Multidisciplinary Association for Psychedelic Studies, Inc.

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1801 Tippah Avenue
Charlotte, NC 28205
Phone (704) 358-9830
FAX (704) 358-1650
Rick Doblin,
MAPS President

"CHANGE", the mantra of President-elect Clinton, is revitalizing the field of psychedelic research. The first flickerings of renewed research began a few years ago in Switzerland (see page 21), in Russia (see page 24), and in the US. These pioneering projects, approved after years of struggle with regulatory authorities, successfully demonstrated that scientific progress could be made without exacerbating drug abuse or catalyzing cultural turmoil. To the contrary, intriguing hints were found suggesting that the appropriate use of psychedelics could help in the treatment of substance abuse and could heal some of the cultural wounds associated with the War on Drugs. ■ In July, FDA's Drug Abuse Advisory Committee recommended the resumption of psychedelic research, subject to the condition that the standards of methodology and proof that the FDA uses to critique claims about other drugs must also be applied to psychedelics. Over the summer, the Massachusetts Department of Corrections approved access to its files so that a follow-up study could be conducted to Dr. Leary's 1962 inquiry into the use of psilocybin to reduce recidivism in prisoners (see page 4). In October, the FDA approved the first human study of MDMA (see page 2-3 and 36). The FDA may soon approve marijuana research in the treatment of HIV-related wasting syndrome (see page 6) and ibogaine to treat substance abuse. Also, NIDA will probably fund DMT and psilocybin research (see page 8). ■ Researchers in Switzerland are using PET scans to study ketamine and psilocybin (see page 18). In Brazil, the religious use of the plant mixture, ayahuasca, has been accepted as legal (see page 29). Dennis McKenna's proposal for a biomedical investigation of ayahuasca, reported in the last MAPS newsletter, has been funded and will begin shortly. In Russia, approval is likely for a study of MDMA's potential to treat alcoholics. In Germany, psychiatrists will soon publish data about MDE research and may obtain approval to research MDMA. ■ For MAPS, the renewal of psychedelic research carries its own imperative for change. Facilitating communication between researchers and regulators is more essential, delicate, time-consuming, and expensive than ever before. This newsletter is our lengthiest ever printed and is being sent to a record 375 MAPS members and 300 interested others. MAPS has demonstrated success by gaining approval for MDMA research after a seven-year struggle. Though I continue to donate my time, responding to the challenge of MAPS' new opportunities requires my full-time attention and has encouraged me to take a leave of absence from a Ph.D. program in Public Policy at Harvard's Kennedy School of Government. To be viable in the long run, MAPS needs additional funds both to pay for research and to support a full-time president. Future progress depends upon the extent to which we conduct scientifically proficient and culturally sensitive research, and upon your generosity in donating funds to support MAPS' work. ■ *Rick Doblin, MAPS President*

The MDMA Phase 1 Protocol: Experimental Design and Methods

This is a Phase 1 safety and tolerance study designed to determine the psychological and analgesic threshold level for MDMA.

Type of Study

This is a Phase 1 safety and tolerance study designed to determine the psychological and analgesic threshold level for MDMA. We will gather preliminary data on MDMA's effect on vital signs and, through blood analysis, on organ and immunological systems. Pharmacokinetic and neuropsychological studies will also be conducted.

Number of Subjects

There will be six subjects in this study.

Inclusion Criteria

Subjects must work full-time in the health care industry in professions such as physician, psychologist or nurse. Subjects must have previously self-administered MDMA and be between the ages of 25 and 55 years. Subjects must be willing to receive two doses of MDMA and a placebo as well as several blood, urine, and psychological tests. In addition, subjects must be willing to refrain from taking any psychiatric drugs during the experiment. Female subjects of child-bearing potential must have a negative pregnancy test and agree to use an effective form of birth control.

Exclusion Criteria

Subjects who have a history of schizophrenia, bipolar affective disorder, delusional disorder, paranoid disorder, or schizoaffective disorder will be excluded, as will any subjects who exhibit psychotic symptoms or have a history of epileptic seizures. Subjects who currently have a substance abuse disorder, or who have severe cardiovascular problems will also be excluded. Female subjects who are pregnant or who are not utilizing effective means of birth control will be excluded.

Dosing Plan

All subjects will participate in three experimental sessions. The experimental sessions will be separated by at least two weeks and at most four weeks from the previous session. All six subjects will be expected to gather together for all the sessions. Subjects will be permitted to skip only one session due to scheduling conflicts. A fourth make-up session will be scheduled if needed.

Each session will involve the oral administration of one capsule to each subject. In the course of the experiment, each subject will receive two different doses of MDMA and an inactive placebo. In the two MDMA sessions, the capsules will contain MDMA in the amounts of .15 and .75 mg/kg. These amounts are intended to produce the following effects:

1) a predicted below threshold dose (.15mg/kg)
2) a predicted threshold dose (.75 mg/kg)

The order in which the capsules will be presented will be randomized on a per subject basis with each subject receiving each of the three possible doses only once. All subjects, investigators, and independent raters will be blind as to which capsule was presented during any specific session.

All experimental sessions will begin at 10:00 am and will take place in the UCI Medical Center. The investigator/psychotherapist and a research assistant will be present and available throughout the session to tend to each subject's needs and handle any difficulties that might arise. Sessions will last four and a half hours. Automobile rides home will be prearranged so that subjects will not have to drive after the sessions. A psychiatrist will be on call 24-hours a day, seven days a week to handle any concerns or emergencies related to the protocol.

Methods of Analysis

Organ Function and Vital Signs

Subjects will have blood drawn immediately before the first session begins and two weeks after the last treatment session. Complete blood workups will be conducted including hematologic, hepatic and renal analysis. Immunological

MDMA RESEARCH - REGULATORY STATUS

We have begun our final set of applications and expect to receive approvals fairly soon. Though the FDA has approved this Phase 1 study, the California Research Advisory Panel must also approve the experiment and the Drug Enforcement Administration must approve the experimenters. Furthermore, the UC Irvine Human Subjects Committee has to approve this specific protocol, even though it previously approved a much larger and more delicate study of the use of MDMA to treat pain and distress in end-stage cancer patients. This experiment will hopefully begin in early 1993. The cancer patient study will probably start after the Phase 1 research is well underway, hopefully in mid 1993.

parameters will also be analyzed. Vital signs and temperature will be monitored every half an hour.

Acute Psychological Effects

The acute psychological effects of the treatments will be measured through the use of the Brief Profile of Mood States-SR (POMS-SR) (McNair et al, 1971) and the State-Trait Anxiety Inventory (STAI) (Spielberger, 1983). These tests will be administered to all subjects before the experimental sessions begin and at the first, second, third and fourth hours of the session. The Hallucinogenic Rating Scale (HRS), currently under development by Dr. R. J. Strassman, will be administered at the fourth hour immediately after the POMS and the STAI.

Pain

All subjects will have a cold-pressor pain test administered thirty minutes before each experimental session begins and again at a half hour, an hour and a half, two and a half, three and a half, and four and a half hours post-treatment.

Neuropsychological Effects

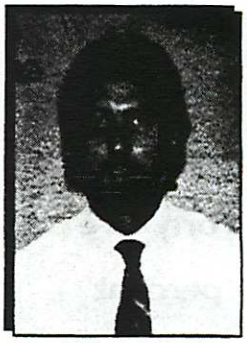
A battery of neuropsychological tests to include the Verbal Selective Reminding Test with delayed free and multiple choice recall, Wechsler Adult Intelligence Scale (WAIS-R) Digit Span, WAIS-R Arithmetic, WAIS-R Digit Symbol, Trail Making Tests A &B, Controlled Oral Word Association Test, a series of 20-point Likert-type scales with endpoints of "Extreme Decrease"/-10 to "Extreme Increase"/+10 for four groups of subjective effects; hallucinogen-associated symptoms, amphetamine-like symptoms, acute psychosis and mood, and other symptoms, and the Profile of Mood States, will be administered one week before the first and one week after the last session.

Pharmacokinetics

Blood for pharmacokinetic analysis will be drawn from each subject once during each session at the time of peak blood level concentrations, as determined by Swiss researcher Dr. Helmlin. ■

PSYCHEDELICS AND THE AMERICAN PSYCHIATRIC ASSOCIATION

Charles Grob, M.D. of the University of California, Irvine and Rick Strassman, M.D. of the University of New Mexico have recently been informed by the American Psychiatric Association (APA) that their workshop submission on "Human Research with Hallucinogens" has been accepted for presentation at the APA's annual meeting in May, 1993 in San Francisco. Drs. Grob and Strassman plan to review the history of psychiatric research with hallucinogens, including an update on recent developments in the field. The progress and current status of human research protocols with N,N-dimethyltryptamine (DMT), psilocybin, 3,4-methylene-dioxymethamphetamine (MDMA) and ayahuasca will be presented. This will be the first presentation at the APA in many years of human research and clinical potentials of hallucinogens.



Dr. Charles Grob

Dr. Gary Bravo

Human studies with MDMA are now possible. To support this study see MAPS membership information on page 34 – 35.

A Long-Term Follow-Up to Dr. Timothy Leary's 1961-1962 Concord State Reformatory Rehabilitation Study

by Michael Forcier, Ph.D., Social Science Research & Evaluation, Inc., and Rick Doblin, Harvard Kennedy School of Government

THE GOVERNOR'S OFFICE of the State of Massachusetts has recently approved our application for access to the files of the Department of Corrections in order for us to conduct a thirty-year follow-up to the Concord State Reformatory Rehabilitation Study, conducted in 1961 and 1962 under the supervision of Dr. Timothy Leary. Our study will be the second long-term follow-up of Dr. Leary's pioneering Harvard psychedelic research. The first long-term follow-up was conducted by Rick Doblin who located 19 out of the original 20 subjects in Dr. Walter Pahnke's Good Friday Experiment into the potential of psilocybin to facilitate mystical experiences. (*J. of Transpersonal Psychology*, Vol. 23, No. 1, p. 1-28, 1991, reprints available from MAPS).

Forty-five percent of the entire inmate group underwent a mystical, transcendent death-rebirth experience.

The Original Experiment

In 1961 and 1962, then Harvard Psychology Professor Dr. Timothy Leary conducted a study at MCI-Concord in which the psychedelic drug psilocybin (an extract of certain mushrooms) was administered to 32 inmates in an experiment to test the hypothesis that criminal behavior, measured by recidivism rates, could be reduced in prisoners exposed to the therapeutic use of psilocybin. Dr. Leary believed that the "consciousness expanding" properties of psilocybin could provide the inmates with insights into their own criminal behavior patterns that they could then use to change their future behavior. As part of the experiment, inmates participated in an intensive six-week program which included two or three psilocybin sessions and intervening discussion and therapy meetings. Post-release support groups were also provided for a short time.

Two follow-ups were conducted with the inmate participants. A short-term follow-up occurred a mean period of 18 months after the first treatment. Twenty-four subjects who participated in the program were paroled within 10 months of first treatment. Of these 19 (77%) showed evidence of good adjustment while five were returned to prison during that time. The recidivism rate was 23% compared to an expected 65%.

A second, longer-term follow-up occurred roughly 3 years after the first treatment and all 32 inmates participated in the project. Of these 32, 27 had been released while 5 were still confined at Concord. As of January 27,1964, 11 (41%) of the 27 released inmates were still out of prison, 13 (48%) had been returned as parole violators, and 3 (11%) were re-incarcerated for new crimes. At this follow-up, the actual rate of recidivism was 59% as compared with an expected rate of 56% for the Concord inmate population as a whole. However, it was also expected that recidivists would be equally divided between parole violators and those committing new crimes when in actuality, those returned to prison were predominantly parole violators.

In his second annual report on the project, Dr. Leary reached three major conclusions. First, psilocybin is safe. There were 131 inmate ingestions of psilocybin with no episodes of violence, lasting disturbances or negative after-effects.

Second, psilocybin was said to produce temporary states of personal and spiritual insight. Forty-five percent of the entire inmate group underwent a mystical, transcendent death-rebirth experience. By the end of the experiment, all of the inmates underwent such an experience. The life-changing therapeutic effects of the psilocybin experience do not last for more than 72 hours unless the subject is in a situation which encourages him to maintain his emotional and spiritual insights. Therefore, psilocybin must be used in on-going programs of therapy or self-help.

Finally, Leary concluded that if ex-convicts who have had a psilocybin experience in a supportive environment meet regularly after release (the data suggested once a month) the chances of their remaining on the street would be dramatically improved. Thus, of those inmates who were contacted after release

by the therapeutic team 6 times or more, 2 out of 12 (18%) were back in prison. Of those inmates who were contacted post-release by the therapeutic team less than 6 times, 5 out of 10 (50%) were returned to prison.

Rationale for a Long-Term Follow-up

Results at the 18 month follow-up were generally impressive. Results after three years were less impressive and consisted chiefly of the intriguing finding that study participants had a lower than expected rate of convictions due to new crimes and a higher than expected rate of parole violations. This may be partially explained by the short life of the post-release support group, which ceased functioning around mid-1963 at the time that Dr. Leary and some of his research associates were fired from Harvard. The best test of the experiment can be determined by a very long-term follow-up which compares the recidivism rates of the study participants to a comparison group of inmates matched on variables predictive of recidivism. At a time when the concept of rehabilitation has been almost totally abandoned, investigating the Concord State Reformatory Rehabilitation Study could help focus attention on strategies for rehabilitation in general and may perhaps bring to light a method that offers some promise.

There are two parts of the long-term follow-up. The first part consists of comparing the criminal histories of the original 32 subjects in the experiment with that of a comparison group of 32 matched inmates retrospectively assembled through the use of Massachusetts Department of Corrections inmate records.

The second part of the experiment will consist of efforts to to locate and interview the original 32 study participants. Subjects will be asked if they wish to voluntarily participate in the long-term follow-up. If they chose to do so, they will be administered an in-depth tape-recorded personal interview and will be asked to fill out a series of personal and psychological questionnaires. These questionnaires will include those administered in the original experiment. The interviews will be primarily informal and open-ended in nature allowing for subjects to recall their experiences with psilocybin and post-release after effects that may have been experienced.

In addition, the researchers will also use the National Institute on Drug Abuse's National Household Survey which obtains information on recent use of alcohol and illicit drugs. This will provide insight into post-release drug used by former study participants.

Results from the in-depth interviews and personality tests will be analyzed and compared to any data that can be found from the original experiment. In addition, the results of the interviews and personality tests will be compared to the criminal histories of the subjects following their original release after the original study was completed.

Dr. Leary has been contacted by the researchers and is searching his files for records pertaining to the original experiment. Contributions specifically for this project can be made through MAPS. ■

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Psychedelic Monographs and Essays

Psychedelic Monographs and Essays is a several volume collection of the foremost in current psychedelic literature. It specializes in academia, psychotherapy, journalism, physics, chemistry, biography and sociology surrounding hallucinogen research. *Volume Six* of *PM & E* presents *Pharmacodynamics and Therapeutic Application of Iboga and Ibogaine* by Drs. Goutarel, Gollnhofer, and Sillans. Dr. Goutarel is research director at the *C.S.R.N*, the French science research facility, and Drs. Sillans and Gollnhofer are ethnologists there. Premier Ibogaine researcher Howard Lotsof has called this fifty-five page synopsis "the finest paper on current Ibogaine research available in the English language."

Since 1985, *PM & E* and publisher Thomas Lyttle have continued to provide outstanding source materials from both the scientific and underground research communities. Each 300+ pp. book contains 25 pp. + of photos and original striking color art on the covers.

Psychedelic Monographs and Essays Vol. 6; Thomas Lyttle (ed.), Boynton Beach, FL; PM &E Publishing Group; ISBN 1-880332-04-3/ISSN 0892-371X $20,00 postpaid, from PM& E Publishing Group, P.O. Box 4465, Boynton Beach, Florida, 33424. Back issues are also available.

Medical Marijuana Update

by Rick Doblin, MAPS President

MARIJUANA is a substance that has been used medically for thousands of years. Recent archeological evidence shows that in the 4th century hashish was used to ease labor pains in a 14 year old girl. History notwithstanding, marijuana is considered by our legal system to be a Schedule 1 drug with no currently accepted medical use, no accepted safety for use under medical supervision, and a high potential for abuse. For over twenty years, physicians, researchers, lawyers and political activists have been struggling with the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) in hopes of getting marijuana reclassified as a prescription drug. Nevertheless, marijuana is still not available by prescription (see related story in MAPS newsletter Spring,1992).

Dr. Abrams has secured approval to proceed with the study from the Consortium's Scientific Advisory Committee, Community Advisory Forum, and Executive Board.

"Those who insist 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," stated Mr. Bonner, the administrator of the DEA, in a March, 1992 Federal Register opinion which sought to justify his ruling to prohibit prescription access to marijuana. As president of MAPS, I took part of his advice to heart and intensified my search for physicans interested in conducting research into the medical use of marijuana, just like I sought out Dr. Charles Grob and offered whatever assistance he needed to help him design, secure approval for, and conduct MDMA research (see FDA-approved protocol on page 2-3). Unlike Mr. Bonner, however, I also see the neccessity of lobbying, public relations campaigns and perennial litigation (which by the way the DEA has *always* lost). Still, I think the most important step to make marijuana available by prescription is exactly what Mr. Bonner recommends, to conduct additional FDA-approved scientific research exploring marijuana's medical risks and benefits.

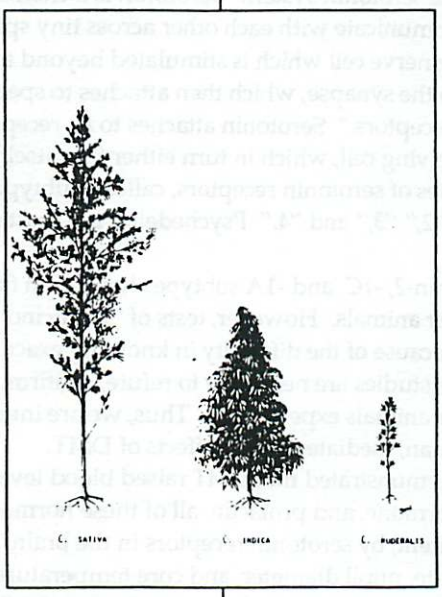
Finally my search has borne fruit, catalyzed by the arrest this summer of Mary Rathbun ("Brownie Mary") while she was baking 2 pounds of marijuana into brownies to give away free to AIDS and cancer patients. For many years, Mary had been a volunteer at San Francisco General Hospital's AIDS Ward. She had seen that marijuana brownies eased the nausea in cancer and AIDS patients and stimulated their appetites. Mary's arrest prompted me to call several doctors at San Francisco General to ask if any were willing to consider conducting research into the medical use of marijuana. One physician who knew "Brownie Mary", Dr. Donald Abrams, decided to consider getting involved. Dr. Abrams is one of the foremost AIDS reseachers in the country. He helps direct the Community Consortium, an association of Bay Area HIV Health Care Providers, and is on the faculty at the University of California, San Francisco.

FOR THE LAST several months, I have coordinated informal discussions between Dr. Abrams and FDA, NIDA, DEA and the White House Office of National Drug Control Policy concerning scientifically testing the medical use of marijuana in the treatment of HIV-related wasting syndrome. Concurrently, Dr. Abrams has secured approval to proceed with the study from the Consortium's Scientific Advisory Committee, Community Advisory Forum, and Executive Board.

The experiment he is considering will be a small pilot study lasting three months comparing weight gain and various safety and quality of life measures in about 20 patients who smoke marijuana and about 20 patients who receive oral THC pills

(Marinol). Previous research has already demonstrated that oral THC pills are effective in promoting weight gain in a significant number of patients. UNIMED, the company that markets Marinol, has successfully gotten the FDA to declare Marinol an Orphan Drug for the treatment of the wasting syndrome, triggering all sorts of financial incentives and FDA guidance.

Dr. Abrams expects to submit a protocol to the FDA within the next month or so, and a decision regarding permission is expected within 30 days thereafter. One main uncertainty at this time concerns securing a supply of high-THC content marijuana for the study so that the AIDS patients will need to inhale as little smoke as possible per unit of cannabanoids. For people whose immune systems are compromised, the less smoke the better. Marijuana, like all medicines, has side effects and it is wise to minimize them whenever possible. Unfortunately, the marijuana supplied to reseachers and patients by the National Institute on Drug Abuse (NIDA) from the government pot farm at the University of Mississippi is of poor quality with a low THC content of around 2-3%. The best NIDA can offer is a few kilos of 5% THC content marijuana.



YOU MAY HAVE HEARD the stories about today's marijuana being so much more powerful than that found twenty years ago (and therefore according to the goverment whatever you previously thought about pot is wrong). While there has always been high-THC content pot around, as well as hashish, it is not unheard of today for skilled growers to produce marijuana with a THC content in excess of 10% or more, with some buds containing 15% THC. Therefore, in the interests of the patients, I have requested that the DEA supply high-THC content marijuana for the experiment from seized supplies; I think my request is being taken seriously (although I would like to hear the discussions around the DEA water coolers about it!)

I have also begun a collaboration with Dale Gierenger of California NORML and Ed Rosenthal, national expert in marijuana cultivation and president of Quick Trading. We plan to study the constituents of marijuana smoke as it comes out of a waterpipe and also a vaporizer (THC vaporizes at about 180 degrees, less than it takes to burn marijuana). We are currently seeking scientific researchers interested in helping determine whether waterpipes and/or a vaporizor would reduce the particulate matter inhaled by the AIDS patients in the study. If successful, then we will have found a way to reduce what I suspect is the main health risk of marijuana, the effect of the smoke on the lungs. We estimate that this study will cost a mere $2,500. Ironically, for that tiny amount of money, we may generate more valuable information about minimizing the harms from smoking marijuana than has been generated in the entire last 25 years of the War on Drugs.

Securing the neccessary funding for the study is another remaining challenge. If you wish to help support this project, donations to MAPS may be earmarked for the medical marijuana study. ■

Dr. Abrams expects to submit a protocol to the FDA within the next month or so, and a decision regarding permission is expected within 30 days thereafter.

DMT and Psilocybin Research

by Dr. Rick Strassman University of New Mexico Medical School

THE National Institute on Drug Abuse (NIDA) has scored highly a grant proposal to continue the clinical research with hallucinogens we have been performing since November, 1990. In all likelihood, funding will begin either late this year or early next. The grant proposal is for three additional years of projects, and the total award is for approximately $500,000. The National Institute on Drug Abuse grant will support three DMT studies, and one psilocybin study.

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DMT Pretreatment Studies

Two of the DMT studies involve attempts to modify DMT's biological and psychological effects by pre-treating subjects with drugs believed to have an effect on brain areas affected by DMT. DMT's effects, like those of other "classical hallucinogens" such as LSD, psilocybin, and mescaline, are probably caused by an interaction with certain nerve cells contained within the brain. These cells are part of the serotonin system. Serotonin is a chemical, a neurotransmitter, which allows nerve cells to communicate with each other across tiny spaces, called "synapses." A serotonin-containing nerve cell which is stimulated beyond a certain threshold "fires," releasing serotonin into the synapse, which then attaches to specialized sites on the "receiving" nerve cell called "receptors." Serotonin attaches to its receptors, thus modifying the electrical activity of the receiving cell, which in turn either fires itself, or is prevented from firing. There are several varieties of serotonin receptors, called "subtypes," including the type "1A," "1B," "1C," "1D," "1E," "2," "3," and "4." Psychedelics are most strongly bound to the 1A, 1C, and 2 subtypes.

Drugs which block serotonin-2, -1C, and -1A subtypes have been found to block the effects of hallucinogens in lower animals. However, tests of "hallucino-genicity" in lower animals are open to criticism because of the difficulty in knowing exactly what the animal is responding to. Clearly, human studies are necessary to refute, confirm, or modify existing hypotheses generated by lower animals experiments. Thus, we are interested in determining which serotonin receptors, in man, mediate specific effects of DMT.

Our original DMT study demonstrated that DMT raised blood levels of beta-endorphin, cortisol, adrenal stimulating hormone, and prolactin; all of these hormones' regulation is believed controlled, to some extent, by serotonin receptors in the brain. In addition, we found rises in blood pressure, heart rate, pupil diameter, and core temperature in response to DMT; these variables also are regulated to some extent by serotonin nerve cells. Finally, we have carefully mapped out the psychological effects of DMT using the Hallucinogen Rating Scale, the development of which was discussed in a previous article. Now that we have this data describing effects of DMT by itself, we can pre-treat subjects with drugs that block certain types of serotonin receptors, and see what happens to these factors. For example, if pre-treatment with a serotonin-1A blocking drug enhances visual effects, but reduces beta-endorphin stimulation, we can suggest that the serotonin-1A receptor mediates those functions. These data could have use in developing antidotes for certain problematic reactions to psychedelics, and provide insights into important brain-mind interactions. They also might provide glimpses of understanding into spontaneous "psychedelic" states, such as some naturally occurring psychotic phenomena.

We have found a likely candidate for a serotonin-1A blocking drug, our first blockade project. However, we have been unsuccessful in locating a serotonin-2 and serotonin-1C drug, the second series of studies. These two latter receptors are extremely similar, and drugs that block the "2" subtype usually block the "1C" as well. There are several "2/1C" agents at various stages of development within human and animal studies, but so far, no one has agreed to provide such a drug to us. Efforts are continuing.

DMT Tolerance Study

The last DMT study is an attempt to develop tolerance to repeated administrations of DMT at one sitting. All other psychedelics, in man, have demonstrated tolerance to repeated administration. Thus, LSD at the same dose every day for three days, prevents that originally

active dose from having any effect on the fourth consecutive day. Several days drug-free are necessary to return to the previous level of sensitivity. DMT, administered twice a day (10 a.m. and 3 p.m.) for five days, in the only published human study that attempted to develop tolerance, demonstrated no tolerance. Animal studies have also given inconsistent results, with one study giving it every 2 hours for 21 days and finding only limited tolerance! Some animal studies have even suggested that sensitivity is increased depending on the timing and dose schedule. Finally, humans tolerant to LSD are not tolerant to DMT. Reports "from the field" are also not consistent. If any of you reading this have experience with repeated administration of DMT, I would be most interested in hearing about them.

THE importance of developing (or not developing) tolerance to DMT derives from at least two perspectives. One is the fact that the inability to generate tolerance to DMT in humans is one of DMT's strongest characteristics suggesting its role in spontaneous psychotic states. Recall that the discovery of DMT in human body fluids set off a flurry of investigations assessing whether it was involved in psychoses. If DMT does have a role in spontaneous hallucinations, and it were possible to develop tolerance to its effects with repeated and/or continuous exposure, then people would only hallucinate when tolerance was no longer in effect. However, that is contrary to clinical experience, inasmuch as people with psychotic illness often hallucinate continuously. Therefore, if we cannot develop tolerance, a role for DMT in mental illness would be supported. Secondly, the "tolerant state" is of great interest in the field of psychopharmacology. Why drugs "no longer work" when they used to is of practical importance in treatment of mental illness, understanding how psychoactive drugs (including alcohol, nicotine, cocaine, LSD, and others) work. Particularly with respect to hallucinogens, how a previously psychedelic dose of LSD could have no effect in someone with repeated exposure to the drug is a fascinating question for mind-brain researchers.

Our study will give the smallest dose of DMT four times, separated by one hour. We will gradually, in a small number of subjects, alternatingly shorten the interval to one-half hour if no increase or decrease in effect is seen with the low dose every hour. If no effect is noted with low dose every half-hour, we will try a higher dose every hour, then every half-hour, and so on, up to a possible high dose every half-hour. Enhanced effects of repeated dosing will be apparent with this systematic approach. Once we have found the right dose and interval, the full group of subjects will be in tolerance development, or lack thereof. In the unlikely event no tolerance is seen with repeated administrations, we might consider a slow continuous administration of IV DMT.

Psilocybin Study

Our last study of this three year project is an oral psilocybin dose-response study. This will be identical in nature to the original DMT study. A low and high dose of psilocybin will be given non-blind, to assess safety and comfort with the drug in the clinical research setting. Then, if subjects are still interested in participation, they will receive in a double-blind, randomized manner: placebo, high and low dose psilocybin again, and two intermediate psilocybin doses. Double-blind means that neither I nor the subject will know what particular dose is being administered that day. However, the pharmacist who prepares the drug will have this information if necessary. Randomized means that the order of dose or placebo is completely random. Blood for several hormones and psilocybin levels will be drawn throughout the day, and blood pressure, heart rate, body temperature, pupil diameter, and psychological effects assessed repeatedly. We are remodelling a room on the Clinical Research Center at the University of New Mexico Hospital, where all studies will take place, so as to provide a less "high-tech" atmosphere for the longer-acting psilocybin.

The majority of funds will go towards salary support for myself, a laboratory technician, and a psychiatric research nurse. In addition, first-year monies will go toward the syntheses of the psilocybin and remodelling of the research unit

(continued next page)

If any of you reading this have experience with repeated administration of DMT, I would be most interested in hearing about them.

One Foot in the Future: A Review and Conversation with Nina Graboi by Faustin Bray

Nina Graboi

HERE IS A PRIMARY SOURCE of historical documentation of the golden age of psychedelics. At 73, Nina Graboi states, "My past falls into two distinct parts; pre-psychedelic and post-psychedelic." For her life example, everyone interested in the MAPS newsletter will want to read this book.

Graboi supplies context; she escorts us down the political trail casting time capsule pebbles The pebbles form a foundation for thinking about what led up to those famous days, deeds and disasters of wonder surrounding the explosion of LSD on the human field.

We can't seem to get our fill of such nostalgic brew-ha-ha, and Graboi's enjoyable perspective is necessary information to the record. The way she came to see our beloved Timothy Leary, a leading figure in her book, "The man is like a leaf, I thought, so free, so easy; he is here to serve evolution in her hour of need, and not as I thought before I knew him, his ego." indicates comprehension of a bigger picture. Her eyes were not those of a young impressionable ingenue, to be swept away by a wave of free sex, drugs and rock-n-roll. On the contrary, we are respectful of her cautious, nay-saying reticence, her choices and her discriminating worldly point of view. Rather than clarify she refines the record. For example, she outlined the flow of the power of the decisions when the elitist Harvard based priesthood headed by Huxley and Heard, audaciously voted for the "sacraments" to be tools of the ivory towered philosopher and not beneficial to the ordinary person, and how that reverberated in the community at large. In contrast, she saw that the egalitarian pacifist trio: Leary, Alpert, and Metzner were convinced that the power of transcendent experience would remove the blinders which have kept us at eternal odds with each other. "A world where all humans have access to the mystical experience would be a world transformed, they believed." And forfeited their chartered academic careers standing by their beliefs.

Nina Graboi was senior member and chaired the Women in Psychedelics panel at the Bridge Conference, Stanford, 1991, and has joined the ranks of notable feminist philosophers, among many other things. *One Foot In The Future: A Woman's Spiritual Journey* recounts the voyage of her life and credits where she got her bright ideas. Graboi intertwines autobiographical recollections and philosophical reflections. It is much more than a list of harrowing adventures; more than a chronicle of transitions between momentous moments. The title of

(continued next page)

DMT...*(continued from previous page)*

room. A significant amount of money is provided for laboratory support for the Clinical Research Center Core Laboratory, for materials, supplies, and maintenance of the equipment, as well as developing a new means of measuring psilocybin in blood.

THE original grant application requested a fourth year of support to assess the role of menstrual stage, in women, on DMT's effects. That is, do DMT's effects differ, either in quality or quantity, depending upon which stage of the menstrual cycle a woman receives DMT? However, the review committee at NIDA did not believe this part of the study was scientifically nor clinically as sound as the other parts, and dropped it and the fourth year of support required to perform it.

We are extremely fortunate, here at the University of New Mexico, to have the opportunity to be involved in this renewal of research with hallucinogens in humans. Although not directly "therapeutic," this type of systematic work goes a long way in carefully describing what the effects of psychedelics really are in humans. Only then, I believe, can people's difficulties be approached by using these drugs in a manner in which symptoms or problems are matched to the effects of the drugs themselves. ■

her book captions the window on Graboi's life, which displays her gracefully spring beyond the imprisoning mental, physical, emotional, spiritual walls of patriarchy; the subconscious state of possession. She reveals herself and allows us to do likewise in the privacy of our own minds.

Childhood

The cozy home life that nurtured the author as a child, then named "Gusti Schreyer," was idyllic. Self described, "A dreamer; a romantic; an idealist; an intellectual snob; a culture sponge; a bookworm; a flirt. And an utterly naive, gullible and trusting child." The world was her oyster until she was cruelly initiated into the peer rites of passage practices at a girls' school of hard knocks. Everyone has their own version of this time but most of us put it in the debit column of our grown-up memory bank. Much to Graboi's credit she counts the trials as tuition for life's lessons and remains consciously pursuing the thread of her search for deeper meanings. Rudolf Steiner, Herman Hesse, Colette, H.G. Wells, Thomas Mann are among many such authors who stimulated Gusti's curiosity and provided a foundation for her later courageous explorations of the inner mindscapes and outer spiritscapes.

The book reads like a screen play, each scene/time accompanied with sound track as vivid as bombs dropping and distant waltzes. The reader is conveyed by the dense texture of life that transports the imagination through trials and adventures demanding extraordinary adaptability. Still today few "liberated" women can boast endurance of such hair raising episodes as this soft spoken person.

War

Her registration of the shock of swastikas sprouting from the rooftops, and the free rein of brutality in her elegant, sophisticated Viennese atmosphere introduces an early chapter in her odyssey. The surreality of the time is conveyed by little asides such as how she initially escaped from Nazi Austria with a lavish wardrobe and her mother's consoling words, "I hope and pray you'll find a good husband who can take care of you." The gift and the wish seem miraculous and slightly ridiculous from our vantage point of post *Diary of Anne Frank*. Unlike Anne, Nina and we have been rewarded for Gusti's clarity and perseverance with a happy ending. We cheer "Gusti," for her successes and for the generations to come that will have both Anne Frank and Gusti's interpretation of that tragic period in human herstory.

We are elegantly forced to confront the superficiality of our "New Age" 20th Century security seeking creature comfort loving narrow mindedness, our willingness to turn our backs on suffering people, and our pass the buck and bucket anorexic /bulemic society.

The challenges that Nina faces are essentially every person's challenges at different stages of maturation: Regarding today's pursuit of the illusory family values —Gusti's parents had to make the choice to send their child away from her anti-Semitic homeland like a note afloat in a bottle to uncertain safety abroad. Gusti's display of trust in her relationships, both as a refugee employee in foreign promise lands, and in her romances holds a promise of the keep on keeping' on attitude that our current hard times prescribe and that we categorically assume comes from a family with the "right" values. Gusti has astounding faith in experience as the best teacher. Whatever the catalyst, though, Gusti's approach to life was guided by an open heart and an ever inquisitive mind.

EVEN while escaping the war, Nina paid enough attention to her surroundings that we can time travel with her un-threatened but not desensitized to the disenfranchising of her people. Subtly, the author reminds us to be ever wary of indications of cruel political attitudes. She is careful with herself and her readers by giving us some of her most foreboding prison camp moments with the tricks she used to lighten. Characteristically, she writes of her insights at that time, "Suffering, whether caused by emotion or by the lack of food and shelter, is always equally severe."

Marriage

Gusti with her husband, Michel Graboi, finally made it to the safety of her siblings in New York to begin a new life. Here is when, by Michel's suggestion,

(continued next page)

"My past falls into two distinct parts; pre-psychedelic and post-psychedelic."

She offers a model for a vital female mature image and a map for the road to get there.

"Gusti" changed her name to "Nina" and her new identity emerges. Nina's transformative strife is tempered with witty self observations, such as, "There were women, even then who knew how to be more then just attractive females, but I was not one of them." We learn with her how to navigate through the stormy waters of liberation as a woman: developing her persona, gaining self-expression, confidence, and meaning through her struggles and triumphs in the sporting life of upper middle-class suburban New York. Her gossip surrounding her associates at the time, recognizable theatrical stars, lets us know all is not right in paradise. Pain is frequently associated with the path to wisdom, and she lets a little show through the glossed and cheery smile presented on the pages "The ladder of worldly success is not worth scrambling up," she existentially concludes after achieving the American dream of being envied for her beauty, charm, wit, house, family, and social status. She closes part two of the book at that juncture in the time of her life and entices us on with, "It was the beginning of a search that would last for the rest of my life."

Divorce

The steps toward independence from a 27 year marriage, at 47 years old, were much more extraordinary at that time then they would be today. As a divorcee, Nina bravely faced a different kind of fearful world and different attitudes than we know now. With that in mind we empathize with her feelings, ..."my thirst for the freedom to pursue my path increased steadily, and the intensity of my desire for self-transcendence was matched by my husband's desire to divert me from my goal." She persisted, moved out, and opened a lecture bureau. What followed was a star studded bevy of events that was one of the cradles of the enlightenment business that has since become an industry utilizing techniques more cut-throat sophisticated than the neighborhood used car lot strategies ever devised. Then and there on the frontier of the New Age industry were more innocent times with less barbed emotional push-me-pull-yous from bedroom communities to the first stop on the Lecture Circuit.

The well-meaning folks who mislead today's audiences to be folded, spindled and mutilated in the name of self improvement and empowerment had some of their modest beginnings in the 60's through Nina's bureau. While we dance to the ring of New Age Expo cash registers in the 90's we must appreciate Nina's authentic desire to make a living at meaningful employment in the style of the Buddhist philosophy of "right livelihoods." Comprised of a list of clients that included Alan Watts, Charles Tart, Peter Stafford, Paul Krasner, Yoko Ono, and advised by Abraham Maslow, The Third Force Lecture Bureau was functioning when an opportunity for Nina to meet already notorious Timothy Leary arose. The first question Nina posed to Tim: "Do you believe that humanity is taking a new step in evolution?" "I do. And I believe that the psychedelics are playing a crucial part in it." Tim succinctly replied. The belief that launched countless thousands of trips.

QUICK hops from Long Island family and theater production to the Lecture Bureau to the infamous Millbrook to The Center for The League of Spiritual Discovery, to the podium on behalf of the psychedelic revolution. "The main benefit I derived from the psychedelics is that they taught me that "I" am not my body but an evolving consciousness clothed temporarily in a body... When the ex-perience becomes integrated into your life, the fear of death disappears—and we can only truly begin to live when we no longer fear death." Nina espoused.

Just as ontogeny recapitulates phylogeny, so Nina's life's transitions seem to mirror a segment of society's mutations through the decades of mind altering, consciousness expanding adaptations as described by Nina' early paper *Evolution in Search of a New Bread of Man*, (she was not yet politically correct), and confirmed by the work of the dynamic trio of Leary, Alpert & Metzner. Notice, the 'ol micro- macrocosm stream of consciousness flowing through her life.

Woodstock

After the New York center came a boutique in Woodstock, a curio shop of occult and spiritual offerings as Nina's attention turned in the appropriate direction and she pied piped through Psychical research, Whitman, Ouspensky, Cayce, Bucke, Jung, etc. until Patanjali's *Yoga Aphorisms* struck a deep chord. "Patanajali tells us to believe nothing without first testing it. This was just right for me. It was the way I had chosen long ago, when I was still a child." Her mental open door policy had the gray-haired matron sampling the full array of exotic fare of the hippie plate at least once: from caravan tours, to bead making, nudity, home birth, the Rainbow Gathering, varieties of entheogenic libations like det, LSD, marijuana, mushrooms, to "one night stands," and noticing, "My age was honored but was no barrier." We vicariously are amused by some of the inconveniences when reading her candid descriptions following: "Their lack of inhibition in my presence was flattering, but it could lead to embarrassing situations."

Creation of another center followed: The Woodstock Transformation Center: "A school for those members of the Community who wish to become more aware spiritually, ecologically and creatively." The Center was the core of Nina's life's ambitions to be a facilitator for the spreading of knowledge about transpersonal states.

FROM princess to refugee to the family to fragile fame, as a women, wife adjunct to man-husband Nina's growing awareness of the inequities of the homocentric Adam and Eve myth and the attendant roles was by this time, augmented by Betty Freidan's *The Feminine Mystique*, and focused by her subjective experience. Now Nina favors Riane Eisler's interpretation of the balance of power. In her book, *The Chalis and the Blade*, Eisler proposes the revival of the partnership society, a model which Nina is gravitating toward rather then the imbalance of the male dominated position of our culture today.

The relevance of this timely book, reminding us of the baby boomers' promises of "everything is possible" while bearing the 60's optimism, and holding high the banner of change in the political wind, is undeniable. The gift is that Nina Graboi awakened on this planet and she is determined to make the best of it, rather then rest complacent in her wisdom, accomplishments and memorabilia. She has made the effort to press the juice from her past and make an offering to the future. She offers a model for a vital female mature image and a map for the road to get there.

For the Akashic Records: Nina Graboi gets my vote for President of the Psychedelic Community College, and *One Foot In The Future* to be number one on the reading list followed by John Lilly's *Programming and Metaprograming of the Human Biocomputer*, Tim Leary's *Neurologic* , Jay Stevens', *Storming Heaven* and Stan Grof 's, *LSD Psychotherapy*. ■

Faustin Bray acts as a media artist and contributes regularly to periodicals dedicated to educating the public regarding transformative technologies. She, with Brian Wallace, co-direct SOUND PHOTOSYNTHESIS, a media publishing and distribution company and is CO- Founder and President of the Association for Cultural Evolution, a not-for-profit corporation for the purpose of collecting, archiving, synthesizing and disseminating culturally relevant material. For a catalog write P.O. Box 2111, Mill Valley, CA 94942-2111, or phone (415) 383-6712.

One Foot In The Future: A Woman's Spiritual Journey
(Aerial Press, $18.95)

This book can be purchased from Aerial Press, POB 1360, Santa Cruz and from the SOUND PHOTOSYNTHESIS CATALOG by phone with credit card (415) 383-6712

Faustin Bray

WORLDS OF CONSCIOUSNESS
THE FIRST INTERNATIONAL CONFERENCE OF THE EUROPEAN COLLEGE OF THE STUDY OF CONSCIOUSNESS

by Richard Yensen, Ph.D. and Donna Dryer, M.D.[1]
Orenda Institute, 2403 Talbot Road, Baltimore, Maryland, 21216

What we consider remarkable about this conference is that it emerges like a phoenix from the ashes of past repression!

ABOUT 500 people attended a remarkable conference in Gottingen, Germany September 24-27, 1992. The European Conference for the Study of Consciousness, the sponsor of this gathering, was developed by some of the members of the old European Psycholytic Association. The original group was made up of pioneers in research with psychedelics as adjuncts to psychoanalytically oriented psychotherapy, its membership roster was a who's who of researchers in the late 50's and early 60's. In Europe as in the United States, psychedelic work fell on hard times in the 1970's. What we consider remarkable about this conference is that it emerges like a phoenix from the ashes of past repression! The College was founded in 1985 as a multidisciplinary forum for advancing research and exchanging experiences in the area of altered states of consciousness whether they stem from psychoactive substances or psychological methods. The disciplines spanned include chemistry, psychopharmacology, psychology, medicine, psychotherapy, ethnomedicine and anthropology.

I (RY) had the pleasure of meeting the founders of the College first in 1988. I met with these luminaries of the European scene in a tiny conference room in Frieburg. This first conference for me was a whirlwind of seasoned leadership from people like Hanscarl Leuner MD, Albert Hofmann PhD, C. Scharfetter MD and Jan Bastiaans MD, all guiding younger colleagues like Christian Ratsch PhD, Peter Hess MD and Rolf Verres MD. These folks were joined by the members of the Swiss Psycholytic Association , a group of seven Swiss psychiatrists who, in 1988, were just granted permission to use psychedelics in therapy buy their government, and an ever changing troop of graduate students from psychology, anthropology and other relevant disciplines.

These early conferences were an exercise in sensory overload with most presentations lasting between 15 minutes and 45 minutes and the schedule completely full from early morning to late evening. The work presented was of excellent academic quality and reminded me of a true University of Consciousness with graduate students presenting their work before an august faculty. The special element was always the combination of intellectual rigor and excellence with an orientation toward the study of consciousness, something I have rarely encountered at other conferences. These folks are more than cheerleaders for a new age, they are the dedicated researchers attempting to understand the real inner frontier that consciousness studies confront. By 1990, the room became a hall and attendance burgeoned to 200 people. It was decided that the time was right for an international gathering.

The most significant aspect of this year's meeting was that it accomplished its goal of going beyond conventional scientific exchange by informing participants about experiences concerning the different domains of consciousness and perception.

Pre-conference workshops offered people the opportunity to become acquainted with or deepened their experience with the influence of sound, music, dance, breathing, meditation and the imagination. Plenary sessions each morning consisted of expert panels discussing: Cross-Cultural Perspectives (with Albert Hofmann, Christian Ratsch and Marlene Dobkin de Rios); Scientific Bases (with Alexander Shulgin, Karl A. Kovar, and Alfred Maelicke); Significance for Psychotherapy (with Hanscarl Leuner and Ralph Metzner); and a final panel of all the College's founders and directors discussing Extraordinary States of Consciousness-Perspectives for the Future.

1 (Note: Richard and Donna have been approved by the FDA to conduct research into the use of LSD in the treatment of substance abuse — more on this is subsequent newsletters.)

Translation for these sessions was excellent and well organized for the plenary sessions and made it possible for real exchange among all the participants. Yet the translators could not be everywhere and most of the smaller afternoon sessions were only in German. The broad range of areas covered were: Experimental Psychology and Systematic Description of Altered States of Consciousness; Near Death Experiences and Out of Body Experiences; Prenatal and Perinatal Psychology; The Therapeutic Applications of Altered States of Consciousness; Traditional Healers, Ethnobotany; Music, Sound, Rhythm, Dance, Body; and On the Chemistry and Neuro-Biology of Psychoactive Substances. In some of these sessions we attended we found the caliber of the information was excellent and discussion was full and often intense. We participated by presenting a paper on the history of our psychedelic research team, *Thirty Years of Psychedelic Research: The Spring Grove Experiment and its Sequels.*

THE conference was a dialogue between the objective and subjective aspects of studying human consciousness that achieved synthesis in its best moments. An example of this was the music therapy session we attended one afternoon. The team of music therapists was advanced in their cross cultural integration of methods and techniques. They explained the underlying theory then gave us a spontaneous experience using gongs, didgeridoo, monochord, and tabla. This amazing integration included an example of Korean shmanic trance dancing by Hiya Park. This experiential panel was an example of how to integrate various approaches to altered states including the wisdom of understanding human development that psychoanalysis brings us while grasping the immediacy and depth offered by trance and shamanism.

An example of the difficulty in achieving a synthesis betwen the subjective and objective was illustrated to us by a PET scanning study about Ketamine HCL (see story on page 24). In the power of this new technology for observing the inner dynamics of cerebral metabolism, we found that our collegues seemed susceptible to the blindness of ignoring subjective experiences. There was much data presented on metabolic events as revealed by the differential emission of positrons, yet no report on the experience of the subjects. Were they terrified or transfixed, happy or sad? In this most enlightened arena we saw that it is still a challenge to combine awareness of consciousness as a variable with the collection and reporting of objective scientific data.

PARTICIPANTS were mostly from Germany and Switzerland but also from as far away as Brazil. The setting was a large hall of the University of Gottingen and was buzzing with continuing discussions between sessions. For many participants this conference was a very complete introduction to a field of study in its pioneering stages. For others it was a heart-warming reunion with many old friends. It made clearer to us how much work we (all of us interested in this field) need to do yet in developing tools to describe experiences that in our languages and cultures ar bring acknowledged once again as valid subjects for scientific study.

The larger questions of how to examine consciousness as a scientific field of knowledge that includes both subjective and objective worlds, and how to integrate this knowledge into our societies in a way to enrich our culture were discussed in the last session. The conference concluded with Dr. Hofmann's hope and vision for a culture informed and enriched by experiences and research in consciousness that surely will manifest in the world as peace.

Proceedings of the conference will be available. For information contact Michael Schlichting, ECSC, Judenstrasse 33, D-3400 Gottingen, Germany, Phone 49-551-484463. ■

The conference was a dialogue between the objective and subjective aspects of studying human consciousness that achieved synthesis in its best moments.

WORLDS OF CONSCIOUSNESS RESEARCHERS

by Rick Doblin, MAPS President

The ECSC is the unifying organization in Europe for psychedelic researchers

IN MY CAPACITY as president of MAPS, I had the pleasure of attending the first international conference of the European College for the Study of Consciousness (ECSC) in late September, 1992. The conference was held in the small University town of Gottingen with its ancient churchs and elevated walls and wooded paths encircling the inner city. Rather than describe the conference itself (see related story on page 14), I will discuss instead what came out of the conference for MAPS.

To distribute to the conference attendees, I brought 500 copies of the latest MAPS newsletter reporting the good news that the FDA Drug Abuse Advisory Committee had specifically recommended that MDMA research in humans be approved and that psychedelic research in general be resumed. This news, I hoped, might help researchers around the world to negotiate successfully with their governments for the resumption of comprehensive psychedelic research.

In a series of conversations I had with Dr. Hanscarl Leuner and Michael Schlichting, conference organizers and founders of the European College, it became clear to me that government regulators in most of Europe were unwilling to approve MDMA research until the FDA had approved human studies in the US. In the only country where limited psychiatric use of MDMA research is approved, Switzerland, political support is weak (see pages 21-23). It also became clear to me that the ECSC is indeed the unifying organization in Europe for psychedelic researchers and that Michael Schlichting and Dr. Leuner had both the depth of experience and the well-earned respect of their colleagues to successfully coordinate the conference as well as the efforts of the researchers to get back into their laboratories to study how psychedelic research could help in understanding the human mind and soul.

Because the FDA has finally permitted human studies with MDMA (see protocol on pages 2-3), MAPS is now in a position to make a uniquely valuable contribution to members of the ECSC interested in securing their government's permission to conduct MDMA research. MAPS' contribution is one that only a non-profit organization would consider, since it involves giving away its most valuable asset in the attempt to stimulate MDMA research in other countries. Because MAPS is not a profit-making corporation with proprietary interests to protect, and because MDMA research in other countries will help to build the data base necessary to eventually secure FDA approval for prescription access to MDMA, MAPS gains by giving away monopoly ownership of its MDMA toxicity studies.

For those of you new to MAPS, or for those who don't recall what I am talking about, I am referring to the 28-day multiple dose MDMA toxicity studies in the dog and the rat that MAPS used in 1986 to open an FDA Drug Master File for MDMA. Today, the studies would cost about $100,000 to duplicate. Data from the studies is owned exclusively by MAPS and only those researchers who specifically get MAPS' permission may use the data as part of their applications to the FDA to conduct human trials.

THESE STUDIES were a prerequisite to the FDA's consideration of Phase 1 studies (preliminary evaluation of safety in humans) and Phase 2 studies (preliminary evaluation of efficacy in humans). Because of FDA's concerns over neurotoxicity, MAPS' toxicity studies were not sufficient to secure FDA approval for human studies even though they showed no evidence of neurotoxicity. It took seven years of MDMA neurotoxicity research, funded by millions of government dollars, and an additional, strategically directed $100,000 from MAPS, before the FDA was willing to approve the first study of MDMA in humans. MAPS' toxicity studies were neccesary but not sufficient to secure FDA approval for MDMA research. In many countries, regulators require similar data.

A very important decision for MAPS emerged from the conference. Once I finally understood the role of the ECSC, and saw what a remarkable organization it was, I decided to give it an FDA-certified copy of the contents of the data in the MAPS Drug Master File as well as

legal rights to the use of that data. The ECSC is being assisted by MAPS to catalyze MDMA research in Europe and is given a head-start in developing a data base that it might use to have MDMA declared a prescription drug in Europe. In return, the ECSC is asked to inform MAPS about data generated by European studies. As soon as MAPS receives from the FDA a certified copy of the contents of our Drug Master File, I will forward the paperwork to Dr. Leuner and Michael Shlichting and they will begin the attempt to assist scientists to conduct MDMA research in Europe.

The researchers in Germany who seem most likely to conduct MDMA research are Drs. Euphrosyne Gouzoulis of the Department of Psychiatry on the Medical Faculty of the RWTH in Aachen and Dr. Leo Hermle of the Department of Psychiatry at Christophsbad in Goppingen. They have conducted rigorous studies into the physiological and psychological effects of MDE, the results of which will be reported in the next MAPS newsletter. Their studies were conducted before MDE was scheduled in Germany. Now that MDE is scheduled, the lack of preclinical animal studies hinders further research. Sasha Shulgin and I suggested to them that MDMA is subtlely but profoundly different than MDE, and therapeutically more useful, and we encouraged them to seek approval to investigate it.

Dr. Franz Vollenweider of the University of Zurich is a Swiss medical researcher who spoke at the ECSC about his work conducting PET scans of people under the influence of ketamine and psilocybin (see page 18-20). Hopefully, he will eventually get permission to conduct PET research with MDMA. Also in attendence was Dr. Hans-Jorg Helmlin, a researcher at the University of Bern who was planning to conduct an MDMA pharmacokinetics study in two patients in mid- October. Dr. Helmlin had previously looked for MDMA metabolites in human urine and was going to follow up that research with an investigation of blood samples. Dr. Helmlin's research will help guide Dr. Grob's Phase 1 MDMA study in that we will take blood samples at the time of the peak concentration of MDMA metabolites, as first determined by Dr. Helmlin. I also met Ulrike Drews, a Swiss Ph.D. student in clinical psychology who is considering doing her dissertation on the use of MDMA and LSD by Swiss psychiatrists (see story on pages 21-23). I gave Ulrike a copy of the MAPS protocol for the use of MDMA in the treatment of pain and distress in end-stage cancer patient; we hope to confer on research design and methodology issues.

TWO observations about terminology. The Europeans seem to have wholeheartedly adopted the idea that MDMA and MDE are part of a new class of drugs and that the word to describe that class is "entactogen", created by Dr. David Nichols of Purdue University to mean "to touch within." Personally, I applaud this idea. I prefer "entactogen" to the alternate term "entheogen", meaning "to reveal the god within", which ignores the role of set and setting in creating the drug experience and the potential of these drugs to catalyze problematical, unpleasant experiences. I also prefer "entactogen" to "empathogen" which is too positively loaded to be scientifically precise. The second linguistic issue was that the European researchers often spoke about psychedelic experiences as "model psychosis," a term that deserves abandonment along with the term "hallucinogen", since however politically expedient those terms may be they both imply that psychedelic experiences can be discounted as crazy and distorted. The word "psychedelic", meaning "mind-manifesting", is still the best.

Above all, the ECSC conference demonstrated the critical importance of international cooperation in psychedelic research. The conference was extraordinarily successful and may be followed next year by a smaller meeting on research methodology. ■

MAPS is giving the ECSC legal rights to its FDA MDMA Drug Master File

New Avenues in the Search for Biological Correlates of Altered States of Consciousness – From Model to Practice

by

Dr. med. F.X. Vollenweider, University of Zurich Psychiatric Hospital Research Department (Director: Prof. Dr. med. J. Angst) Box 68, CH-8029 Zurich, Switzerland

NOTE TO READERS: Dr. F.X. Vollenweider obtained his MD from the University of Zurich in 1986 and did a thesis in the field of experimental neurotoxicology at the Institute of Toxicology of the Swiss Federal Institute of Technology and the University of Zurich (1982-1986). From 1987-1989 he served as a Research Assistant in neurobiology at the Brain Research Institute, University of Zurich, particularly in the field of the neurochemistry and neurophysiology of the NMDA receptor. Dr. Vollenweider has been engaged at the PUK, Zurich (Burgholzli), since April 1989 and has been trained in Psychiatry and undergone 6 years of Freudian psychoanalysis. In addition to clinical work Dr. Vollenweider has also been actively concerned with basic research in the neurobiology of schizophrenia. In particular, since 1990 he has been responsible for the initiation and performance of the ongoing PET projects at the PUK. 1991 Dr. Vollenweider earned the "Twinning Grant 1991" (an achievement grant) given by the Swiss Society for Biological Psychiatry for his outstanding PET-project on model-psychosis.

In 1990 I initiated the PET project, "Brain energy metabolism in human experimental psychosis."

The Burgholzli-Tradition in Psychedelic-Research

For more than half a century, research work in the field of hallucinogens and related substances has been conducted at the Psychiatric University Hospital in Zurich. In 1926, Maier presented a monograph on cocainism [1]. In 1932, Wertham and Bleuler studied Rorschach-tests of volunteers who had taken mescaline [9]. In the late 1940's, Stoll [13], together with Condrau [8] did some clinical trials to study the effect of LSD-25 on schizophrenics.

More recently, as Professor J. Angst's directionship of the research department was established, the very real problems experienced by youngsters when they take hallucinogens and related drugs motivated us to continue the department's research in this field [2,11].

Dittrich initated and performed a series of studies to investigate with standardized methods (APZ) the psychic efffect of cannabinoids, dimethyltryptamine (DMT), psilocybin, nitrosoxide (N20), and nonpharmacological inducers of altered states of consciousness (sensory deprivation) in healthy volunteers. His work led to the publication in 1985 of a monograph on altered states of consciousness (ASC) demonstrating by dimensional analysis and algorithms of classical theory of mental testing that the main themes (content clusters) of ASC are three (oceanic feeling of merging with the cosmos, fearful ego-disintegration, perceptual changes of surroundings) and that they arise independent of the inducing technique [4,15]. Ego-disorders and perceptual changes are especially prominent features of psychedelic states as well as of "endogenous" psychotic states. Scharfetter developed an internationally accepted operationalization of the most important psychopathological terms [3]. He further developed and studied empirically a new differentiated approach to the psychopathology of schizophrenia [5]. He published about the differential diagnosis of hallucinations under various conditions [6] and presented a book entitled "Observations and Reflections on Delusions and Altered States of Consciousness" (1990, in print).

In 1990, I have been the motivating factor for the initiation of the PET project "Brain energy metabolism in human experimental psychosis" as described below [7,17].

"Chemical scalpels" for exploring the human mind

Hallucinogens and related drugs are remarkable "chemical scalpels" for exploring the human mind. They are useful laboratory tools in the study of the neurochemical changes associated with altered states of consciousness, variously experienced as psychotomimetic, psychedelic or mystical states.

Thus far, the analysis of psychedelic drug actions has been one of the most effective approaches to generate heuristic biochemical hypotheses underlying experimentally induced psychopathological conditions ("model-psychosis"). However, little attention has been paid to holistic neurophysiological explanations of psychedelic experiences.

This failure has both conceptual and methodological bases. The conceptual basis relates to the foundation of a biological theory of consciousness, insofar as the foundation of such a theory is restricted to inherent metaphysical issues, such as ontological and epistemiological constraints. However, the development of a physiological model of altered states of consciousnesss which is based on correlations between mental and neuronal activity is not beyond scientific methodology.

In this respect, the recent development of functional neuroimaging techniques such as the position emission tomography (PET) allows scientists to investigate neuronal activity throughout the brain by measuring brain energy metabolism in vivo in man . This approach brings together the disparate lines of neurochemistry, neurophysiology and psychology.

Research strategies to investigate biological correlates of altered states of consicousness using hallucinogens and PET (Positron-Emission-Tomography).

In 1990, the Psychiatric University Hospital (PUK), Research Department and the Paul Scherrer Institute (PSI), PET unit (Head: PD Dr. K.L. Leenders), have started a project to investigate the intra-individual effects of amphetamine, ketamine, and psilocybin on cerebral energy metabolism in a group of selected healthy volunteers. The practise and theory of "model-psychosis" as employed at the PUK is used as an experimental paradigm of schizophrenia. Brain energy metabolism is measured using PET and the radioligand [18-F]-fluorodeoxyglucose, a technology used on a routine basis at the PSI. The experimental protocols have been approved by the University Ethics Committee while the use of psychoative drugs has been approved by the Swiss Federal Health Office, Department for Pharmacology and Narcotics, in the Swiss capital city of Berne.

The psychoactive drugs used in this study are of paramound interest because they interfere with distinct neurotransmitter systems thought to be disturbed in schizophrenic psychosis. Amphetamine interferes predominantly with the catecholaminergic, psilocybin with the serotonergic and ketamine with the glutamanergic neurotransmitter systems. Moreover, during recent years schizophrenia research using PET technique has emphasized absolute or relative decreased metabolic activity in the frontal cortex (hypofrontality), while other PET-studies could not confirm this so-called hypofrontality but instead demonstrated bilateral hyperfrontality, hypertemporality and lateral asymmetries of glucose utilization. Hyperfrontality in acute and subacute schizophrenics seems to be associated with positive symptoms. However, whether these metabolic changes are a consequence or a cause of schizophrenic symptoms is not clear.

Therefore it is crucial and fundamental to know to what extend mental activity under psychotomimetic or psychedelic conditions contributes to cerebral metabolic changes.

Thus the first aim of the study was to investigate which brain regions metabolically respond to specific pharmacological stimulation under psychedelic conditions. A second aim will be to elucidate complex interrelationships between cerebral metablic changes and psychopathological alterations. Moreover, it is important to compare the metabolic data ("patterns") obtained from these "model psychoses" with the results of metabolic PET studies of schizophrenic patients. And last but not least, we think that such investigations will be decisive in the foundation of biological models of altered states of consciousness.

Outlook

A cortical-subcortical model of sensory information processing, the "complex-loop" model (CSTC-loops), is advanced to interpret psychedelic drug actions (for details see [7,16]). According to this model, psychotic and psychedelic symptoms may be produced by blocking neuronal information flow within cortical-striato-thalamo-cortical feedback-loops (CSTC-loops) resulting in a cortical overload of information, especially of the frontal cortex.

Indeed, our PET-data analysed so far indicate that ketamine and psilocybin induce different metabolic "patterns," but that both drugs dramatically stimulate

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...the recent development of functional neuroimaging techniques such as the position emission tomography (PET) allows scientists to investigate neuronal activity...

...our PET-data analysed so far indicate that ketamine and psilocybin induce different metabolic "patterns,"

glucose utlization in the frontal cortical regions (for details see [10,12,14]). This "hyperfrontality" corroborates the PET-findings as seen in acute hallucinating persons hospitalized for the first time with the diagnosis of schizophrenia, but stands in contrast to the observed "hypo-frontality" of chronic schizophrenics. Whether or not this "hyperfrontality" is a common feature of psychedelic mental states and acute hallucinatory phenomenons as seen in schizophrenics remains open for further investigations.

The difference between ketamine and psilocybin is rather complex. Psilocybin significantly stimulates glucose uptake in the frontal and occipital brain regions only in the right brain hemisphere while ketamine does so in both hemispheres. Similarly, the insula, a part of the brain that is involved in language and hearing, is stimulated in both brain sides only under ketamine. A common characteristic of both drugs may be the disruption of the frontal-to-ventral striatal metabolic gradient, and a right brain side hyper-frontality.

Under subanesthetic conditions, ketamine blocks the NMDA receptor (glutaminergic neurotransmission) which seems to be involved in psychotic processes such as schizophrenia. And if there is a difference between ketamine and psilocybin induced effects, it is important because psychedelic experiences are not simply psychotic processes. ■

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THE ENTHEOGEN REVIEW- A NEW NEWSLETTER

Jim Dekorn is putting out *The Enthogen Review* "to keep people abreast of the latest information concerning the shamanic use of entheogenic ("to reveal the God within") plants. It will be published quarterly — on the solstices and equinoxes — and will comprise a clearing house for hard-to-find empirical data... I am writing a book on this subject and therefore it serves my purpose to edit a periodical devoted to it... The season is long overdue to shed a little light on this topic and seperate a few facts from what appears to be limitless mythology... The price of a one year subscription is twenty dollars with a refund of the unused portion of your subscription available on demand. (That's five bucks a copy for information you'd be hard pressed to find synthesized anywhere else— I know because I've looked.) The first issue will summarize some of the data on ayahuasca analog plants." To get the newsletter, send $20 to James B. DeKorne, editor, *The Entheogen Review*, P.O. Box 778, El Rito, New Mexico, 87530

The Political and Psychological Dynamics of Psychedelic Psychotherapy in Switzerland

by Dr. Med. Juraj Styk, Birmannsgasse 39, 4055 Basel, Switzerland

I BELONG TO THE GENERATION of Czechoslovakian psychiatrists who had access to LSD in the sixties. As Drs. Grof and Dytrich stated in their 1964/1965 report on the Prague Psychiatric Research Institute, the experience of the so called "model-psychosis" evoked by LSD is of great educational value for residents and staffs of psychotherapeutic departments.

At the clinic where I used to work at that time, some favourable circumstances enabled me to take part in and conduct LSD sessions with volunteers. Not long after that I was able to have my own LSD experience. After a short stay in the Research Department I got my LSD ampules. Before my emigration to Switzerland in 1968 I returned a large part of them. I lost contact with psychedelic ther-apy, was trained in Freudian analysis, later in Gestalt therapy and became interested in body-oriented psychotherapy.

Beginnings

Quite unexpectedly, in spring 1985 I received — together with all 800 or so other Swiss psychiatrists — a request with a questionnaire from a colleague, asking whether I would be interested in hallucinogen-supported therapy. In December 1985 more than 20 doctors met in Bern and founded the Swiss Medical Society For Psycholytic Therapy. There for the first time I met Samuel Widmer, who had been engaged with the Federal Health Office (FHO) in an ongoing struggle to get permission to work with LSD. Later he stated in his book *Listen into the Heart of Things:* "Not much can be done about the rigid structures of bureaucratic departments and about the hostility of the psychiatric community. Despite such structures a lot becomes possible as soon as somewhere a relationship arises."

The first presentation of our research work with MDMA was in Germany in 1988, at a conference of the European College for the Study of Consciousness (ECSC) organized by Professor Leuner. At this conference, Drs. Baumann, Roth and Widmer were able to report about our work in different settings. I reported about experiential group therapy and a year after that about LSD therapy with a terminal cancer patient, and I tried to evaluate the results of psycholytic treatments. Our efforts were worthwhile: five members of the Board of our Society received special permits from the Swiss Government to work with MDMA and LSD while one member — a director of a psychiatric hospital — still had his permission from the seventies. The medicine capsules could legally be ordered at a pharmaceutical institute. Widmer wrote in 1989: "It seems that granting us special permission is like a domestication attempt. If the dangerous potential cannot be suppressed, it should at least be controlled by a specially trained elite that safeguards it."

I will give you some information about the group process and our settings. As psychotherapeutically oriented psychiatrists, we knew that we needed to learn by self-experience. First we used to meet three times a year, later on twice, for a self-experience weekend. We decided that every participant of the self-experience group had to write a diary-like journal with the following items:

- personal condition in the week before the self-experience group and our preparation for the session
- the trip (how the ritual, the meditative, and the interactive part was experienced)
- the effects in the following days/two weeks.

The journals were photocopied and sent off to all participants. The majority agreed with this arrangement. There were personal journals from which we could gain a lot of information and knowledge. Some of the journals were withheld and it was perceivable that the writer struggled with fear and distrust. Apart from that, there were sessions of the research group, intervisions and a supervision by Stan Grof. I remember best the board-sessions at which

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there used to reign a friendly atmosphere where we openly discussed our conflicts and gathered strength for the difficult negotiations with the authorities. Our medical society had elected a president and a cashier as it is common in every club but right from the beginning it was a leaderless group in which the group dynamic processes — for instance who has more power — were difficult to clarify.

Differences

The "adult" side of the doctors made us resist the anxiety, the loss of control, power and the feeling of helplessness. We could hardly afford the regression work promoted by MDMA which is so useful for our clients at the beginning of their psycholysis. We reacted in splitting, repression and isolation of the anxiety and this compelled us to stubbornness or power-games. This was caused by our different theoretical opinions, approaches, and experiences. The fascination of the MDMA effect opened the hearts of affection for others but it also strengthened our impatience and tendencies of greed in the moments in which inward sight and voluntary discipline would have been more important than "creative chaos." Looking back at the development of our association I think we haven't worked hard enough on dependency, separation, autonomy, and reproachment issues and therefore couldn't strengthen the unity of the group. As we were aware of separation tendencies as a symptom of resistance, we tried to be more caring during the sessions, especially if someone was stuck in Grof's Basic Perinatal Matrix II (feelings of no way out) or III (feelings of death and rebirth). We gave more structure to the sessions and arranged for somone to lead an opening ritual and chose special music.

NOT only information about the favorable effect of MDMA in couples but also personal experience made it suitable to open the group for the partners. The group became larger, rivalries and jealousy more hidden and difficult to manage. The journal of the session remained the only source of information when there was no personal contact between the participants. Younger colleagues become interested in our work and applied for membership in our association. It was necessary to offer an educational training and to organize the self-experience in two groups. In January 1990 the "old" members attempted to solve the interpersonal conflicts in a drug-free session. The situation was complicated. On one hand we felt that we were on the right path to open the hearts, to face fear and to make friendships, on the other hand some injuries were not healed, the pain of not being understood less exactly observed. There was a disagreement about the structure of the sessions. Some reproached that they were missing the necessary care in working with the substances. On the other level we realized that due to this development we felt more empathic, intuitive, witty, and self-confident in our professional as well as in our private lives.

The fruitful time of our work lasted 4 years during which we learned a lot about the transpersonal dimension of being by reading Ken Wilber and others. For our work it was very important to learn about the pre-trans confusion.

Crisis

In the summer of 1990 the Federal Health Office (FHO) used an opportunity to withdraw all our licenses because a patient — where a similar substance Ibogaine had been used — died under circumstances with which we were unjustifiedly connected. As Widmer noted "This all appeared as a good occasion to help the unwished psychotherapy — the undesired child — to abort. The new fights with officials, bargaining for conditions and new permits, the obstructions and limitations were not the

only challenges to be faced. The effect of the media caused a libel campaign, the envious colleagues showed their real faces and cowards turned away. The spirit of our association slipped into the old structures of so-called "emotional plague", according to Wilhelm Reich. The lively exchange and love disappeared. Structures, rules, regulations, papers became important so that finally it was hardly perceivable that originally the main concern was to liberate the lively present moments from these elements."

AFTER the withdrawal of licenses the energy flowed into the fight with the FHO. Four of us appealed to the Ministry of Interior. We managed a hearing at the FHO and were able to negotiate with a relevant lawyer. Again it was proved that personal contact and persuasive arguments can result in success. After tough negotiations, supported by a self-organized Ethics commission, we succeeded in renewing permits with harder conditions at least until the end of 1993. Our appeal was accepted, it was partly confirmed that we were treated unjustly. The patients whose therapies without psycholytic substances made no or only small improvements have been able to participate in psycholytic sessions since October 1990. The substances which we have sent to the government were replaced again. We were obliged to report to the FHO the therapy results with the patients' initials and diagnosis. Two M.D.'s will conduct theses on our work under the auspices of Professor Scharfetter. In the first thesis the journals of the sessions of our patients will be evaluated, in the second those of my patients whose therapy was carried out and finished between 1988 and 1989 will be interviewed.

Clinical Research

Due to everyday's hard work, for us as practicing psychiatrists there remains little time and energy for research. Yet clinical research is necessary for the professional development of our work. However, the research in practice should above all serve the patients. Yet we are required to carry out research according to international clinical standards. We cannot imagine working in a spiritual way with double-blind placebo controlled studies or while conducting blood-, urine-, or liquor-tests during the sessions. The scientific consultant who will supervise us expects us to work on a prospective clinical study with a standardized diagnosis and narrow inclusion and exclusion criteria. Therefore I am interested to find the way out of this dark forest. What kind of psychotherapy testing methods are reasonable? The major question is: "What is demanded from my patients? What helps us politically (nationally and internationally) without disturbing the therapeutic relationship." To obtain new licenses we are our previous situation. The officials have no confidence in us and try to exhaust us with never ending "homework." As soon as we fulfill the new tasks we may get new regulations again but we still hope to get the permits if the government doesn't present us with international restrictions.

It is important to prove that LSD and MDMA are effective in psychotherapy and should not be put in the same schedule with hard drugs. We will try to get in personal touch with FHO.Our personal and transpersonal experiencse with the assistance of psycholytic and psychedelic therapy cannot be erased. The experience with our patients proves the sense and benefit of this work..

Note: The members of the Swiss Medical Society For Psycholytic Therapy will meet on January 15, 1993 to review new research protocol designs prior to submitting them to the FHO for review. ■

After tough negotiations, supported by a self-organized Ethics commission, we succeeded in renewing permits with harder conditions at least until the end of 1993.

KETAMINE PSYCHEDELIC THERAPY (KPT) OF ALCOHOLISM AND NEUROSIS

by EVGENY M.KRUPITSKY M.D., Ph.D.
Chief of the Research Laboratory Leningrad Regional Dispensary of Narcology
Novo-Deviatkino 19/1, Leningrad Region 188661, Russia

We began to use ketamine for alcoholism therapy in 1985. At that time, we did not know very much about psychedelic therapy. So at the beginning of our research we put an accent on making suggestions for sobriety during the ketamine session, on personality oriented psychotherapy (to resolve personality problems), and also on the association between negative emotional experiences during the ketamine session with the smell and taste of alcohol (aversive conditioning aspect). We supposed that ketamine would give us an opportunity to direct our psycho-therapeutic influences and suggestions to the deep subconscious levels of the psyche which would help us to make our alcoholism therapy more effective. But than we found out that our patients often had deep mystical and transpersonal experiences during the ketamine session. At the same time we received some excellent books and articles on psychedelic therapy and transpersonal psychology. Both of these circumstances led us to change our KPT paradigm and we began to use a more existentially-transpersonally oriented paradigm.

All psychedelic drugs were forbidden for use in Russia in the 1980's. However, ketamine was allowed for use in anesthesiology for general anesthesia. Nevertheless, it was necessary for us to receive special permission from the Pharmacological Committee for ketamine psychedelic therapy of alcoholism because we were going to use ketamine for another indication than anesthesiology. It was not so easy but eventually we got permission for ketamine psychedelic research.

We began to use ketamine for alcoholism therapy in 1985. At that time, we did not know very much about psychedelic therapy.

First Stage

Three main stages in our method of KPT can be distinguished. The first stage is preparation. In this stage, preliminary psychotherapy is carried out with patients. During these psychotherapeutic sessions it is explained to the patient that the removal of their dependence from alcohol will be induced in a special state of consciousness in which they will have deep experiences that will help them to realize the negative sides and results of alcohol abuse, and the positive sides of sobriety. Such realizations and sharp experiences of the negative aspects of alcoholism and the positive sides of sobriety will cause a subsequent psychological unacceptability of alcohol abuse and a stable orientation towards sobriety. We also explain to the patients that during the psychedelic session important insights concerning the meaning and values of their life and their personality's problems will take place which will be very auspicious for their new sober life.

Second Stage

The second stage is KPT itself. During this procedure aethimizol (1.5% 3 ml, i.m.) is injected into the patient and after this bemegride (0.5% 10 ml, i.v.) and then ketamine. We use ketamine doses from 2 - 3 mg/kg, i.m. Bemegride being anxiogenic enhances the negative emotional experiences and visions produced by ketamine, and aethimizol promotes the stable fixing of experiences in long-term memory. Moreover, both of these drugs (aethimizol and bemegride) are analeptic drugs which enhance cortical activity and thus widen the opportunities for psychotherapeutic dialogue with the patient during the ketamine sessions. In the last several months we have begun to prescribe a central calcium channel antagonist (nimodipine) before the KPT session to improve the patient's memory about their psychedelic experience because it was shown that calcium channel antagonists reverse the memory disturbances produced by ketamine in rats.

With a background of special music, the patient having a KPT session is exposed to psycho-therapeutic influences. The content of these influences is based on the concrete data of the patient's an-amnesis [case history] and is directed toward the resolution of the patient's personality problems and toward the formation of a stable orientation towards sobriety. We try to create a new meaning and purpose of life in our patients during this session. The specific character of our KPT method allows us to carry out a special psycho-therapeutic

dialogue with the patient undergoing their psychedelic experience. We emphasize the positive values and meaning of a sober style of life and the negative aspects of alcohol abuse during this dialog which has a specific personal orientation for each patient. The second stage of KPT is conducted by two physicians, a psychotherapist and an anesthesiologist, because some complications and side-effects (such as: increased blood pressure, convulsions, stoppage of breath) are possible though exceedingly rare.

Third Stage

In the third stage, group psychotherapy is carried out with the patients taking KPT the previous day. During this session the patients discuss and interpret the individual personal significance of the symbolic content of their psychedelic experience with the psychotherapist. This discussion is directed toward helping the patient make a correlation betwen their psychedelic experiences with their personality's problems and with the problems of their life (first of all connected with alcohol abuse), and thereby to a realization and solidification of their desire for a new sober life. We are also trying at this stage to help our patients to accept new attitudes to one's self and the world around them, new values, and a more spiritual world view produced by the ketamine psychedelic experience.

The KPT was carried out in 86 alcoholic male patients at the end of their three-months of in-patient treatment in our hospital. All patients wished voluntarily to take this therapy and gave their written consent for this treatment. The control group consisted of 100 alcoholic male patients who took the same course of treatment with the traditional methods in the same hospital. There were no significant differences between the experimental and control groups either in the age or in the severity of alcoholism.

According to the data from a follow-up study of patients taking KPT, total abstinence for more than one year was observed in 60 subjects (69.8%). In the control group, sobriety for more than one year was only observed in 24 patients (24%). Thus, the data from the follow up study testify to a considerable increase of efficiency of the alcoholism treatment owing to KPT.

We try to create a new meaning and purpose of life in our patients' personalities during this session.

Results

According to MMPI data, our analysis of psychological changes in the experimental group testifies to a definite, rather expressed dynamic in the patient's MMPI profiles. Particularly, after the KPT the indices were decreased for the majority of the main MMPI scales. The most expressed, statistically significant decrease in the profile was in the scales "hypochondria", "psychostenia" "schizophrenia" and also in Taylor's scale of anxiety. On the whole, such favorable psychological dyanimics testifies to the fact that the patients became more sure of themselves, their possibilities, their future, less anxious and neurotic and more emotionally open after KPT.

A Subsequent Study

In our subsequent study we investigated changes in the psychosemantic domain induced by KPT. The study used the data from 32 alcoholic in-patients treated by KPT in our hospital. All patients were examined by the personality differential test (PD) (a personality oriented version of Osgood's semantic differential) and also by the color test of attitudes (CTA) before the treatment and after it.

Both PD and CTA were organized in such a way so that one could define peculiarities of the alcoholic patients' personality attitude systems. The combination of PD and CTA allowed us to assess to a certain extent changes of attitudes which occured both at the conscious and subconscious levels after KPT. Using these tests for the above purpose allowed us to analyze the following spheres of a person-ality's relations: the relation to oneself, to one's close relatives, to the ideal image of self, to a psychotherapist and one's own alcoholic disease, to the images of "Me sober" and "Me drunk". CTA were performed in the following way: at first a patient was requested to arrange 8 colors of Luscher's test in order of correspondence (similarity) to each of the above-mentioned images. In conclusion, he was requested to arrange the same colors in order of preference (by the preference degree). After that, to

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assess the attitude to the definite image two allotments were compared. In the first one the patient arranged 8 colors of Luscher's test in the order of correspondence to the image: for the "most similar, suitable" to the "most different, unsuitable"; as for the second allotment (the same for all images) the patient arranged the same colors in the order of preference.

Results

The analysis of the CTA results revealed that after KPT there occurred significant positive changes in the nonverbal emotional attitude to a psychotherapist, close relatives, to the ideal image of self, and to the image "Me sober".

At the same time, the attitude to the image "Me drunk" became more negative; in respect to alcoholism there occurred certain negative changes. The attitude to the person himself before treatment was hardly changed at all. According to the PD data, significant positive changes occurred after KPT only in respect to the attitude toward the person himself.

After KPT there occurred a considerable decrease in differences between the indicies of CTA and that of PD in respect to the same images. This decrease evidenced the reduction of the difference between the verbal (realized) and nonverbal (unrealized) assessments of personal attitudes. Such reduction was mainly related to the change in the CTA indices and appeared to be the strongest for the sphere of attitudes to a psychotherapist, relatives, the image "Me sober" and the ideal image of self.

Thus, the KPT produced considerable and significant positive changes in the domain of personality attitudes, which took place due to the transformation of nonverbal (unrealized) emotional attitudes.

One should also underline the fact, that according to the CTA data, there occurred strong positive changes in patients' nonverbal (unrealized) assessments of the attitudes to a psychotherapist, close relatives, to the image "Me sober", and to the ideal image of self. This means that the patient has internally grown to emotionally accept these images and, in its turn, the attitudes to sobriety connected with them.

the KPT produced considerable and significant positive changes in the domain of personality attitudes, which took place due to the transformation of nonverbal (unrealized) emotional attitudes.

A special note should be made of the discrepancies between the verbal and nonverbal estimates of a patients' personal attitudes registered before KPT. These discrepancies, obviously, reflect the presence of an essential discord between the conscious and unconscious estimates of a personality's attitudes. Such discord may give rise to psychological discomfort, internal tension, to difficulties in the communication with the environment, i.e. to the reduction of a person's adaptation, which after all leads to the alcholism relapse. Therefore, the reduction of such discord due to KPT should be considered as an achievement of a personality's psychological status which favors sobriety.

It is important to note that the reduction of differences in verbal and nonverbal assessments of a per-sonality's attitudes which occurred due to KPT may be considered to result from the realization of a personality's repressed main internal conflicts and negative aspects of concepts of one's "Self" in one's mind during the KPT procedure.

Thus, this complex psychological research shows that KPT results in a correction of the personality of alcoholic patients which promotes sobriety. Regarding that correction, the processes occurring at the unconscious level play a considerable role in it.

Content Analysis

We also carried out content-analysis of psychedelic experiences written down by our patients after their KPT sessions. These descriptions often had common plots: the feeling of separation of consciousness from the body, losing of the sense of "Ego" and self control, one's self ("Ego") death and rebirth experience, the journey of consciousness in strange multidimensional bright "holographic" other worlds, the complex "oceanic" sense of being dissolved and united with the Universe, encounter with God or Higher Power, etc. But it is necessary to note that in spite of the presence of common plots in patients' experiences, they always were individually specific, reflecting in direct or symbolic form the patients' specific personality problems.

Analysis of the data of content-analysis and MMPI scores revealed statistically significant correlations

between the scores of some MMPI scales and the character of psychedelic experiences. It is possible to conclude that the character of the ketamine psychedelic experience is determined to a certain extent by the personality features of the alcoholic patient. We also identified a strong positive correlation between the character of the psychedelic experience and the clinical result of KPT with alcoholics: the more negative was the psychedelic experience, the longer the period of sobriety lasted.

Effects on Spirituality

In our latest work we have shown that a profound mystical experience during the KPT results in an increase in the level of the spiritual development of the alcoholic patient. For the assessment of the changes of spirituality we used our own special Spirituality Scale based on the combination of the Spirituality Self-Assessment Scale developed by Charles Whitfield, who studied the importance of spirituality in alcoholism therapy, and the Life Changes Inventory developed by Ken Ring to estimate the changes into values and purposes of life produced by near-death experiences. It was demonstrated by our Spirituality Scale that the increase in the level of spiritual development of our alcoholic patients due to KPT was comparable with the increase induced in healthy volunteers by a special course of meditation and was much greater then the changes in spiritual development induced in alcoholics by a relaxation technique training program. It is evident that the increased spiritual development induced by KPT in alcoholic patients is very auspicious for sobriety. Moreover, the results of the study of KPT's influence on spirituality testify that KPT is much more than simply a creation of an attitude in alcoholic patients toward a sober life. These results testify that KPT brings about profound positive changes in life values and purposes, in the attitudes to the different aspects of life and death, and, in its turn, in the alcoholics' world view.

Biochemical Investigations

We also carried out biochemical investigations of the underlying mechanisms of KPT. The results of the biochemical investigations have shown that during the KPT procedure there occurred a real decrease in the activity of monoaminoxidase type A (MAO-A) in blood serum and MAO type B (MAO-B) in blood platelets, and also there was an increased dopamine level in blood. Serotonin concentration was not altered significantly. Increase of ceruloplasmin activity was statistically significant and the B-endor-phine level increased during the KPT procedure.

The influence of different ketamine concentrations on MAO-B activity in blood platelets in vitro was investigated in two series of investigations distinguished by the concentration of the substrate (benzylamine). The obtained result (intersection of straight lines of dependence on enzyme activity on inhibitor concentration on the abscissa in Dixon's graph) testified to the noncompetitive character of the inhibition of MAO-B activity by ketamine. It was also established that ketamine induced a similar increase of oxidative ceruloplasmin activity by its dimension in samples both of human blood serum and of crystallinely clear ceruloplasmin.

The changes of the neuromediatory metabolism have some notable aspects. First, they allow some opinions about the neurochemical mechanisms of keta-mine's psychedelic action to be formed.

Second, the fact that the pharmacological action of KPT effected both monoaminergic and opioidergic systems, i.e. those neurochemical brain systems which are connected to the pathogenesis of alcohol dependence, is an important result of this biochemical investigation. It is possible that this fact exactly causes to a certain extent the efficiency of this method.

KPT and Neuroses

We are currently continuing with our research of KPT. In 1990-1991 we began to develop a large project researching ketamine psychedelic therapy in the treatment of neuroses. We are carrying out research into the clinical efficacy of KPT for different kinds of neuroses and also are studying the psychological, biochemical, and neurophysiological underlying mechanisms of KPT in neurotic patients. We are also studying the subtle psychosemantic alterations induced by KPT on the conscious and subconsicous levels in alcoholic and

The increase in the level of spiritual development of our alcoholic patients due to KPT was comparable with the increase induced in healthy volunteers by a special course of meditation

neurotic patients. The main tool for measuring these alterations is the original version of the verbal and nonverbal repertory grids tests which were specially worked out for this purpose in our laboratory. Our repertory grids were organized in such a way as to assess the key aspects of being of the self andthe surrounding world in existentially-transpersonally oriented terms.

Another direction of our research now is EEG computer-assisted analysis of the underlying mechanisms of KPT of alcoholism and neuroses.

We currently have only preliminary data on the effect of KPT on neuroses. According to this data, KPT is more effective in the treatment of neurotic depression, post-traumatic stress disorders, and phobias; hysterical neuroses are more rigid after KPT.

The preliminary data of our research with verbal and nonverbal repertory grids have shown that KPT brings about positive changes in the verbal (realized) and nonverbal (unrealized) attitudes to the different aspects of being of the self and the surrounding world in our patients. KPT results in positive changes in the world view, and KPT also causes a existentially-transpersonally oriented world view to be more acceptable to our patients.

According to the preliminary data of EEG computer-assisted analysis we discovered that KPT increases theta-activity in different regions of the brain cortex. There is evidence of limbic system activation during KPT, as well as evidence of the reinforcement of the limbic-cortex interaction. This fact can be also considered to a certain extent as indirect evidence of the strengthening of the interactions between the conscious and subconscious levels of the psyche during the KPT.

In 1990-1991 we began to develop a large project researching ketamine psychedelic therapy in the treatment of neuroses.

If permission is granted for our MDMA research project, we will need to receive outside funding, hopefully from MAPS, so that we can afford to conduct the research.

We have already treated with KPT more than six hundred alcoholic patients, and we hope we will have an opportunity to continue our KPT research in St. Petersburg in spite of the economic collapse in Russia and the breakdown of the Russian science and health systems.

Future MDMA Studies

In addition, we are also trying to receive permission from the Russian Medical Authorities to carry out MDMA (Ecstasy) psychedelic therapy of terminal cancer patients and alcoholic patients. If permission is granted for our MDMA research project, we will need to receive outside funding, hopefully from MAPS, so that we can afford to conduct the research. ■

In conclusion I have to note the names of all collaborators of our research team who participated in our KPT research programs in Leningrad Regional Dispensary of Narcology:

Principal Investigator:
Krupitsky, E.M. — psychiatrist, M.D., Ph.D., Chief of the Research Laboratory.

Main Researchers:
Paley, A.I. — psychotherapist, psychologist, Ph.D.
Berkaliev, T.N. — psychotherapist, psychologist.
Ivanov, V.B. — psychotherapist, M.D.
Dubrovina, O.O. — psychologist.
Kozhnazarova, D.A. — psychologist.
Karandashova, G.F. — biochemistrist, Ph.D.
Dunaevsky, I.V. — anesthesiologist, M.D., Ph.D.
Rzhankova, E.V. — anesthesiologist, M.D.
Katznelson, Ya. S. — anesthesiologist, M.D., Ph.D.
Ruzina, M.S. — physiologist.
Petrov, V.N. — psychiatrist, M.D.
Grinenko, A. Ya. — Chief of the Leningrad Regional Dispensary of Narcology, M.D., Ph.D.

Associate Researchers:
Kungurtsev, I.V. psychiatrist, psycho-therapits, M.D.; he took part in the beginning of the research of the KPT of neuroses for several months.
Luchakova, O.M.D., Ph.D., neuroscientist; she carried out the course of teaching of meditation with volunteers in control group.
Priputina, L.S. — psychopharmacologist, M.D., Ph.D., specialist in calcium channel antagonists.

To support the work of MAPS see pages 34 – 35

The Use of Ayahuasca in Brazil by the Santo Daime Religion

by Rex Beynon, Friends of the Amazon

THIS YEAR has been a historic one for the Santo Daime doctrine. I returned from Brazil in July of 1992 where I attended the Earth Summit conference and in this article I am going to report on some developments that received little attention outside of Brazil. In order to put those developments in context, I will first give some background on the Santo Daime doctrine.

In the earlier part of this century a seven feet tall black man named Raimundo Irineu Sera was working among the Indians in the state of Acre (in Brazil), on the border with Bolivia and Peru. During this time he was introduced to the drink known as Ayahuasca, which is translated as "vine of the soul." This drink is a tea made from the vine *Banisteropsis Caapi* and, generally, also the leaves of the plant Psychotria Viridis. It has been used in religious rituals since ancient times by the native peoples of the region, including the Incas, both as a medicine for healing and as an agent for spiritual enlightenment.

During a retreat in the forest, Master Irineu, as he later came to be called, received visions of the Virgin Mary in the form of the Queen of the Forest, who revealed to him a religious doctrine which he was to bring to the world through the specific rituals that he was shown. Gradually master Irineu gathered a group of people around him and started to receive hymns from the astral plane, which became an integral part of the rituals which they practised.

The word "Daime," which became the name of the doctrine as well as the drink, comes from these hymns in which the words often occur as a prayer - "Dai-me forca, dai-me amor, dai-me luz," - "Give me strength, give me love, give me light." The doctrine which is revealed in them is a Christian doctrine blended with the native religions, with a profound reverence for Mother Nature, especially the forest, personified as the Virgin Mary.

There are several types of ritual. In the "official works," the community will dance for up to 12 hours in a specific formation and rhythm to generate an energy current, with the Daime being drunk several times during the night. In the healing rituals, the participants generally sit around the altar and one or more people are the recipients of the healing. The deeper cause of the illness is often revealed during the work, in a vision which is called a "miracao." The making of the Daime is also done in a ritual called the "feitio" in which the vine and the leaf are cooked together into a tea. It is said that the vine gives the "strength" and the leaf gives the "light" or the capacity for visions.

In the past 20 years or so the religion and the use of the tea has spread throughout Brazil, giving rise to churches in many of the major cities. This has occasionally brought persecutions by groups of people who do not understand the practise, trying to confuse the issue by claiming that the tea is simply a drug and should be banned, even though the churches have actually become well known for their work in helping people to effectively overcome alcohol and drug addiction.

FORTUNATELY the CONFEN (the Federal Drug Council) has consistently upheld the right of the Daime Church to practice its religion and healing practices using the Daime tea. A study was made of the Daime by the CONFEN in 1987 which included visits to the various churches and observation of

(continued next page)

In the past 20 years or so the religion and the use of the tea has spread throughout Brazil

In the last issue of the MAPS newsletter Dennis McKenna proposed a bio-chemical investigation of ayahuasca. He has since been pledged $50,000 and is planning to begin his study in early 1993.

the making of the Daime. It also included study of another group of ayahuasca users, who call the drink Vegetal. The work group which made the study included representatives not only of the CONFEN but also of several other government agencies. The conclusion of the study was that the Daime was a very positive influence in the community, encouraging social harmony and personal integration. It was emphasized that, rather than simply considering the pharmacological analysis of the plants, one must consider the whole context of the use of the tea — religious, social, and cultural.

In June of 1992 a definitive decision was made by the CONFEN, putting the matter to rest once and for all, stating that the use of the Daime is perfectly legal. Domingo Bernardo Da Silva, the president of the CONFEN, had visited the community of Mapia, in the state of Ama-zonas, and taken part in the rituals as part of his study. During the Earth Summit in Rio in June there was a conference on medicinal plants of Amazonia, in which three of the members of the CONFEN, including Domingo Bernardo, took part in a panel and explained their study of the Daime and their conclusions. They had taken part in the rituals and showed a great deal of respect for religious and cultural tolerance and emphasized that there is no evidence of any harmful effects or potential for abuse of ayahuasca.

THE study was published in a detailed document with many thoughtful insights into the matter. At one point it is stated that "altered states of perception do not necessarily signify a negative or harmful situation" - on the contrary these effects can be channeled for the benefit of society and the individual. As a government document, there are many words of wisdom in this study which deserve serious consideration in this country.

At the same time that this occurred another historic event happened when the Daime church was invited to take part in an inter-religious vigil as part of the program at the Global Forum section of the Earth Summit conference. All of the major religions of the world were represented. The Santo Daime, now being considered a major religion in Brazil, had its own tent and 600 people took part in an all-night ritual. The Daime was served and the people took part in the sacred dance, in rhythm to the Daime hymns. To me this official recognition was a fitting tribute for the hundredth anniversary of Master Irineu this year. There will be further celebrations of the centenary in December this year when people will gather in Rio Branco, Acre, from all over the world to celebrate the Master's birthday.

The expansion of the Santo Daime doctrine has created a movement also to help the people of Ama-zonia to protect the rainforest which is the natural habitat of the vine and the leaf used in the Daime. Mapia is, in fact, now the center of a one and a half million acre protected reserve. The ecological work of the people of Mapia is a natural extension of a religion which was born in the rainforest, and is being supported by the United Nations and the non-profit organization Friends of the Amazon Forest in the U.S.

There are also moves towards organizing the healing works of the Daime, creating a center which will include not only the traditional healing rituals of the Daime but also include psychotherapy, a clinic, a hospital and birthing center, along with training programs and workshops. The intention is to create a center for consciousness with a complete healing program. Serious scientific research into the properties of Ayahuasca is also welcomed by the community in Brazil. ■

If you would like more information on how to take part in these programs, including retreats in the rainforest, you may contact: FRIENDS OF THE AMAZON FOREST at P.O. BOX 625, CAMBRIDGE, MA 02140.

LSD AND THE WAR ON DRUGS

THE SPRING, 1992 issue of the MAPS newsletter discussed the controversy concerning sentencing guidelines for people convicted of the manufacture, sale or possession of LSD. Because the weight of the carrier (blotter paper, sugar cubes, liquid, etc.) is added to the amount of LSD, people caught with the same amount of LSD can get widely varying sentences. Because these unequal punishments for the same amount of LSD are inconsistent with equal justice under the law, the U.S. Sentencing Commission is considering changes to the Guidelines. The letter to MAPS, reprinted below, from Michael Sommers, a prisoner serving time for the sale of LSD, illustrates another illogical and tragic aspect of our current Guidelines.

"You are already cognizant of the specific sentencing guidelines but are you at all aware of how the Bureau of Prisons (BOP) looks at LSD convictees when they enter the system? This is an interesting twist. The BOP has a whole typically bureaucratic amalgam of figures derived from various aspects of a persons' particular crime and their past criminal history which when added together form the "security and custody point total," which is the signifier of what security facility is necessary to adequately house this particular girl or boy. The mechanisms by which these numbers are derived are to be found in the Custody Classification Form of the BOP. There are four different levels of security currently designated for BOP facilities, minimum or camp, low, medium , and high. In the classification form there are five levels of severity of the crime; lowest, low moderate, moderate, high, greatest. The severity of crimes involving drugs are, like sentencing, based on the amount of the drugs involved. With regard to LSD, the amount is gauged on the amount of doses involved rather than on the total weight of the LSD plus the carrier, and is on a totally different scale than the sentencing guidelines. As the BOP sees it, anyone caught with 10,000 dosage units or less is placed in the low moderate severity level. This accrues for them one point towards their security point total. My crime was distribution of 28 grams of LSD and places me in level 32 of the guidelines with a sentence of 121-151 months. But since it only involved 4000 dosage units of LSD I am considered low moderate by the BOP and subsequently am camp eligible since I am such a low security risk. It would have taken greater than 70 grams worth of LSD for me to be placed in a higher severity level. So virtually all of the LSD convicted inmates who are non-violent, non-gun toting, non-escape attemptees with not much of a past history of crime are on the lowest level of security risk assigned by the BOP. Meanwhile their counterparts convicted of other substance related crimes are all immediately placed in a higher category. The BOP is tacitly signalling that they too see the LSD purveyor as much less serious an offender than their sentencing belies.

Senator Kennedy has twice attempted to get amendments through Congress that would take the carrier weight out of the sentencing for LSD but each attempt, although it was passed by the Senate, was not passed by the House. I think you should all let him know your appreciation for his past attempts and encourage him to try, try again. Also, Senator Biden is at the very moment compiling a dossier of LSD cases with which he can bolster another attempt by himself (one previous attempt met the same fate as Kennedy's) to send an amendment through the next Congress. So actually the Senate has it's shit together on this subject but the House of Representatives needs some work."

For those wanting to write to the U.S. Sentencing Commission, write to: William Wilkens, Jr., Chairman, U.S. Sentencing Commission, 133 Pennsylvania Ave. NW, Suite 1400, Washington, D.C., 2004. For those wanting to write to Michael, his address is Michael Sommers 56156-080, P.O. Box 1010, Bastrop, Texas, 78602-1010. ■

The Bureau of Prisons (BOP) is tacitly signalling that they too see the LSD purveyor as much less serious an offender than their sentencing belies.

MDMA:
PATENTABILITY AND ORPHAN DRUG DESIGNATION

by Rick Doblin, MAPS President

I decided to hire a patent attorney to try and insure that MDMA's potential medical use would not be bottled up by anyone else's use patent.

WHY IN THE WORLD would MAPS hire a patent attorney? After all, MDMA was patented in 1914 in Germany by the Merck Pharmaceutical Company. That patent has long since expired, leaving MDMA in the public domain. If MDMA could be manufactured legally no payments to Merck would be required. The answer is that there are several kinds of patents for molecules, composition of matter, manufacturing process, and use patents. Even if the composition of matter patent has expired, it is still possible to gain legal control over the use of a particular molecule for a particular purpose by obtaining a use patent or by patenting an inexpensive and efficient manufacturing process. While the composition of matter patent for MDMA has expired and excellent manufacturing processes have been published in the scientific literature, I wasn't so sure about the legal possibilities for a use patent.

The issue of use patents for MDMA is very timely now that human studies can begin. MAPS has opened a Drug Master File for MDMA at the FDA and is preparing to sponsor FDA-approved MDMA research. If the research goes extraordinarily well, MAPS may one day have the opportunity and responsibility to manufacture and market MDMA to appropriately trained and licensed physicians. It could be a major setback if MAPS funded MDMA research and secured approval for its medical use only to have someone else control it through an inexpensively obtained use patent.

I decided to hire a patent attorney to try and insure that MDMA's potential medical use would not be bottled up by anyone else's use patent. I also wanted to explore whether MAPS might obtain such a use permit itself. Howard Lotsof, the founder of NDA International, a for-profit corporation which has obtained several use patents for ibogaine in the treatment of heroin and cocaine addiction and for the amelioration of the symptoms of narcotic withdrawal, referred me to his patent attorneys, Miskin & Mandelbaum of New York. I found them to be both genuinely interested in MAPS' unusual question and expertly qualified to address it.

My first hope, obviously, was that no use patents for MDMA were in existence. Less obviously, I hoped that there was already too much written about MDMA's therapeutic potential for anyone, MAPS included, to patent its use. The goal of MAPS is to facilitate research with psychedelics and to help develop their medical uses, not to corner any market. If any well-funded pharmaceutical company thinks they can profit from MDMA by sponsoring research and gaining FDA approval before MAPS does, I want them to feel free to step right in and do so. However, if MAPS does succeed in securing FDA approval to market MDMA for some clinical indication, sales might generate some financial return which could be used for further research consistent with our non-profit agenda. Perhaps MAPS could even become self-supporting, a possibility that would certainly be a relief to me, and to those of you whom I repeatedly ask for additional donations.

As I hoped and expected, there are no current use patents for MDMA. Attorney Ursula Day of Miskin & Mandelbaum had the following to say about the chances that MAPS, or anyone else, could obtain such a patent: "Without the benefit of more exhaustive background research on the therapeutic uses of MDMA, we are of the opinion that it would be rather difficult for someone to obtain patent protection on such use of MDMA. While there is always a possibility that somebody might wish to file such an application unbeknownst to you, an applicant in this situation would have to overcome any other possible prior art which the Examiner might have available. You are correct in pointing out that published references to prior use would indeed be a bar to obtaining a patent for the therapeutic use of MDMA. However, in the event that an applicant were to obtain a patent on the therapeutic use, there is a great likelihood that the patent would not withstand an attack based on invalidity... Although the search we conducted was far from exhaustive, it appears from the few references

that you have submitted to us that there is sufficient publication on the therapeutic uses and a variety of indications and applications for MDMA that would prevent another from obtaining patent protection on a method."

Hence it is unlikely that anyone can get use patents for MDMA. But that is not the end of the story.

Rick Doblin

Orphan Drug Designation

It still might be possible to obtain a seven-year exclusive right to market MDMA for a particular clinical indication under the sponsorship of the FDA's Office of Orphan Products Development. When a drug treats a rare disease, occurring to fewer than 200,000 people a year, or when for whatever reason the drug developer cannot make its money back in seven years, the financial incentives are usually not sufficient for a pharmaceutical company to develop a drug. Congress created the Office of Orphan Products Development to change the set of incentives facing drug developers so that Orphan Drugs would be developed for the benefit of society. These incentives include protocol assistance, tax credits for investors, and most importantly, if the FDA ever determines that MDMA is safe and effective for some clearly defined clinical condition, a seven year exclusive right to market the drug for that clinical indication. Furthermore, these incentives are available to profit-making pharmaceutical companies, non-profit organizations, educational institutions, or private individuals.

For a real-life example of just how this works, consider drug development in the field of the medical use of marijuana. The FDA has already approved an oral THC pill (Marinol) but limited its use to nausea control in cancer chemotherapy patients. The company that markets Marinol, Unimed, became intrigued by the possibility that THC might be helpful in stimulating appetite in AIDS patients. They were able to make a credible case to the Office of Orphan Products Development that oral THC for the treatment of the HIV-related wasting syndrome deserved Orphan Drug designation. For the last several years they have been gathering data which supports the appetite stimulating properties of oral THC. They are conducting Phase 3 trials and seem not all that far away from being able to market Marinol for the wasting syndrome, maybe even within 1993.(See story on pages 6 – 7 about the proposed study comparing smoked marijuana to Marinol in the wasting syndrome).

From what I can tell, an excellent case can be made that MDMA in the treatment of pain in end-stage cancer patients deserves Orphan Drug designation on financial grounds. Over the next several months, I will be exploring these issues further with the Office of Orphan Products Development. ■

an excellent case can be made that MDMA in the treatment of pain in end-stage cancer patients deserves Orphan Drug designation

The December 1992 edition of *High Times* magazine features an in-depth interview with MAPS President, Rick Doblin

Gnosis Features Psychedelics and Spirituality

Gnosis, the critically-acclaimed quarterly journal of the Western Inner Traditions takes a penetrating look at psychedelics and the spiritual path in their winter 1992-93 issue (#26). Featured authors include: Ram Dass, Myron Stolaroff, Roger Walsh, Jean Paul Sartre, Bruce Eisner and Gracie & Zarkov. Available mid-December to mid-March at your local bookstore or for $6 (US) postpaid from: P.O. Box 14217, San Francisco, CA 94114. US subscriptions: $20 year. CA residents add 8.5% sales tax on all orders..

PUBLICATIONS AVAILABLE FROM MAPS

(Simply circle the ones you want and enclose payment)

1. Exploring Ecstasy: A Description of MDMA Users. Final Report to the National Institute on Drug Abuse. Marsha Rosenbaum, Principal Investigator, Patricia Morgan, Co-Principle Investigator, Jerome Beck, Project Director. 253 pages. Cost - $30.
2. The MDMA Controversy: Contexts of Use and Social Control, Jerry Beck's Ph.D thesis for a Doctor of Public Health from the U. of Cal., Berkeley. 271 pages. Cost - $30.
3. Hallucinogen-Assisted Psychotherapy: A Survey of the Swiss Association for Psycholytic Therapy, Dr. Ernst Benz's Ph.D. thesis for the University of Zurich, 100 pages. Available only in German. $30.
4. Through the Gateway of the Heart, edited by Sophia Adamson and Ralph Metzner and signed by Ralph Metzner, $9.95 plus $1.50 postage.
5. Proceedings of the MAPS Swiss Psychedelic Research Methodology Conference, talks and papers by Albert Hofmann, Lewis Seiden, George Ricaurte & others. 150 pages, $25.
6. PIHKAL by Sasha and Ann Shulgin. $18.95 (+$4.00 p/h), California residents add $1.38 tax.
7. MDMA Psychotherapy in End-Stage Cancer Patients -The Protocol - 49 pages, $10.
8. The Good Friday Experiment Follow-Up, the article on psychedelics and experimental mysticism by Rick Doblin, published in the August, 1991 *Journal of Transpersonal Psychology*, $8.
9. Against Excess: Drug Policy for Results, Mark A. R. Kleiman - $26.
10. Journal of Nervous and Mental Disease paper analyzing self-reports of 20 psychiatrists about their own MDMA experiences, OUT Magazine article on MDMA, and December 1992 High Times interview with Rick Doblin, 23 pages, $8.
11. Complete set of MAPS Newsletter back issues, 1988–1p., 1989–4p., 1990–10p., 1991–12p., 1991–4p., 1991–12p., 1992–16p., 1992–24p., $25.

Now Available – A Complete Set of Back Issues of the MAPS Newsletter

AUDIOTAPES AND VIDEOTAPES AVAILABLE FROM MAPS

1. MAPS February, 1990 Benefit Video – 3.5 hour Extended Version, $35.
2. MAPS February, 1990 Benefit Video – 1.5 hour Artistically Edited Version, $35.
3. Stanford, February, 1991 Conference Video – 2 hour Artistically Edited Version, $35.
4. Prague, June, 1992 Video – 2 hours Rough Unedited Version, Panels #1 & 2, $35
5. Prague, June, 1992 – 3 hour audiotape of MAPS discussion on working with the terminally ill with psychedelics, Ram Dass, Ken Ring, and Richard Yensen, $20.

On February 24,1990 a unique group of speakers gathered to discuss "Psychedelics in the 1990's-Regulation or Prohibition" as part of a benefit for MAPS. These speakers included Jerry Beck, Ram Dass, Rick Doblin, Bruce Eisner, Laura Huxley, Emerson Jackson, Mark Kleiman, Timothy Leary, Dennis McKenna, Terence McKenna, Ralph Metzner, Andrew Weil, and Robert Zanger.

On February 2 and 3, 1991, a large conference on psychedelics was held at Stanford University featuring Tim Leary, Terence McKenna, Francis Huxley, Ralph Metzner, Robert Anton Wilson, Steven Gaskin, Mountain Girl, John Lilly, Rick Doblin, Charles Grob, David Nichols, Alison Kennedy and others. Compilation by Sound Photosynthesis.

On June 24 & 25, 1992 the International Transpersonal Association held a conference in Prague. Speaking about the past history of psychedelics were Ram Dass, Stan Grof, Ralph Metzner and Richard Yensen. Speaking about current research were Rick Strassman (DMT), Yevgeny Krupitsky (Ketamine), and Juraj Styk (LSD and MDMA).

1801 Tippah Avenue
Charlotte, NC 28205
Phone (704) 358-9830
FAX (704) 358-1650

❑ YES! I would like to join the Multidisciplinary Association for Psychedelic Studies.
Enclosed is my tax-deductible contribution of: ❑ $30 ❑ $100 ❑ $250 or more ❑ $ other____
❑ If outside the US, add $10 for postage. NOTE: Your donation *will not* be spent on animal studies.

Name

Address

City State Zip Country

PATRONS – CHECK THE MEMBERSHIP BENEFIT YOU PREFER:

❑ I prefer the Prague 2-hour rough unedited videotape of Panels #1 & 2.
❑ I prefer the MAPS Benefit 3.5 hour Video.
❑ I prefer the MAPS Benefit 1.5 hour Video, artistically edited by Sound Photosynthesis.
❑ I prefer the Bridge Conference 2 hour Video, artistically edited by Sound Photosynthesis.

MAPS Membership Information

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 two hundred members. MAPS' founder and current president, Rick Doblin, is on leave of absence from 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.

MAPS has previously funded basic scientific research in both humans and animals into the safety of MDMA (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 and other psychedelics, with the goal of eventually gaining governmental approval for their medical uses.

Albert Einstein wrote that *"Imagination is more important than knowledge."* If you can even faintly imagine a cultural re-integration 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 Newsletter Each quarterly newsletter will report on MAPS research in progress. In addition to reporting on our own studies, the newsletter will focus on psychedelic research both in the US and abroad and on conferences, books and articles of interest. Issues raised in letters and calls from members will be addressed, as will political developments that effect psychedelic research and usage.

General Membership: $30. *(If outside US add $10 postage.)*

General members will receive the newsletter and the June 1992, Journal of Nervous and Mental Disease article on the self-reports of 20 psychiatrists about their personal use of MDMA, with critique and commentary by Dr. Charles Grob, the OUT Magazine feature story on MDMA, and the December 1992 High Times interview with Rick Doblin.

Supporting Membership: $100. *(If outside US add $10 postage.)*

Supporting members will receive all the benefits sent to the General Members plus the Prague audiotapes of the MAPS discussion on working with the terminally ill with psyche-delics, featuring Ram Dass, Ken Ring and Richard Yensen.

Patron: $250 or more. *(If outside US add $10 postage.)*

Patrons will receive all the benefits sent to Supporting Members plus one item of your choice from among the four different videotapes. Patrons may also request research updates at any time on matters of personal interest and will receive advance information and discounts to MAPS events.

"The real difficulty, the difficulty
that has baffled the sages of all times,
is rather this: how can we make our teaching
so potent in the emotional life of man,
that its influence should withstand the pressure
of the elemental psychic forces in the individual?"

— Albert Einstein

San Francisco Examiner

THURSDAY, NOVEMBER 12, 1992

FDA gives approval to testing of Ecstasy

By Sarah Pekkanen
STATES NEWS SERVICE

WASHINGTON — In an unprecedented decision, the Food and Drug Administration has cleared the way for a UC-Irvine researcher to study the effects of a hallucinogenic drug known as MDMA, or Ecstasy, on human subjects.

Dr. Charles Grob last week won FDA approval for his study, expected to take place at the campus in two months.

During Grob's study, six health professionals, who have not yet been selected, will take two low-level doses of the drug and a placebo during three separate sessions to determine the level for a noticeable effect of the drug.

The FDA approval is a major breakthrough for researchers who have, with few exceptions, been denied permission to administer hallucinogens, including LSD, to human subjects since officials moved to outlaw the drugs in the late 1960s.

Rick Doblin, president of a nonprofit organization called the Multidisciplinary Association for Psychedelic Studies, said the subjects will be volunteers who all took Ecstasy before it was outlawed by the FDA in 1985.

The subjects have already assumed any risks associated with the drug, which may also have contributed to the FDA approval, Doblin said.

The six volunteers participating in the drug study will be subject to a battery of non-invasive tests, including mood status, analysis of pain reduction and cognitive tests, said Grob.

Grob still has two more hurdles to clear before his study can take place: He must win approval from the Drug Enforcement Administration and the California Research Advisory Panel. Doblin said he did not expect either agency to oppose the study.

The drug Ecstasy has been reported to increase self-confidence and self-acceptance and induce feelings of empathy and love, which could make it a useful tool for psychotherapists, some researchers say.

Although some negative side effects of the drug include decreased appetite and decreased desire to perform mental or physical tasks, the drug may also help alleviate pain, which could benefit certain terminally ill patients, Doblin said.

Grob said he hopes to eventually win FDA approval for a study that would involve administering the drug to end-stage cancer patients.