dr. Abrams' protocol has come from Congressman Barney Frank, Congresswoman Nancy Pelosi, the Physicians Association for AIDS Care (the nation's oldest and largest association of physicians interested in AIDS research and treatment), the Federation of American Scientists, NORML, the Drug Policy Foundation, and numerous policy analysts, activists, patients, and physicians. The main arguments we are making are that the controversy over the medical use of marijuana should be decided through scientific research, and the medical needs of patients should not be sacrificed to the War on Drugs.

Due to the controversial nature of this issue, the decision about access to NIDA's marijuana will be made by Dr. Philip Lee, the Assistant Secretary of Health. Participating in the decision are representatives of the White House Office of National Drug Control Strategy, DEA, FDA, NIDA, the National Institutes on Health, and a few Senators and Representatives who have the courage of their convictions. A decision is expected very shortly. MAPS will keep you informed as to the latest developments. ■

## Water Pipe and Vaporization Study

The \$25,000 MAPS/California NORML marijuana smoke filtration study is well underway. Marijuana smoke from three different water pipes, a prototype of a hot-air vaporizer, a specially-designed filtered cigarette and unfiltered marijuana are all being evaluated by one of the nation's premier smoke analysis laboratories. MAPS has already made the initial payment of \$9,000 as well as a second payment of \$8,000 which was due at the midpoint of the six-month experiment. Final results are expected by Spring, 1995. This study is part of a larger effort to test the safety and efficacy of smoked and vaporized marijuana in the treatment of a variety of clinical indications. A grant application for an expanded analysis of the most effective filtration devices has been submitted to the Drug Policy Foundation. ■

## ketamine: Russia

MAPS received a \$2,000 grant to support the research of Dr. Evgeny Krupitsky, a Russian scientist who uses ketamine in the treatment of alcoholics and neurotics. Since Dr. Krupitsky already has published scientific papers describing his positive results (which have been discussed in past issues of the MAPS newsletter), the next step in the scientific process is for other researchers to try to replicate his findings. Therefore, MAPS is sponsoring a visit to the United States by Dr. Krupitsky in late January and early February, 1995. Dr. Krupitsky will visit Albuquerque, New Mexico in order to work with Dr. Rick Strassman, who is actively researching DMT and psilocybin. He will also visit Los Angeles to meet with Dr. Charles Grob, who is conducting MDMA research. Another stop will be Baltimore to meet with Richard Yensen, Ph.D. and Dr. Donna Dryer, who are planning to study the use of LSD in the treatment of substance abuse. While in Baltimore, MAPS will also try to arrange for Dr. Krupitsky to visit with officials at NIDA's Medications Development Division, which is investigating the use of ibogaine in the treatment of cocaine and heroin addiction. Dr. Krupitsky will also visit Miami to meet with Dr. Sanchez-Ramos and Deborah Mash, Ph.D., who are conducting the first safety studies with ibogaine. Finally, Dr. Krupitsky will visit Tampa to meet Dr. Eli Kolp, a psychiatrist who immigrated to the US from Russia and is interested in investigating ketamine in the treatment of alcoholism. If any MAPS readers would be interested in meeting Dr. Krupitsky during his travels, please let the MAPS office know and we will try to make the necessary arrangements. ■

## ibogaine: Miami

Dr. Juan Sanchez-Ramos and Deborah Mash, Ph.D. have completed the first portion of their Phase 1 study of the physiological and psychological effects of ibogaine in human volunteers. They have administered very low doses of ibogaine to a small number of subjects and have submitted their data to the FDA for review. They expect to be permitted to continue their experiment using higher doses in another small group of subjects. ■

## psilocybin: New Mexico

Dr. Rick Strassman of the University of New Mexico at Albuquerque has now begun his Phase I study of the physiological and psychological effects of psilocybin in human volunteers. These experiments are being conducted with a standard dose-response design. Dr. Strassman is also continuing with his studies of DMT. The next issue of the MAPS Bulletin will contain a report by Dr. Strassman on these studies. ■

### NATIONAL MEDICAL MARIJUANA DAY

NOVEMBER 15, 1994 was National Medical Marijuana Day. The Cannabis Action Network (CAN) organized about 100 local educational and cultural events, and NORML organized a special press conference at the National Press Club in Washington, DC. These events were designed to bring this issue to the attention of the American public.

At the press conference, patients from around the country joined with physicians and activists to explain this issue to the media, and through the media to the American public. Though an extraordinarily persuasive group of speakers appeared at the National Press Club, there was unfortunately very little press attention.

The main lesson MAPS learned from this disappointment is that the strategy of trying to force politicians to accept the medical use of marijuana through testimonials alone is not likely to succeed. While the tragic spectacle of having a patient get arrested and tried for the medical use of marijuana can get media attention, and change public opinion to some extent, government policy against the medical use of marijuana is deep-seated. It is for this reason that MAPS continues to pursue a complementary strategy based on FDA-approved scientific research aimed at making marijuana into a prescription medicine. ■  
Commemorative flying disc available - see order form.

#### NEW BOOK AVAILABLE!

### THANATOS TO EROS

MYRON STOLAROFF was early convinced of the value of psychedelic substances, and devoted his career to studying them. This book is a detailed account of his own personal experiences. It is a journey from the grip of Thanatos, the drive for death that effectively defeats enjoyment of life, to Eros, the drive for life that brings ultimate fulfillment. Order your copy of *Thanatos to Eros* now from Thaneros Press @\$17.95 per copy (add \$3.00 per copy S&H, CA residents add \$1.39 sales tax for each book). Thaneros Press, PO BOX 773 (M), Lone Pine CA 93545. The next issue of the MAPS Bulletin contains the Foreword to this book by Sasha and Ann Shulgin. ◆