MAPS

NEWSLETTER OF THE MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

Politics & Protocols: In Search of a Balance

THESE LAST several months, my work has focused more on the politics of research than on the research itself. I'm hoping that the balance will shift back toward research in the coming months. The political work has mostly been in support of Dr. Abrams' proposed study into the use of smoked marijuana in patients suffering from the HIV-related Wasting Syndrome (p. 11). The study is still not fully approved, though it is gathering momentum. The political and scientific issues are highlighted in an exchange of letters between myself and Robert Peterson, Michigan State Drug Czar (p. 44). ■ The marijuana smoke analysis study is further along. The National Institute on Drug Abuse (NIDA) has agreed to donate 250 grams of marijuana to the MAPS/California NORML water pipe/vaporizer study (p. 19). For a comprehensive overview of MAPS' strategy for evaluating marijuana's safety and efficacy in treating the AIDS Wasting Syndrome, see MAPS' Clinical Plan (p. 16). MAPS is also working with other organizations in support of National Medical Marijuana Day on November 15, 1994 (p. 24). ■ In the world of psychedelic research, the focus is decidedly on protocols, especially in Dr. Rick Strassman's clinic. Dr. Strassman's article describes the expansion of his DMT work, and his upcoming psilocybin project (p. 32). Laura Berg's article describes her work as a research nurse in Dr. Strassman's DMT studies (p. 34). Research nurses perform some of the most sensitive work in psychedelic research, but their voices are almost never heard. Not any longer! One component of the psilocybin research is Tamara Allen's Archetypal Art Therapy project, to which MAPS donated art supplies (p. 39). ■ Additional progress includes NIDA's plans to conduct a phase 1 safety study with ibogaine (p. 30). Psychedelic research has been approved in Germany, and is being proposed in Israel (p. 41). ■ In MDMA research, the MAPS-sponsored study by Nicaraguan psychiatrist Dr. Manuel Madriz Marin into the use of MDMA in the treatment of Post-Traumatic Stress Disorder is well into the protocol design phase (p. 26). In England, Nicholas Saunders investigated MDMA and the placebo effect (p. 28). In the U.S., the news from Dr. Charles Grob's MDMA research is music to the ears. On May 18, 1994, the first legal dose of MDMA in the United States in almost nine years was experienced by a subject in Dr. Grob's research (p. 25). ■ In a stroke of incredible good fortune, Dr. Grob received a substantial donation for MDMA research through a combination of high-tech wizardry and old-fashioned generosity. As part of MAPS' outreach efforts, Dr. Grob's article from the last MAPS newsletter was posted on the Internet (p. 8). Three days later, Dr. Grob received a call from someone at the LA airport who had seen the article. He had a few hours to spare between planes, and asked to visit. He took a cab to Dr. Grob's office, stayed about forty-five minutes and left a check for $25,000. Then he flew home to Hong Kong. How about that for pennies from heaven! ■ Speaking of donations, this issue contains MAPS' annual report for FY 93-94, which officially ended May 31, 1994 (p. 4), MAPS' organizational strategy (p. 2), and letters from members (p.10). With your continued support, we *can* make a beneficial difference.

Rick Doblin, *MAPS President*

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maps' organizational strategy

RICK DOBLIN,
MAPS PRESIDENT

MAPS IS A RESEARCH and educational organization focused on psychedelic studies. In combination with MAPS' annual financial statement (page 4), and the articles on most of the research projects that are being directly sponsored by MAPS (pages 11, 19, 26), this organizational strategy report should enable both new members and long-time supporters to obtain a more complete overview of MAPS' priorities, capabilities, and upcoming activities. Your comments, criticisms, and suggestions are especially welcomed so that MAPS may remain an effective agent on behalf of its members, staff and research teams.

MAPS' Research strategy

Psychedelic studies is a vast topic, especially considering that Dr. Humphrey Osmond, who coined the word "psychedelic" in 1956, intended it to mean "mind-manifesting". MAPS is primarily focused on scientifically investigating and obtaining legal sanction for the medical uses of psychedelic drugs. While some religious and non-medical uses of psychedelics may be potentially beneficial and may eventually become socially sanctioned in some manner, the medical use of psychedelics is likely to be integrated into our culture before other uses. Furthermore, since the public has been exposed to so much misinformation and disinformation about psychedelic drugs, medical research is essential to begin the process of replacing fear with facts.

MAPS is primarily focused on scientifically investigating and obtaining legal sanction for the medical uses of psychedelic drugs.

MAPS' core mission is to seek FDA permission for the prescription use of MDMA. Due to MDMA's uniquely gentle yet profound effects, the medical use of MDMA is more likely to be integrated into psychiatry before other more powerful, longer-lasting and more psychologically challenging psychedelics like LSD, psilocybin or mescaline. In addition to MDMA research, MAPS actively supports research with other psychedelics, each of which has its own therapeutic potential and risk profile. However, MDMA is the "orphan drug" that MAPS has adopted. To further its core mission, MAPS has funded MDMA animal and human safety studies, opened an FDA Drug Master File for MDMA, assisted Dr. Charles Grob in obtaining permission for the first FDA-approved human study of MDMA ever conducted (p. 25), and is preparing to support efficacy studies into MDMA-assisted psychotherapy in the U.S. and abroad (p. 26).

Given that MAPS concentrates its efforts on the medical use of psychedelic drugs, it must be somewhat surprising to see that most of the articles in this issue of the newsletter focus on the work that MAPS is doing to develop the medical use of smoked marijuana. While marijuana can be considered a "mind-manifesting" drug, researching the "marijuana munchies" to promote weight gain in AIDS patients suffering from the HIV-related Wasting Syndrome certainly seems a long way from most people's picture of psychedelic research.

Marijuana research

The main reason that MAPS is involved in facilitating the first FDA-approved clinical trial with marijuana, as well as the first FDA-approved clinical trial with MDMA, is that there is a strong cultural bias against acknowledging that any drug that our government has made illegal has any beneficial uses at all, even under medical supervision. Since this cultural

bias would inhibit the rescheduling of MDMA for prescription use even if the necessary scientific data were in hand, part of the work of obtaining social sanction for the medical use of MDMA must be to address this cultural bias. For both scientific and cultural reasons, at this time the medical use of marijuana is a more effective point of departure than the medical use of MDMA from which to address this bias. The scientific data that is necessary to submit to the FDA in support of an application to approve marijuana's prescription use would require about two years to gather, while the same quality of data regarding MDMA will take at least five years. Also, several polls suggest that a majority of the American public is ahead of the government and already approves of the medical use of marijuana (the most recent is a June, 1994 Parade magazine call-in poll that showed that 89% (!!) of the callers favored the legal prescription use of marijuana). Strategically, obtaining legal approval for the medical use of marijuana will make it much more likely that legal approval for the medical use of MDMA can be obtained, as well for the other psychedelic drugs.

MAPS' top priority for this next year is to help MDMA research advance from Phase 1 safety studies to Phase 2 efficacy studies.

Once permission for Dr. Donald Abrams' study has been obtained and the pilot study begins, MAPS' work on the medical use of marijuana will have reached a major turning point. The door will have been opened to FDA-approved research, and a major step of the overall clinical plan for the development of the medical use of marijuana will be underway. After the conclusion of the pilot study, I hope that MAPS' efforts on behalf of the medical use of marijuana will be joined by other organizations whose mission focuses more directly on marijuana and/or AIDS research. In particular, I hope that marijuana research will be supported by the Drug Policy Foundation (DPF), which has been given a 3 million dollar matching grant to distribute to various demonstration projects in drug policy reform, one of which may include medical research with marijuana.

MDMA research

MAPS' top priority for this next year is to help MDMA research advance from the Phase 1 stage of gathering basic safety data about its physiological and psychological effects, to the Phase 2 stage of investigating its therapeutic potential. If all goes well, the Nicaraguan study into the use of MDMA in the treatment of Post Traumatic Stress Disorder will become the first scientific controlled study of MDMA's therapeutic effects ever conducted, and Dr. Grob's proposed study into the use of MDMA in the treatment of pain and distress in end-stage cancer patients will follow. In order to support Dr. Grob's study, MAPS is committed to try to raise its entire budget of $160,000. I hope to obtain a matching grant from a major foundation, and raise the rest from individual donors and other foundations. MAPS is also working to initiate MDMA research in Israel (p. 41).

Conclusion

MAPS' organizational strategy is continually evolving. By making the strategy explicit, the members of MAPS are able to more fully assess where their organization is headed. Your comments and suggestions are encouraged, for this strategy is effective only to the extent that it is supported by the membership.

maps' financial report - fiscal year june 1, 1993 to may 31, 1994

RICK DOBLIN

AS AN IRS-APPROVED 501 (c) (3) non-profit organization, MAPS has a responsibility to use its limited funds wisely and strategically, and to be accountable to its members and the public about exactly where and how MAPS' funds are being spent.

This annual report will provide you with a window into the inner operations of MAPS. It will permit MAPS members to assess how well their funds were spent, and evaluate MAPS' capacity and potential for action. Writing this report gives me a chance to reflect on the accomplishments of last year, and the challenges of the next.

MAPS' total income for FY 93-94 was $106,650

Income

MAPS' total income for FY 93-94 was $106,650.48. This reflects the largest sum of contributions in MAPS' eight year history. Though MAPS' total income for FY92-93 was $113,962, over $22,000 of that was comprised of conference admission fees, almost all of which simply covered costs for MAPS' 50th Anniversary of LSD events held in Santa Cruz and San Francisco.

The amount of money in MAPS' bank account at the end of the year rose to the rather astonishing sum of $55,946.58. Of this sum, $48,820 was restricted for specific research projects. By the time you read this report, several months after the close of MAPS' fiscal year, $1,568 of the restricted funds will have been spent on the Nicaraguan project, and $9,000 will have been spent on the water pipe/vaporization study. At the time of this writing, $38,252 remains earmarked for specific research projects

MAPS had a balance of $7,126.58 in unrestricted operating funds at the end of the fiscal year. Most of this sum has now been spent on this newsletter, to pay for operating expenses, and Tamara Allen's psilocybin-art research project (p. 39).

Restricted funds

The research projects to which restricted funds have been committed includethe following, a) $22,953 for the study of the use of MDMA-assisted psychotherapy in the treatment of Post-Traumatic Stress Disorder (PTSD) in Nicaraguan soldiers and civilians traumatized during the Nicaraguan Civil War (p. 26), b) $9,000 for the study of the effectiveness of water pipes and vaporizers in filtering marijuana smoke (p. 19), c) $4,399 for the study of the use of LSD in the treatment of substance abuse, and 4) $2,000 for the study of ketamine in the treatment of alcoholism.

The fact that MAPS had any carryover at all reflects both its success in raising funds for research as well as some disappointments in the pace of the research as it moves into the implementation phase. Of course, considering the kind of research that MAPS supports, delays are to be expected and the fact that anything at all gets accomplished is still rather remarkable. The Nicaraguan MDMA/PTSD study is still in the protocol design stage, the water pipe/vaporizer study was delayed due to complications in obtaining the marijuana needed for the study, the LSD in the treatment of substance abuse study has been approved by the FDA but is still without Institutional Review Board approval, and the small grant for the study of ketamine in the treatment of alcoholism will fund Dr. Krupitsky's studies and lectures in the United States in the fall. While frustrating, these delays are temporary.

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Total FY 93-94 Expenses	83,052.25	37,260.30	27,373.71	7,487.74	10,930.50

By the close of this current fiscal year, I hope that most if not all of MAPS' carryover restricted funds will have been used for the research projects for which they are earmarked. I'd also like to raise an additional $160,000 in restricted funds specifically to support Dr. Grob's Phase 2 MDMA research project exploring the use of MDMA-assisted psychotherapy and guided imagery in the treatment of pain and distress in end-stage cancer patients. This will be MAPS' most ambitious fundraising endeavor ever, and I'll discuss it in more detail at a later time.

MAPS' accounting of restricted funds does not reflect the sum total of its efforts to raise funds for research. I'm very pleased to report that Dr. Grob's Phase 1 MDMA research project received a contribution of $25,000 given directly to Harbor-Hospital UCLA Medical Center. This sum was donated by a

single benefactor who fortuitously saw, on the Internet, Dr. Grob's article from the last issue of the MAPS newsletter which a MAPS member, Robert Jesse, had helpfully posted.

In other MAPS-facilitated direct contributions, Dr. Donald Abrams' study comparing smoked marijuana to the oral THC capsule in promoting weight gain among people suffering from the HIV-related wasting syndrome has received a pledge of $50,000. Once this study is finally ready to begin, and all the legal authorizations have been obtained, this sum will be made available to Dr. Abrams (p. 11).

Expenses

MAPS spent $10,930.50 for research during this last fiscal year. Of that sum, $4,260 went to support Dr. Grob's Phase 1 and Phase 2 MDMA research projects, and $3,479 went to support Dr. Madriz's effort to conduct MDMA research in Nicaragua. MAPS contributed $1,000 to the ibogaine research of Dr. Mash and Dr. Sanchez-Ramos, and sent $1,101 to support Drs. Richard Yensen and Donna Dryer's efforts to get their LSD in the treatment of substance abuse study off the ground. A sum of $1,088 was spent on marijuana research, with the single largest expenditure being a patent search of water pipes to try to find methods of filtering marijuana smoke.

MAPS' operating expenses are covered by income by rather slim margins.

On the operating side, MAPS' financial condition lacks any significant carryover surplus. MAPS' operating expenses are covered by MAPS' income by rather slim margins. The constant effort to manage MAPS' cash flow limits my ability to work on long-term projects and prepare research grant applications.

Education

In FY 93-94, MAPS spent $37,360.30 on communication and education. This sum includes the costs of the newsletters, books, videos, and articles that were sent to members along with phone bills, postage, and conference expenses. The single largest item in this category is the MAPS newsletter, for which printing, postage and related production costs amount to about $20,000. This sum does not reflect the value of the time donated by the talented and dedicated graphic designer who gives the MAPS newsletter its polished look. If MAPS' staff time were to be factored into the production of the newsletter, the costs would rise to about $27,500, about one-third of MAPS' entire unrestricted budget.

As many of you have commented, the MAPS newsletter has been growing in size and quality. Over this last year, I've chosen to focus a significant portion of MAPS' resources on the newsletter. This decision was made partly to enhance the benefits to members, and partly to help the ideas expressed in the newsletter reach a wider audience and have more impact. This year the newsletter is sent gratis to an increasingly large circle of government regulators, policymakers, scientists and even to opponents of the medical use of psychedelics and marijuana, in the United States and abroad.

I think it is essential that the news about the renewal of psychedelic research be told in a professional and respectable manner and be shared with those who influence and make policy. I hope the MAPS newsletter will enable scientists and policymakers to gain knowledge, inspiration and courage from reports about the progress made by their peers in their own country as well as in other countries. And through exposure to views contrary to their own, political opponents may come to see that this line of research is not so threatening and can be considered on its own merits, distinct from larger issues relating to drug control. Ideally, if we can help political opponents to focus on the personal, they might even be able to see that they and their loved ones can benefit from this research. Given the inexplicable turns of fate, the medical use of MDMA for treating pain and distress in cancer and terminal illness can be of potential benefit to anyone, since such illnesses don't discriminate according to political views.

I have edited the newsletter with this larger audience in mind, and hope the membership agrees with this use of MAPS' resources. "MAPS and the Internet" (p. 8) reports on the efforts to make this information more accessible to interested people around the world.

MAPS/Heffter collaboration

In the spring of 1995, MAPS members will see the fruits of a growing collaboration between MAPS and the Heffter Research Institute (see MAPS newsletter Vol. IV, No. 4, Page 34). Heffter will prepare its first Annual Psychedelic Research Review which will report on developments in psychedelic research around the world. This publication will be

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circulated to all MAPS members in the form of a special edition of the newsletter. This review will highlight the scientific expertise of the Heffter Research Institute, and further its quest to raise funds for a psychedelic research center. In addition, MAPS members will be assured that they will be kept abreast of the latest developments in psychedelic research.

Staff

Staff expenses amounted to $27,373.71. This includes my salary of $1,000 gross per month for full-time work, Sylvia Thyssen's gross salary of $1,440 per month along with a small educational fund to help her learn more about psychedelic research and its practitioners, and the fees to MAPS' professional accountant. So far it has not been possible to raise my salary to a level more appropriate for professional work, so I continue to donate the majority of my time. If MAPS obtains more operating funds, I'd like to raise my salary to the level of Sylvia's.

Additional operating expenses include office expenses of rent, office supplies, and bank and licensing fees in the amount of $4,891.74. A one-time capital outlay of $2,596 was used to purchase a portable computer which receives almost constant use.

Fundraising strategy

For the past several years, I've endeavored to use membership donations to cover operating expenses, and to solicit larger restricted donations from funders, with the commitment that 100% of their donation will go to the specific research project of their choice. I believe that this strategy has been successful, as evidenced by the considerable support attracted to various aspects of MAPS' research agenda. However, as a result of the increasing number and importance of MAPS' ongoing research projects, MAPS' responsibilities have also increased. In addition, MAPS now has grown in size to 800+ members, and membership services take a greater amount of time than ever before. As many of you have found out, I am slower to answer mail these days due to the increased work load.

As a result of the increased administrative demands on MAPS, it has been absolutely necessary for MAPS to take on one more staff person. Fortunately, Sylvia Thyssen, with whom many of you have spoken or corresponded, joined MAPS full-time in March. She is learning fast and doing an excellent job. The only reason that it was possible to hire Sylvia full-time (she had previously volunteered her services or worked part-time for several months) was that MAPS received a grant of $15,000 for operating expenses from a single donor. This sum enabled MAPS to cover more than half of Sylvia's annual salary, taxes and benefits. In order for MAPS to avoid collapsing under the weight of its growth and success, Sylvia's continued service to MAPS is essential. In order to assure her long-term employment, Sylvia's salary will need to be generated from an expanded membership and increased contributions for operating expenses. Accordingly, I'm considering it a top priority to try to increase MAPS' membership to about 1250. In this project, every one of MAPS' current members can play a vital role in keeping the organization thriving, and your continued support is sincerely requested.

I'm considering it a priority to try to increase MAPS' membership to about 1250 members. If each member could find just one friend to join MAPS, financial stability would be assured.

Growth

I am pursuing three main strategies to help MAPS grow. The first is by conducting a few targeted mailings to groups of people who might be interested in becoming MAPS members, and receiving the newsletter. The second strategy is directed at MAPS' past membership. We have started to phone past donors who have not renewed their membership to learn their reasons for discontinuing support, and to see if they might decide to renew. So far, this telephone outreach has more than paid for itself, and does not seem to have annoyed anyone overmuch.

The third strategy is an appeal to MAPS' current membership, and to all of the readers of this newsletter. If you aren't a member, please consider becoming one. If you are a member, please renew. Most importantly, if each member could find just one friend to join MAPS, financial stability would be assured.

There you have it, MAPS' financial report for FY 93-94. MAPS continues to grow as does its research agenda, responsibilities, and membership. With your continued support, and that of new members who share an interest in MAPS' priorities, the report from FY 94-95 will demonstrate even more accomplishments. This year's priorities are to spend our current carryover funds, get MAPS' operating budget on a more secure footing, and raise $160,000 for Dr. Grob's study of the use of MDMA to reduce pain and distress in terminal cancer patients. With your help, it can be done! ■

putting maps on the **internet** map

SYLVIA THYSSEN

IN THE WAKE OF THE SPRING ISSUE, with its article "Psychoactives and the Internet" by Bob Harris and Robert Jesse, many of you have inquired about putting MAPS online. We started with an email address, rickmaps@aol.com, added sylviamaps@aol.com to accomodate the increasing specialization at MAPS homebase, and things have exploded from there. Ten or so people have offered to help with various options: FTP, World Wide Web (WWW), mailing lists, facilitating forums, etc. Those of you familiar with the Internet will attest to the dizzying array of choices.

A benefactor spotted the article from the MAPS newsletter on the Internet, contacted Dr. Grob to discuss the MDMA research project, and donated $25,000

World Wide Web

The newest and most ambitious Internet service is World Wide Web. WWW browsers such as the program Mosaic can display text and graphics and allow for sound and video bites and reader feedback. We are currently developing a WWW site, available with WWW clients such as Mosaic, at "http://www.bonnell.com/passenger-deck/maps/". This server also provides an excerpt from PIKHAL, and hopes to expand the online options for those wishing to explore current trends in the area of psychedelic culture and research. All four issues of Vol.IV (1993-94) of the newsletter are now online, including the gorgeous back cover of the Spring 1993 issue! Future enhancements with the hypertext will evolve, and remaining back issues will be available as they are converted. The MAPS newsletters are also available via anonymous ftp from ftp.bonnell.com/pub/maps. They can be found in the directory ftp/pub/maps and are archived by issue, in Unix compressed, tar format. The newsletter articles are in plain text form. Special thanks are in order to William King of Mount Bonnell, Inc. for expediting this project, and providing the technical expertise, extra hours, and support that the World Wide Web demands.

Another member, Julie Petersen, has also offered to MAPS her wealth of knowledge and experience with facilitating online forums. Julie is Cruise Director (online editor) for WIRED magazine's new electronic venture, HotWIRED, coming in September. In the fall, she will also be maintaining a World Wide Web MAPS site at Indra.net. Currently, she is inquiring into the possibility of a version of MAPS for AOL, possibly in the Education and Research or Science sections. Another member, Amos Clifford, has proposed an outline for such a forum, which could include all the back issues, scheduled chats, special guests, articles from related fields, current events newsflashes, lists of archive sites and allied organizations, and a place for ordering or signing up online. This option is still in a conceptual state; look to further issues for updates.

MAPS Gets Noticed Online

We've been considering how to time the online posting of new issues of the newsletter, so as to be sensitive to the supportive members who subscribe only via "snail-mail". The online newsletter will not be available until after members receive their newsletter in the mail. Storing the electronic format of MAPS and messages pointing to it at one or several points on the Net can only enhance our efforts at providing accurate, timely information about the budding state of psychedelic research. The power of posting information accomplishes more than just serving the public interest. Bob Harris posted the Vol. IV No. 3 issue at the Harvey Mudd College FTP site (ftp hmc.edu)

and several people have joined MAPS as a result. Only three days after Robert Jesse posted the Harbor-UCLA MDMA research update in March, another most welcome form of attention resulted. Dr. Grob received a call from a someone who had spotted the article, was changing planes at L.A. airport, and wished to drop by and discuss the MDMA research project with him before continuing on the last leg of his journey. After a short conversation, in which Dr. Grob convinced the visitor that he sincerely intended to conduct a fair and honest appraisal of MDMA's risks and benefits, the visitor decided on the spot to support Dr. Grob's research. He wrote a check for the full sum needed to begin the Phase 1 study: $25,000!

In addition to the email and other services MAPS gets through America Online, we have also established an account with an excellent local Internet service provider, Creative Cybernetics. The first Internet territory I explored was Usenet Netnews. In a single four hour session, I found 32 Newsgroups that yielded useful information and to which I'd like to post articles or messages about MAPS. If you would like to take on part of this task, please email me at st.maps@cybernetics.net. This is also the address to which you may direct your questions about ordering, renewing, or the status of MAPS online. I encourage members to point us to any interesting sites or situations that you come across on the Net.

With patience and your ongoing support, we'll continue to develop the exciting online options available to us. Thanks to all those who have provided and offered help with this project. ■

psychedelics and psychiatric drugs:
national institute of mental health update

IN THE LAST MAPS NEWSLETTER we alerted readers to a study we are conducting at the National Institute of Mental Health on the interaction of hallucinogens and antidepressants. We asked to interview people who have taken both of these types of drugs at the same time. The response was tremendous and we'd like to thank everyone who took time to be interviewed about their experiences.

What we've been finding seems to break down into two types of responses, dependent on which class of antidepressant a person was taking. Those people who had been taking an antidepressant with selective effects on the serotonergic systems in the brain (drugs such as Prozac, Zoloft, Paxil) and then took LSD had a greatly diminished response to the hallucinogen. This decrease in response to LSD was also seen in those people who had been taking an MAO inhibitor.

In contrast, people who had been taking tricyclic antidepressants (such as Tofranil, Norpramine), which have primary effects on norepinephrine systems in the brain, and then took LSD had a potentiated response to the hallucinogen. This is similar to what happened to people who were taking lithium, either alone or in combination with a tricyclic antidepressant — there was also an increased response to LSD.

I have had only one report with MDMA thus far. A person took MDMA after taking an MAO inhibitor and had a hypertensive crisis (he collapsed for several hours). This is a very dangerous and potentially fatal combination which could have been anticipated based on the way both of these drugs work. Do not try this at home!

Please note that all the reports we received were from people who had been taking their antidepressants for at least 4-6 weeks. This is the timeframe when biochemical systems in the brain are significantly altered and therapeutic effects begin to occur. We do not know what the effects of short-term use of antidepressants might be on the hallucinogenic response.

This study is important because it helps scientists to better understand both how hallucinogens affect neurochemical systems as well as to understand how antidepressants act in the brain. The case reports that we have gathered (numbering over 40 now!) were presented at the Serotonin Club meeting in Chicago at the end of July and will be submitted for publication soon.

Anyone who has additional information can contribute to our study by contacting me at their earliest convenience. ■

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• maps forum

Dear MAPS,

I am a 76 year old woman who was recently introduced to MDMA by a psychologist and dear friend. There are a number of us who are doing innovative and responsible work here in uptight, rigid Orange County. We are starting a "Gentle Revolution" - one in which we fight, not each other but the forces which keep us from expressing all of our truly wonderful human qualities. We greatly appreciate and admire your work!

Emily Coleman

Dear MAPS,

One article I differ with fundamentally is the one written by Jose Stevens on "The Macho Ingestion Syndrome".

It has been my experience that larger doses can produce significantly different experiences than smaller doses. What may be an heroic dose for someone may be an "aesthetic" dose for another. But that is not exactly all of the point he makes or the point I am making. It seems to me there is a quantitative difference between low dose and high dose, and different states can be achieved with different dosages. This doesn't have to be a "macho" thing.

Stevens makes several good points. Essentially more is not necessarily better. However, he leaves out some things, which in my experience seem important. Sometimes a higher dose is necessary to "break thru". Sometimes the "ego death" experience is necessary for growth. Sometimes we have to face all the biographical/psychodynamic stuff to go further. In fact, I'm beginning to realize it is a prerequisite to move into the transpersonal experiences. Not an absolute prerequisite, but it seems to help.

Stevens also says the psyche was never meant to question its own integrity or viability. That is pretty far from my own paradigm. I agree, however, when he says that when the person becomes suicidal, fears instant annihilation, or travels to hell and can't get out, that this isn't the time to push the dose.

My thoughts on this are a little vague, and a little defensive. I'm a big proponent of the all or none, 'the heroes journey', providing there is good set and setting, and a stable individual. Certainly there is risk.

David R. MD

dlr@netcom.com

Dear MAPS,

I have read all the MAPS' issues from 1989 to the present. I wholeheartedly congratulate you on your persistence over the past few years in developing a high quality newsletter. The reason I enjoy this publication is due to its rational and scientific approach to a fascinating topic— psychedelics. You are doing a great favor to many people.

Some aspects of an article in the Spring 1994 issue disturbed me; the one about Dr. Kungurtsev discussing spirituality. I agreed with many of his points, but there were some that shocked me. What is "spirituality"? I have yet to hear a satisfactory definition for this word. Some people define it as "Praise the Lord", others define it as "human love and connection", still others define it as "The nonphysical world is the ultimate reality". Dr. Kungurtsev's implied explanation seems to largely include the third definition. "You are not your body", he claims. If we are not the body, what are we? Has he ever had sex with a non-body? It's a ludicrous statement.

He continues, "Psychedelics... in significant doses, can give a direct experience of conscious existence without the body". What?! Did I read that right? Has Dr. Kungurtsev studied any neuroanatomy and neurochemistry? Doesn't he realize that all of our mental states, thoughts and feelings, no matter how "bizarre", "spiritual", "pure consciousness", "out of this world", "near death", etc. are due to the interplay of neurotransmitters and electrical signals within the brain? Consciousness does not exist without the physical brain; it is born with it, develops and enhances as the brain forms more intricate neural connections, and disappears when the physical brain dies. I thought that most scientists had given up archaic Descartian thinking. The new paradigm is: I am, therefore I think.

Let's not underestimate the human brain. It has had millions of years to develop to the fascinating state it is at this time. It is still evolving rapidly. I have taken high doses of Ketamine and other psychedelics and experienced the "out of body" perceptual states he discusses in his articles. However, I do not believe these states were "nonphysical". They were due to neurochemical alterations. A chemical was introduced into the brain that changed a state of con-sciousness. How can it be "nonphysical"? Let's be real.

In the Spring 1992 issue, Dr. Kungurtsev discussed his use of Ketamine in neuroses. I learned from reading about his research and hope he continues contributing this type of useful scientific information. In the meantime, let's leave unsubstantiated "old faith" claims to the myriad other publications by the checkout counter at the supermarket.

Realistically,

A body from Los Angeles, CA

the medical use of **marijuana** -

A progress report on Dr. Donald Abrams' pilot study comparing smoked marijuana and the oral THC capsule for the promotion of weight gain in patients suffering from the HIV-related wasting syndrome

RICK DOBLIN

TIME GOES BY, and the approval process for Dr. Donald Abrams' protocol seems to move from one political or scientific obstacle to another. As each obstacle is surmounted, the protocol gains momentum, yet additional obstacles have continually appeared on the horizon. The starting date for the protocol is still too difficult to predict. Fortunately, the approval process is inexorably moving forward. The study can be delayed but I don't think it can be prevented.

Widespread, bipartisan and powerful social forces are coming into play in support of MAPS' strategy of conducting FDA-approved research into the medical uses of marijuana. The image in my mind is of a slow-moving stream dammed at all outlets except for one (the FDA), forcing the flow of water to move in that direction. One example of popular support is a June, 1994 phone-in poll of the readers of Parade, a mainstream magazine with a circulation larger than any other magazine in America. The poll indicated that 89% of the callers favored the medical use of marijuana.

With respect to the AIDS study, the protocol design process is now complete. For the last two years, multiple drafts have bounced back and forth between the FDA, the Scientific Advisory Committee of the San Francisco Community Consortium (which helps coordinate all AIDS research in the San Francisco Bay area and whose research director is Dr. Abrams), the Institutional Review Board of UC San Francisco (where Dr. Abrams is on the faculty), and the California Research Advisory Panel. Finally, every agency with statutory responsibility to review the protocol design has approved the final draft of the study.

The last remaining obstacles involve obtaining DEA permissions for the study. Dr. Abrams has been waiting over four+ months for his DEA Schedule 1 license, and it is proving impossible at this time to obtain DEA permission to import high-potency marijuana from the Netherlands for the study. Before reporting on the unresolved aspects of MAPS' effort to conduct research into the medical use of marijuana and on the various strategies and options that are possible at this point, I'll first outline the agreements that have been reached concerning the protocol design.

Approved Protocol Design

The study will be a pilot project, rather than a full-scale clinical trial designed to get statistically significant results. With so many variables in this groundbreaking and very important project, it is wise to conduct a pilot study first. This will permit the research team to determine if the experimental procedures work as well in practice as they appear to on paper, and to decide if the experimental design needs any major modifications. In addition, the pilot study will gather statistical data that will enable a statistician to determine the number of subjects that will be required for the full-scale multi-site trial.

The starting date for the protocol is still too difficult to predict. Fortunately, the approval process is inexorably moving forward.

The pilot study calls for 40 volunteers with a clinical diagnosis of the AIDS Wasting Syndrome. Subjects will be randomly assigned to one of four different experimental groups, each composed of ten people. The study will last for a period of three months, with the primary outcome variable being each subject's weight.

The subjects in three of the groups will receive smoked marijuana within the context of a double-blind methodology. One group will receive marijuana of high potency (10% THC), another group will receive marijuana of medium potency (4% THC), and the control group will receive marijuana of low-potency (1.5% THC). The subjects in each of the three marijuana groups will know that they are receiving smoked marijuana, but will be blind as to the potency of the marijuana they receive. The experimental team will also be blind as to which potency each subject is receiving. This range of potencies is intended to produce an effective double-blind. The range of potencies also permits the researchers to investigate whether high-potency marijuana significantly minimizes marijuana's potentially harmful effect on the lungs by virtue of the fact that less tar and particulate matter is inhaled per unit of THC.

Subjects in the fourth group will receive the oral THC capsules in what is considered an "open label" control group. This term is used because both the subjects in the group and the experimental team will be

told the identity of the test drug being administered.

A double-blind methodology for all four groups was not possible. To begin with, the Scientific Advisory Committee of the San Francisco Community Consortium rejected the use of any inactive placebo on the grounds that it would be unethical not to provide terminally ill patients with some form of treatment. Given that only active drugs could be used in the study, there is no known method of blinding people as to whether or not they are receiving an active THC capsule or are smoking active marijuana. Even if subjects were given both a pill and a cigarette, one of which was a placebo and the other was active, the patient would easily be able to tell which was the active drug. The clue would be the dramatically different times of onset of the subjective effects caused by the oral THC capsule and smoked marijuana. The subjective effects of the THC capsule generally take about 45 minutes to become noticeable. However, this time of onset varies considerably in the same person from day to day, depending on the contents of their digestive systems. Meanwhile, smoking marijuana produces virtually immediate effects.

The current reason the protocol is delayed is DEA reluctance to issue Dr. Abrams' his DEA Schedule 1 license.

A maximum of two grams of marijuana per day will be provided to the subjects in the three marijuana groups. This upper limit on the amount of marijuana each group can smoke will ensure that the members of the different groups do in fact receive different amounts of THC. If there were no quantity limits and the subjects were permitted to smoke as much as they wanted, it would be possible for the subjects receiving the low and medium potency marijuana to obtain the same dose of THC as the subjects in the high potency group. As a result, this could eliminate any differences in therapeutic levels of THC between the groups and leave the study without a marijuana control group. In any case, providing subjects with unlimited quantities of marijuana would be unacceptable to the DEA, and might increase the likelihood that some of the marijuana from the study would be diverted to other people (which could cause the entire project to be halted).

The Experimental Hypothesis

The study is designed to gather preliminary evidence about possible differences in weight gain between the subjects in the medium and high potency groups as compared to the control subjects receiving the low potency marijuana, and the control subjects receiving the oral THC capsule. If the hypothesis that smoked marijuana is effective in promoting weight gain is to be supported, the study will need to demonstrate that the subjects in the high and medium potency groups gained more weight than the subjects in the low potency group. The inclusion of the oral THC control group provides another point of comparison, though the lack of a double-blind for this group lessens its value. Due to the small number of subjects in each group, neither the FDA nor Dr. Abrams expects this pilot study to produce a statistically significant difference in weight gain between the subjects in the different groups. All this study is designed to determine is whether there are nonsignificant trends that suggest marijuana's efficacy, trends which might justify a larger scale multi-site study designed to be of sufficient size to generate statistically significant conclusions.

The DEA's Reservations

The current reason the protocol is delayed is DEA reluctance to issue Dr. Abrams' his DEA Schedule 1 license. Dr. Abrams needs the license in order legally to receive, store and distribute the marijuana that will be used in the study. Dr. Abrams submitted his application to DEA headquarters over four months ago, and at the time of this writing hasn't received any information as to its status.

The DEA official in charge of the department that reviews Schedule 1 licenses is Mr. Gene Haislip, Deputy Assistant Administrator, Office of Diversion Control, who has taken a personal interest in this study. Of the many people at the DEA with whom it is crucial to try to build bridges of understanding, Mr. Haislip is among the most important. Mr. Haislip recently wrote a letter to the FDA outlining his concerns about the protocol, both scientific and otherwise, concerns which he felt justified a delay in the approval of Dr. Abrams' Schedule 1 license. The matter is now in the hands of the FDA, which needs to respond to Mr. Haislip's concerns. Hopefully, the FDA's response will successfully address Mr. Haislip's concerns and convince him that the protocol should proceed. If not, the progress that has been made in moving from politics to protocols will be temporarily reversed, and the medical use of marijuana will once again become predominantly a political rather than scientific issue.

Governmental forces in support of the protocol

Fortunately, there are bureaucratic forces in motion that give rise to the hope that the DEA will issue Dr. Abrams his Schedule 1 license in the near future. Ironically, the support for FDA-approved research with marijuana has been strengthened by the total failure of all other efforts to secure legal prescription availability for marijuana. For example, 36 states have endorsed the medical use of marijuana. Nevertheless, since Federal law prevails, the medical use of marijuana in these states is still prohibited, and only FDA approval can change the situation.

Similarly, the main contribution of the 22-year long lawsuit against DEA by NORML, the Alliance for Cannabis Therapeutics, and the Drug Policy Foundation, has been to make FDA-approved research inevitable. The aim of the lawsuit was to force the DEA to reschedule marijuana into Schedule 2 to permit its medical use by prescription. After marijuana's proponents won an unbroken string of legal victories over the course of two decades, their hopes were crushed in February, 1994 when the United States Court of Appeals (D.C. Circuit) rejected their arguments and supported the position of the DEA. It is now clear to all the protagonists that the DEA has finally been able to craft a set of criteria that pass Court of Appeals scrutiny, criteria which permit the DEA to justify on solid legal grounds its refusal to reschedule marijuana. What this means is that short of congressional action (which even incurable optimists like myself think is out of the question for the foreseeable future), the only way to obtain the legal availability of medical marijuana is through FDA approval.

In an unusually helpful comment, even ex-DEA Administrator Mr. Robert Bonner, pointed the way to the FDA. In his ruling rejecting the rescheduling of marijuana, Mr. Bonner suggested that "Those who insist that marijuana has medical uses would serve society better by promoting or sponsoring more legitimate scientific research, rather than throwing their time, money and rhetoric into lobbying, public relations campaigns and perennial litigation." When research was not imminent, the DEA was more than willing to endorse that approach. Now, the DEA seems to need time to get used to the fact that MAPS actually took its advice and started working with Dr. Abrams to conduct FDA-approved research.

Two pronouncements this July by officials at the upper levels of the Department of Justice and the Department of Health and Human Resources further reinforce the lack of alternatives to conducting FDA-approved research. As you may recall, in 1992, the Assistant Secretary of Health in the Bush Administration, Dr. James Mason, shut down the FDA's Single Patient IND Program (Compassionate Access) for medical marijuana patients because it was growing too large, too visible, too expensive and too time-consuming for the FDA to administer. Over the course of the last year, the current Assistant Secretary of Health, Dr. Philip Lee, has been pressed by various congresspeople to review Dr. Mason's decision. In a letter sent in mid-July to Representative Barney Frank and the other congresspeople and senators who contacted him about this issue, Dr. Lee announced that he has finally reached a decision concerning his course of action. Sadly, but not unexpectedly, Dr. Lee indicated that he has decided not to reopen the Compassionate Access Program. According to Dr. Lee, the fatal flaw of that program was that it did not generate data that could be submitted to the FDA to either support or reject the hypothesis that smoked marijuana had a safe and efficacious medical use. Dr. Lee did not offer any government funds for research, yet indicated that only FDA-approved research could resolve this controversy.

Similarly, the Department of Justice announced in July that there would be no change in current policy. The old policy was affirmed in a letter from Jo Ann Harris, Assistant Attorney General, that was sent to medical marijuana advocates Valerie Corral and Elvy Musikka. The women had met with aides to Attorney General Janet Reno at the Justice Department earlier this year and had asked for a moratorium on prosecutions of medical marijuana patients. The letter indicated the Department of Justice was not willing or able to declare a moratorium on prosecutions of patients who use marijuana for its medicinal properties, nor would the Attorney General overrule the DEA Administrator and reschedule marijuana. According to the Attorney General's office, "this administration remains open to the possibility that sufficient medical and scientific evidence may be presented to permit a re-evaluation of the scheduling of marijuana." In other words, the only potential remedy for this situation is FDA-approved research leading to FDA approval of the prescription use of marijuana.

The DEA seems to need time to get used to the fact that MAPS actually took its advice and started working to conduct FDA-approved research.

The Clinton Administration seems to have adopted a uniform position that focuses on the lack of, and need for, FDA-approved clinical trials into the medical use of marijuana prior to any policy changes. Given the momentum forcing the issue into the hands of the FDA, I doubt the DEA can succeed in halting all research, even if it wished to do so. It's hard for me to imagine that the DEA doesn't realize that if marijuana moves into clinical trials, it will take years before the FDA may possibly have enough data to approve marijuana for prescription use, and during that time all the outside pressure for action shifts from the DEA to the FDA.

Professional organizations in support of the protocol

Several very prominent professional organizations, the American Medical Association and the Federation of American Scientists, are interested in seeing the controversy over the medical use of marijuana resolved through scientific research. In the June 1, 1994 issue of the Journal of the American Medical Association, an article reports on Dr. Abrams' protocol. Under the subheading, "Why Not Just Prove It?", the reporter quotes John Ambre, MD, Ph.D., the director of the

American Medical Association's Department of Toxicology and Drug Abuse. Ambre says, "It is important, in the subjects affected, to have control groups and use pure, well-defined material." The impression left with the reader is that a well-designed study that did have control groups and did use pure, well-defined material would receive the support of the AMA. Dr. Abrams' study seeks to do just that. As for the Federation of American Scientists, its enthusiastic support for Dr. Abrams' protocol has already been obtained. As important organizations within the medical and scientific establishment, as well as the FDA, express support for Dr. Abrams' study, the likelihood that the DEA will grant Dr. Abrams his Schedule 1 license is increased.

The search for high-potency imported marijuana

Not surprisingly, after Dr. Abrams receives his Schedule 1 license, there is still one more hurdle to surmount. We still need to find a legal source of high-potency marijuana for the study. Low-potency marijuana is available from NIDA (this is what will be used in the water pipe/vaporizer study, page 19). NIDA also has just enough medium-potency marijuana to supply the needs of the 10 patients who will be randomized into the medium-potency group. Unfortunately, there is no legal domestic supplier of high-potency marijuana.

The third option, which I think is the best in the long-run, is to create a non-profit marijuana research and production company.

The only fully licensed grower of high-potency marijuana that MAPS is aware of is HortaPharm, a marijuana research firm in the Netherlands. HortaPharm has offered to donate all the marijuana needed for the study if the necessary import and export permits can be obtained. Four months ago, Mr. Larry Snyder, the DEA official in charge of overseeing the international importation and exportation of Schedule 1 drugs, rejected an application to import 250 grams of high-potency marijuana from HortaPharm for the water pipe/vaporizer study. Mr. Snyder's rationale was that he was obliged to reject the application for an import permit because the Dutch government does not currently have procedures in place that allow HortaPharm to export its marijuana. While this is formally true, the Dutch regulatory authorities have taken the position that they are bound by the International Convention on Psychotropic Substances which specifically states that an import permit must be issued before an export permit can be granted. The Dutch regulators are thus asking for the DEA to issue an import permit before they consider changing Dutch laws to permit HortaPharm to export marijuana.

Each government is asking the other to make the first move, which neither is willing to do at this time. Until the U.S. or the Dutch government changes its policies, I see little hope that an import permit will be obtained. There is a possibility that the Dutch government will change its policies before the U.S. government grants an import permit, but such a change will not occur for several months at the earliest, if at all.

The search for high-potency domestic marijuana

Several domestic sources of high-potency marijuana might be available, each with different sets of advantages and disadvantages. One option is for MAPS to attempt to contract privately for a supply of high-potency marijuana from the scientific team that currently grows marijuana for the National Institute on Drug Abuse. This team is fully licensed to grow marijuana and has the authority to produce marijuana legally for authorized uses such as an FDA-approved research protocol. A contract of this sort might cost MAPS in the neighborhood of $20,000 to $50,000, depending on whether the marijuana was to be grown indoors or outdoors. If a contract could be arranged, the earliest delivery date for the marijuana would be at least six months and probably a year away.

One problem with this option is that the cost of $20,000 to $50,000 is prohibitive. The second problem is the amount of time it would take. If AIDS were not a fatal disease, and if there were substantially effective medicines for the Wasting Syndrome, a delay of a year wouldn't matter so much. But time is of the essence for people with a fatal illness.

A second option is to seek permission to use seized supplies of high-potency marijuana for the pilot study. While seized marijuana might still comply with Dr. Ambre's requirement for "pure, well-defined study materials", the marijuana used in any subsequent studies would almost certainly be from a different seed stock with different genetic characteristics, resulting in marijuana with a somewhat different chemical profile. This would make it difficult to combine the data from the pilot study with that of any subsequent study. This isn't such an important limitation since Dr. Abrams' pilot study is not intended to form the basis of an application to the FDA to approve marijuana's medical use. Its purpose is rather to gather preliminary data that will guide researchers in deciding whether it is worth the effort to conduct a full-scale multi-site controlled study, and if so, how that study should be designed. Using seized supplies, assuming DEA permission for this could be granted, would be an acceptable solution to the supply problem. While Dr. Abrams' pilot study was underway, the search for a more permanent supply of high-potency marijuana could continue.

A non-profit marijuana cultivation and research company

The third option, which I think is the best in the long-run, is to create a non-profit marijuana research and production company chartered and licensed specifically to develop the medical uses of marijuana and its constituents. Naturally, it would be very difficult to arrange. It would take a lot of time and careful planning to find the right people for the Board of Directors, administrative officers and staff. This project would probably require about $500,000 in start-up funds, and would require at least a year or more to obtain all the necessary governmental permissions. While the practical challenges are formidable, there are no theoretical obstacles to this concept. The idea is similar to the strategy of the Population Council, a non-profit organization which is undertaking the U.S. testing and development of the controversial abortion pill RU-486. I am proposing that a non-profit organization be created that will function like a traditional pharmaceutical company, but with marijuana and its constituents as its only products. With a drug as controversial as marijuana, it may be that a non-profit organization without private financial interests to protect may end up being more trusted by the public than a profit-making company, and permitted to operate more freely.

This approach gets the government out of the uncomfortable and untenable position of supplying ever larger amounts of marijuana for research, marijuana for which it is not supposed to charge. It also gives the DEA one centralized entity to regulate, which it should be able to handle without too much work. If ever the company were to obtain marketing approval for marijuana for any clinical indication, profits would be used to support further research, eliminating or reducing the need for constant fund-raising.

Of course, neither the money nor the start-up time that this project would require would be easy to come by. For the purposes of Dr. Abrams' protocol, this option would take too long to implement, even if the people and the funds for the project were available today.

Giving up on high-potency marijuana

The last option is simply to abandon the effort to use high-potency marijuana and ask the FDA if it would consider accepting a revised protocol with just medium- and low-potency marijuana. With all the recent media attention about the flood of highly potent marijuana sweeping the United States and making everything previously known about marijuana obsolete, it would be rather ironic if we couldn't obtain any for a government-approved study. However, if a legal source of high-potency marijuana could not be arranged, it may be best to give up that part of the study for the sake of moving forward.

In order to determine if high-potency marijuana is absolutely necessary, MAPS and California NORML are trying to have three samples of marijuana tested for potency. These samples would be gathered from the San Francisco Buyers Club, which distributes marijuana to AIDS patients who use it for treating the symptoms of their Wasting Syndrome.

Anecdotal evidence indicates that all the samples have some therapeutic properties. One of the samples would their least expensive variety and the other two would be their most expensive marijuana. Since marijuana from the Buyer's Club has never been analyzed for potency, no one knows what the THC-content of these samples is going to be. If their expensive samples test out to contain around 10% THC, then we would still need to find high-potency marijuana for Dr. Abrams' study.

If these samples turn out to be 5% THC or less (which we consider to be medium potency), then it doesn't seem essential to delay Dr. Abrams' study until the search for a legal supply of higher-potency marijuana is obtained. (This finding would put into question claims about the increased potency of today's marijuana.) While it would be a compromise to give up on the reduced risk profile of high-potency marijuana, it seems that a greater risk to the health of the AIDS patients in the study would be to wait and do nothing.

function like a traditional pharmaceutical company, but with marijuana and its constituents as its only products

Eliminating the high-potency group from the protocol might take some time to implement since the FDA and all the other regulatory agencies have approved a protocol design that specifically includes high-potency marijuana. Any modifications in the protocol would require additional reviews and approvals, which could take several months to obtain. Still, such a change would probably be approved, and the study would still be worth conducting.

Conclusion

After two years of effort, Dr. Donald Abrams' proposed pilot study comparing the safety and efficacy of smoked marijuana vs. the oral THC capsule is getting closer to actually beginning. It seems very likely that the study will start before the end of 1994. Whether the study will include high-potency marijuana is still to be resolved.

For a study that hasn't even taken place, this protocol has received an enormous amount of media attention. Stories about it have already appeared in Science, The New York Times, USA Today, and the Journal of the American Medical Association. Remember, you read about it here first, in the MAPS newsletter! ■

a comprehensive clinical plan for the investigation of **marijuana's medical use** in the treatment of the hiv-related wasting syndrome

RICK DOBLIN

THIS NEWSLETTER features two long articles about two marijuana research projects that MAPS is working to facilitate. One of the studies focuses on evaluating methods of reducing the health risks of smoking marijuana through the use of smoke filtration devices like water pipes and vaporizers (p. 19). The other study is focused on gathering pilot data about the possible benefits of smoked marijuana in promoting weight gain in patients suffering from the HIV-related wasting syndrome (p. 11). Both of these studies are designed to gather information that, in the long-run, may play a role in securing FDA approval for the prescription use of marijuana.

The working assumption of this Clinical Plan is that is will take about two years of research and $500,000

As of yet, I have not fully explained how these studies can contribute to such a goal. Since donations from MAPS members are a critical element in enabling these studies to proceed, I feel a responsibility to provide a complete picture of the long-term strategy involved in MAPS' approach to medical marijuana research. I therefore offer the following outline of a sequence of studies designed to lead from here, where patients in need of the medical use of marijuana still risk arrest and jail, to there, where the medical needs of patients take priority over a self-destructive war against a humble weed and the people who value it.

Clinical Plan

This Clinical Plan outlines a program of scientific investigation designed to evaluate the safety and efficacy of smoked marijuana for the promotion of weight gain in patients with HIV-related wasting syndrome. The Clinical Plan has been submitted to the Food and Drug Administration (FDA) as part of Dr. Donald Abrams' Investigational New Drug (IND) application #43,542. Previous drafts of the Clinical Plan have been reviewed and critiqued by Dr. Dan Spyker, FDA Medical Review Officer. This Clinical Plan is a tentative outline of the studies that the FDA will require in order to produce sufficient data to enable a comprehensive analysis of marijuana's safety and efficacy for the wasting syndrome. This Clinical Plan is based on current data, and may be modified as additional data becomes available.

All data gathered during the course of this investigation will be submitted for review to the Pilot Drug Evaluation Staff of the FDA. If two "adequate and well controlled" trials demonstrate that smoked marijuana has a safe and efficacious medical use for the wasting syndrome, a New Drug Application (NDA) will be filed with the FDA.

The working assumption of this Clinical Plan is that it will take about two years of research to demonstrate whether marijuana is safe and effective for the Wasting Syndrome, and roughly $500,000. Marijuana will be evaluated through the combination of one pilot study (N=40), one large scale multi-site clinical trial (N=150), and a series of about 150 single-patient trials designed according to an appropriate N=1 methodology.

This Clinical Plan also includes an investigation of various drug delivery devices and marijuana extracts that may reduce health risks caused by the inhalation of marijuana smoke.

Proposed Clinical Plan Study 1: The health effects of water pipes, vaporizers and filters – August '94 - January '95*

In August, 1994, scientists at a highly respected research center began a six-month study analyzing the constituents of marijuana smoke after filtration by various marijuana delivery devices. The primary aim of the study is to determine which of the devices, if any, are preferable to the use of an unfiltered marijuana cigarette. The study will quantifythe effectiveness of several different water pipes, filters, and a vaporizing device in selectively removing potentially harmful constituents of the smoke from marijuana. Once the most effective device has been identified, a subsequent smoke analysis will be conducted using a sample of pure THC (to establish a reference standard) and also a concentrated extract of marijuana (hash oil) which contains virtually no remaining vegetable matter.

If the data from any of the smoke analyses is encouraging, follow-up studies may be undertaken to develop further drug delivery devices and marijuana extracts that minimize non-therapeutic ingredients.

The first clinical trial will be a double-blind placebo controlled pilot study

Study 2: A Pilot Study Investigating Smoked Marijuana v. Oral THC in the Treatment of HIV-Related Wasting Syndrome – October '94 - March '95

The first clinical trial will be a double-blind placebo-controlled pilot study by Dr. Donald Abrams investigating weight gain in the HIV-related Wasting Syndrome. This will be a single-site study coordinated by the San Francisco Community Consortium, where Dr. Abrams serves as research director.

The study will investigate the use of high, medium and low THC-content smoked marijuana administered in a double-blind manner with an open label control group receiving the oral THC capsule (Marinol). The study will involve forty subjects, ten in each of the three smoked marijuana groups and ten in the Marinol comparison group.

The THC-content of the marijuana to be used in the study will range from approximately 10% in the high-THC group, 4% in the medium-THC group, and 1.5% in the low-THC group. The marijuana available for research purposes from the National Institute on Drug Abuse (NIDA) is primarily of low potency. Medium potency marijuana may possibly be available from NIDA but high potency marijuana definitely is not available. Therefore, we are seeking a procedural mechanism under the Single Convention to import marijuana from HortaPharm B.V. in the Netherlands, where it is grown legally for research purposes.

This study will take about six months to conduct. At the conclusion of the pilot study, we hope to have gained valuable information for power analysis calculations concerning sample size for a full-scale controlled clinical trial. We also hope to have determined the best methodology for reducing experimenter and subject bias when both smoked marijuana and the oral THC pill are used in the same experiment.

Study 3: "N=1" Study of the HIV-Related Wasting Syndrome – From Compassionate Use to Research – October '94 – June '96

Beginning about October, 1994, numerous (150) single patient "N=1" studies will start to be initiated into the use of smoked marijuana in the treatment of the HIV-related Wasting Syndrome. Unlike the Single Patient IND program, this research design will provide the FDA with some of the scientific data it needs to evaluate the safety and efficacy of marijuana. In this study design, each subject acts as their own control. Subjects will be administered smoked marijuana of medium potency, oral THC and placebo in a double-dummy randomized sequence. As data from the pilot study becomes available concerning the potency of marijuana that is the most effective, the potency of marijuana used in this study may change. Experimental data will be gathered about the effects of the different medications on the weight of the subjects, the incidence of adverse effects,

*(all dates are tentative)

and quality of life. Those patients in the study who demonstrate a favorable risk/benefit from smoked marijuana would, upon the conclusion of their "N=1" trial, be allowed the option of continuing treatment to assess long-term safety and efficacy.

This study will be coordinated by a Principal Investigator (PI). The PI will develop the detailed design of the study in consultation with the FDA. After the study design is finalized, the PI will primarily interact with other physicians who want to enroll their patients in the study. The PI will assume the responsibility of reviewing each physician'sapplication for their patient to participate in the study. The physicians who serve as sub-investigators will need to obtain DEA licenses to administer marijuana. They will supervise patients' trials according to the approved protocol, administer outcome measures, and report their results to the PI.

After 150 reports are collected, the PI will collect the data and summarize the results for submission to the FDA along with the individual patient data. The data from all the separate "N=1" trials will be combined into one "adequate and well-controlled trial" of the use of smoked marijuana for the treatment of the Wasting Syndrome.

Additional studies, if any, will be considered after consultation with FDA

Study 4:
Pharmacokinetics/Pharmacodynamics (PK/PD) January, '95 – June '95

A series of pharmacokinetic/pharmacodynamic (PK/PD) investigations will be conducted. These PK/PD studies will be concluded before the start of the full-scale clinical trials, and may be used to guide their design. PK/PD studies will be conducted with about 10 subjects.

Study 5:
Multi-Site Clinical Trial for the Wasting Syndrome – June '95 – June '96

If Dr. Donald Abrams' pilot study generates encouraging data about the safety and efficacy of smoked marijuana in treating the wasting syndrome, a large scale multi-site study would then be conducted. This experiment will include about 150 patients located at five to fifteen different locations, each of which used the identical protocol. Results from the pilot study, the drug delivery device study, and the pharmacokinetic/pharmacodynamic study would all be used in the design of this clinical trial. This design will need to be determined by the FDA to be "adequate and well-controlled" since it is intended to be one of the two clinical studies required for NDA approval (the other being the combined N=1 trials).

Possible New Drug Application (NDA) June 1996 —

The series of studies listed above are designed to gather sufficient data to enable the FDA to determine whether or not smoked marijuana is safe and efficacious for the promotion of weight gain in patients suffering from the HIV-related Wasting Syndrome. If the data significantly demonstrates marijuana's safety and efficacy, an NDA will be filed with the FDA. If the data does not significantly demonstrate marijuana's safety and efficacy, an NDA will not be filed with the FDA. Additional studies, if any, will be considered after consultation with FDA. ■

2nd international congress for the study of modified states of consciousness: ethnocognition, shamanism, plants and cultural context, spain, october 1994

This conference is being organized jointly by the Institut de Prospectiva and the Institut d'Estudis Ilerdencs. The conference will be held at the Institut d'Estudis Ilerdencs from October 3-7, 1994, in Lerida, Spain.

The first conference was entitled '1st International Congress on Plants, Shamanism and States of Consciousness', and was held in San Luis Potosi, Mexico during November of 1992. The objectives of the 2nd International Congress are to further transdisciplinary collaborations by sharing the results of our investigations into modified states of consciousness through the arts and sciences. We intend to increase the number of interested participants from the previous meeting, in order to enrich the perspectives initially opened by the conference in Mexico, however, we've planned to limit the number of participants to 150. ■

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Be sure to ask for the cool poster! I can answer some questions if needed. jace callaway: callaway@jolla.uku.fi

the maps / california norml **marijuana** waterpipe / vaporizer study

RICK DOBLIN

EVERYTHING IS FINALLY IN PLACE for the beginning of the long-awaited MAPS/California NORML marijuana smoke filtration study. By the time you read this, 250 grams of marijuana, donated by the United States Government, will almost certainly have arrived at the research laboratory. After six months of trying and failing to import high-potency marijuana from the Netherlands for this study, MAPS has succeeded in obtaining marijuana from the National Institute on Drug Abuse (NIDA). NIDA has kindly agreed to supply the research project with the same variety of marijuana that NIDA supplies to the eight patients who receive marijuana legally for their medicinal use.

Purpose of the study

The smoke filtration study is aimed at gathering scientific data about several possible methods of reducing the amount of harmful constituents of marijuana smoke. The researchers will conduct a thorough analysis of the chemical constituents of marijuana smoke both before and after it has been filtered by a variety of methods. Researchers will quantify the total emissions of tar, various cannabinoids (the THC and other chemically similar therapeutic ingredients), volatile aldehydes (which inhibit lung function), and carbon monoxide (which is highly toxic). If the results of the initial study are promising and if funds can be obtained, a subsequent study will analyze marijuana smoke for tumor-promoting compounds like benzene, volatile phenols, benzo(a)pyrene, and volatile N-nitrosamines. These studies are part of an overall clinical plan to evaluate marijuana's safety and efficacy for the treatment of the HIV-related Wasting Syndrome (p. 16).

This study is needed because there are no scientific data currently available describing the filtration effects of water pipes and vaporizers on marijuana smoke. Data about the filtration effects of water pipes for tobacco smoke are encouraging (see MAPS Vol. 3, No. 2, p. 4), so it may well be that with marijuana smoke these devices would substantially reduce the proportion of tars and particulate matter inhaled along with the THC and other cannabinoids. This study is especially important since the patient population in which the medicinal use of marijuana will soon (I hope) be tested is composed of AIDS patients, who already have a compromised immune system (p. 11). If delivery systems can be developed that minimize the potentially stressful effect of marijuana smoke on the immune system, the risk/benefit ratio for the medical use of marijuana may decrease dramatically. This research will help the FDA balance the harmful effects of marijuana against its beneficial effects. Of particular interest in this regard is a recent scientific study at the University of Florida which demonstrated that THC itself seems to enhance immune system functioning in AIDS patients. The more that the non-therapeutic ingredients in marijuana smoke can be filtered out, the greater the beneficial effect of smoked marijuana.

Some critics of this study suggest that it will provide ammunition for the argument that marijuana is not safe enough for medicinal use when its smoke is not filtered. They fear that this study will thus undermine the effort to secure approval for unfiltered marijuana smoke as a medicine, and place people who claim a medical necessity defense at greater risk of losing their cases. I personally believe that these fears are unfounded. Moreover, I think it is irresponsible and ultimately self-defeating to ignore the risks of marijuana smoke. The search for safer and more effective methods of helping severely ill patients must be conducted in the most comprehensive and highly scientific manner. Marijuana, like any other drug, has it risks. It behooves those who believe it has benefits to seek ways to minimize those risks.

Rather than pretending that marijuana has no harmful effects, MAPS continues to explore ways to clarify and minimize those harms.

MAPS' Harm-Reduction Strategy

This study is an excellent example of a harm-reduction strategy in action, a rising-star strategy in the world of drug policy analysis. Rather than pretending that marijuana has no harmful effects, MAPS continues to explore ways to clarify and minimize those harms.

MAPS' approach to the risks associated with marijuana smoking contrasts dramatically with the approach taken by the tobacco industry regarding the health risks of the cigarette. In a fascinating series of articles in the New York Times (June 16 -18,1994), the

secret research projects of the tobacco industry were described. A major direction of research was called Project Ariel, which was a series of studies in the 1960's intended to produce a nicotine delivery device safer than the cigarette. Project Ariel was abandoned after initial prototypes were unsuccessful, in part because they delivered too much nicotine in too short a time. After Project Ariel was closed down, all reports about this direction of research were kept secret.

In the effort to develop safer methods of smoking marijuana, MAPS will report all the data that are gathered, whatever the results.

The experimental team

The water pipe/vaporization study will take place at a respected research center which has been at the forefront of tobacco smoke analysis, so much so that when the tobacco companies recently released their top secret list of tobacco ingredients, the main person quoted by the media about the health risks of those ingredients was the research director of MAPS' study. As always, MAPS seeks out the most respected scientists in their fields to conduct its research. Since MAPS' research agenda is so controversial, it is essential that the scientists who conduct the research have the respect of their peers across the political spectrum. Otherwise, the results of the studies will not be given much credence and MAPS' limited resources will have been wasted.

The Scientific Issues – Water Pipes

Whether water pipes and vaporizers will actually prove useful is an open scientific question. Combustion gases like carbon monoxide are water soluble, making water an effective filter medium for these kinds of components in marijuana smoke. On the other hand, THC and other cannabinoids are not water soluble, permitting them to pass through water and to be inhaled. While tars and particulate matter are not water soluble, water nevertheless does seem to retain some of them. On the other hand, the cannabinoids have certain chemical properties that make them "sticky". The practical implication of this chemical property is that the cannabinoid molecules tend to adhere tightly to the tars (particulate matters) produced when marijuana is burned. Therefore, when marijuana smoke is filtered through a water medium, some of the cannabinoids will be filtered out along with the tars to which they are chemically bonded.

The key question is whether the tars will be selectively filtered out to a greater degree than the cannabinoids, resulting in a smoke that has a higher proportion of cannabinoids than before it passed through the water. If the cannabinoids and tars are filtered out equally, smokers will still end up inhaling the same proportion of each to reach the desired therapeutic levels of the cannabinoids.

The Scientific Issues – Vaporizers

Vaporizers are another story entirely. Vaporizers theoretically permit the cannabinoids to be inhaled virtually without any particulate matter. Vaporizers work by heating the marijuana to a temperature at which the cannabinoids boil out from the marijuana, creating a vapor that can be inhaled. The temperature at which the cannabinoids turn into vapor is below that at which the marijuana leaf combusts, so there are presumably few or no combustion products such as carbon monoxide and tars. This is the theory this study will put to the test.

Vaporizers also have another extremely useful property; they are extraordinarily efficient. When marijuana is burned, only a fraction of the cannabinoid constituents are turned into a vapor and inhaled with the smoke. Cannabinoids are highly combustible, so much so that a large proportion of them in a marijuana joint are burned up and destroyed. With a vaporizer, the same amount of marijuana can produce at least twice as many inhaled cannabinoids, and probably much more. Given that AIDS patients in the final stages of their disease have usually exhausted all financial resources, the efficiency of the vaporizer can dramatically reduce the cost of the medicinal use of marijuana.

Whether water pipes and vaporizers will actually prove useful is an open scientific question.

Whether vaporizers will work as they theoretically should is an open scientific question not previously tested. Some anecdotal reports indicate that the subjective experience of marijuana smoke that has been vaporized is somewhat different than when the same marijuana is smoked in a joint. It remains to be determined what these differences are, and what implications, if any, they have for the therapeutic effects of the vaporizer.

The Experimental Water Pipes

A rather unique collection of water pipes will be used in this experiment. One factor that may influence the filtration potential of a water pipe is the volume of water that the marijuana smoke is forced to pass through. Common sense suggests that the more water the marijuana smoke passes through, the more filtration will take place. However, this may not be the case, especially if the tars and cannabinoids are filtered out at an equal rate. To evaluate this, the study will test a water pipe especially designed to prolong the mixing time of the smoke and the water. This water pipe,

called the HealthPipe, was manufactured in the 1970's. Thousands were sold before it was driven off the market by aggressive paraphernalia laws. The pipe is rather ingenious. It looks like a fairly small, traditional water pipe, except that it has a battery-operated paddle blade extending down into the water. When activated by a push button, the paddle blade spins and creates turbulence in the water. This turbulence promotes a more thorough and vigorous mixing between the smoke and the water, breaking up the smoke into smaller particles and increasing the surface area of the smoke that is placed in contact with the water. These pipes are not inexpensive, and would cost about $40 each to manufacture. However, if they do reduce the amount of particulate matter that an AIDS patient needs to inhale, they will be well worth the cost.

The second water pipe that will be tested was manufactured by a MAPS member and donated to the project. This pipe is basically a hookah, with a long plastic hose attached to a bowl. It may be that the passage of marijuana smoke through a long hose will cause some of the heavier particulates to become deposited in the hose, leaving smoke with a higher concentration of cannabinoids. This pipe is also designed to release the smoke at the bottom of the water bowl, for maximum contact with the water.

The third pipe to be studied will be a standard water pipe, just like the varieties that used to be commercially available in some stores (usually with a note saying that they are for tobacco use only) before a recent Supreme Court ruling outlawed them. This water pipe is simply a long plastic cylinder about a foot long and several inches in diameter. A short air tube is positioned near the bottom of the cylinder so that it lies under a few inches of water. I imagine that most water pipes in use in the United States today are of this variety.

Experimental Vaporizers – The Complex Model

The vaporizer to be used in this study is a remarkable find. Several AIDS patients showed me their homemade prototype a few months ago when I visited the San Francisco Cannabis Buyers Club, an organization of hundreds of AIDS and cancer patients who have formed a co-op to obtain marijuana for medicinal purposes. The members of the co-op feel that they have a medical need for marijuana, and that their use is therefore legal under a defense of medical neccesity. Many members of the Buyers Club are aware of (but not overly concerned with) the health risks of marijuana smoking, and have experimented with vaporizers to try to reduce that risk.

The vaporizer that I saw was an ingenious combination of a vaporizer and a water pipe, and was designed to get the benefits of both devices. For those of you who have access to the Internet, in particular the alt.drugs discussion group, you may have noticed a long-running discussion on vaporizer theory and design. All of the vaporizers that have been mentioned have utilized a hot plate of some sort, often a car cigarette lighter, with a temperature control device permitting the user to heat the marijuana to the desired temperature.

The vaporizer we will use in this study is of a completely different design. Rather than using a hot plate for the heating element, this vaporizer uses hot air. The hot air is generated by a commercially available paint stripper gun available at hardware stores, at a cost of about $40. The tool blows a stream of hot air through the interior of a round metal tube with a diameter of about an inch, at a range of temperatures from several hundred degrees up to and exceeding 1000°F. When used as a marijuana vaporizer, the temperature is set at about 450°F. The end of the tube is positioned about an inch above a small pipe bowl which has a hole at the bottom, just like a standard pipe bowl. That small bowl is placed on top of a much larger beaker which is filled with several inches of water. Attached to the hole in the bottom of the small bowl is a glass rod and a small metal wire, both of which descend almost to the bottom of the beaker, below the level of the water. The wire acts as a heat sink, and the glass tube guides the vapor down into the beaker and releases it into the water. A small tube for inhaling the vapor has been inserted into the larger beaker.

Rather than using a hot plate for the heating element, this vaporizer uses hot air.

The vaporizer/water pipe works rather simply. The hot air blows down on the marijuana that is in the small bowl. A screen is secured on both the top and the bottom of the bowl so that the marijuana stays in place. As the temperature of the marijuana increases, the cannabinoids start to vaporize. The downward pressure of the hot air pushes the vapor down through the glass tube into the beaker below. The vapor passes through the water and collects in the air volume inside the large beaker. When enough vapor has collected in the beaker, the smoker inhales on the tube. This draws the vapor into the lungs. At no time does the marijuana burn. The people at the Buyers Club report that the smoke is so smooth that sometimes they are not even sure that anything has been inhaled. The used marijuana changes color slightly, and loses weight due to the removal of the cannabinoids by vaporization.

One disadvantage of this system is that it requires an electric outlet, and is not portable. Another is that the paint stripper gets extremely hot and can inflict pain if touched. If this technology proves useful after scientific analysis of the smokestream, further modifications of the prototype will be made.

Experimental Vaporizers – The Simple Model

A clever and industrious MAPS member made a prototype vaporizer that operates in a much simpler manner. This vaporizer is a simple glass pipette about five inches long with a crimp about one inch from one end. Marijuana is placed in the end up to the crimp. Then, a steady heat source such as an oil lamp, a cigarette lighter or a candle is used to heat the marijuana inside the glass pipette. When a small vapor stream of cannabinoids starts to swirl off the marijuana, the smoker removes the heat source and inhales the vapor from the other end of the pipette. The crimp in the pipe prevents the marijuana itself from being inhaled. I took about 20 of these vaporizers to the Buyers Club and gave them away to appreciative patients. The main advantage of this vaporizer is that it is portable. The main disadvantage is that a great deal of care must be used so as not to burn the marijuana in the pipette. It also does not work all that well with marijuana that is powderized, or of low-potency. For experimental purposes, it is difficult to standardize the output of this pipe. Thus, the pipe that will be used in the experiment is the more complex combination vaporizer/water pipe.

The nature of research is that your cherished beliefs and deepest hopes may turn out to be wrong. But, after all, isn't it better to know for sure?

The Marijuana Filter-Tippped Cigarette

The scientists conducting the study have a great deal of experience measuring the effects of cigarette filters. We have therefore requested that they design a filter for a marijuana cigarette, and test its effectiveness. Their initial impression was that a standard tobacco filter would not work well for marijuana, since it would filter out the cannabinoids as well as the particulate matter. The filter that may be used in this study will be designed to filter out harmful combustion gases rather than tars, particularly removing carbon monoxide. The filter will probably be a short thin empty tube with perforations which increase the amount of oxygen getting into the smoke stream, converting some of the carbon monoxide to the safer carbon dioxide.

The cost of the study

This study will take six months and will cost $25,000. MAPS is providing $18,000 for the study and California NORML is committed to providing the remaining $7,000. MAPS' support for the study was made possible by a donation of $18,000 from one donor, $14,000 of which was donated directly to the study and $4,000 of which was donated by the same person for the two original art drawings from the Doonesbury Brownie Mary/ medicinal marijuana series, donated to MAPS by Garry Trudeau.

MAPS has made an initial $9,000 payment toward the study's cost, paid at the commencement of the research phase of this project. After MAPS receives a progress report at the three month point, an additional $8,000 will be paid. The final $8,000 will be paid upon receipt of the final report, in part by MAPS and in part by California NORML. In addition to its report to MAPS and California NORML, the scientists conducting the study have agreed to prepare a scientific paper describing its results which will be submitted to a peer-reviewed scientific journal for publication.

If this initial study is promising, it would be desireable to conduct a subsequent study to further analyze the constituents of marijuana smoke. This study would include the vaporizer, the most effective of the different water pipes tested, and both a filter-tipped and a nonfilter marijuana cigarette. The cost of this study has been already negotiated and would be $15,000. This sum has not yet been raised.

Conclusion

Out of all the tens of millions of dollars that have been spent by the U.S. government on marijuana research, not one penny that I know of has gone toward studies designed to see if the health risks of marijuana smoke could be reduced. One of the primary functions of MAPS is to identify strategic gaps in the scientific literature, and to ensure that those gaps are filled. For a relatively small investment of $25,000, MAPS and California NORML might help identify several methods for reducing what is probably the greatest health risk of marijuana, its harmful effects on the lungs. In terms of the medical use of marijuana, this study may fundamentally change the risk profile of smoked marijuana, and provide data to the FDA that makes its approval of the prescription use of marijuana much more likely. It is also possible that this research may demonstrate that water pipes and vaporizers don't really have that much of a beneficial health effect.

The nature of research is that your cherished beliefs and deepest hopes may turn out to be wrong. But, after all, isn't it better to know for sure? ■

spreading the good news in atlanta and los angeles

SYLVIA THYSSEN

On APRIL 2, 1994, MAPS was represented at the Fifth Annual Great Atlanta Pot Festival. Rick Doblin was invited to speak about the developments and objectives of medical marijuana research. Unfortunately, Rick was unable to attend. However, taking courage in both hands, I agreed to represent him and MAPS on the stage in Atlanta. I would chalk up my debut public speaking occasion to experience, I thought, rattled at the prospect of speaking to the 30,000 people scattered across Piedmont Park.

Speaking to a crowd

For the purpose of disseminating news of MAPS and the two medical marijuana studies that MAPS is supporting, a small informational flyer was prepared. (This same flyer was also distributed by a MAPS member at the Ann Arbor Hash Bash held on the same day.) I spent most of the day at an information table answering questions from whomever stopped and looked quizzically at the newsletters and books on display. The word "psychedelic" was eliciting sly grins and giggles among some festival-goers. Several newsletters and books were sold, and the 50th Anniversary LSD t-shirts were very popular. I spent time explaining to people the therapeutic potential of MDMA, LSD, and marijuana. Young people, in particular, were astonished to learn of the early LSD research. It was an educating experience for me, as well; I experienced first-hand some of the myths and misinformation that is circulated about psychedelics and became familiar with responding to frequently asked questions. It was surprising how much attention the book LSD Psychotherapy by Stan Grof was receiving. Many people perused it and wanted to buy it!

The day culminated in the "public service announcement" about Dr. Donald Abram's FDA-approved study comparing the effectiveness of smoked marijuana with the oral THC capsule in treating people suffering from the HIV-related wasting syndrome, and about MAPS' water pipe/vaporizer study. I went onstage in the late afternoon, and briefly yet firmly declared to all the people on the lawn that there was something to rejoice about in the wake of all the vigorous complaints about the government. I repeated my litany, "though scientific inquiry was prohibited for years in this country, governmental restrictions ARE lifting!" I feel it was essential to share the message of hope. A few people who had not already decided "the government sucks" listened and took note. When I remembered that the crowd to which I spoke was a supportive one, I was much less frightened than I'd anticipated.

A skeptic stops and listens

Rick and I also attended the April 30th Los Angeles Hemp Rally and spoke onstage there. This was a more vigorous declaration of the role that sanctioned scientific research plays among the disparate marijuana agendas. In the parking lot, when I was putting flyers under windshield wipers, I gave one to a woman who was standing near her car. She looked at it and replied tersely "I don't think there needs to be any research, I know it's a good, safe medicine." Here was an avid cannabis supporter who could use her horizons expanded. It was essential to listen to her strongly held belief and address it. I looked at her and kindly agreed with her, while suggesting that there are many people who can't relate to an assertion about marijuana's safety and efficacy until it is firmly established by scientific studies. It is also important to explore and address those risks that do exist with smoking. The feeling that I got when she looked up and said "yes, I understand now that this is a good thing" was truly inspiring. I took it up onstage with me and felt much more comfortable about communicating to the people attending the rally. If you are interested in becoming an advocate for medical marijuana, familiarize yourself with marijuana's history and give it a context among other medicines. Comfort comes with familiarity with the facts. Honest information and the relief of suffering are understandable to most anyone. ■

Honest information and the relief of suffering are understandable to most anyone

plans underway for national **medical marijuana** day

SYLVIA THYSSEN

TAKE NOTE, NATIONAL MEDICAL MARIJUANA DAY IS NOVEMBER 15, 1994. The objectives for this day are to communicate the message that the U.S. government should stop and listen to what a growing number of citizens are saying: medical marijuana is an issue that deserves attention. Under the umbrella organizations of the Emergency Coalition for Medical Cannabis (ECMC) and Cannabis Action Network(CAN), a range of efforts are being planned both in Washington, D.C. and all around the country.

The champions for medical marijuana are coming out in force

ECMC

The slogan that rallies ECMC is "stop arresting sick people!" This cry for compassion will culminate with a civil disobedience event in Washington, D.C. designed to turn heads and open hearts. Patients with legal access to marijuana for medicine (there are only 8 such people in the U.S.) will smoke side by side with patients who do not benefit from the remnants of the Compassionate Investigative New Drug (IND) program, which was abruptly halted in 1992 and which the Clinton Administration has refused to reopen. An excellent Medical Marijuana Background Packet (90 pgs) has been compiled by the organizers of ECMC.

CAN

Under the banner "Plant the Seeds of Healing," the Cannabis Action Network (CAN) has declared a six-month grassroots lobby campaign to make marijuana immediately available for medical use. The projects include registering voters, getting postcards to the White House, and organizing local events to synchronize with the demonstrations in the Capitol. So far this summer, CAN has collected 7,500 postcards destined for the president's mailbox! For the purpose of training citizen-lobbyists, CAN is planning a three-day conference and symposium to take place in September.

MAPS

MAPS is trying to inform the efforts of these two umbrella organizations with updates on the status of FDA-sanctioned research with marijuana. One objective of this medical marijuana initiative is to raise money for research to study both the benefits of marijuana and the risks involved with its use. Dr. Donald Abrams' UC-San Francisco study comparing the effectiveness of smoked marijuana v. the oral THC capsule in enhancing appetite and promoting weight gain in patients suffering from the HIV-related wasting syndrome is the first step. Should the study support the anecdotal reports about marijuana's usefulness, an expansion of this study will be undertaken in order to establish a solid body of research to submit to the FDA in support of marijuana's prescription use. Controlled studies for other indications (glaucoma, spasticity, arthritic pain, etc.) are also possible.

It is important to remember that a crucial aspect of research is to study the risks involved with the inhalation of marijuana, and to learn how to minimize them so as to protect the health of those in need of marijuana's healing properties. MAPS' water pipe/vaporizer filtration study has already been fully funded, with results expected in six months (p. 19).

Should the public come out strongly in favor of research, the government agencies under whose jurisdiction medical research falls will hopefully get the message and start supporting these much needed yet expensive studies. Please consider attending a National Medical Marijuana Day event on November 15, and show support for this crucial agenda!

Efforts to educate the press (and thus the public) about the facts in all their complexity are growing. Parade magazine, the most widely

distributed magazine in America, featured a front page story about marijuana on June 12. On July 31, Parade announced that a telephone call-in poll of its readers found that 89% supported the medical use of marijuana, and 75% supported legalizing marijuana. When someone smirks that medical marijuana is just a front for a well-financed pro-drug culture lobby, they are trying to dodge the issue of medical marijuana. Though some of the main people and organizations supporting the medical use of marijuana do support marijuana's legalization, the medical use of marijuana is a separate issue to be judged on its own merits.

When people insist that marijuana smoke is harmful, they deserve to hear some facts about harm reduction. When they dismiss the plant and say there's a "pot pill" (Marinol), the truth about the comparative benefits of smoked marijuana vs. oral THC needs to be explained. It is up to each and every one of us to arm ourselves with honest information and let our voices be heard.

Local organizers

Organizers for media events, benefit concerts, rallies, and teach-ins who haven't yet started planning with a local group are urged to contact either Cannabis Action Network (CAN) at 2560 Bancroft Way #46, Berkeley, CA 94704, phone: (510) 486-8083, or NORML/ECMC at 1001 Connecticut Ave. NW, Suite 1010, Washington, DC 20036, phone: (202) 483-5500.

If you want to get directly involved in this issue, being a local organizer would be an excellent way to do so. A starter package for local organizers is available for $25 from Cannabis Action Network. It contains information about how to organize a local event, background information about the issue, a video, and a copy of MARIJUANA: THE FORBIDDEN MEDICINE by Dr. Lester Grinspoon. A different, text only, *Medical Marijuana Background Packet* is available from ECMC/NORML for $15. These materials are rich in resources for people who want to be successful advocates.

Get ready to put aside other agendas for the day, to concentrate on the medical applications of marijuana! This will be an opportunity to come together to educate people about this plant, and find common ground with those who might not support legalization but who can understand the importance of marijuana as a medicine. ■

If you want to get directly involved in this issue, being a local organizer would be an excellent way to do so

On May 18, 1994 Dr. Charles Grob administered the first legal dose of MDMA in almost nine years.

new **cannabis** journal

Journal of the International Hemp Association
Vol. 1, No. 1, Summer, 1994

THE INTERNATIONAL HEMP ASSOCIATION is a non-profit organization established in 1992 to promote the beneficial uses of hemp products worldwide. The IHA wants to encourage and facilitate the accumulation and exchange of information on Cannabis. In accordance with these goals, the IHA sponsors projects in several countries and publishes a Journal for its members. The IHA is supported by membership and by donations from foundations, corporations and individuals. Although many IHA members may feel that in light of the great economic potential of Cannabis the current legal restrictions hampering Cannabis research and hemp cultivation should be reconsidered, the IHA does not endorse a political stance on Cannabis legalization, nor will it serve as a forum for the Cannabis legalization debate. The IHA has three types of membership: Student (US $25/yr), Individual (US $50/yr) and Sustaining (US $100 or more/year). Please send International Postal Money Order or an American Express or Thomas Cook Money Order. IHA, Postbus 75007, 1070 AA Amsterdam, The Netherlands, Tel.fax +31 20 6188758, e-mail Hemp.net@f701.n280.z2.fidonet.org Articles in the first issue include an interview with Dr. R. Mechoulam, a description of the IHA's Cannabis seed preservation project in St. Petersburg, stories about the economics of hemp paper in several countries, medical marijuana, a study of the effect of marijuana on driving, and more. This premier issue is printed on hemp paper. ■

volunteers needed for **mdma** research

RESEARCHERS AT THE HARBOR-UCLA RESEARCH AND EDUCATION INSTITUTE in Torrance, California, are currently recruiting volunteers to participate in an FDA-approved study on the effects of MDMA in humans. Volunteers will receive brain scans as well as other tests designed to examine the physiological and psychological effects as well as safety aspects of MDMA use. Volunteers must have prior experience with MDMA. If you would like to participate, please call 310/222-1663 for more information. ■

mdma in the treatment of post-traumatic stress disorder (PTSD): status report on the nicaraguan project

BY RICK DOBLIN

MDMA-assisted psychotherapy, by virtue of its ability to help people experience and integrate difficult and complex emotions, may prove uniquely valuable in the treatment of patients suffering from PTSD. Anecdotal reports of the therapeutic use of MDMA by Vietnam Vets and rape victims are encouraging. Yet anecdotal reports are not sufficient to prove scientifically that MDMA is beneficial, and without scientific proof the FDA will not even consider a request to make MDMA available to psychiatrists and psychotherapists for the treatment of PTSD.

In late 1993, Dr. Manuel Madriz Marin, the chief psychiatrist at the Military Hospital in Managua, Nicaragua, contacted MAPS. Dr. Madriz requested support from MAPS for a clinical trial he wanted to conduct into the use of MDMA-assisted psychotherapy in the treatment of soldiers and civilians traumatized during the Nicaraguan Civil War (see MAPS, Vol. 4, No. 3, p. 3). Dr. Madriz's project is exactly the sort of research that MAPS was created to facilitate, and I enthusiastically offered MAPS' help.

Determining the feasibility of the project

My first task was to assist Dr. Madriz in obtaining permission for his study from the Nicaraguan Ministry of Health. To support Dr. Madriz's efforts, I mailed him a large collection of scientific papers evaluating MDMA's safety and efficacy to submit to the Ministry. These papers included information from standard 28-day safety studies in the dog and the rat that MAPS funded in 1986. The FDA requires these animal toxicity studies as prerequisites before human studies with any drug are normally permitted. To supplement the scientific data, Dr. Madriz prepared a rough draft of a research protocol. After some months of discussions with officials in the Ministry of Health, Dr. Madriz was assured in writing by the Nicaraguan Minister of Health that permission would be granted for his study.

The second essential task was to locate a source of MDMA for the study. In 1986, MAPS had contracted with Dr. David Nichols of Purdue University, Department of Medicinal Chemistry to manufacture MDMA for research purposes. MAPS' initial animal toxicity studies were conducted with some of this material, with the rest remaining in storage at Purdue awaiting future projects. Since MAPS intends to submit whatever data is gathered from the Nicaraguan study to the FDA, it is imperative that the MDMA used in the experiment be approved by the FDA as genuine and pure. Using the MDMA manufactured by Dr. Nichols would resolve any concerns the FDA might have over the nature of the drug itself, assuming that the MDMA had not deteriorated over the eight years it has been in storage. Fortunately, MDMA is a very stable molecule when kept out of excessive heat, light or moisture, and when Dr. Nichols retested it there were no signs of deterioration.

Though pure MDMA was available for research purposes, legally shipping it from the United States to Nicaragua requires permissions from the governments of both the United States and Nicaragua. Preliminary discussions with officials in the DEA's International Drug Unit, Office of Diversion Control, indicated that there are established procedures for exporting drugs from the US to other countries for research purposes. I learned that it would be possible to obtain all the necessary approvals for doing so if the appropriate official in the Nicaraguan Ministry of Health were to provide an import permit for the MDMA. Dr. Madriz was able to determine that the Minister of Health would provide an import permit once the final draft of the protocol was submitted for her review and we knew exactly how much MDMA would be required for the study.

The last preliminary hurdle involved the issue of funding. This issue has now also been resolved, as a result of the unfortunate inability of Dr. Evgeny Krupitsky to obtain permission for a MAPS-sponsored project involving MDMA research in Russia. In April, 1993, MAPS received a donation of $28,000 to support a project investigating the use of MDMA in the treatment of alcoholism and neurosis in Russia. The study was to be conducted under the direction of Dr. Krupitsky at the St. Petersburg Regional Dispensary of Narcology, a 600 bed in-patient alcoholism treatment facility. Due to the political turmoil in Russia, Dr. Krupitsky was unexpectedly unable to obtain permission for his study. After trying for over a year to obtain permission, Dr. Krupitsky reported that in April, 1994 he was no closer than when he began (see MAPS Vol. 4, No. 4, p. 9). While political factors delaying permission for research are nothing new, Dr. Krupitsky felt unable to say when, if ever, the situation would change. Dr. Krupitsky graciously suggested that MAPS consider reallocating the funds from his project to Dr. Madriz's research, raising additional funds for his Russian project were permission to be granted. After consultation with the original donor for Dr. Krupitksy's project, the fundswere shifted to the Nicaragaun study.

The Protocol Design Phase

With the availability of funding and legal permissions, the project has shifted into the protocol design phase. MAPS has been extremely fortunate to receive the assistance of Sylvia Garma, Ph.D., an expert in PTSD who speaks fluent Spanish. The protocol design phase is the key to the success of the entire project. When working with such a controversial subject as the therapeutic use of a psychedelic drug such as MDMA, the scientific design of the study has to be able to withstand exhaustive critique, both from sincere skeptics as well as from people ideologically opposed to psychedelic drug research. Compounding the protocol design process are differences in research methods between Nicaragua and the United States, uncertainty about whether PTSD is diagnosed identically in the US and in Nicaragua, and the lack of availability in Spanish of some important outcome measures.

While the protocol design has not been finalized, some basic design elements are likely. Dr. Madriz's current treatment for PTSD involves patients coming from all over Nicaragua to his hospital for a three week in-patient treatment program. The MDMA study may also use a three week in-patient treatment program. There will be two experimental groups, an MDMA group and a randomized matched control group that will not receive MDMA. Those patients who receive MDMA during their treatment will probably be administered two sessions, the first at the end of the first week and the second at the end of the second week. This schedule will give the patients a week to get comfortable with the therapeutic team before their first MDMA session, a week between MDMA sessions, and a week to integrate their experiences before leaving the hospital. The two groups will receive the same sort of overall treatment, with the control group receiving two special therapeutic sessions of the same length of time as the MDMA sessions but without any drug. Music might be substituted, or perhaps more talk therapy.

MAPS-sponsored PTSD research seminar in Managua

As a result of their discussions about protocol design, Dr. Madriz and Dr. Garma decided that it was important for Dr. Garma to come to Managua to offer a four-day seminar on PTSD research. The seminar took place August 1–5. It was attended by Dr. Madriz's research team which includes two psychiatrists in addition to himself, two psychologists, several graduate students in psychology, and other staff members of the hospital. Joining Dr. Garma in offering the seminar was a psychiatrist from New York also fluent in Spanish, Dr. Lleni Pach.

The seminar focused on a series of issues related to treatment and research with PTSD. These include: 1) evaluation/ diagnostic issues ; 2) psychometric evaluation; 3) group and individual therapy; 4) family therapy; 5) broad outline of PTSD treatment; 6) clinical demonstrations of the use of measures and interviewing technique with in-patients in Dr. Madriz's PTSD unit.

The therapeutic use of MDMA in PTSD will be covered in a separate seminar later in the year, when Dr. George Greer and Richard Yensen, Ph.D. travel to Managua to help further train the Nicaraguan research team. Dr. Greer has conducted pioneering MDMA research in the US in the early 1980's, and Dr. Yensen, who speaks Spanish, researched LSD and MDA in the mid-1970's. Their seminar will include discussions about MDMA-assisted psychotherapy and will also offer guided MDMA sessions for the research team. In that way, the research team will gain a theoretical understanding of how to work with MDMA along with an experiential understanding of the effects of MDMA.

Financial details

As you can see in MAPS' financial report (p. 4), MAPS spent $3,479 on this project in FY 1993-1994. Of that sum, $1,259 was sent to Dr. Madriz for a fax and modem so that we can exchange documents faster than by mail, which can take a long time in Nicaragua (this price includes hefty Nicaraguan import taxes); $120 was spent on translating two documents from Dr. Madriz into English; $2,100 was sent to Dr. Madriz to pay for a translator to translate several outcome measures into Spanish, a telephone line for the modem, copies of various documents, filing fees for the protocol, and for Dr. Madriz's expenses to go to a 1994 Latin American Psychiatric Conference in Panama where he spoke about the protocol. Since the end of MAPS' fiscal year on May 31,1994, an additional $1,568 was spent on airplane fares to Nicaragua for Dr. Garma and Dr. Pach, making the total spent on this project $5,047 to date. Dr. Garma, Dr. Pach and Dr. Madriz have so far donated their personal time for this project.

Hopeful timetable

If all goes as rapidly as I would like (when has that ever happened?), the protocol design process will be completed by the end of September. Obtaining permission to export MDMA to Managua for the experiment will hopefully take only a month or so after the protocol is completed, with the MDMA arriving in November. The MDMA psychotherapy seminar could then take place in Managua in late November or early December. If the first patient is treated with MDMA before the end of 1994, I'll be extremely satisfied.

By the end of 1995, if the results of the pilot study are encouraging, I hope that additional studies will be initiated in the United States, most likely at several VA centers, and also in Israel. We shall see... ■

herbal "ecstasy" – an experiment into the placebo effect

NICHOLAS SAUNDERS

A FEW WEEKS AGO, I was phoned by a man who told me he had a terrific new product, an herbal extract that had the same effect as MDMA, called e-line Ecstasy, "Better, actually, it's great for sex". He told me how it was becoming really popular in the States because it was safe and nontoxic, 100% vegetarian – vegan, in fact – without chemicals, additives, preservatives, sugars or anything artificial. He said its effects last 4-8 hours without causing disorientation, and he would like me to see for myself so I could recommend them.

I was planning to go to Glastonbury – a three-day festival which is traditionally experienced in a pleasantly altered state of consciousness by well over 100,000 people – so I asked for plenty of samples. They arrived complete with a leaflet telling of all the good things they contained such as Gurana and Ginseng. The instructions said that you should "open your heart and allow yourself to become overwhelmed, because then and only then can you feel the true force of this experience"... "All six senses may become intensified. Things may seem crisper and clearer. Sounds may sound louder and feel more intense. Touch becomes more enhanced, things just simply feel better to touch, taste, see, smell, and feel. Imagination will flow more rapidly, thoughts may become clearer and new ideas may appear at a more rapid pace."

At Glastonbury I set up a stand with a sign offering people the opportunity to try a new herbal subtitute for Ecstasy for free, providing they left a deposit, to be returned upon completion of a questionnaire. Each of 100 people got a small brown envelope containing two pills, along with instructions and the questionnaire. This asked them how to rate the herbal product's qualities compared to the best E they'd ever had, scoring 1 to 10 for empathy, free-flowing movements, insight, well-being, hangover, etc. However, I was sneaky: only half were e-line Ecstasy, the rest herbal vitamins. But instead of buying matching funky brown lumpy vitamin pills which were expensive, I went for cheap little white pills. This turned out to be a false economy. Although giving out 'placebos' is an accepted procedure, I'll never do it again: I not only had to mislead people and use them as unwitting guinea pigs, but when they questioned me, I had to lie. And when a group called the Rainbow Tribe all decided to take it together, they of course noticed that the pills were different and quickly guessed the truth. I was then lectured by self righteous tribe members

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as an easy method of evaluating overall positive effects, I asked, "How much would you have paid?"

about the divine principles of trust and of our bodies being our temples, while trying to avoid a riot by lying through my teeth that both types were as real as each other.

But this mistake had a virtue. Besides the test group and control group, I now had a third group – people who believed they were given a placebo. And they weren't going to get their £5 deposit back until they filled in the questionnaire like the others. It was hardly surprising that these people reported that the white pills had practically no effect and valued them at nil. But other people reported all kinds of effects from a bad hangover to providing the best E experience they'd ever had! The e-line Ecstasy also produced an extreme range of responses, although there was a tendency to report a more speedy effect. As an easy method of evaluating overall positive effects, I asked "How much would you have paid?", and the result was much the same: those who put more than £0 valued e-line Ecstasy at an average of £3.98 compared to vitamin pills at £4.12.

the e you take is just one factor affecting your experience

The conclusion is not that people can be fooled. It is that even veteran drug users' experiences are largely determined by other factors than the substance they have just consumed. Everybody's response to drugs depends very much on what they expect; how good they feel and how supportive are their surroundings. But, when you experience some definite change in mood, it can be hard to believe that it was caused by anything else than the chemical in the pill you've just taken. It may well be that the same mechanism occurs naturally inside the brain, in any case. Ecstasy puts the mind into a particular state by releasing 'neurotransmitters' called serotonin and dopamine, resulting in a particular mood. But when moods occur naturally, for instance when falling in love, it is through these neurotransmitters being released. So expectations and situations may cause this release, resulting in a mood change even without the need for a drug. It's like the thought of eating making your mouth water, i.e. releasing saliva in your mouth. The same explanation is thought to apply to 'contact high' – being surrounded by people who are in a particular state triggers the release of a neurotransmitter in the brain to match the mood of those around. It could be a similar mechanism at work when excitement spreads through large crowds.

Maybe, way back in evolution, our tribe would have to been in the same mood to survive – like when under attack – and developed ways to match one another by releasing the right neurotransmitter. It may also explain how the mood at a rave can be so universally luvvy when the majority of people 'on E' have been sold other drugs such as mixtures of speed and LSD. The lesson to know and accept is that the E you take is just one factor affecting your experience. Realise that MDMA is not a 'happy pill' but one that allows you to let go, but not in any particular direction. When you feel good in yourself, comfortable with the people around and expecting to have a great time, then a good E can let you take off. Ravers often get into the rhythm of the bass, which helps to launch them in a fairly predictable direction, but in quieter situations the direction you take is more dependant on surroundings and expectations.

There is another lesson to be learned from this, and one that I suspect many dealers and the makers of e-line Ecstasy already know: that if you can convince someone that a particular pill will produce a particular mood, then it will. Users will write glowing testimonials. And pay you good money. ■

the national institute on drug abuse and the may 16,1994 **ibogaine** protocol development meeting

RICK DOBLIN

A MOST REMARKABLE DISCUSSION about scientific research into ibogaine, a psychoactive alkaloid derived from a root found in Africa, took place on May 16, 1994 under the auspices of the Medications Development Division (MDD) of the National Institute on Drug Abuse (NIDA). The meeting was the second in a series (the first was on October 28,1993) whose purpose is to assist MDD in choosing the most appropriate methodological design for an initial ibogaine safety study. What made the meeting all the more remarkable is that NIDA intends to provide all the necessary funding for the safety study.

NIDA intends to provide all the necessary funding for the safety study

Furthermore, if the results of the safety study are encouraging, NIDA might fund subsequent efficacy studies into the use of ibogaine to treat cocaine abusers. NIDA's efforts concerning ibogaine have come about as a result of a long-term campaign by Howard Lotsof of NDA International, Inc., Bob Sisko of the International Coalition for Addict Self-Help (ICASH) and a growing number of other people who have seen first-hand the therapeutic potential of ibogaine. The development of new treatments for drug abuse is a national priority.

Now that NIDA has decided to enter the field of ibogaine research, it is sparing no expense in gathering the required data. Its leisurely timetable, however, leaves something to be desired. NIDA's ibogaine protocol development meeting involved about 60 invited participants from around the country. Among the participants familiar to readers of past issues of the MAPS newsletter were Dr. Rick Strassman, DMT and psilocybin researcher from the University of New Mexico; Dr. J. Sanchez-Ramos and Dr. Deborah Mash, ibogaine researchers from the University of Miami; Howard Lotsof and Bob Sisko; Richard Yensen, Ph.D. and Dr. Donna Dryer, LSD researchers; and Dr. Curtis Wright of the FDA. Also present were representatives of the Drug Enforcement Administration, the National Institute of Mental Health, the White House Office of National Drug Control Policy, and MAPS.

Protocol Design

The protocol design proposed by MDD is called a double-blind dose run-up study. In a design of this type, small doses are tested for safety in one group of subjects before higher doses are administered to another group. This study will involve four different groups of fifteen people each. Twelve of the people in each group will receive the same dose of ibogaine, and three will receive a placebo. The first group will be administered 150 milligrams of ibogaine, about one-sixth of a full therapeutic dose. If all goes well, subsequent groups will receive 300 mg, 600 mg, and 900 mg. The final dose of 900 mg is on the low end of the therapeutic range. After 12 subjects have received the same initial dose of ibogaine and 3 people have received the placebo, the data will be evaluated to determine whether it is safe to administer the next highest dose (or placebo) to another group of 15 people. Due to the complexity of the study, scientists at two or three different research centers will simultaneously conduct the research, pooling their data. Subjects will be evaluated for acute and long-term psychological and physiological effects. Various data will be collected prior to

the administration of the ibogaine or placebo, during the time of administration, within the next two days, and at one week, one month, three month, six month, nine month, and one year intervals. The effects to be measured are grouped into three distinct categories; neurological, cardiovascular and general bodily functions. The neurological evaluation will include a battery of tests of cognitive function, psychiatric state of mind, and neuro-psychological functioning. Special attention will be devoted to motor control, since very high doses of ibogaine given to rats demonstrated some neurotoxicity in an area of the brain that influences motor control.

This was not evident in primates. Acute psychological effects will be measured by Dr. Strassman's Hallucinogen Rating Scale as well as the Psychosis Scale of the Brief Psychiatric Rating Scale. The cardiovascular evaluation will include measurement of pulse and blood pressure, and electrocardiographs. The general bodily function tests will include measures of temperature and respiration, and multiple blood tests and urinanalysis. Pharmacokinetics tests will also be conducted.

NIDA's study is not intended to prove or disprove the efficacy of ibogaine in treating patients with a cocaine-related substance abuse problem. In fact, many of the tests designed to gather safety data may interfere with the efficacy of the treatment. Nevertheless, preliminary data will be gathered about efficacy using urine tests, measures of the intensity of craving for cocaine, and reports from subjects and counselors.

"Go- No Go" Rules

From my perspective, there was one defining moment of the entire meeting. This revealing moment took place during a discussion of the proposed "go- no go" rules. These rules would govern the review of the safety data from one dose level and guide FDA and NIDA in determining if it was appropriate to administer the next higher dosage level (or placebo) to fifteen more subjects. Dr. Sanchez-Ramos volunteered that perhaps it might be wise to stop the study if any evidence of neurotoxicity were to be determined, even if there were no significant functional or behavioral consequences at that dose level. In response, Dr. Curtis Wright of FDA made the point that substance abuse is a very serious problem with an often fatal outcome. Dr. Wright reminded everyone that the drug approval process involves weighing risks against benefits, and that some risk of neurotoxicity could be accepted if a counterbalancing benefit of ibogaine was the elimination or significant reduction of episodes of drug abuse. This interchange revealed that a generation of repression has sometimes made psychedelic researchers act more cautious than good medicine requires. It also showed that the winds of change at the FDA (begun in the Bush administration) have resulted in sensible and helpful regulators who are willing to give psychedelics a fair review.

Single or multiple dosing

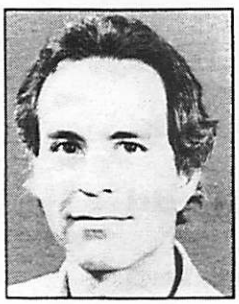
The main concern I have about the protocol is that it involves only one administration of ibogaine to each subject. Unfortunately, this ensures that the data will not be completely relevant to the most likely use of ibogaine in therapy. Ibogaine is not a miracle cure, as the proponents of the therapeutic use of ibogaine all now admit. Most drug abusers will probably need to receive several doses over the course of one or two years, along with a great deal of other non-drug therapy and support. NIDA's protocol could be revised at this point to include multiple administrations. A "go- no go" rule could easily be prepared to determine whether it was safe to administer a second dose to a subject. If the design is not revised before the study is initiated, it will take much longer to get this necessary data.

With some luck, NIDA will add "respected psychedelic research agency" to the list of things it can be

The fact that NIDA is planning to conduct and fund this safety study is remarkably good news, and represents significant progress. NIDA deserves a great deal of credit for going ahead with this study. Nevertheless, a more rapid timetable need not result in any lowering of the quality of data that will be gathered. Given the seriousness of the problem of cocaine abuse, too slowly developing a useful medicine can be as bad as approving a useless or harmful medicine. Still, NIDA needs time to develop its expertise in psychedelic research. Those of us who support ibogaine research should apreciate NIDA's effort. With some luck, NIDA will add "respected psychedelic research agency" to the list of things it can be. ■

update on university of new mexico studies

RICK STRASSMAN



AFTER A QUIET SPRING, we have begun another DMT study, attempting to determine what brain receptors mediate this its effects. After our pindolol study, where serotonin (5-HT)-1A receptor blockade enhanced the psychological effects of DMT, we are now investigating the role of the 5-HT-2 subtype of serotonin receptor. We had been hoping to use the selective and specific 5-HT-2 blocking drug, ritanserin, for this study, but failed to obtain it after several years of negotiations with the company that makes it. Anticipating using ritanserin with DMT, Dr. Mark Geyer and Kirsten Krebs, one of his graduate students, kindly performed some toxicity studies in rodents combining DMT with ritanserin, and determined the combination was safe. However, this was to no avail. We have settled on a less satisfactory drug, but one that is readily available by prescription. This is an antihistamine called cyprohepta-dine, also known as Periactin, which has potent 5-HT-2 blockading effects. One of the advantages of using cypro-heptadine with DMT is that a University of Chicago study in the 1970s combined the two drugs in humans, and noted no adverse effects, although the degree of modification of DMT's effects was equivocal. Animal studies using cyproheptadine to block hallucinogens effects, however, seems relatively consistent, although there are exceptions.

We hope to begin some preliminary work with oral psilocybin this summer

DMT Research

This will be a similar study to our pindolol one, in which case volunteers come in for all possible (i.e., four) combinations of DMT or placebo-DMT, and cyproheptadine or placebo-cyproheptadine. We will look at effects on endocrine markers (ACTH and prolactin), cardiovascular responses (blood pressure and heart rate), temperature, and psychological responses using clinical interviews and the Hallucinogen Rating Scale (HRS). We are now determining the optimally safe combination of doses to use for this study, in a small group of volunteers. Once these are determined, 12 people will participate.

Dr. Rick Strassman, U. of New Mexico Med. School –Psychiatry, 2400 Tucker Ave NE, Albuquerque, NM 87131-0001 RSTRASSM@medusa.unm.edu

Psilocybin Research

We also hope to begin some preliminary work with oral psilocybin this summer. Our first goal will be to determine an appropriate range of doses of psilocybin. Hofmann originally described 6 mg as "hallucinogenic," while a German group some years ago administered 90 mg, and was able to perform complex psychological testing on their volunteers. Leary, Metzner and Alpert gave 60 mg in their Harvard studies, and the highest dose I could find in the traditional psychiatric literature was 32 mg, with a 20 mg threshold before psychedelic effects were noted. I have spoken with the investigators in Zurich who are performing a PET scan study of psilocybin effects, and they state that 15 mg is clearly active. We will begin with 4-5 mg (in a 70 kg person), and gradually increase the dose until full psychedelic effects are noted. We will also have determined a "very low" dose, in which case people can barely, if at all, tell they have received a drug. Then, we will calculate two intermediate doses. Once we have determined these doses, we will perform the full study in 12 people.

Dose-Reponse Study

This will be a dose-response study, identical to our original DMT study. Volunteers will receive initial "screening" low and high doses of psilocybin, to see if they are comfortable in the hospital setting. No blood drawing or other invasive procedures will be done. If the initial days go well, they will come in 5 times for 4 doses of psilocybin and placebo, with blood drawing and temperature monitoring (using a ear drum thermometer, that takes only seconds to use, rather than our infamous rectal probe!). We will measure blood levels of psilocybin, ACTH, growth hormone, prolactin and cortisol. We also would like to measure psilocin, the de-

phosphorylated form of psilocybin, which is believed to be the active compound, psilocybin only acting as a precursor to psilocin.

We are a little apprehensive about how to manage the at least 6 hour psilocybin sessions in our little room on the Clinical Research Center. DMT effects are so short that we have found the room to be completely suitable. What to do during a 6-8 hour session in the hospital will be more of a challenge. We hope to use our same, non-intrusive style of sitting for people, encouraging volunteers to use eyeshades and lay in bed for as long as they comfortably can, using the hospital environment to go into the state as fully as they can. We have comfortable chairs, and a desk, for writing, reading, and art work (see below). However, I clearly anticipate people will want to walk around the ward and stretch their legs during the day, which will take some educating the ward staff on the research unit.

We will also be performing more psychological assessments of volunteers, than just the HRS. We will be giving volunteers the opportunity to express their experiences using art media, in a project initiated by Tamara Allen, an Art Therapy graduate student at the University of New Mexico. This will be a pilot project, determining if the nature of the art productions while under the influence of psilocybin are different than those under placebo conditions, and if so, how they differ. What would be most interesting is to see if there is a dose-response relationship; that is, the higher doses producing greater alterations in the art. Interpretation of these data may shed some light on the nature of how psilocybin affects the symbol-making processes of the mind and brain.

In addition, we will tape-record 30-minute monologues from volunteers at some point in their sessions, for later transcription and scoring by Dr. Robert Langs from the Nathan Kline Psychiatric Research Center in Orangesburg, NY. Dr. Langs is one of the earliest American LSD researchers, and was the "Langs" of the "Linton-Langs" questionnaire, one of the standard rating scales used for hallucinogen effects. Dr. Langs is a renowned psychoanalytic educator and therapist, and has published extensively on the "psychotherapeutic field" that exists between therapist and patient. Inspired by Ralph Abraham's mathematical modelling on non-linear processes, he has recently developed a system of scoring monologues or dialogues that reveal "deep structure" of emotionally-charged language.

Therapeutic Potential

Both of these pilot projects will begin the painstaking process of seeing if and how psilocybin in particular, and hallucinogens in general, may affect mental processes in such a way as to be called "therapeutic" or somehow helpful in one's thinking, feeling, and image formation. It is our belief that "psychotherapy" protocols using these drugs must have a theoretical basis for their application, and not rely upon purely empirical, impressionistic, or intuitive "shots in the dark." By so doing, valid, testable, and "communicateable" process can be built up for other centers to use in their work, and sophisticated psychotherapy protocols can be devised for use in particular disorders in which hallucinogens' effects can be exploited for useful purposes.

These pilot projects will begin the painstaking process of seeing if and how psilocybin in particular, and hallucinogens in general, may affect mental processes in such a way as to be called "therapeutic"

Book Plans

Last but not least, the book on the DMT studies, partially supported by generous MAPS donations. We failed to interest any of the New York publishing houses our agent sent it to. We are revising it now, and will send it off to several more publishers, taking into account the many suggestions contained in our rejection slips. If this next level of publishers fail, we will consider taking the self-publication route. ■

notes from a **psychedelic** research nurse

LAURA BERG

IN MARCH OF 1993, I began working with the psychedelic study research team at the University of New Mexico (UNM), under the leadership of Dr. Rick Strassman. Rick had recently received National Institute on Drug Abuse (NIDA) funding for 3 years of studies investigating the effects of DMT and psilocybin in experienced hallucinogen users, and funding included a position for a half-time Psychiatric Research Nurse. Was I willing to leave a high-pay high-pressure job paying significantly more to join Rick as research collaborator? Yes, with great enthusiasm! Certainly few other work opportunities would be as challenging, momentous and exciting.

I'd like to provide a few "nursing notes," offering my current perspective on nursing roles of the past; my own preparation for work in this field; characteristics of set and setting within our UNM studies; and plans for the future. In a future issue, I'd like to describe the range of activities and responsibilities associated with my contemporary, day-to-day nursing role, activities which range from volunteer recruitment to intravenous line monitoring, to psychiatric screening and on-going volunteer follow-up.

The Role of Nursing in Psychedelic Studies: A Brief Historical Review

As a psychedelic research nurse beginning my professional journey in the 1990's, I realized I would not find role models or mentors in the contemporary field of nursing. But I did hope to hear the voices of nurses from the "Golden Era" of psychedelic studies, preserved in clinical and research literature from the mid-1950's to early 1970's. As I undertook my "archeological expedition" into the medical and nursing literature, I was surprised that very few traces of the nursing legacy or presence were documented.

Throughout the late 1960's and early 1970's, journals of nursing published sporadic articles on "The Drug Culture" and the effects of hallucinogenic drugs. Reflecting the socio-cultural tone of the times, these articles were almost exclusively authored by male physicians and pharmacists. In my search, I was able to find only two RNs who wrote first-person accounts of their clinical experience working with late-60's psychedelic "trippers": Margaret Sankot (1968), Head Nurse of the Haight-Ashbury Clinic, co-authoring with the Clinic Director, a physician, and Kathryn Dansky (1970), a nurse who worked in the "Medi-Rock" project at a 1960's rock festival. (Authorship of the second article was under the pen name of "Mrs. Dansky" and the RN designation was omitted.)

Nurses had significant roles as sitters, guides, facilitators or "presences"

While clinical writing related to psychedelic nursing is relatively meager throughout the '60's, writing by nurses about their experiences during the thousands of hours of intensive psychedelic research is virtually non-existent. No nurses, to the best of my knowledge, served as co-authors on published research papers, and no narrative or journal notes by nurses working in psychedelic studies are available.

Since few nursing sources exist, those who describe the roles of "Golden Era" research nurses were physician investigators. References are scattered and fragmented, most often discussed in conference proceedings rather than in published papers. Passages do indicate that nurses had significant roles as sitters, guides, facilitators or "presences" in a wide range of psychedelic studies. Studies were both naturalistic and

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controlled, involving administration of a wide range of psychedelics and drug dosages to schizophrenic, depressed, alcoholic, anxious, "neurotic," and terminally ill patients, as well as to "normals," artists, and the countless graduate student study subjects. Although these RNs remain nameless, many served as dedicated "flight nurses."

The bedside care and one-to-one constancy for experimental psychedelic subjects was not infrequently delegated to nursing staff. MDs described the work as "time consuming and tiring," "exhausting" and "too time-constraining." Physician researchers frequently maintained clinical and administrative responsibilities for other patients and wards, with psychedelic research projects and sessions taking place as secondary or competing endeavors. References indicate that physicians were not continuously present during psychedelic sessions or experiments, but nurses usually were. RNs present in this capacity were undoubtedly exhausted as well, yet practiced, over time, the art and skill of "being there" throughout the treatment.

Unger describes Spring Grove research guidelines in which "the psychiatrist or at least a nurse should stay with the patient throughout the (LSD) intoxication." (Unger, 1969). In other LSD study protocols with schizophrenics at the New York State Psychiatric Institute, "someone, usually a nurse or attendant is always in attendance, taking notes. The physician is there at the beginning for about 3/4 of an hour," ...and check(s) in on the patient at 15 to 20 minute intervals." (Malitz, 1960) In Danish studies with psilocybin and LSD, the physician researcher would "sometimes pay a control visit to the patient before the (psychedelic) treatment is over," but "more often the nurse and patient would be alone for the 4 to 5 hours of the experience..." Perhaps the most extraordinary aspect of this study was the expectation that "the nurse and psychiatrist would constantly communicate over the phone during the treatment." (Geert-Jorgensen, 1968).

There are few further references which recount the specific skills, training or therapeutic interaction styles offered by nurses in past psychedelic studies. In the above New York protocols, there was an "overall supervisor who is trained, but the nurses themselves have varied...levels of investment and training." (Malitz, 1960). Characteristics of training or investment are not described. In the Danish study cited above, "the nurse who was to be in charge of them is instructed to approach the patients in a motherly, consoling and reassuring way during the psychedelic treatment." Whether or not "constant communication by phone" interfered with consoling and reassuring maternal contact is not addressed!

In Sandison's studies in the late 1950's in England, RNs on all 4 psychiatric wards were "trained in the use of LSD therapy." As Sandison describes, "Their role is a difficult one, and it has taken much time to indoctrinate them. We encourage them to take an active part in the treatment situation. Here we may differ from others, in that we also encourage the nurses, to a limited extent, to handle some of the patient's material when the physician is not there." Responding to a seemingly incensed colleague, Sandison goes on to clarify that nurses did not "have enough training to interpret patient's material," but they were able to "support their ventilation" (Sandison, 1960). While the term "indoctrination" of nurses seems archaic, Sandison stands out as one of the few physicians to support and encourage an active therapeutic role for RNs in his psychedelic investigations.

physicians were not continuously present during psychedelic sessions or experiments, but nurses usually were

One final reference overtly highlights the pervasive and restrictive stereotypes enacted by predominantly female nurses and male physicians in the '50's and '60's. "If (the physician) does not have the patience or inclination to be with (the patient) during the 5 or 6 hours of the psychedelic treatment, then (he should) get a nice gentle, kind and preferably good-looking nurse to remain with them... There are large numbers of such pleasant and capable young women and their presence (does) a great deal of good even if nothing else is done" (Osmond, 1969). Many difficult interpersonal and political issues percolate in this citation. As a present-day nurse, what can I extract that is of value? Perhaps that kindness, gentleness and "simple presence" - the traditional female talents - may have been more important to psychedelic sessions and positive outcomes than previously suggested.

I will continue my historical review, searching for the stories, documents and voices of women and nurses

who preceded me in this realm of research. And I hope to add my part to the archives of the present era, sharing my perspectives and insights from "the bedside" (and wider regions) of current psychedelic studies. Complete resources from earlier eras are not easily accessible, and if MAPS readers have further material to share, I'd appreciate the opportunity to review it. Perhaps there are MAPS members who are past psychedelic research nurses, study subjects or research collaborators, who would be willing to speak more fully about the role of nurses in their studies?

There and Back Again: The Flight Nurse

While attending my baccalaureate nursing program in the early 1980's, I had wistfully imagined working at Spring Grove Hospital of the Maryland Psychiatric Research Center, where compassionate and fully-sanctioned research on the therapeutic use of psychedelics had taken place until the early 1970's. However, by the time I was in school, the door to that realm of research seemed firmly and unequivocally shut. Nursing work in psychedelic research seemed to be a daydream and a fantasy, so I moved forward to work in more accessible and "reality-based" spheres of nursing.

I APPLIED MYSELF in a variety of nursing fields, including oncology and HIV nursing, substance abuse and acute psychiatry, teaching and administration. Over the years, I also participated in several Grof Holotropic Breathwork and Elisabeth Kübler-Ross Center workshops, and served as an emotional support volunteer for persons with HIV. I later returned to school and received a Masters in Psychiatric-Mental Health Nursing, completing my clinical and academic work in Atlanta, and conducting my master's thesis in New Mexico. My thesis examined the coping resources of 47 individuals across a range of symptom levels with HIV.

Masters and Houston encourage psychedelic guides to be "widely divergent" in interests, skills and experiences

Before beginning nursing school at age 27, I had worked as a waitress, apple-picker, rock-and-roll singer, and nursing assistant. Along the way, I also lived in an "alternative" community for 5 years - "New Age" before that term had ever been coined. I found myself leaving that focus on "ascension" for a path of more "immanence." My search and practice has been ongoing, and I have explored a range of paths and perspectives. All have been valuable.

I provide this mini-autobiography because I perceive that all of my experiences, from apple-picking to HIV nursing, support my present professional work. Masters and Houston encourage psychedelic guides to be "widely divergent" in interests, skills and experience. As a support person and nurse for many psychedelic voyagers, I recognize my responsibility to be as authentic, well-rounded, and experienced as I can be. Friends and study volunteers have nicknamed me "the flight nurse," and I gratefully accept that designation!

The UNM Studies: Setting

Set and setting are essential components influencing the psychedelic drug experience. Our studies take place in the Clinical Research Center (CRC) of the University of New Mexico Hospital, one of 78 such research centers funded by the NIH. Facilities include administrative services, an in-patient nursing unit, an out-patient clinic, an on-site laboratory, kitchen, computer center, research equipment, and an experienced research nursing staff.

We conduct the studies in a standard hospital room at the UNM Hospital, although more "homey" furniture and artwork has been gradually added over the last few months. The room is at the end of busy nursing unit, where other research protocols, including high-dose cancer chemotherapy, are conducted. Because of the clinical hospital setting, the IVs, blood drawing or temperature monitoring, some potential volunteers choose not to participate.

Nearly all that do participate have found the setting to be safe and comfortable. Volunteers are prepared to undergo an experience that may feel like dying, and the hospital setting can be a more reassuring place to have that experience. The volunteer is then free to "go out" as far as possible, leaving Rick and I to monitor basic survival functions and "bring them back home," if needed. Most volunteers say that the external setting becomes uniquely superfluous during peak effects of DMT. Volunteers wear eyeshades, and are encouraged to keep these on until the drug effect has waned. Disorientation can occur when one tries to get one's bearing by looking around in a highly altered state, and eyeshades keep attention within; we feel that the most valuable experience will be accessed internally rather than in the external environment. Our most recurrent problem in the hospital setting has been noise pollution, from the occasional vacuum cleaner or jet sounds that intrude into DMT sessions.

It is very clear that attributes of human language also function as an aspect of set and setting in research studies. Some of our volunteers have been adamant

that DMT and other hallucinogens be spoken of as "medicines" rather than drugs. The term "drug" has connotations of somnolence and decreased states of awareness, and perhaps even of addiction. "Medicine" is a term that appears more neutral or positive in approach. Although it is a word commonly under the aegis of modern medicine, it also hearkens back to Native American traditions, in the context of "medicine men," "medicine circles," or "good medicine."

In referring to DMT, Rick and I most frequently use the terms "psychedelic" or "hallucinogen." For relatively naive audiences, the term "psychedelic" is still associated with the upheaval and intemperance of the 1960's; few are aware of etymological root of the term as originated by Osmond, signifying "mind-manifesting." In contrast, the term "psychedelic" seems to be more descriptive and comprehensive, encompassing the wider range phenomena that accompany (or distinguish themselves) from hallucinations, per se.

We have also chosen to use the term "volunteer" to refer to our research participants, since the term "research subject" connotes images of cold sterile laboratories and passive bodies being "subject to" strange experiments. While some might agree that our studies do involve "strange experiments," our volunteers are truly active rather than passive participants. Volunteers are collaborators and co-investigators; they are "expedition scouts" who take the journey into terra incognita and return to share in mapmaking. And qualities of human warmth and spirit do infuse research setting, however "sterile" it may seem at times.

Volunteers are collaborators and co-investigators; they are "expedition scouts" who take the journey into terra incognito and return to share in mapmaking

The UNM Studies: Set

Set is commonly associated with the psychological preparation undertaken by the person and the state in which they enter the psychedelic encounter. Set may include cognitive, behavioral, and affective components, and can also be strongly influenced by the attitude, attributes and styles of the research team or guide(s). With most other psychedelic substances, the individual and guide are often able to prepare and plan for the locus of the session, which may be to address specific therapeutic issues, heighten psychodynamic transference, or to impel "transcendent" states. The internal "mind-manifesting" experience can also be modified by the use of music or other environmental cues, and the altered state arises and dissipates much more slowly.

In contrast, UNM study volunteers receiving DMT at the 0.4 mg/kg level have rarely been able to "program" or focus their experiences once they begin. The intensity and speed of the higher doses of intravenous DMT seem to "rip away the ego, the body, and the mind." Once psychedelic effects begin, they are not subject to conscious control, nor altered by input from the research team. During onset (the "rush"), several volunteers have felt that they were actually physically dying, and many others have wondered if they were "overdosed " by the research team.

As one volunteer summarizes, "DMT has its own agenda." In the "DMT hyperspace" experience, volunteers have being eaten by insects, crushed by reptilian entities, challenged by spear-wielding African warrior goddesses, cast adrift in a sterile and mechanical universe, and subjected to experiments by alien life forms. (Only rarely do these resemble Rick or me!) Other volunteers have merged into Clear Light, journeyed to the Tree of Life, visited with multidimensional circus clowns, or received healing energies and feelings of hope and renewal. Some have had an amazing range of experiences, from blissful to monstrous.

As a "psycho-pharmacological" protocol, our DMT sessions are not specifically designed to "treat" or be therapeutic in nature. However, the DMT experience frequently brings up or intensifies the volunteers' significant personal issues and associated emotions. While the more subtle or unconscious elements of "set" may influence the DMT experience, Rick and I find few patterns, and are far from synthesizing any theories in this regard. At this time, we remain neutral, avoiding intellectual analysis, offering "simple presence" at the bedside. We believe that the ability to be empathic, consistent, and warm, while at the same time remaining free from over-involvement or intrusiveness, is fundamental to the success of our work. To the greatest extent possible, we remain unbiased, open, and supportive. We encourage a set of relaxation, acceptance, and surrender in all phases of the study - preparation, DMT session, and integration - echoing the wisdom and advice of many intrepid UNM DMT study volunteers: "Expect the unexpected." "Go with it." "Catch the wave, don't fight it." "Don't try to control." And, most succinctly, "Don't forget, you'll be back soon." ➡

Research Models and Paradigms: Toward the Future

As contemporary researchers, Rick and I must have an understanding and acceptance of non-Western philosophies and alternate paradigms of experience, yet also operate coherently and professionally within the forms of traditional scientific and medical research design. By doing so, we hope to lay a foundation for future clinical research which may be more explicitly therapeutic in nature.

In the course of rigorous scientific structure - IVs and neuroendocrine markers, flexible rectal probes, double-blinded, placebo-controlled and randomized experiments - the experiences of humor, insight and amazement still occur. And these do occur for the research team as well as the study participants! (More about flexible rectal probes in my next MAPS article...)

We anticipate beginning our NIDA-funded studies with psilocybin later this summer, while continuing our ongoing research with DMT. As we begin the work with psilocybin, Rick's and my role as psychedelic guides will be heightened and refined. At the present time, we anticipate following the approach developed during our DMT work, which supports a primarily inner-directed experience. As sessions will be significantly longer and include expanded onset and "re-entry" phases, we will offer volunteers the opportunity to listen to music and to explore a range of art media. Communication and exchange with experienced guides is most welcome!

Human psychedelic studies offer a profound, unusual and exciting research milieu, one in which the distinct yet synchronous pathways of brain neurochemistry and human consciousness meet in a (literally!) extraordinary way. As researchers elucidate the processes of these two intertwining psychedelic phenomena - microcosmic neurochemistry and macrocosmic human experience - they undertake an appropriate and timely endeavor.

Through our work at UNM, it is my hope that financial and regulatory support for human psychedelic studies will be significantly expanded. I anticipate that successful studies will include the full and dynamic participation of many nursing collaborators and many women co-investigators, and I look forward to the work to come. ■

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research in archetypal art therapy with **psilocybin**

TAMARA D. ALLEN

Art is a universal language that can be spoken by any population

THIS STUDY is part of a research project conducted by Rick J. Strassman M.D. at the University of New Mexico Clinical Research Center entitled, "Human Psychopharmacology and Neuroendocrinology of Psilocybin." In this study, volunteers will be administered the Ulman Personality Assessment Procedure (UPAP) and a Multi Medium Art Studio Situation (MMASS). In addition, volunteers will be interviewed and asked to describe how their psychological information was processed and perceived visually through the art they created during periods of normal activity, and after they have received a placebo or various doses of psilocybin.

Hypothesis and specific aims

This study seeks to determine whether, and to what extent, that conscious and unconscious psychological material can be recognized in the art of volunteers. It is hypothesized that differences and correlations will be evident between the administration of small, medium, and large doses of psilocybin, and placebo.

Background

In preparation for this project, this investigator met with experienced researchers in the field, Betty Eisner and Oscar Janiger, to explore their work and archives. Eisner's 1964 study of the use of LSD in group psychotherapy utilized art production, with volunteers given specific drawing material while under the influence of LSD. Janiger's 1955 study of LSD and creativity (Janiger, 1989) also used a range of art materials and had particular directives regarding subject matter.

A review of the literature on art and hallucinogens suggests that research methodologies placed limits on at least one aspect of the art process or limited interpretations of the potential aspects of meaning (Grof, 1975; Krippner, 1985; Di Leo and Kellogg, 1977). These initial studies have been valuable and useful, with researchers agreeing that art is a powerful tool to communicate hallucinogenic experiences. No studies reviewed have indicated that psilocybin or an Archetypal approach was used.

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Archetypal Art Therapy (AAT) is a new approach in therapy that requires licensing and accreditation with the National Art Therapy Association. It has been in use in psychiatric, medical, and penal settings since the 1980's. The AAT masters program at UNM is the only one of its kind out of all the accredited university art therapy programs in the United States.

AAT is a modality that engages people to create a piece of art and to reflect upon that process of creation metaphorically. Hillman (1983, p.3) believes that metaphor is the "primary and irreducible language" of the archetype. Through the experience of AAT, people are able to gain insight, problem-solve, and communicate through the language of art, in ways that verbal therapies do not utilize. Art provides a variety of safe and contained media to explore psychological material even if one lacks traditional art training. AAT is far-reaching in its multi-cultural benefits (McCoghey, 1986), because art is a universal language that can be spoken by any population.

Study design

This study will begin with the administration of the Ulman Personality Assessment Procedure (UPAP), devised by Eleanor Ulman in 1965. The UPAP will first be administered several days prior to the volunteer's initial experimental session with psilocybin (or placebo). The UPAP procedure involves prescribed art materials and specific instructions. The UPAP allows the researcher to assess the psychological environment of the volunteer, their decision making process, ability to

follow instructions, and ability to relax defenses and work with unconscious material. This study will contribute new data to an ongoing study of the UPAP, and provide an initial indication of volunteers' attitudes towards the art process.

At the second and fourth hour after the administration of the test drug, subjects will be asked to try to create a work of art

After the administration of the UPAP, the volunteer will then be introduced to the Multi Medium Art Studio Situation (MMASS), which has been devised by the investigator. The MMASS is an art studio with a broad range of art materials which will be accessible to the volunteers throughout the study. In the preliminary session, volunteers will be introduced to all media and be given the opportunity to ask questions about the technical aspects of the media. Then, using the medium of their choice, they will be asked to represent an image of their choice from among those previously created for the UPAP. After its completion, they will be asked to give a written or verbal account of the session using techniques of metaphor that will be explained to them by the investigator. The AAT process requires that the volunteer "stick to the image" and describe only what is confirmed by it, yet not impose limits on its interpretation. This can help to ensure that only the material in the image created during a session will be reflected upon. Once the volunteer is familiar with the MMASS, the introductory session is concluded.

On several subsequent days, volunteers will be administered various doses of psilocybin or placebo. At the second and fourth hour after administration of the test drug, they will be asked to try to create a work of art using the art studio media. After the fourth hour, if the volunteer has not yet created any art, they will be reminded hourly to try to do so. At least eight hours after the administration of the psilocybin or placebo, the volunteers will be asked to participate in a brief interview.

A hermeneutic methodology will be applied to all imagery and its relationship to entopic phenomena (Reichel-Dolmatoff, 1972; Lewis-Williamson and Dowson, 1988, 1989; Kellogg, 1978, Edwards, 1986) that occurs in the art of subjects. Entopic, from the Greek, means "within vision". Horowitz defines entopic phenomena as "images experienced as intrapsychic, related to perception, since they arise from stimulation of the optic structures within the eye or in some portion of the optic neural circuits as they travel to higher brain centers" (1978, p.25). One hypothesis of this study is that entopic constructs carry archetypal information of the personal and collective unconscious. The interviews conducted with the subjects will note if entopic imagery is mentioned, and determine, through the subject's reports, if it is meaningful or relevant.

Data will be compiled from these reports into statistical formulations. Quantitative findings will be analyzed comparing small, intermediate, and large doses of psilocybin, and placebo.

In addition to art production and various physiological and psychological measurements, Dr. Strassman's experiment will analyze volunteers' verbal responses in the form of an extended monologue that will be recorded during the psilocybin session. This has fascinating implications for the AAT study because is will record what may arise verbally parallel to the process of creating art. Ultimately, the use of the Archetypal method will give the vol-unteers in the study a unique way to reflect upon and communicate about their experiences with psilocybin. Hopefully this study will also draw attention to the field of AAT and demonstrate that AAT can be a useful adjunct to current research methodologies. ■

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the israeli opportunity

WHILE IN ISRAEL attending my cousin's wedding this June, I arranged a meeting with the Chief Scientist of the Israeli Ministry of Health, Dr. Michael Silbermann. The purpose of the meeting was to discuss the likelihood of MDMA research being legally approved in Israel, perhaps for use in treating Post Traumatic Stress Disorder (PTSD), Obsessive-Compulsive Disorder (OCD), or in helping reduce pain and distress in terminal cancer patients. To my delight, Dr. Michael Silbermann indicated that the essential elements in the decision to permit MDMA research in Israel would be the safety of the human subjects and the scientific rigor of the protocol design.

My main question for Dr. Silbermann concerned the possible existence of any overriding political concerns that might prevent medical research. In particular, we discussed the fact that the use of MDMA in all-night raves in the Jerusalem hills had been reported in the Jerusalem Post, and that the practice was looked on with disfavor by the police. Dr Silbermann indicated that such non-medical uses were no secret, but that research into the medical use of MDMA would be considered on its own merits.

We then discussed the possibility that MAPS might help arrange a two-day scientific seminar in Israel with scientists from the United States coming to Israel to lecture on the topic of medical research with MDMA, ibogaine, DMT and psilocybin, marijuana, and drug policy. Dr. Silbermann thought the idea had promise and suggested that it might be possible for an organization on whose Board of Directors he serves, the American-Israeli BiNational Science Foundation, to sponsor the meeting. The key to such a sponsorship is finding an Israeli scientist to co-sponsor the meeting.

Fortunately, Dr. Joseph Zohar, an Israeli research psychiatrist who focuses on OCD research, is interested in MDMA's potential in treating patients with OCD who do not respond to other treatments. He is considering helping to plan the seminar, and said he would contact a few other scientists in Israel who might be interested in the topics.

I am now in the process of drafting a proposal for the meeting, to send back to Dr. Silbermann for submission to the American-Israeli BiNational Science Foundation. If this seminar actually gets arranged, it will probably take place sometime in middle or late 1995. ■

update: research in germany continues

LEO HERMLE

GOOD NEWS REGARDING THE CONTINUATION OF OUR STUDIES in the field of experimental psychosis in Germany: We have finished the study with psilocybin (N=12 volunteers, double blind with placebo). The aim of the study was to assess the changes of facial expression and cognitive functions during the drug's action, and to evaluate psilocybin metabolism and pharmocokinetics. The results will be published in different well-known journals.

We are now beginning comparative studies with psilocybin, MDE, methamphetamine, and placebo using Positron Emission Tomography (PET), VEP, and different neuropsychological assessment strategies.

Another pilot study (8 volunteers, double blind) will be conducted with R and S-enantiomers (isomers) of MDMA using functional Magnetic Resonance techniques and different psychometric scales in order to understand the basic differential mechanisms of action of the entactogens. We assume that the S-MDMA represents the pure entactogenic effects and can be distinguished from the racemic MDMA (Hermle, Spitzer, and Kovar).

Editor's note: Every molecule is actually a composite of its R- and S-enantiomers, two identically structured molecules which are the mirror image of each other. Because of the exquisite sensitivity of the human brain, the R- and the S- enantiomer of a particular molecule often have different effects. Racemic MDMA refers to MDMA in which both enantiomers are present in equal proportions. Racemic MDMA is what is being used in Dr. Grob's research, and is also what is sold in the illicit market. ■

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Video	Audio
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2. Highlights from San Francisco	

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❑ YES! I would like to support MAPS by becoming a member.

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Enclosed is my tax-deductible membership donation of:

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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 800 members. MAPS' founder and current president, Rick Doblin, is currently in the Public Policy Ph.D. program at Harvard's Kennedy School of Government and has graduated from Stan and Christina Grof's Holotropic Breathwork three 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, other psychedelics, and marijuana, 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 reintegration of the use of psychedelics and the states of mind they engender, please consider joining MAPS in supporting the expansion of scientific knowledge in this area. Progress is possible with the support of individuals who care enough to take individual and collective action. In addition to supporting research, your contributions will return to you the following benefits:

The MAPS Newsletter:

Each newsletter will report on MAPS research in progress. In addition to reporting on our own studies, the newsletter may 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 may be addressed, as may political developments that effect psychedelic research and usage.

General Membership: $30.

(If outside US add $15 postage.)
Renewing General members will receive the newsletter for one year and a copy of Dr. Grob's protocol *MDMA in modification of pain and distress in end-stage cancer patients.* New General members will receive the newsletter for one year and a copy of the comprehensive Spring 1994 sixty page MAPS newsletter.

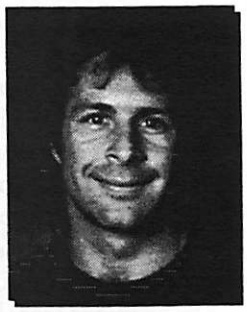
Supporting Membership: $100.

(If outside US add $15 postage.)
Supporting members will receive all the General membership benefits plus their choice of either the audiotapes from the 50th Anniversary of LSD event in Santa Cruz, April 16, 1993, or the Prague 1992, MAPS-sponsored discussion on working with the terminally ill with psychedelics, featuring Ram Dass, Ken Ring and Richard Yensen.

Patron: $250 or more.

Patrons will receive all the General and Supporting Member benefits plus one item of their choice from among the videotapes from the 50th Anniversary of LSD events. Patrons may also request research updates at any time on matters of personal interest and will receive advance information and discounts to MAPS events.

MAPS MEMBERSHIP INFORMATION



Rick Doblin, MAPS President

Sylvia Thyssen, Member Services & Project Coordinator

"I think I might have been stupid in some respects, if it weren't for my psychedelic experiences."

Kary Mullis, PhD., new MAPS member
(and recipient of the 1993 Nobel Prize in Chemistry)

"We must free science and medicine from the grasp of politics and give all Americans access to the very latest and best medical treatments."

President W. J. Clinton,
January 22nd, 1993

medical marijuana: point/counterpoint

Dear Rick, June 14, 1994

Thank you for the materials on MAPS and related matters. While we do not agree on many issues, I do review and read material expressing various viewpoints.

I have enclosed some material related to marijuana and cancer that causes particular concern. This material resembles the early information on tobacco cigarettes and lung cancer. Of course, the tobacco industry attempted to discredit the early studies and to hold research to impossible standards. I hope the marijuana lobby will not be as successful as the tobacco lobby was in dodging the data and studies. Did you know that the Indian Hemp Report also lauded the medicinal value of tobacco smoke?

On the medical marijuana issue, I think the verdict is pretty much in among true medical scientists, researchers, and practitioners. I generally consider the credibility and direct experience of the source of such research and when I see a reliance on non-clinical research, or researchers, it throws up a red flag in my mind. The primary movers behind the "pot as medicine" propaganda, are the leaders and longtime affiliates of pro-drug liberalization organizations and pot smoker lobbies, such as NORML.

Only by remaining open to the evidence will you ever know for sure.

I am not aware if any of them, even those with medical degrees, have actually performed and published original medical or clinical research in the past twenty years. It seems as though they primarily serve as the tobacco industry's "experts" do, to downplay and discredit the work of others. In an ironic twist to normal consumer protection standards, they assume that all mind altering toxic chemicals are safe for human consumption and disregard all studies to the contrary. They give the benefit of the doubt to the drug seller, and let the consumer suffer the consequences. The pharmaceutical companies will make a killing (pun intended) if this becomes the new standard for all drugs.

Rick, while we are diametrically opposed on most issues, I do sense that you are a sincere and sensitive individual. You may find that not all of those around you are as sincere and that your views were wrong and unintentionally damaging, especially to children. Only by remaining open to the evidence will you ever know for sure.

Sincerely,
Robert E. Peterson
Director - Office of Drug Control Policy
State of Michigan

Dear Robert, July 11, 1994

Your letter of June 14 concerning the medical use of marijuana stressed the lack of clinical research supporting marijuana's safety and efficacy for any clinical indication. Clearly, I place more stock than you in the value of anecdotal evidence (which was sufficient "to identify the therapeutic potential of chloral hydrate, the barbiturates, ether, nitrous oxide, chloroform, curare, aspirin, quinine, insulin, thyroid, epinephrine, local anesthetics, belladonna, antacids, sulfonamides and penicillin, to give a partial list" - Dr. Louis Lasagna, Director, Center for the Study of Drug Development, Tufts University- Reprint Series #8695). Nevertheless, anecdotal evidence can be misleading. Therefore, I agree with you that clinical research is essential to prove (or reject) marijuana's medical value.

You indicated in your letter that you thought I was sincere and sensitive. I appreciate those kind remarks, along with the time you spent to write the letter and your implicit hope that I would listen to your ideas.

I'm writing now to challenge us both to live up to your admonition to "remain open to the evidence." For the last two years, Dr. Donald Abrams of UC San Francisco and I have been working to secure all the necessary permissions required to conduct a controlled clinical trial comparing smoked marijuana to the oral THC capsule in the treatment of the HIV-related Wasting Syndrome. The protocol has finally been approved by the FDA, the UC San Francisco Institutional Review Board, the Scientific Advisory Committee of the San Francisco Community Consortium, and the California Research Advisory Panel.

Unfortunately, Dr. Donald Abrams' application for a DEA Schedule 1 license has been pending for more than three months. I believe that you are sincere in stating that this issue should turn on the scientific merits of clinical trials. I'm writing now to ask you to consider contacting Mr. Gene Haislip, DEA Deputy Assistant Administrator, Office of Diversion Control (202-307-7165) to express your support for Dr. Donald Abrams' Schedule 1 license. Then, we can both await the results of his pilot study to see what light it sheds. Without permission to conduct research, the claim that there is no scientific support for the medical use of marijuana rings hollow. I'm sure you see this, and hope you choose to support Dr. Abrams' research.

Respectfully yours,
Rick Doblin
MAPS President