MAPS

NEWSLETTER OF THE MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

Opportunity Amidst Obstacles

MAPS HAS HAD A PRODUCTIVE SPRING. In the last three months, MAPS awarded grants totaling $23,000 in support of psychedelic research. A $10,000 grant went to Dr. Charles Grob's Phase 1 MDMA study *(p. 2)*. This grant provides all the funds necessary to complete this crucial study. Once the Phase 1 study is concluded, Dr. Grob can begin the process of securing final permission and implementing the MAPS-supported Phase 2 study into the use of MDMA in the treatment of pain and distress in end-stage cancer patients. This upcoming transition from preliminary studies of the physiological and psychological effects of MDMA to studies of its therapeutic potential will mark an historic turning point that MAPS members can take pride in helping to bring about. MAPS also awarded Dr. Grob a $5,000 grant for SPECT and MRI brain scans of experienced MDMA users *(p. 2)*. This study is designed to evaluate whether long-term use of MDMA causes an increase in cerebral blood flow. ■ MAPS awarded a $5,000 grant to Dr. Deborah Mash's study of the pharmacokinetics of ayahuasca, a psychedelic tea from the Amazon *(p. 4)*. Dr. Mash's study analyzes blood samples taken from members of the União do Vegetal Church in Brazil and is part of a larger biomedical investigation of the religious use of ayahuasca. While MAPS concentrates its efforts on the medical use of psychedelics, MAPS will try to facilitate studies of the religious use of psychedelics whenever possible. ■ MAPS also made a $3,000 grant to Dr. Evgeny Krupitsky's study of the psychological effects of ketamine treatment of alcoholics *(p. 8)*. Dr. Krupitsky is the only researcher currently working to evaluate the clinical use of a psychedelic drug, though this kind of research will hopefully become more widespread in the near future. ■ Dr. Rick Strassman's work with DMT and psilocybin continues to move forward though at a somewhat slower pace due to his recent move to Canada *(p. 10)*. ■ There have been some setbacks, however. After a prolonged political struggle, NIDA has refused to supply marijuana to Dr. Abrams' MAPS-sponsored study of marijuana in the treatment of the AIDS wasting syndrome *(p. 11)*. NIDA's fear of scientific research will delay, but not prevent, medical marijuana research. ■ Hopeful signs include the results of a scientific poll revealing that support for the medical use of marijuana, if proven effective, is in excess of 80% of voters. Also encouraging is the publication in the Journal of Addictive Diseases (Vol. 14, No. 1 1995) of two opposing editorials; "The Medical Use of Marijuana: The Case for Clinical Trials" by Rick Doblin and Mark Kleiman, Ph.D. and "Marijuana as Medicine: Making a Silk Purse Out of a Sow's Ear" by Drs. Richard Schwartz and Eric Voth. Dr. Barry Stimmel, the Journal's editor, wrote an introductory editorial supporting the position that clinical trials with marijuana should be conducted. I'm also happy to report that MAPS is initiating a new project under the direction of Sylvia Thyssen called the Cannabis Patient Registry (CPR) *(p. 12)*. ■ As you will read in this issue, MAPS members are making a considerable difference in the fledgling field of psychedelic research. Please ask your friends and colleagues to consider becoming MAPS members so that we can accomplish even more. *Rick Doblin, MAPS President, June, 1995.*

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MAPS • 1801 Tippah Avenue, Charlotte, NC 28205 • Phone: (704) 358-9830 • Fax: (704) 358-1650 • Internet: rickmaps@aol.com • st.maps@cybernetics.net • ISSN 1080-8981

RESEARCH UPDATE

harbor-ucla **mdma** research

CHARLES S. GROB, MD
RUSSELL E. POLAND, PH.D.
LINDA CHANG, MD
THOMAS ERNST, PH.D.
DEPARTMENTS OF PSYCHIATRY, NEUROLOGY AND RADIOLOGY, HARBOR-UCLA MEDICAL CENTER

THE HARBOR-UCLA PHASE I RESEARCH investigation of the effects of 3,4-Methelenedioxymethamphetamine (MDMA) in humans has finished comprehensive study of twelve subjects administered MDMA at dosages up to 1.75 mg/kg. All subjects enrolled in the study have participated in three randomized experimental drug administration sessions, receiving different dosages of MDMA on two occasions, and an inactive placebo on a third. Subjects as well as research staff remained blind to whether active drug or placebo was administered for each particular session. A variety of measures designed to evaluate MDMA's short and long term effects have been obtained. These include basic medical status parameters (blood pressure, heart rate, temperature) during actual experimental drug sessions, psychological instruments examining subjective mental states during drug administration, analyses of serial blood samples (obtained from an indwelling intravenous catheter) for pharmacokinetics and neuroendocrine challenge testing and neuropsychological evaluation administered before the first experimental MDMA session and one week following the last. Plans for completion of this Phase I study call for the recruitment of six additional subjects who will be administered MDMA in dosages ranging form 1.75 to 2.5 mg/kg.

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Brain Imaging

Brain imaging scans have also been included in our research design in order to ascertain both short and long-term effects that MDMA has on cerebral blood flow and brain neurochemistry. Thus far, we have studied fifteen subjects (inclusive of some but not all of the subjects experimentally administered MDMA, as well as several others who were not included in the experimental MDMA administration wing of the study) with SPECT (single photon computed tomography) scans, several of whom were studied both before their first dose of MDMA and after their last. SPECT scan procedures called for co-registration with MRI (Magnetic Resonance Imaging), thus allowing for greater resolution and detail of images obtained. Magnetic Resonance Spectroscopy (MRS) has also been obtained on a large number of our subjects to examine integrity of brain neuronal membranes and to explore for the presence of abnormal CNS metabolites.

Cerebral Blood Flow

Preliminary SPECT scan findings in particular have aroused interest. Although it is premature to publish our preliminary data at this time, basic science research utilizing small laboratory animals reported in the scientific literature several years ago (McBean et al, 1990) does provide intriguing clues concerning MDMA's long-term effects. Weeks following serial administration of repeated large dosages of MDMA, these experimental animals were found to have significantly elevated rates of cerebral blood flow compared to normal control animals never administered MDMA. Given what we know of serotonergic neuronal innervation of blood vessels, such findings are not surprising. If these laboratory findings do indeed generalize to the human data, several important questions must be asked. First of all, what are the clinical implications of increased blood flow in the brain? We are aware of a variety of neuropsychiatric disorders associated with measurements of low blood flow, including Alzheimer's Disease, HIV Dementia, Major Depressive Disorders and Chronic Cocaine Abuse. However, there are no known clinical disorders or drugs which

induce long-term elevations of rates of cerebral blood flow. If indeed MDMA can reliably increase blood flow in the brain, this would presumably be an entirely novel phenomenon. And if MDMA can cause elevations of cerebral blood flow, then in order to establish what the clinical implications are, it will be necessary to evaluate the short and long term effects of MDMA on memory, cognition, mood and overall psychiatric status in a larger group of subjects.

Reports have surfaced over the years attesting to possible therapeutic and salutary effects of MDMA use. However, reports have also appeared, particularly in the neuroscience and psychiatric literatures, alleging various degrees of adverse outcome to MDMA use. Unfortunately, rigorous objective methodological assessment of this phenomenon has remained limited, in spite of the serious public health questions which still await elucidation. We believe that brain imaging investigations can provide valuable clues in helping us unravel the truth about MDMA, and whether it has genuine application as a medicine, or conversely, must be avoided because of risks for inducing brain injury. Only with additional studies of MDMA's effects on brain function and neuronal integrity will we obtain answers to these questions.

Subjects needed

Will SPECT scans of humans corroborate animal findings that MDMA increases cerebral blood flow? If this is the case, is it a dosage or time-limited phenomenon, where initial elevations are followed by decline or return to baseline? In order to address these problems, it is necessary to pursue additional investigation in human subjects. To that end, we are interested in recruiting individuals willing to undergo brain imaging procedures as well as psychiatric and neuropsychological evaluation who have personally used MDMA in excess of several hundred times. Anyone wishing more information concerning possible participation in the Harbor-UCLA Phase I MDMA research protocol can contact our research coordinator, Gayle, at (310) 222-4266. We would also like to point out that these brain imaging studies are very costly, and that in order to continue our work in this area we will need additional funding support. Given the increasing difficulties in obtaining government funding for this type of research endeavor, we are counting on private donations to allow us to move forward with our studies. Anyone interested in making such a contribution to our ongoing research efforts may do so through MAPS, or else directly to the Harbor-UCLA Research and Educational Institute, a non-profit tax-exempt research organization. With continued financial support, it is our hope that we will be able to shed new light on this critical yet perplexing area, and in so doing hasten the opportunity to pursue formal, sanctioned Phase II clinical trials with MDMA in the treatment of pain and distress in end-stage cancer patients.

We would also like to take this opportunity to thank MAPS for its generous contribution of $15,000 to our ongoing efforts conducting human research with MDMA. Without such support, it would not be possible to continue this work.•

We are interested in recruiting individuals who have personally used MDMA in excess of several hundred times and who are willing to undergo brain imaging procedures as well as psychiatric and neuropsychological evaluation.

Charles S. Grob, MD
Harbor-UCLA Medical Center
Box 498, 1000 West Carson St.
Torrance, CA 90509

the **hoasca** project: current status

DENNIS J. MCKENNA, PH.D.
RESEARCH DIRECTOR,
BOTANICAL DIMENSIONS

CHARLES S. GROB, MD
DEPARTMENT OF PSYCHIATRY
HARBOR-UCLA MEDICAL CENTER

REGULAR READERS of the MAPS Newsletter are already aware of the Hoasca Project, a multidisciplinary effort to investigate the human pharmacology of Hoasca, a botanically-derived psychedelic beverage which is utilized as a sacrament in ritual practices of the União do Vegetal (UDV), a Brazilian syncretic religious movement. The background and rationale for the proposed research was reported in the MAPS newsletter for Summer 1992 (Vol. III no. 3), and an update on the status of the research as of the end of 1993 was presented in the MAPS newsletter for Spring 1994 (Vol. IV, no. 4).

. . . we have engaged Dr. Debra Mash and her colleagues at the University of Miami Medical Center to complete the pharmacokinetic arm of the study

As of this writing (May 1995) several of the original objectives of the proposed research have been met. The assessment of the possible long-term effects of hoasca teas in platelet serotonin receptors in members of the UDV has been completed by Dr. Jace Callaway and his colleagues at the University of Kuopio, Finland. The results, which have been published recently (Platelet serotonin uptake sites increased in drinkers of ayahuasca; J. C. Callaway, et al., Psychopharmacology 116:385-387, 1994) were unexpected, and hence, worthy of further investigation. The anomalous increase in the density of platelet serotonin uptake sites in long-term users was a surprising finding. While numerous psychotropic agents, as well as other treatments such as electroconvulsive therapy, are known to downregulate platelet serotonin receptors, no other pharmacological model, other than ayahuasca, has been demonstrated to increase uptake site density in platelets. The possible implications of this long-term effect, as well as the question of whether it reflects a similar effect occurring in the central nervous system, remains unclear. Dr. Callaway's investigations on the long-term effects of ayahuasca on other serotonin receptor sites in platelets are still in progress.

Dr. Callaway and his colleagues are also working on the quantitative phytochemical analyses of the alkaloids present in various samples of hoasca teas and the source plants utilized in the making of hoasca. These studies, apart from their intrinsic interest, are also essential for the projected pharmacokinetic studies, as they will provide the baseline data needed to correlate the volume of tea administered to the volunteers, to the amount of active alkaloids in the test samples. Publication of their results is anticipated shortly.

neuropsychological parameters

In addition to the biochemical measurements, an additional, major component of the study was the assessment of various neuropsychological parameters in long-time UDV members in comparison to non-users with a similar age and cultural background. This was accomplished using various standardized questionnaires such as the TPQ (Tridimensional Personality Questionnaire) and the WHO/UCLA Auditory Verbal Learning Test, as well as the Hallucinogen Rating Scale developed by Dr. Rick Strassman at the

University of New Mexico. The questionnaire-based screening was coupled with extensive, in-depth psychiatric interviews of the 15 UDV members and the control subjects. The interviews and administration of the psychological screening instruments took place under the supervision of Dr. Charles Grob, of the Psychiatry Department, Harbor UCLA Medical Center. The data from the psychological investigations has now been analyzed and the results have been submitted to the Journal of Nervous and Mental Disease.

pharmacokinetic measurements

A major component of the biochemical measurements planned for the study has not been completed: the pharmacokinetic measurement of the levels of DMT and ß-carbolines in the plasma of UDV volunteers who ingested the tea. Plasma samples were obtained from test subjects prior to ingestion of the tea and at known time-intervals during and after the acute intoxication phase of the hoasca tea experience. In addition, urine samples were obtained at 12 and 24 hours after ingestion. The objectives of this portion of the study were to obtain a time-course profile for two of the major components, DMT and harmine (harmine is the major ß-carboline present in hoasca, and the most potent MAO inhibitor of the three major ß-carbolines in the tea). The pharmacokinetic measurements are important for several reasons:

1. They will provide a measurement of the metabolism of DMT when ingested orally in the presence of peripheral MAO inhibitors. This will supplement the data on human metabolism of parenterally-administered DMT which was previously reported by Rick Strassman (Strassman, et al., Dose-response study of N,N-dimethyltryptamine in humans: I. Neuroendocrine, autonomic, and cardiovascular effects. Archives of General Psychiatry 51:85-97, 1994). We anticipate that the pharmacokinetic profile of orally-ingested DMT in the hoasca teas will reflect a less rapid plasma uptake and clearance, consistent with the more prolonged time-course of the hoasca subjective experience.

2. They will provide a measurement of the simultaneous metabolism of DMT and harmine, the MAOI which primarily potentiates oral activity of DMT. One question is, "what levels of harmine must be achieved in plasma in order to manifest the effects of orally ingested DMT?" An obvious corollary question of interest here is the relationship between plasma levels of DMT and harmine and the amounts of alkaloid ingested in the tea; in other words, how much alkaloid must be taken in the tea in order to elicit a perceptible subjective response.

3. A third question of interest is the relationship, if any, between the subjective intensity of the experience and the pharmacokinetic characteristics of the active constituents. Does the most "intense" part of the hoasca experience correlate with the highest plasma levels of DMT? These are obvious questions which can be addressed experimentally via the analysis of the time-course plasma samples.

MAPS funded study

Originally we had engaged Dr. Kym Faull, of the UCLA Neuropsychiatric Institute, to develop the analytical methods for the pharmacokinetic study. Unfortunately, due to other pressing priorities, Dr. Faull has been unable to fulfill this commitment and so we have engaged Dr. Debra Mash and her colleagues at the University of Miami Medical Center to complete this aspect of the study. Dr. Mash's group is eminently qualified to carry out this work as they have been conducting similar studies of ibogaine metabolism in connection with a NIDA project to investigate the potential of this compound as an anti-addictive agent. As a result, many of the methodological challenges which are sure to be present in the hoasca pharmacokinetic study have already been addressed and solved. We are grateful to Dr. Mash for kindly agreeing to collaborate on this project and are looking forward to her results.

One of the few problems that cannot be addressed or adequately resolved in the laboratory for a study of this type is that of continued funding; we have been extremely fortunate in this regard as well. Rick Doblin, the president of MAPS, has generously provided a $5,000 grant to Dr. Mash which has been earmarked for the completion of these pharmacokinetic measurements. We want to express our extreme appreciation to Rick, to MAPS, and to the entire MAPS community for recognizing the significance of this work and for providing the funds that will allow it to go to completion. With Dr. Mash's help and unstinting effort, we are hoping that this final and important phase of the study can be completed in the near future. Further updates on the progress of the study will be reported in future issues of the MAPS newsletter, as will the development of our plans for additional investigations. •

Dennis McKenna, Ph.D.,
P.O. Box 224, Marine on St. Croix, MN 55047

Charles S. Grob, MD, Box 498, Harbor-UCLA Medical Center, 1000 W. Carson St. Torrance, CA 90509,

ketamine: scientific journey through the united states:

new connections, new questions, new ideas, and new commitments

EVGENY KRUPITSKY, MD, PH.D.

OUR RUSSIAN RESEARCH TEAM has been working with ketamine psychedelic therapy (KPT) since 1985. We have obtained very positive results in the treatment of alcohol dependence and neuroses. Fully 69.8% of our patients abstained from alcohol for at least a year after KPT, more than twice the number of patients in control groups who take part in routine treatment programs. The next step in the scientific process is for other researchers to try to replicate our results. Therefore, in late 1994, MAPS sponsored my visit to the United States. I met with psychiatrists and researchers to try to inspire them to replicate our positive results with KPT in the treatment of alcohol dependence. (Alcoholism Treatment Quarterly, Vol. 9(1) 1992; MAPS Newsletter, Vol. 3, N 4 1992; Vol. 4, N 4 1994).

Our Russian research team has been working with ketamine psychedelic therapy (KPT) since 1985.

I delivered lectures, carried out seminars, and had many interesting discussions in various universities and scientific centers across the United States. These included the Substance Abuse Treatment Center of Cornell University, New York City (Drs. Robert Millman and Ann Beeder); the Center on Addictions, Substance Abuse and Alcoholism (CASAA) at the Department of Psychiatry, University of New Mexico (Drs. William Miller and Rick Strassman); the Heffter Research Institute, New Mexico (Dr. George Greer); the Open Society Institute, New York (Ethan Nadelmann); the Department of Psychiatry, Veterans Administration Hospital in Tampa, Florida (Dr. Eli Kolp); the National Institute on Drug Abuse and National Institute on Alcohol Abuse and Alcoholism; the National Institutes of Health's Office of Alternative Medicine (Dr. Alan Trachtenberg); UCLA (Drs. Charles Grob and Jeff Wilkins); UCSF (Dr. Reese Jones); the Center on Alcoholism and Substance Abuse, Columbia University (Dr. Herb Kleber), and the Department of Psychiatry of Yale University (Dr. John Krystal).

Evgeny Krupitsky, MD, Ph.D., Head of the Research Laboratory, Leningrad Regional Dispensary of Narcology, Novo-Deviattkino 19/1, Leningrad Region, 188 661. Russia, Internet: kru@lond.spb.su

combining KPT with AA

In San Francisco, I visited Salus International Institute, which is trying to bring Western techniques of alcoholism treatment to Russia, primarily with different variants of Alcoholics Anonymous (AA) treatment such as the Hazelden and Minnesota models. The Salus Institute carries out its mission through its sister branch in Moscow. Three of my lectures on Russian drinking patterns and alcoholism treatment in Russia were videotaped at the Salus Institute.

During discussions with Dr. B. Rosen and his psychiatrist colleagues at the Institute, we noted some similarities between the spiritual issues of psychedelic therapy and AA treatment programs. It is not very well known that AA founder, Bill Wilson, had several very beneficial LSD experiences after he was sober. As a result, he thought that LSD could play an important role in AA. Salus's staff pointed out some problems of bringing AA programs to Russia, where the strong spiritual and religious nature of this approach might sound unusual and strange to Russian alcoholics brought up with atheism. I told the staff that ketamine psychedelic therapy often caused a conversion experience in our alcoholic patients, and afterwards made spiritual and religious knowledge much more understandable to them. Thus, perhaps it is worthwhile to try AA treatment in combination with ketamine therapy, as in this case AA spiritual issues might become more understandable and acceptable for Russian alcoholics.

ketamine psychopharmacology

At the end of my visit I met Dr. Herb Kleber (Columbia) and Dr. John Krystal (Yale). They were quite interested in our ketamine studies. With Dr. Krystal we developed a plan of mutual studies into the human psychopharmacology of ketamine and the similarities in the underlying psychopharmacological mechanisms of action of ketamine and alcohol. To carry out this study we are going to apply for a grant to the Foggerty Foundation Program for Eastern Europe and Former Soviet Union countries.

why has KPT had such positive results?

After my lectures and during seminars and meetings, people often asked me to explain to what our Russian research team attributed the high rate of positive clinical results we obtained after just one ketamine psychotherapy session. It was a very good question. I usually replied that for many years we have been carrying out special studies of the underlying biochemical, neurophysiological and psychological mechanisms of ketamine psychedelic therapy in order to find an answer to this question. As a result of our biochemical studies, we found that ketamine affects monoaminergic and opioidergic metabolism, i.e. those neurochemical systems of the brain which are involved in the development of alcohol and drug dependence. We hypothesized that this explains a significant portion of its efficacy. According to computer-assisted analysis of EEG "brain maps", we found evidence of the activation of the limbic system during the ketamine session, as well as evidence of the reinforcement of the limbic-cortex interaction. This fact can be considered to a certain extent to be indirect evidence of the strengthening of the interaction between the conscious and subconscious levels of the psyche during the ketamine session. Thus, ketamine psychotherapy influences multiple levels of the psyche, including the deeper ones. This may also contribute to its efficacy.

It is the psychological studies, however, that shed the most light on the underlying mechanisms of KPT. Many psychiatrists consider ketamine-induced states of consciousness to be a form of psychosis, and ketamine itself to be a psychotomimetic. However, the changes in the Minnesota Multifactor Personality Inventory (MMPI) after KPT sessions testified to positive personality changes. Changes in the Color Test of Attitudes (CTA) after KPT testified to a positive transformation of the unconscious emotional attitudes of our alcoholic patients towards themselves, their significant others, and the world. Changes in our Spirituality Scale testified to a significant increase in the level of spiritual development after the ketamine session. As a rule, we observed a positive transformation of our patients' systems of life values, purpose and meaning, and even some world view changes after KPT. Our patients began to see other goals, other values, other pleasures in their lives, and this was quite possibly the main reason for their sobriety.

new research instruments

A question often asked in seminars and meetings was, "How did you measure life values, purpose and meaning?" Primarily, we relied on our clinical impressions after post-session psychotherapeutic work and changes in responses to the Spirituality Scale. However,

The next step in the scientific process is for other researchers to try to replicate our results with ketamine psychedelic therapy.

The study funded by MAPS evaluating the effect of ketamine psychedelic therapy on psychological changes in life values, purpose and meaning is another important step.

this is not an adequate answer. Clinical impressions and indirect evidence from research instruments do not constitute rigorous scientific proof.

Fortunately, several years ago, two psychological tests that should prove useful in gathering more scientifically sound data were translated into Russian and evaluated in Russia. The first of these is the Questionnaire of Significant Life Values and Purposes (QSLVP), which will allow us to assess quantitatively the significance of different spheres of life values, purposes and goals. The second is the Personal Orientation Inventory (POI) developed in the United States by Shostrom. The POI will allow us to assess our patients' self-actualization, which is an important determinant of the meaning they impart to life.

Now that I have returned to Russia, I am in the midst of an investigation of 30 alcoholic patients using the QSLVP and POI before and after KPT. The goal of the research is to see if we can demonstrate statistically significant changes in life values, purpose and meaning which we have previously observed during post-treatment therapy. To administer this study, our research team needed modest financial support of $100 per patient, totaling $3,000 for the entire study. MAPS is sponsoring this study, for which I am deeply grateful.

a collaborative study ahead

My scientific journey was very thought-provoking and useful for me, and I sincerely hope it was so for my American colleagues as well. I carefully elaborated a detailed protocol for a nearly double-blind controlled study of ketamine psychedelic therapy with alcoholics, in hopes that Dr. Eli Kolp, (VA Hospital, Tampa, Florida) can seek to replicate the Russian findings in the United States. This protocol has been presented to the VA Hospital psychiatric administration in Tampa, where it was positively received. We hope to obtain approval for our study soon, because ketamine is currently not scheduled as severely as other psychedelics as it is already FDA-approved for administration in anesthesiology. In sub-anesthetic doses it produces profound psychedelic and transpersonal experiences. Hopefully, this summer or fall, a ketamine research project can begin in Tampa, and the Psychedelic Renaissance of rigorously scientific psychedelic research begun in recent years can continue to flourish. The study funded by MAPS evaluating the effect of KPT on psychological changes in life values, purpose and meaning is another important step in this renaissance. •

Acknowledgments

I am grateful to MAPS and Rick Doblin, MAPS President, for organizing and sponsoring my visit to the United States and to Scott Kremer, MAPS member, for providing the initial $2,000 donation for my visit. I very much appreciate the $3,000 contribution from an anonymous MAPS member which made possible our current investigation of 30 patients. I am also thankful to Michael Gilbert, Dr. Charles Grob, Dr. Ray, Dr. Rick Strassman, Dr. George Greer, Dr. Eli Kolp, Drs. Richard Yensen and Donna Dryer, Dr. Reese Jones, Dr. Gary Bravo and David Presti, Drs. John Krystal and Herb Kleber, and to many other American colleagues and friends whose help and support were so important for me. Thank you very much indeed.

Scott Kremer and Dr. Evgeny Krupitsky

CORRESPONDENCE

Dear MAPS,

I had a lovely stay with Evgeny and his family last week. He has a charming wife and two beautiful children. I arrived in St. Petersburg on Thursday and left on Sunday night.

St. Petersburg is an epic city with incredible architecture, public sculpture and museums. The ballet was unbelievable. I now see why they say it is the best in the world.

St. Petersburg has a darker side as well. It is a city out of control. It's like being in the movie Clockwork Orange to be there. Authoritarian police, Mafia, gangs of drunken adolescents, crazy erratic driving on ripped up roads. Evgeny is working with very little resources and under great preasure to continue the work he is pioneering in the field of alcohol and drug treatment. He is a good guy struggling in a system that is going through incredible social, political and economic change. The stress he is experiencing is hard for us as Westerners to appreciate unless you live there. The typical treatment program is still patterned after the old soviet system that includes injections that the patient believes are drugs that will kill him if he drinks alcohol. They are in fact placebos.

The ketamine session is a radical departure from this form of treatment. It emphasizes spiritual and positive life changes instead of fear. It is carried out in a fairly sterile hospital environment and two anesthesiologists are present at all time. They administer the drug and monitor vital signs. There is a very small chance of respiratory failure which is watched for closely.

I participated in a session as the patient and felt very safe. I'm the first person from the West to go through the ketamine psychedelic therapy procedure, I've been told. Evgeny put me through a screening process that is carried out with all patients to determine my suitability. I received an IM shot of 1.5 mg/kg in the buttocks. The drug took a few minutes to take effect and those attending seemed surprised at how long it took. They gave me a booster shot in the arm and I lost feeling of my body. I was lying down on a bed with blankets over me and wearing eyeshades. Music was played during the one hour session and Evgeny offered emotional support during the entire experience. The visualizations were very vivid and I had a feeling of traveling and flying through holographic landscapes. It was very transcendental or transpersonal or whatever it's called. You pass over the threshold as you do with other psychedelics like LSD or mescaline. It is a profound experience. I could see how given the right set and setting and the proper follow-up and support, such a profound experience can contribute to the healing process of alcohol treatment.

John Mcclusky
Masters in Social Work Candidate who is researching alcohol abuse in Lithuania.
mcclusky@ucssun1.sdsu.edu

Heffter Online

On May 24, 1995, the Heffter Research Institute (HRI) officially opened public access to its home page on the World Wide Web. For those of you with the capability to browse the Web, the HRI home page can be found at http://www.heffter.org/. The home page presently lists basic information about the Institute: its mission, the founders, the scientific advisory board, etc., and also has links to related Web sites, including MAPS. In addition, it contains an interesting biography of Arthur Heffter, who was quite a remarkable individual, as well as molecular graphics of several psychedelic substances. It is anticipated that in the future the HRI home page will be expanded to include research reports, announcements of scientific conferences and meetings, and other public service information appropriate to the mission of the Heffter Institute, which is to foster legitimate scientific research utilizing psychedelic agents. After viewing the HRI home page, if you have comments and suggestions, you may email them to the address listed on the home page.

MAPS Online

The MAPS home page is experiencing a revitalization. It can be reached at http://www.blueline.com/passenger-deck/maps/ . In the coming months, we hope to add more links and pictures to report on current psychedelic research and interest the Net community in MAPS' efforts and achievements. To retrieve individual articles from back-issues, send mail to: Majordomo@server.blueline.com with the message <index maps> <help> <end>. The subject line gets ignored by Majordomo, so you can leave it blank or type anything there. The help message which you will receive will guide you to selecting and retrieving articles. Please send comments and questions to st.maps@cybernetics.net.

university of new mexico **dmt** and **psilocybin** studies

RICK STRASSMAN, MD

THE RESEARCH at the University of New Mexico has changed pace, with my move to Victoria, British Columbia. This move was, as many moves are, based on family needs.

After negotiations with the National Institute on Drug Abuse (NIDA), which funds our research, and Sam Keith, the Chairman of Psychiatry at UNM, I have been able to keep the NIDA funding, and will be in a quarter-time position at the University. This will translate into spending two weeks every two months in New Mexico to run sessions. The two remaining projects are the DMT-cyproheptadine study, and the psilocybin dose-response study.

We have described the DMT-cyproheptadine study in detail before. This is about 1/2 completed. Regarding our psilocybin study, we have decided to use 0.7 mg/kg oral psilocybin (free base) as our high dose for the psilocybin study, and 0.06 mg/kg as our low dose. There will be two intermediate doses, and a milk sugar (lactose) placebo involved in the full study. This study is just beginning. It should take somewhat over a year to complete, at this reduced pace.

The research at the University of New Mexico has changed pace, with my move to Victoria, British Columbia.

Finally, we have received the final approval from FDA to begin an LSD dose-response study, comparable to that performed with DMT, and ongoing with psilocybin. We have permission to go as high as 500 mcg in a 70 kg person, but will most likely opt for lower doses because of the constraints of the hospital environment. Our low dose will be somewhere around 20 mcg. More on this later.

Two personnel changes have taken place. Laura Berg, RN, MSN, has decided to leave the program because of the difficulties involved in working such an erratic schedule with my 3/4 absence. Laura has been a valuable, trusted, and well-liked member of the research team. Her loss will be hard to make up. For the time being, Research Center nurses who are familiar with the studies and the volunteers, and are sympathetic to the work being done, will help us out.

The other change is an addition, in the person of Nancy Morrison, MD, who is joining the team. She is a solid clinician, teacher and administrator, and will be "standing in" for me while I am in Canada. She has a keen interest in the role of psychedelics as psychotherapeutic adjuncts, and has been primarily responsible for writing and pushing through the psilocybin project with the terminally ill we have been developing the last six months. Nancy has been sitting in on DMT and psilocybin sessions since late last year, and will be my co-sitter for as many of the upcoming DMT and psilocybin sessions as possible.

While in Canada, I will be focusing primarily on a re-write of the book (first drafted in 1992, during a sabbatical from the University) describing our research with DMT and psilocybin and using our volunteers' first-person accounts as the primary material. In addition, there will be a fair amount of personal reflection about my interest in this field, how this work was begun, the set and setting, chemistry and pharmacology, religious/spiritual questions raised by psychedelic experiences, pineal gland role in these states, government-academic interface, and other aspects tying our research into a cohesive whole. I also will work to obtain my license to practice psychiatry in British Columbia.•

Rick Strassman, MD, University of New Mexico Department of Psychiatry, 2400 Tucker NE, Albuquerque, New Mexico 87131-5326
Internet: rstrassm@medusa.unm.edu

Hallucinogenic Drugs in Psychiatric Research and Treatment: Perspectives and Prospects, by Rick Strassman, MD was recently published in the Vol. 183, No. 3 issue of The Journal of Nervous and Mental Disease, pages 127–138.

medical **marijuana** research: NIDA Just Says No to Science

RICK DOBLIN

The struggle to conduct Dr. Abrams' study continues.

Background

For the last three years, MAPS has been working with Dr. Donald Abrams, a world-renowned AIDS researcher on the faculty of UC-San Francisco. We have been attempting to obtain governmental permission to conduct a double-blind pilot study comparing the use of smoked marijuana and the oral THC capsule in the treatment of weight loss associated with the AIDS wasting syndrome. Thousands of AIDS patients are using marijuana illegally to treat the wasting syndrome and are reporting beneficial results, making a controlled clinical trial the logical next step. What makes our effort so difficult is that the federal government has not permitted a single study into any of the reported beneficial medical uses of marijuana in over a decade.

After years of effort, critique, review and redesign, Dr. Abrams' study design has been approved by the Food and Drug Administration (FDA), the UC San Francisco Institutional Review Board, the California Research Advisory Panel (which must approve all research in California with Schedule 1 and 2 drugs), and the Scientific Advisory Committee of the San Francisco Community Consortium (where Dr. Abrams is research director). Dr. Abram's study has also been endorsed by the Physicians Association for AIDS Care (the nation's oldest and largest association of physicians involved with AIDS research and treatment) and the Federation of American Scientists.

For the last year, the only remaining bureaucratic hurdle has been the need to obtain a legal source of marijuana for Dr. Abrams' study. MAPS initially tried to import marijuana from a legally licensed marijuana research firm in the Netherlands. However, the Drug Enforcement Administration (DEA) refused to grant a Permit to Import, citing Dutch lack of compliance with provisions of the Single Convention, an international drug treaty. Though the Single Convention contains special exemptions for the import/export of marijuana for medical purposes, we have not yet succeeded in reversing DEA obstructionism.

NIDA says "No science"

In August 1994, Dr. Abrams requested marijuana from the National Institute on Drug Abuse (NIDA), which has a monopoly on the domestic supply of marijuana for research purposes. On April 19, 1995, after almost nine months of silence, NIDA Director Dr. Alan Leshner wrote to Dr. Abrams to say that his request for marijuana was rejected. Dr. Leshner claimed that the study's design, scientific merit and rationale were inadequate.

Not surprisingly, Dr. Leshner's critiques of the protocol were without merit. For example, he claimed that the study was too small to generate reliable results. While this seems to be an important issue, Dr. Leshner purposefully overlooked the fact that Dr. Abrams' study was not intended to be a large-scale clinical trial designed to generate reliable results. Dr. Abrams' study was designed to be a small preliminary pilot study, one of the purposes of which is to generate information about how many subjects should be included in the subsequent large-scale clinical trial. The use of a pilot study is well-established in scientific research and is a procedure preferred by the FDA. Dr. Leshner's other critiques, such as the concern that Dr. Abrams did not require that subjects smoke every bit of their daily maximum allowance, directly contradicted FDA policy as established in the clinical trials for the oral THC capsule. As Federal law specifies, FDA, not NIDA, is the government agency with responsibility for the design of clinical trials. NIDA's position that FDA policies are inadequate reflects NIDA's political opposition to medical marijuana research, which NIDA tries to cover with specious scientific arguments.

What now

The struggle to conduct Dr. Abrams' study continues. MAPS is exploring the possibility of purchasing marijuana directly from NIDA's supplier, thus privatizing the entire research effort. In addition, we are exploring the option of creating our own legally licensed marijuana-growing company. We are also working to overcome DEA opposition to the importation of marijuana. Though the Clinton Administration lacks the courage to stand up for scientific freedom and the needs of patients, MAPS will not give up.

Related research

The MAPS/California NORML marijuana smoke filtration study, designed to evaluate drug delivery devices such as water pipes and vaporizers for possible use in Dr. Abrams' study, will be completed soon. The next MAPS Bulletin will report on the results of the study. •

the **Cannabis** Patient Registry

Made possible by a grant from the Drug Policy Foundation

Sylvia Thyssen

SINCE I have been involved in the struggle to initiate clinical studies into the therapeutic uses of marijuana, a significant amount of my time at MAPS has been spent trying to mobilize medical marijuana patients. Many contact the MAPS office for information and write letters describing their medical condition and the relief marijuana provides. In an effort to influence the decision of the National Institute on Drug Abuse (NIDA) on whether or not to provide marijuana to Dr. Abrams' pilot study (see page 11), I've had to scramble to locate medical marijuana patients, hoping to encourage them to write their representatives. At the National Organization for the Reform of Marijuana Laws (NORML) and Cannabis Action Network (CAN), there are files of notes and phone messages, often with just the name and number of a patient. Here at MAPS, over a dozen patients are on file. Dr. Lester Grinspoon and the Cannabis Buyers' Clubs have their own sizable files of cases, as do many patient advocates all over the country.

The Cannabis Patient Registry is conceived as a database and archive specific to medical marijuana patients, their caregivers, and their legal support.

I've come to realize how useful it would be to consolidate information about the thousands of patients who use or have used marijuana for medical purposes. As a result, in the first quarter of 1995, MAPS submitted a proposal to the Drug Policy Foundation Grants Program to initiate the Cannabis Patient Registry. I'm happy to report that MAPS received its entire grant request of $7,400.

What is the CPR?

The Cannabis Patient Registry is conceived as a database and archive specific to medical marijuana patients, their caregivers, and their legal support. Its goal is to contribute to the growing effort to protect the rights of seriously ill Americans who choose to self-medicate with marijuana by creating a central repository of letters, documentation, and contact information. Documents to be collected will include those relating to the patients' medical histories, extent of physician support, legal problems if any, willingness to speak to the media, and extent of media coverage of their situations, if any.

What are the advantages of consolidating, updating, and expanding records of patients, caregivers, and attorneys? Primarily, it will assist patients in making their case to the American public and elected officials in an organized manner. In the political arena, the potential exists to mobilize strongly and effectively for media inquiry and lobbying efforts and to break the political logjams that are blocking even FDA-approved scientific research. In the scientific arena, the CPR offers researchers the opportunity to contact patients for possible inclusion in FDA-approved research projects or for more anecdotal data gathering. The CPR can also eventually serve as a support system for patients who want to be in touch with fellow patients, empathic doctors, and experienced legal counsel.

Is there really a need for the CPR?

What about the other organizations and people who already help patients? Many patients have benefited from the courageous

Sylvia Thyssen
MAPS-CPR Coordinator
(704) 358-0518, FAX (704) 358-1650
Internet: cpr@cybernetics.net

efforts of Cannabis Buyers Clubs and individuals who provide marijuana to patients despite the law, and patient advocates who testify in court for people who've had trouble with the law. The CPR seeks to complement their efforts. It seeks to reach out as well to people who are very private about their choice, yet who want to contribute to data-collection and also improve their legal case for a medical necessity defense in the unfortunate event of their arrest.

The unique idea which the CPR wishes to field-test is that of a card of affiliation. Many people such as organ donors, people with acute allergies, diabetics and hemophiliacs carry identification about their medical conditions, in case of an emergency. The common emergency among medical marijuana patients is that of a possible arrest. The CPR is developing a network of affiliation for patients, physicians and attorneys so as to provide support for a medical necessity defense for patients who have the additional misfortune of running afoul of our perverse legal system. Patients whose doctors provide a letter to the CPR documenting their patient's need for the medical use of marijuana will receive a wallet-size card from the CPR that could be shown to law enforcement officers if necessary. While such a card will probably not prevent an arrest, documented preexisting affiliation with the CPR may be helpful in any subsequent court case, and can lend a sense of legitimacy to the stigmatized marijuana patient.

The CPR is also trying to provide information about the epidemiology of the medical use of marijuana – who are the people who use it, how many of them are there, in what form is it used, for what indication, and with what results? This information, though less useful than data from clinical trials, may be the best that can be collected until the political climate changes.

The Next 12 months

Over the next year, the CPR will endeavor to consolidate existing records from (including but not limited to) the offices of MAPS, NORML, CAN, Cannabis Buyers' Clubs and Dr. Lester Grinspoon. We will develop, implement, and evaluate questionnaires and database formats for patients, doctors, and lawyers, seeking the most useful instruments possible.

Any medical marijuana patient, past or current, will be invited to register with the CPR. Each patient will be asked, by phone or written questionnaire, questions about their use, whether their doctor is supportive, what prescription drugs they've taken for their symptoms or illness, and whether they've been prescribed Marinol. In this way, anecdotal data can be gathered in an organized fashion in order to guide controlled research and lobbying efforts. Legal counsel in regard to lists of people engaging in illegal activity will be sought. An Internet presence will be developed for wider dissemination of questionnaires, testimonials, and information specific to medical marijuana patients and the status of marijuana research. Finally, information about physicians and attorneys who specialize or empathize with the situations of medical marijuana patients will be solicited. [A national 1-800 legal referral clearinghouse called the Legal Defense Network is being established for pro-marijuana attorneys to respond to the needs of activists in the Southeast. For more information or to get involved, call New Orleans Cannabis Action Network at (504) 861-2956.]

What about privacy?

Some people are more public than others about their medical marijuana use. Some communities are medical marijuana-tolerant. In other communities, patients may feel isolated, and may face (or have faced) severe penalty and criticism for their need for medication, either from law enforcement or from their own family or caregivers. The CPR is intended to document accurately as well as respect the various levels of privacy which a patient and his or her physician may desire. The information in the CPR is confidential and will not be freely distributed. To preserve the security of the database file, it will be encrypted. Direct access to the CPR will be limited to the staff of MAPS. Data about individual patients and physicians will be shared with other medical marijuana patients, physicians, advocates, and media only if the patients and physicians specifically authorize us to do so. The CPR will be used only to further strengthen the community of medical marijuana patients and their caregivers and advocates.

This report is the first public notice about the Cannabis Patient Registry. We encourage readers of this MAPS newsletter to help patients get in contact with the CPR. We will not give up on this issue until patients can be prescribed the medicines which they most need. •

We encourage readers of this MAPS newsletter to help patients get in contact with the CPR.

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10. THANATOS TO EROS, by Myron Stolaroff, 291 pages.....$20.95 for domestic orders/$23.95 for non-U.S. orders (includes shipping). This price good till August 1, 1995, after that add $5.00.

Mail forwarding is expensive. Please notify MAPS of address changes promptly.

MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

MAPS is a membership-based organization working to assist psychedelic researchers around the world design, obtain governmental approval, fund, conduct and report on psychedelic research in humans.

Founded in 1986, MAPS is an IRS approved 501 (c)(3) non-profit corporation funded by tax-deductible donations from about 1,000 members.

MAPS' founder and current president, Rick Doblin, is currently in the Ph.D. program in Public Policy at Harvard's Kennedy School of Government and has previously graduated from Stan and Christina Grof's Holotropic Breathwork 3-year training program.

Sylvia Thyssen is responsible for member services and coordinates MAPS' outreach efforts. She is a Phi Beta Kappa graduate of the University of North Carolina at Chapel Hill, where she majored in Art History and French.

MAPS has previously funded basic scientific research in both humans and animals into the safety of MDMA (3,4-methylenedioxymethamphetamine, *Ecstasy*) and has opened a Drug Master File for MDMA at the U.S. Food and Drug Administration. MAPS is now focused primarily on assisting scientists to conduct human studies to generate essential information about the risks and psychotherapeutic benefits of MDMA, other psychedelics, and marijuana, with the goal of eventually gaining governmental approval for their medical uses.

Albert Einstein wrote: **"Imagination is more important than knowledge."** If you can even faintly imagine a cultural reintegration of the use of psychedelics and the states of mind they engender, please consider joining MAPS in supporting the expansion of scientific knowledge in this area. Progress is possible with the support of individuals who care enough to take individual and collective action. In addition to supporting research, your contributions will return to you the following benefits:

The MAPS Publications:

Each publication will report on MAPS research in progress. In addition to reporting on MAPS studies, the publications may focus on psychedelic research both in the U.S. and abroad and on conferences, books and articles of interest. Issues raised in letters and calls from members may be addressed, as may political developments that effect psychedelic research and usage.

General Members: $35.

(If outside U.S. add $15 postage.)
General members will receive MAPS publications, which appear on a quarterly basis. In addition, General Members will receive a copy of the article entitled, "Careful Research of Psychedelics Resumes" from the May 1995 *Journal of Alternative Therapies.*

Supporting Members: $100.

(If outside U.S. add $15 postage.)
Supporting members will receive MAPS publications, plus the audio tape from the public session of the *1995 Esalen Pacific Symposium on Psychedelics.*

Patron: $250 or more.

Patrons members will receive MAPS publications, plus the bound volume of MAPS back issues 1988–1994. Patrons may also request research updates at any time on matters of personal interest.

MAPS

MEMBERSHIP

INFORMATION

Rick Doblin, MAPS President

Sylvia Thyssen, Networks Coordinator

"Those who insist that marijuana has medical uses would serve society better by promoting or sponsoring more legitimate scientific research, rather than throwing their time, money and rhetoric into lobbying, public relations campaigns and perennial litigation."
— DEA Administrator Robert Bonner, March, 1992

"We have reviewed your [Dr. Abrams] request that the NIH supply marijuana for a study of the effects of smoked marijuana on weight changes in persons with HIV-related wasting syndrome. Unfortunately, we have determined that we cannot comply with your request."
— NIDA Director Alan Leshner, April, 1995

maps funds **psychedelic** research

grants awarded from march to may 1995

$10,000 Dr. Grob's MDMA Phase I Study
Harbor-UCLA Medical Center
Report on pages 2–3

$5,000 Dr. Grob's MDMA Brain Scan Study
Harbor-UCLA Medical Center
Report on pages 2–3

$5,000 Dr. Mash's Ayahuasca Pharmacokinetics Study
University of Miami Medical Center
Report on pages 4–5

$3,000 Dr. Krupitsky's Ketamine and Alcoholism Study
Leningrad Regional Dispensary of Narcology
Report on pages 8–11

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