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**United
States**

Multidisciplinary Association for Psychedelic Studies, Inc.

August 1991 – Brief Summer Overview by Rick Doblin, MAPS President

The FDA has definitely approved Drs. Al Kurland, Richard Yensen and Donna Dryer's research protocol for the investigation of the use of LSD-assisted psychotherapy in the treatment of substance abusers. Their next steps are to obtain Institutional Review Board approval and then to seek funding.

Drs. Charlie Grob and Gary Bravo, both of the U. of California Irvine, and I are developing a protocol for the investigation of MDMA-assisted psychotherapy in the treatment of physical and emotional pain in terminal cancer patients. We're currently seeking expert consultants to assist with the design of the experiment. Submission of the completed protocol to the FDA is several months off.

Over the past four months I have been exploring the possibility of serving my two-year Presidential Management Internship (PMI) award within the FDA office that regulates the medical use of MDMA, LSD, marijuana, and other Schedule 1 drugs. Though a job offer was not forthcoming (I was told hiring me would be like letting the camel into the tent), I was able to meet at length with several key FDA officials. Relationships of mutual respect are developing which will make my MAPS work more effective. As a result, I've withdrawn from the PMI program and will focus on MAPS.

In mid-August *The Journal of Transpersonal Psychology* will publish my paper on the follow-up to Walter Pahnke's Good Friday experiment into psychedelics and mystical experiences. A previous draft of the paper was sent to all MAPS members several months ago. On July 1, *The Journal of Clinical Oncology* published my paper on the medical use of marijuana. *The Economist* featured my research in an article dated July 6th (reprinted on page four of this newsletter). *The New Republic* printed an article on medical marijuana in its July 15-22 issue which I highly recommend. Also recommended is the July issue of *Gentleman's Quarterly*, which contains a fascinating article about the use of psychedelic substances by people involved in Silicon Valley's computer industry.

The June 1991 issue of *High Times* has a very well written article discussing the February, 1991 conference on psychedelics held at Stanford. MAPS was described as "advocating a strategy of reconciliation with the authorities, based on the assumption that accumulation of scientific evidence favoring the benefits of psychedelics would eventually change the government's position." This was contrasted with the position of Timothy Leary, summarized as "Fuck the government."

Switzerland

On June 24, after a one-year hiatus, official governmental permission was given to four Swiss psychiatrists to resume work with 100 patients previously treated with LSD, MDMA, or 2CB. Switzerland is once again the only country in the world where psychiatrists have legal permission to treat patients with these substances. As you may recall, permission was withdrawn as a result of a tragic situation in France when a woman died after taking the African psychedelic root ibogaine. When the autopsy results were finally released by the Swiss and French authorities there was no evidence MDMA, LSD or 2CB was involved.

Treating new patients will require a rigorous research context and a separate permit. Several Swiss doctors are currently discussing protocol designs with consultants recommended by the Swiss government. Approval for treating new patients is expected by October, 1991. Human pharmacokinetic studies of MDMA are being planned at Berne University to take place in late 1991.

Soviet Union

MAPS was contacted by Dr. Yevgeny Krupitsky, a psychiatrist in Leningrad who works as director of a government research team into the treatment of substance abusers. Yevgeny has successfully incorporated Ketamine into the inpatient treatment of alcoholics and is interested in initiating an effort to conduct MDMA research in Leningrad. MAPS arranged a visit for Yevgeny to Baltimore, where he met with Drs. Charlie Grob, Richard Jensen, Donna Dryer, Al Kurland, and myself. We reviewed the LSD and MDMA protocols and discussed research collaboration.

Mexico

MAPS member Dr. Jim Prescott has begun to collaborate with Drs. Grob, Bravo and I along with Dr. Fernandez, a Mexican physician, on the design of a protocol to investigate MDMA-assisted psychotherapy in the treatment of young women with breast cancer. This protocol will be submitted for approval to the Mexican health authorities, possibly before the end of 1991.

**MAPS
Organizational
News**

MAPS recently received a generous donation of \$10,000. The donors said their gift will be annual "*as long as there is a need for such an organization and as long as MAPS continues to be effective... I trust this long-term pledge will help you in planning your budget as well as encouraging others to be charitable.*" Since last year's MAPS budget was \$45,500, there is still a need for donations of any size.

The largest single item in last years MAPS budget, \$26,000, was devoted to the Swiss conference. The remainder supported part of Dr. Krupitsky's travels in the US, a study examining the Swiss use of psychedelics, several small meetings to discuss the design of the MDMA protocol, the production and mailing of the MAPS newsletters and video, and office expenses, copies, and phones. No salaries were paid. This year's expenditures will focus on protocol development, support for any hearings called by the FDA to discuss the protocol and, hopefully, the experiment itself.

The MDMA protocol in progress involves one experimental group and two matched control groups. The subjects will be terminal cancer patients with an estimated remaining life span of less than four years and more than six months. The volunteers will be patients suffering from clinically diagnosed anxiety and depression who are in significant physical pain. The experimental group will receive four MDMA-assisted psychotherapy treatment sessions and one session with an inactive placebo. The setting will be relaxed with the patient listening to music with eyes closed, intermittently interacting with the therapists. One control group will receive no MDMA but will receive five music therapy sessions lasting the same length of time as the MDMA-assisted psychotherapy sessions. The other control group will be a no-treatment group. These patients will be encouraged to seek treatment from whomever they choose. All subjects will be evaluated and followed up in an identical manner.

The protocol is not designed as a double blind study. In part this is because following such a methodology would have required administering stressful spinal taps and tryptophan challenge tests even to seriously ill subjects who did not receive MDMA. In addition, the double-blind probably would not fool either the patients or physicians about who received either the placebo or the MDMA.

The protocol now has five separate sections:

A) For the investigation of neurotoxic risk to the serotonin system, volunteers will be administered both a spinal tap and a tryptophan challenge test. Drs. George Ricaurte and Lewis Seiden have been asked to review this aspect of the protocol to ensure that our methodology will be state of the art.

B) Research into the effect of MDMA on the immune system will be conducted as part of the risk analysis and also in order to determine whether positive cathartic experiences are associated with improved functioning of the immune system. This research will help determine if imagery work conducted under the influence of MDMA can assist in a holistic approach to the treatment of cancer. Information will also be gathered about the risk of MDMA-assisted psychotherapy in AIDS patients, where some preliminary reports suggest that productive psychotherapeutic work can be conducted.

Preliminary contacts have been made with officials of the Fetzer Foundation and with Dr. George Gellert, a researcher funded by the Fetzer Foundation to investigate the survival rates of some patients in Dr. Bernie Siegel's Exceptional Cancer Patients program. Dr. Gellert has met several times with Charles Grob and is interested in assisting with protocol design. If all goes well, this aspect of the protocol may help to attract some financial support and will provide excellent data on the remarkable mind/body interaction that MDMA can facilitate.

C) Another aspect of the protocol involves the investigation of the effect of MDMA-assisted psychotherapy on physical pain. We will monitor amounts of pain-killing anesthetic drugs needed and will also conduct a series of pain sensitivity tests before, during and after the sessions.

D) An attempt will be made to describe the effect of MDMA on the psychological functioning of the volunteers during the acute period of MDMA's action. We are hypothesizing that MDMA may be an effective adjunct to psychotherapy due to its ability to strengthen the therapeutic alliance, deepen the experience of emotion, reduce anxiety and fear, and promote a heightened sensitivity for non-habitual thinking. We will try to measure some of these concepts through non-intrusive ratings of tape and possibly video recordings of the sessions, scored by independent raters. We will also try to gather some direct information through short questionnaires and tests. David Lukoff, co-author of an excellent review of psychedelic research in the late 1990 issue of the *Journal of Transpersonal Psychology*, has already helped suggest some tests. Additional consultants will soon be contacted.

E) We will also seek to determine if volunteers experience a lifting of the anxiety and depression related to their terminal status. We will be using a variety of standard measures to evaluate psychotherapy outcome, quality of life, and an index of spirituality.

The MDMA Protocol – proposed methodology of the experiment

Personal Note:
If anyone has any suggestions for the design of any portion of the protocol, please contact me. I will be out of touch travelling from August 7-September 5, visiting Israel, Egypt, Germany and Switzerland. I will respond to all calls or letters beginning about September 5th.

Research does
make a
difference...

*The Medical Use
of Marijuana
Study* of Rick
Doblin and
Mark Kleiman,
has been
reported in
The Economist,
July 6, 1991

*The New York
Times*,
May 1, 1991

USA Today,
May 1, 1991

LA Times,
May 1, 1991

*San Francisco
Chronicle*,
May 1, 1991

*NBC National
News*,
May 1, 1991

*Wall Street
Journal*,
May 2, 1991

Today Show,
May 6, 1991

Boston Herald,
June 28, 1991

New Republic,
July 15 etc. etc.

And...
On June 30th -
Ann Landers
came out in
support of
Medical
Marijuana!!!

The Economist

JULY 6TH-12TH 1991

Medical marijuana

Cross-eyed and painless

CAMBRIDGE, MASSACHUSETTS

DRUGS can be medicinal or recreational: marijuana is both. For nearly 20 years advocates of its medical use—to relieve the nausea of chemotherapy, to treat glaucoma and to help AIDS patients gain weight—have fought in the American courts to have the drug reclassified so that doctors can prescribe it. Currently marijuana is grouped with the most disapproved of drugs, such as LSD and heroin. The government argues it must remain so because it has no “currently accepted medical use in treatment”. A new study by researchers at Harvard refutes this.

Mainly because of its effectiveness in treating the vomiting common among cancer patients during chemotherapy, tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana, was approved for medical use in America in 1985. A synthetic form of THC is sold in pill form under the trade name Marinol; last year almost 100,000 doses were prescribed. Smokable marijuana, however, is available to just 34 people through a “compassionate use” programme. To the confusion of many a police officer, these patients are given a supply of marijuana cigarettes rolled by government hands at a research farm in Mississippi.

Proponents claim that smoking marijuana works better than taking oral THC. In 1988 Francis Young, a judge who examines administrative issues for the Drug Enforcement Agency, recommended that marijuana be reclassified on the ground that “current acceptance” of a drug is present if a “respectable minority” of doctors endorse it. The administration disagreed, claiming that the vast majority of doctors believe oral

SCIENCE AND TECHNOLOGY

THC is as reliable and effective as smokable marijuana and produces fewer side-effects.

Enter Rick Doblin and Mark Kleiman, two drug-policy researchers at Harvard's Kennedy School of Government. To test the administration's thesis, they conducted a random survey of members of the American Society of Clinical Oncology. Some 1,035 responded, about 10% of America's oncologists. The results, published in the July 1st issue of the *Journal of Clinical Oncology*, surprised even Mr Doblin and Mr Kleiman: nearly half of the respondents said they would prescribe smokable marijuana if it were legal. Indeed 44% of them said they had, in effect, done so already by recommending it to one or more of their patients, despite the possibility of prosecution.

Nearly two-thirds of the oncologists agreed that marijuana was an effective anti-emetic, while 77% of the 157 who expressed a preference said that smokable marijuana is more effective than oral THC. A majority said that marijuana was no worse than Marinol in terms of producing bad side-effects.

Predictably, such numbers have the Bush administration's drug-policy office all out of sorts. Not long ago it chided Mr Young by suggesting that only one in 200 doctors would support medical use of marijuana, and that this was not a “respectable minority”. When some of Mr Doblin and Mr Kleiman's results were published recently as a letter in the *Annals of Internal Medicine*, the adverse publicity led Herbert Kleber, number two in the drug-policy office, to declare that anyone who really needed medical marijuana could get it through the compassionate-use programme within 30 days.

But last week the administration admitted it was planning to limit that already tiny programme. Now, under strong pressure from AIDS activists—marijuana has proved especially helpful to people taking AZT to fight the AIDS virus—Mr Kleber has said he will soon call an inter-agency meeting to decide what to do. Meanwhile a federal appeals court has rejected the government's response to Mr

Young's recommendation that marijuana be reclassified. The court said the government's interpretation of “current acceptance” was impossible to meet.

Despite all this, the administration is unlikely to yield. There are other, non-medical, issues at stake. One official agreed that to admit that marijuana might ever be “safe and effective” would make a mockery of the government's strident anti-drugs campaign. In some ways the research by Mr Doblin and Mr Kleiman already has.

