The Multidisciplinary Association for Psychedelic Studies, Inc. (MAPS)
"The People's Psychedelic Pharmaceutical Company"

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Newsletter from Rick Doblin, MAPS President

WHAT AND WHO IS MAPS?

This MAPS newsletter is the first since the summer of 1989. It follows the MAPS benefit conference which was held in Berkeley on February 24,1990, where a superb group of speakers discussed "Psychedelics in the 1990's : Regulation or Prohibition?" (Video and audio tapes available from Sound Photosynthesis, P. O. Box 2111, Mill Valley, Ca. 94942, (415) 383-6712)

Though some recipients of this newsletter have known about and supported MAPS since our founding several years ago, many people have only recently learned about us. MAPS is a non-profit (501) (c) (3) research and educational corporation funded by tax-deductible contributions. MAPS is guided by a small Board of Directors, administered by a president, and contained on one Macintosh computer. All of us donate our time. Our annual budget for the past three years has averaged about $45,000, with funding dependent on intermittent contributions from sympathetic supporters.

MAPS has about 750 people on our mailing list and with this newsletter will begin raising funds through membership fees. Contributors of $30 will receive a semi-annual newsletter, contributors of $100 will also receive quarterly reports and the NIDA MDMA report , contributors of $250 or more will also receive Jerry Beck's Ph.D. thesis and an edited videotape of the MAPS benefit. Details on the enclosed information sheet. Contributions in excess of membership fees help fund research.

This last year was mostly one of waiting for the completion of several long term studies at Johns Hopkins investigating MDMA neurotoxicity in the primate. These studies, which MAPS helped support, are now almost completed (see p.3-4). Personally, I concluded my studies for a Master in Public Policy degree from Harvard's Kennedy School of Government, with an area of concentration in drug policy. My thesis surveyed oncologists about the medical use of marijuana in the treatment of nausea associated with cancer chemotherapy and is being used as evidence supporting marijuana's rescheduling in a lawsuit against the DEA. This next year I will be a special student at the Kennedy School taking classes, being a teaching assistant in a Drug Policy class, and working on MAPS.

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THE TWO FUNCTIONS OF MAPS

MAPS has two basic functions. **The first is to support research** and advance knowledge into the medical, scientific, religious, therapeutic, and recreational uses and abuses of psychedelic substances and techniques. **The second is to serve as an educational organization** to disseminate information from our research, facilitate discussion and promote the integration of psychedelic usage into our culture in whatever slow, gradual approaches suggest themselves.

Psychedelic, a word coined in the 1950's by Humphrey Osmond meaning "mind-manifesting", refers to more than just LSD. It includes a wide variety of substances and non-drug techniques that have in common the ability to facilitate the bringing forth, the manifesting, of portions of the contents of an individual's mind into more conscious awareness. Psychedelically-assisted experiences are only one small step in the long, slow process of discovery, integration, and growth.

Primarily, MAPS is involved with research into MDMA (Ecstasy) and has opened a Drug Master File for MDMA at the Food and Drug Administration. MAPS assists the efforts of researchers both in the US and abroad who seek to explore the risks and benefits of MDMA-assisted psychotherapy. MAPS attempts to act as a bridge between the psychedelic research community, who have been driven out of their research labs for a generation, and government regulators who must give their permission before legally approved research can begin.

MAPS also explores the consequences of the non-medical use of MDMA, supports the Native American Church in their struggle to continue the religious use of peyote, encourages efforts to renew LSD research, investigates the medical use of marijuana, and explores ways in which psychedelic psychotherapy may prove useful in the treatment of drug abuse.

THOUGHTS ABOUT THE ETHICS OF ANIMAL RESEARCH

After the MAPS benefit, several people wrote to express their disapproval of MAPS support for animal research investigating MDMA neurotoxicity, required by the FDA as a prerequisite for human studies. One writer suggested that computer technology or human research be substituted for animal research while another wrote that animal studies were inexcusably cruel, egocentric, and paternalistic. These are important issues, particularly in light of a request contained in this newsletter for the funding of several additional primate MDMA neurotoxicity studies at Johns Hopkins. The explanation of why I support animal research may not satisfy, but will hopefully be informative.

Certainly, taking of the lives of otherwise healthy animals to enlarge scientific knowledge is not above ethical criticism. If animal experiments can be justified at all, they must generate information which cannot be gotten any other way and for which there is a very important and specific need. The research must be conducted in a respectful and kind manner, with the animals well treated. Conducting animal studies places a heavy burden on the experimenter to use as few animals as possible, to gather as much data as possible, to use the data to its fullest, and to move into human studies at the earliest opportunity. *If any of these conditions are violated, the experiment cannot be justified. In my view, the proposed primate neurotoxicity experiments pass these first tests.*

Unfortunately, technology does not yet exist to gather sufficient information about MDMA neurotoxicity without direct physical dissection of brain tissue. The physical existence of a primate at Johns Hopkins is pitiful compared to life in the wild, but is healthy and clean. Being exposed to

Johns Hopkins is pitiful compared to life in the wild, but is healthy and clean. Being exposed to MDMA, even in large doses, seems not to be painful. There are no obvious functional consequences of the induced serotonin neurotoxicity. The carefully designed research is conducted with as few animals as statistics allow. The data contributes to a basic understanding of brain function and is used in negotiations with the FDA and in communications with MDMA users. Many of us involved with primate research volunteer for human studies when possible (See call for human subjects on page 6).

Though the primate research is not blatantly unjustified, more must be said. Essentially, I am willing to sacrifice the lives of tens of primates for the good of untold numbers of humans. I also believe the use of psychedelics to help people get in touch with a more healthy, holistic sense of themselves may in an indirect but plausible way help to build appreciation for the preservation and protection of our environment and the life it contains, including primates.

When the first MDMA toxicity studies were being conducted, I made a point of visiting the research laboratory in Little Rock, Arkansas. The day I visited twelve dogs were scheduled to be sacrificed and examined. That night, I dreamt of dogs as did one of the doctors. Watching the lethal injection, I was surprised at how fast life vanished. The awesome sacred fragile mystery transcended the powers of understanding of all the physicians in the hospital and all their sophisticated equipment. Within seconds, the lifeless dogs were placed on operating tables and highly refined scientific methods designed to help apprehend nature without bias were put into motion. To my surprise, the feeble efforts of science to plumb life's mysteries seemed sacred in its own small way. While the doctors carefully took apart, weighed and measured the many organs which had previously sustained the life of each dog, I told stories about various people's transformative MDMA experiences. All in the room were made aware of the reasons for our sacrifice of the dogs. That day, I learned I could shoulder the responsibility of animal research. I welcome further comments on this issue.

NEUROTOXICITY OVERVIEW

MAPS has assisted several research groups prepare applications for FDA approval of MDMA research in humans, all of which have been denied. FDA required MDMA's neurotoxic risk to be clarified in animals before human studies would be permitted. *The three critical questions about MDMA neurotoxicity are, 1) does it occur at human relevant doses, 2) If it occurs is it permanent or temporary, and 3) If if occurs, is it beneficial, harmful, or neutral?*

While the risk/benefit calculations of the FDA are politically skewed, they are constrained somewhat by data. Millions of dollars invested by the government in MDMA research are beginning to yield a clearer picture of the risks of MDMA. MAPS builds on government funded research by using our limited resources to support small pilot studies examining the effects of human relevant doses, overlooked in most studies which tend to explore the effects of higher doses.

The scientific data tends to support the conclusion that MDMA neurotoxicity, if it even occurs at average doses, extracts no measurable price when MDMA is used irregularly and in normal amounts. The scientific data, however, cannot yet precisely evaluate the risk to subjects in an MDMA research protocol. *What is* required for FDA approval is continued support for small pilot studies defining the threshold dose at which MDMA no longer causes neurotoxicity, the rate and extent of regeneration, and functional consequences, if any, of neurotoxicity. Your contributions to MAPS, however small, make a critical difference in this research.

PRELIMINARY FINDINGS FROM PRIMATE STUDIES

Two studies to which MAPS contributed have been completed. The following report is based on preliminary findings and is not to be quoted for attribution or cited in any report or media article. Publication of scientific papers about the findings are pending.

The Neurotoxic Threshold

Previous primate research funded in part by MAPS demonstrated that a single oral dose of 5 mg/kg of MDMA (about 3X larger than average human doses) caused some neurotoxicity in some brain regions though a single oral dose of 2.5 mg/kg (about 1.5X larger than average human doses) did not. To determine if a dose of 2.5 mg/kg was actually below the neurotoxic threshold, MAPS contributed to a primate study at Johns Hopkins in which 2.5 mg/kg was administered orally every two weeks for four months for a total of eight exposures.

Preliminary data suggests that multiple exposures to 2.5 mg/kg of MDMA had no neurotoxic effect in all brain regions studied except one, the thalamus.

This news is somewhat discouraging. If a primate no-effect level for MDMA neurotoxicity had been established at the 2.5 mg/kg dose, securing FDA permission for human studies using less than that dose might have been possible. The finding that eight doses of 2.5 mg/kg of MDMA seem to produce a small neurotoxic effect in one brain region calls into question the assumption that one dose of 2.5 mg/kg is without neurotoxic risk, however slight. However, since so few animals were studied, the effect in the thalamus may be a statistical aberration. More research is needed.(See p. 10!)

Without a clear primate no-effect level, the case for human exposure to doses less than 2.5 mg/kg remains complicated by the concern over neurotoxicity. This data suggests, however, that the neurotoxic threshold is very close to 2.5 mg/kg.

The Extent of Recovery

Previous studies in rats have shown that serotonin levels decreased by 90% return to normal after 12 months. In previous primate studies, serotonin reductions of 90% climbed to 50% of normal levels after only 4 months, recovering more rapidly than the rat. To test the assumption that primates would show complete recovery, MAPS contributed to another Johns Hopkins primate study which examined primates with 90% reductions after 12 and 18 months.

Preliminary data yielded unexpected results, and suggest that total recovery may not occur after severe neurotoxicity. Persistent reductions of serotonin of about 70% were seen after 18 months, indicating that the process of recovery noticed at 4 months had halted and even reversed itself. Whether total recovery occurs after more moderate toxicity needs to be explored (See page 10!).

Most surprising are indications that other neurotransmitter systems may be increasing in number, possibly acting to counteract the loss of serotonin neurons.

When considering the implications of this new data, it is important to keep in mind that MDMA has been used for almost twenty years in the United States without a single case in the scientific literature suggesting that anyone, user or abuser, suffers from MDMA-related brain damage. Fenfluramine, an FDA-approved prescription drug for over twenty years, has recently been discovered to cause serotonin neurotoxicity more readily than MDMA, yet it too has failed to result in a single case of fenfluramine-related brain damage being reported in the literature.

DR. NICHOLS CONFIRMS THAT PROZAC BLOCKS MDMA NEUROTOXICITY

At Purdue University's School of Medicinal Chemistry, Dr. David Nichols replicated an experiment conducted by Dr. Schmidt in which rats were given both MDMA and Prozac (fluoxetine), a new drug for the treatment of clinical depression. Prozac is extremely popular, returning sales of about $400 million a year and growing to Eli Lilly. Prozac stimulates the serotonin system in a manner somewhat similar to MDMA but to a lesser degree and without neurotoxicity.

The simultaneous administration of Prozac and MDMA completely blocked the neurotoxic properties of MDMA. This finding may be the key to unlocking the door to FDA-approved human studies with MDMA, since it seems possible that the MDMA neurotoxicity risk, difficult to estimate, can instead be entirely eliminated.

It may be that both the dopamine neurotransmitter itself, released by the MDMA, and MDMA metabolites are neurotoxic, not the MDMA itself. Several hours after Prozac and MDMA are administered, the brain has broken MDMA down into its metabolites and released extra dopamine. These compounds, which usually would be absorbed by the serotonin nerve terminal re-uptake sites, are blocked from doing so by Prozac molecules which have filled the re-uptake sites. Neurotoxicity is prevented and the dopamine and MDMA metabolites are eventually reabsorbed or broken down into their harmless components, without having caused any damage.

Two basic questions remain, 1) Can Prozac's prophylactic effect in rats be replicated in primates or man? (See p. 10!) and 2) Does Prozac change the subjective experience of MDMA, and if so how.

REQUESTED: SUBJECTIVE REPORTS OF THE PROZAC/MDMA COMBINATION

Determining if there is a method of eliminating MDMA's neurotoxicity without diminishing its valuable subjective, therapeutic effects would provide important information to MDMA users and could play a major role in the initiation of FDA-approved human studies. Several people who have tried a combination of Prozac and MDMA report the MDMA experience to be essentially unchanged. Others feel there is some effect. Reports from experimenters in the field (that hopefully means some of the intrepid readers of this newsletter) are the only sources of information on this matter.

MAPS requests people who have tried an MDMA/Prozac combination to send in written reports on their subjective experiences. The combination of most interest is a standard dose of Prozac (20mg) with 75-100 mg of MDMA, taken simultaneously.

If the reports suggest the MDMA experience remains unchanged, a small study to determine if Prozac blocks neurotoxicity in primates would follow (See p. 10!). If successful, an application for an FDA-approved study to investigate therapeutic uses of the combination would be submitted.

FINDINGS FROM THE TWO NIDA-FUNDED HUMAN STUDIES

NIDA has funded two major studies of the effects of MDMA on humans, neither actually administering MDMA to the subjects. A sociological description of MDMA users based on their self-reports cost NIDA $200,000 and was completed over the course of two years by a research group in San Francisco, with Dr. Marsha Rosenbaum as principle investigator and Jerome Beck, Deborah Harlow, Douglas McDonnell, Patricia Morgan, and Lynne Watson as co-investigators. A study comparing MDMA users to non-users for signs of serotonin neurotoxicity is costing NIDA $500,000 and is halfway through its three year schedule at Johns Hopkins, conducted by Dr. George Ricaurte.

In the sociological study, researchers interviewed 100 MDMA users in depth. Jerry Beck went on to analyze the study for his Ph.D. thesis in Public Health at the University of California at Berkeley. The recently minted Dr. Jerry Beck reviewed the data from 100 MDMA users and concluded in his Ph.D thesis that virtually all the people who were interviewed felt they had benefited from their use of MDMA, and that very few experienced periods of problem use. He observed,

"Based on MDMA's reputed qualities, one might assume that a significant number of users would eventually experience major problems resulting from abuse and/or dependence in the pursuit of "Ecstasy". However, the low levels of such problems seen with MDMA are perhaps best explained by limiting factors intrinsic to the experience itself."

(The NIDA report, which has not been widely publicized by NIDA, is available from MAPS for $30. Jerry Beck's Ph.D. thesis is also available from MAPS for $30.)

A CALL FOR VOLUNTEERS FOR THE JOHNS HOPKINS HUMAN STUDY

The NIDA serotonin neurotoxicity study compares 24 MDMA users, who each must have taken MDMA 10 times or more, with two control groups also of 24 people each. The study measures serotonin levels of the subjects through the analysis of serotonin metabolites found in the spinal fluid, and examines most of the subject's physical and mental systems wholly or partially mediated by the serotonin system. Since serotonin is involved with the sleep/waking transition, two nights are spent in a sleep laboratory where brain waves are monitored. Various psychological tests are given which explore the subjects concentration, memory, visual and pain perception, appetite, reaction times, etc.

Each MDMA subject is age, sex, educational history, health and socioeconomically matched, more or less, with two controls, one with a similar drug history but without exposure to MDMA and the other without any history of drug use. Needless to say, finding exactly matched controls is the weak part of this experiment. Having people act as their own controls, tested before and after MDMA use, would be an ideal experimental design but would require the actual administration of MDMA and is not permitted.

MAPS has helped recruit many of the subjects for this experiment. Participating in this experiment is one way to make a major contribution to MDMA research. NIDA has set out to find evidence of MDMA-related brain damage and it seems an appropriate response by MDMA users to give them their best shot at finding it, in ourselves. <u>If you are opposed to animal studies, this is an alternative.</u>

Subjects in this study enter Johns Hopkins Hospital in Baltimore, Maryland on any Monday night of their choosing, completing their tests Friday around noon. NIDA pays all transportation expenses of the subject and $400 compensation. NIDA is spending about $6,000 per subject, and at completion of the experiment all personal data will be given to the subjects. The spinal tap procedure has a reputation much more fearsome than deserved. Though it feels very weird, it is relatively painless. The main complication, which occurs to about a third of the subjects, is spinal headaches which go away when you lie down but can last a week or more. I had one after my first spinal tap and not after my second, two years later. For more information about participating in this experiment, contact Dr. George Ricaurte at (301) 550-0993. Feel free to contact me as well.

SWITZERLAND PSYCHEDELIC RESEARCH UPDATE

Last summer, the MAPS newsletter began with the heading GREAT NEWS and reported on the legal therapeutic use of LSD and MDMA in Switzerland, at the time the only place in the world where such work was legally taking place. Permission to prescribe MDMA or LSD was granted by the Swiss Health Authorities to a small group of six Swiss psychiatrists, all of whom belonged to the Swiss Association for Psycholytic Therapy (SAPT). A custom designed in-patient treatment ward was opened at the Swiss Red Cross Hospital in Bern for the more seriously ill patients.

Since permission was granted, several hundreds of patients have been successfully treated with MDMA and LSD-assisted psychotherapy for psychological conditions ranging from post-traumatic stress syndrome, anorexia, depression, phobias and obsessive/compulsive disorders to marital counseling and psychological aspects of terminal illness.

A survey of the six Swiss psychiatrists using psychedelics was conducted under the direction of Dr. Christian Scharfetter by Swiss researcher Ernst Benz, for his Ph.D thesis. Also newly minted, *Dr.* Benz reported that "MDMA was described as the safest of the drugs, since it caused anxiety in so few patients, and effected a mild and positively experienced emotional expansion so that patient resistance to the drug rarely occurred. Patients rarely had feelings of physical disintegration or isolation from their bodies [Note: As sometimes occurs with LSD]. MDMA inspires symbolic understanding and, above all, physical sensation and insight, strengthening patients enthusiasm for interaction and making communication more direct so that they deal with one another more easily and feel better able to tolerate others. All members of SAPT are of the opinion that MDMA in a standard dose of up to 150 mgs. is relatively non-toxic." (Ernst Benz's thesis, which also reviews the work of Drs. Grof and Leuner, is available for $30 from MAPS but only in the original German.)

UNSUCCESSFUL MAPS ATTEMPTS AT COLLABORATIVE RESEARCH

Due to the opportunity Swiss psychiatrists had to actually administer MDMA, MAPS attempted to initiate collaborative research on MDMA neurotoxicity between Swiss psychiatrists and Dr. George Ricaurte. Dr. Ricaurte visited the Swiss psychiatrists and prepared a protocol which called for spinal fluid to be taken from patients before and after exposure to MDMA, then placed in liquid nitrogen for shipment to Johns Hopkins for analysis.

Unfortunately, the Swiss psychiatrists decided that MDMA neurotoxicity was not an important concern of theirs. They were also less than enthusiastic about conducting research into the therapeutic use of MDMA and LSD, despite the offer of psychiatrists at Harvard Medical School to collaborate on experimental design.

The Swiss psychiatrists are psychotherapists and not researchers, who realize that research protocols often inhibit the process of psychotherapy. Protocols preferred by the FDA are double-blind placebo studies. Because of the placebo, half of the therapeutic sessions, often conducted with patients who seriously need treatment, are seen by the psychiatrists as being less effective therapeutically than the patients deserve. In addition, the studies fail to remain double blind since experienced therapists and patients can determine the content of the pill by the presence or absence of the dramatic effects which psychedelics catalyze. Since the Swiss Health Authorities did not explicitly require formal research, scientific studies were never begun in Switzerland.

SWISS RESEARCH HALTED - RESUMPTION POSSIBLE BUT NOT CERTAIN

Early this summer, a very tragic, unfortunate, incident resulted in the temporary withdrawal of official permission for the medical use of LSD and MDMA.

At the present time, all use of LSD and MDMA in Switzerland has been stopped. There is currently nowhere in the world where LSD and MDMA are legally available to psychiatrists for the treatment of patients. Use will resume about November 1.

One of the Swiss psychiatrists led a psychotherapy group in France using psychedelics. Instead of LSD or MDMA, one patient received ibogaine, a drug derived from an African root which has been used to assist psychotherapy for many years and has recently been reported to be effective in the treatment of addictive disorders. Ibogaine produces vomiting in most people who take it and has not found a wide use. For reasons which are still uncertain, the person who tried the ibogaine experienced medical complications and died. An explanation for what occurred awaits autopsy results. In the psychedelic literature, deaths from ibogaine have not previously been reported.

As a precaution, the Swiss Health Authorities decided to halt all medical use of all psychedelics pending receipt of the autopsy report. The psychiatrist is facing legal complications and a patient is dead. Since the autopsy indicated that neither MDMA or LSD was involved, the Swiss authorities have decided to allow the Swiss psychiatrists permission to resume their work with MDMA and LSD, which have an excellent safety record and have demonstrated therapeutic efficacy. One new condition is being insisted upon by the Swiss authorities. Future use must be part of a research protocol, excellent news for those of us interested in psychedelic psychotherapy research.

NEW MAPS MDMA RESEARCH PROJECT - CZECHOSLOVAKIA

Another country may be about ready to open the door to psychedelic research. In July, I met with Czechoslovakian psychiatrist Dr. Zdenek Dytrych in Washington, D.C., during his visit to the US for a conference. Dr. Dytrych had been told about MDMA by Dr. Stan Grof, with whom he used to conduct LSD research in the 1950's and 1960's. Dr. Dytrych is the head of social psychiatry at a psychiatric research institute in Prague and has extensive experience with LSD research.

Dr. Dytrych feels that securing permission for MDMA research will be possible in the current political climate in Czechoslovakia, and is primarily interested in conducting research. To begin the process of MDMA research in Czechoslovakia, Dr. David Nichols and MAPS are seeking permission from the Drug Enforcement Administration to export for scientific purposes 100 grams of MDMA to Dr. Dytrych's research institute.

Dr. Nichols originally synthesized the MDMA several years ago for use in legal research. The MDMA which will hopefully be sent to Prague is from the same batch as that used in the animal toxicity studies which form the basis of the MAPS Drug Master File. Czech research using MDMA identical with that used in the previous US studies will simplify the process of securing FDA permission to enter data from Czech studies into the MAPS Drug Master File.

DEA approval for the export permit depends upon Dr. Dytrych obtaining an importation permit from the appropriate Czechoslovakian governmental authorities and Dr. Nichols obtaining DEA licensing as an exporter. The entire process is currently in motion, and just might happen. *Stranger things have happened.*

THE MAPS RESEARCH METHODOLOGY CONFERENCE

MAPS is organizing a working conference in Switzerland in early December to discuss the difficult methodological issues in psychedelic psychotherapy research. The meeting will be held in Bern, where the psychedelic psychotherapy in-patient treatment center was established by Swiss psychiatrist Dr. Jorg Roth. Invitations are being extended to the Swiss psychiatrists who worked with psychedelics, to Dr. Dytrych and associates from Czechoslovakia, to Dr. Lester Grinspoon from Harvard Medical School, to Dr. George and Una Ricaurte from Johns Hopkins, and Dr. Charlie Grob from U. of C. Irvine. Psychiatrists from the USSR and from Germany will also be invited.

The purpose of the conference is twofold. The Swiss will share the results of their therapeutic use of psychedelics over the last several years with psychiatrists from several countries. Building on the Swiss reports, the entire group will try to design one or several research protocols which would generate valuable scientific data about both risks and benefits, while interfering as little as possible with the therapeutic treatment of the subjects.

The opportunities for MDMA research in Czechoslovakia, the strong possibility that the Swiss research will eventually be resumed, and the continual clarification of the risk of neurotoxicity, all suggest that legal permission for MDMA research will eventually be granted in one or several countries. The lack of a satisfactory research protocol which adequately addresses and resolves the scientific challenges inherent in conducting research into the psychotherapeutic potential of psychedelically-assisted psychotherapy remains a major factor inhibiting research.

PHARMACEUTICAL COMPANIES STUDY THE MARKET FOR PSYCHEDELICS

A consortium of the largest European pharmaceutical companies has hired a consultant to prepare a research report on the potential medical market for consciousness-expanding drugs. The remarkable study, to conclude spring 1991, will focus on therapeutic applications and political considerations.

MAPS' RESEARCH AGENDA AND FINANCIAL REQUESTS

Several research projects are necessary to help make legal approval of human research with MDMA more likely. One project, the research methodology conference, will help prepare the way for human studies. The other three projects involve small primate studies at Johns Hopkins and will provide data required by the FDA prior to any approval of human psychotherapy research.

These research projects require $27,500. If everyone on the MAPS mailing list becomes a member, all can occur. This research can make a difference with FDA.

The Swiss methodology conference will gather together an international group of experts in psychedelic psychotherapy and research in order to discuss and design research protocols for human studies. In the process, the conference will facilitate international coordination of research.

Cost- $7,500

The no-effect level and recovery study will seek to answer two questions. After administration of multiple doses of 2.5 mg/kg, are the reduced serotonin levels found in only one brain region out of ten a statistical aberration or a valid finding? If the reductions are valid, will the the relatively minor neurotoxicity permit the brain to fully recover pre-treatment levels of serotonin, unlike major neurotoxicity which seems to permit only partial recovery ?

Cost- $5,000

The growth of alternate neurotransmitter systems study will help to determine if other neurotransmitter systems expand to take the place left by reductions in the serotonin system. This finding, if borne out, will significantly change the picture of MDMA neurotoxicity.

Cost- $10,000

The elimination of neurotoxicity study will help determine if Prozac blocks the neurotoxicity of MDMA in primates in a manner similar to its effect in the rat. This study will take place only if field reports indicate that Prozac does not reduce the beneficial subjective effects of MDMA. If Prozac eliminates MDMA neurotoxicity in the primate as in the rat, the neurotoxicity risk, which has prevented human studies for the last five years, may be effectively finessed.

Cost- $5,000

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