

MAPS

VOLUME XX NUMBER 2

From the desk of Rick Doblin, Ph.D.



THE BAROMETER of success for social change movements is whether their struggles, spanning decades or longer, are taken for granted by new generations. I saw hints of this July 29 when I spoke about MAPS' research into MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) to about 50 psychiatrists, psychotherapists and other medical professionals in the Department of Psychiatry at Kaiser Permanente Hospital in San Francisco. To my surprise and satisfaction, the healing professionals were not that interested in my chronicle of our quarter-century of struggles between the DEA's criminalization of MDMA on July 1, 1985, which outlawed all uses, and the July 19, 2010, *Journal of Psychopharmacology* publication of the results of MAPS' U.S. MDMA/PTSD pilot study. The Kaiser staff were far more interested in practical details regarding our safety and efficacy data from the world's first completed, controlled study of the therapeutic use of MDMA.

I knew we'd entered a new era when I was asked about the casualties of a recent Bay area rave that resulted in an Ecstasy-related death and lasting damage to a young woman who was treated at this very same hospital. Within a few minutes, I was able to acknowledge and differentiate the risks of Ecstasy taken in uncontrolled settings with the risks of pure MDMA administered to screened subjects in therapeutic research. For decades, fears about the risks of the non-medical use of Ecstasy were sufficient to derail research and interest in the medical uses of MDMA. My experience at Kaiser demonstrated to me how far we have progressed in our mission to mainstream psychedelic psychotherapy.

Meanwhile, our new MDMA-assisted psychotherapy study with veterans suffering from war-related PTSD is fully approved and about to begin, while signs of our growing mainstream acceptance can be found in the more than 140 media articles about our paper.

- On July 19, Roger Pitman, M.D., PTSD expert and Professor of Psychiatry at Harvard Medical School and Massachusetts General Hospital, was quoted in an article in *The Boston Globe*. He called our research "promising," and the results impressive and deserving of further investigation.

- In a July 20 WebMD article, Charles R. Marmar, M.D., Chair of Psychiatry at New York University's Langone Medical Center, referenced our work as a "well-conducted clinical trial showing positive effects. MDMA appears to be reasonably safe and effective and requires more trials. ...The fact of the matter is that these are difficult-to-treat patients, so having another tool in the armamentarium would be helpful. Assuming it is done under highly professional conditions and patients didn't have history of abuse, there is no reason to believe it would be dangerous – yet we need more work to find out what the risks are." Marmar's comments are especially relevant because he represented Pfizer, manufacturer of Zoloft, in the FDA's 1999 Advisory Committee hearing that resulted in the approval of Zoloft for the treatment of PTSD.
- Also in WebMD, Harriet deWit, Ph.D., Professor of Psychiatry and Behavioral Neuroscience at the University of Chicago and a NIDA-funded neuroscientist who has seen the MDMA neurotoxicity debate from the beginning, remarked, "The results were quite dramatic and it is proof of concept and very good early evidence."
- In the Aug. 4 edition of the *Toronto Sun*, Lt. Col. Rakesh Jetly, a psychiatrist and senior health adviser for the Canadian Armed Forces, said about our research, "We're in the business of stopping suffering and if something is shown to do it, then we would certainly give it serious consideration."

With these experts calling for more research, our momentum is building. MAPS' so far fruitless efforts to collaborate on MDMA/PTSD research with the U.S. Department of Veterans Affairs, the Department of Defense and the National Institute on Mental Health no longer seem so far-fetched.

The incredible progress we have made in the past few years allows us to move beyond the politics of MDMA and expand our research into the healing potential of psychedelics. While unfortunately our medical marijuana research efforts are still blocked by politics over science, even that will change eventually. With your continued support for our expanding research agenda, we look forward to being taken for granted.



Rick Doblin, Ph.D., MAPS Executive Director,
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mdma research news updates

Journal of Psychopharmacology Publishes Paper about MAPS' U.S. MDMA/PTSD Pilot Study

On July 19, 2010, the Journal of Psychopharmacology published a paper about the MAPS-sponsored U.S. MDMA/PTSD pilot study. The paper is titled "The safety and efficacy of 3,4-methylenedioxymethamphetamine-assisted psychotherapy in subjects with chronic, treatment-resistant posttraumatic stress disorder: the first randomized controlled pilot study," and is authored by Michael Mithoefer, M.D., Mark Wagner, Ph.D., Ann Mithoefer, B.S.N., Lisa Jerome, Ph.D., and Rick Doblin, Ph.D. This is cause for major celebration since this is the first paper ever published about a completed study of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD).

Our drug development efforts do not require our research to be published in peer-reviewed scientific journals, but this greatly enhances our public education efforts. Since the publication was released, there have been more than 150 news reports around the globe about the study, some as far away as Pakistan and Australia. Many of these news reports were in major media outlets such as Time.com, New Scientist, the Boston Globe, and Fox News. Media reports also appeared in significant medical resources such as Medscape, WebMD, and Nursing Times. Even Military.com, whose ten million members make it the most active online news source for persons associated with the U.S. military, reported positively about the study. This article will help us gain support for our upcoming study in veterans with war-related PTSD. We have reposted many of these reports on our website at: www.maps.org/media

The full text of the journal article can be found at: www.maps.org/mdma/ptsdpaper.pdf

Long-term Follow-up of U.S. MDMA/PTSD Pilot Study is Complete

On July 27, 2010, MAPS Deputy Director Valerie Mojeiko and Clinical Research Associate Berra Yazar-Klosinski, Ph.D. completed data collection for the long-term follow-up to our flagship U.S. MDMA-assisted psychotherapy for PTSD study led by Principal Investigator Michael Mithoefer, M.D. and Co-Investigator Ann Mithoefer, B.S.N. in Charleston, SC. Independent rater Mark Wagner, Ph.D., from the College of Medicine, Department of Neurology, collected Clinician-Administered PTSD Scale (CAPS) measurements from 17 of the 20 subjects who received treatment. All 20 subjects filled out a questionnaire developed internally to assess long-term effects. The average length of time between the final experimental treatment session and the follow-up data collection was three and a half years. Preliminary analysis of the results suggests the benefits of the treatment were maintained. MAPS' clinical research volunteers are inputting data into a validated database at the MAPS office in Santa Cruz, CA. After the data is analyzed, Dr. Mithoefer, et al, will write a new paper for submission to a scientific journal around the end of 2010.

Mithoefer Receives DEA License for Phase 1 Psychological Effects/Therapist Training Study; License for U.S. MDMA/PTSD Veterans Study Coming Soon

On August 9, Michael Mithoefer, M.D., received a Schedule I license from the Drug Enforcement Administration (DEA) to administer MDMA in our Phase 1 study to investigate the effects of MDMA on healthy volunteers (limited to therapists enrolled in our therapist-training program). He waited approximately seven months to receive the license. This is a relatively short period compared with 19 months last time he was licensed. The DEA also told Dr. Mithoefer to expect his license for our Veterans study soon, which would be only 4 months from the time of application. The FDA and Institutional Review Board (IRB) approved both of these studies months ago, so we've just been waiting on the DEA's Office of Drug and Chemical Evaluation (ODE) to issue the licenses. The studies are co-lead by Ann Mithoefer, B.S.N.

Psychological Effects on Healthy Volunteers/Therapist-Training Study

On October 3, 2009, the FDA approved our protocol for studying the effects of MDMA on healthy volunteers. On December 21, 2009, the protocol was approved by the IRB. In this study the Mithoefers will administer MDMA to healthy volunteers who are part of our therapist-training program. The goal of this study is two-fold: (1) the study will allow us to learn more about the psychological effects of MDMA-assisted psychotherapy in healthy individuals; and (2) the therapists in our training program will have the opportunity to have a first-hand experience with MDMA, which we suspect will enable them to be better therapists in our future studies.

We are anticipating we will need 20–30 therapist teams in approximately three years for our two large-scale, multi-site, Phase 3 studies. Since the training program can take a long time, we are currently soliciting more applications from qualified therapists interested in conducting clinical research with MAPS. Applications are encouraged from therapists with some or all of the following qualifications: 1) treated patients with PTSD, 2) worked with non-ordinary states of consciousness, and/or 3) conducted clinical research. Applications from male/female teams are highly encouraged. If interested, please contact Berra Yazar-Klosinski, Ph.D. at: berra@maps.org

Veterans Study

We are in the process of recruiting subjects for our MDMA-assisted psychotherapy study for veterans with war-related PTSD. We are recruiting subjects primarily from Charleston, SC, to save approximately \$5,600 in travel expenses for each out-of-town subject. We are mostly seeking veterans from the Iraq and Afghanistan wars, but subjects with PTSD from the Vietnam War are eligible. We are trying to recruit equal numbers of men and women.

The study will be our second MDMA/PTSD study to take place in Charleston, SC. Subjects in the Mithoefer's previous study primarily had PTSD brought on by sexual assault, abuse and violent crime, with just two veterans with war-related PTSD. This new study will only enroll veterans, so that we can evaluate if the treatment for war-related PTSD is the same or different than the treatment for the aforementioned causes.

We will also be able to enroll subjects with the previously excluded risk factors of Hepatitis C and controlled hypertension, with additional screening evaluations and safety measures for these subjects.

Canadian MDMA/PTSD Study Gains Institutional Affiliation

On July 19, 2010, Health Canada informed principal investigator Ingrid Pacey, M.D. that they would accept a letter from the director of the University of Victoria's (UVic) Center for Addiction Research of British Columbia (CARBC) as proof of affiliation with UVic/CARBC. This was a major hurdle in getting the Canadian MDMA/PTSD study started. In Switzerland and the U.S., we have been able to conduct our research without any outside institutional affiliation, but Health Canada required affiliation with a Canadian institute before we could import MDMA for the study. We had obtained approval for the actual protocol from both Health Canada and a Canadian Institutional Review Board (IRB) by March 2009, so this delay for institutional affiliation has been especially prolonged and frustrating. Fortunately, we were not deterred from continuing to strive for full approval for what will become the first psychedelic research study to take place in Canada in almost 40 years.

On July 22, 2010, Tim Stockwell, Ph.D. the Director of CARBC, sent a letter to Health Canada confirming CARBC's support and affiliation with Dr. Pacey. In the letter, Stockwell wrote, "I have reviewed the paper about the results of the [MAPS-sponsored] U.S. MDMA/PTSD study... As a result, I found the results to be promising and think it is of significant scientific importance that a Canadian MDMA/PTSD study is conducted to see if the results can be replicated with a new co-therapist team in a new location."

Switzerland MDMA/PTSD One-Year Follow-Up Study Proceeds

On January 8, 2010, the last of the experimental treatments were completed in the Swiss MDMA/PTSD study. The study, led by Principal Investigator Peter Oehen, M.D., with Co-Investigator Verena Widmer, R.N., treated 12 subjects with chronic, treatment-resistant PTSD. The investigators are currently collecting data for the one-year, long-term follow-up phase of the study. Eight subjects have already completed the long-term follow-up, three subjects have not yet done so, and sadly, one subject has died from an unrelated cause.

On June 14, 2010, at our office in Santa Cruz, CA, volunteer clinical research intern Tim Whalen finished building and validating the database for this study. On July 19, volunteer research intern Audrey Redfield, Ph.D. candidate (Institute of Transpersonal Psychology) finished entering the preliminary data into the database. Katharina Kirchner, M.A., who is assisting our Swiss end-of-life anxiety study, will also assist the investigators of this study with resolving data queries. The final analysis is scheduled for completion in January 2011, after the last measurements are collected from the final subject. We anticipate that the results will be submitted for publication in Spring 2011.

Jordanian MDMA/PTSD Research Team Visited U.S. for Training

From April 7-12, 2010, our Jordanian MDMA/PTSD team, led by Nasser Shuriquie, M.D., participated in a six-day therapist-training program conducted by the Mithoefers in Charleston, SC. The Jordanian team consisted of Tayseer Shawash, Ph.D., Mona Abdulhamid Alnsour, Ph.D., and licensed social worker Rodina Abubaker. The training included a review of our treatment manual in order to learn how to conduct therapy in accordance with our treatment method. A major portion of the training was viewing videos from our first U.S. MDMA/PTSD study. Now that the team has participated in the non-drug training, each team member has the option to experience MDMA by participating in our Phase I study of the psychological effects of MDMA administered in a therapeutic setting to healthy volunteers.

On April 13, 2010, the Jordanian team traveled from Charleston, SC, to San Jose, CA, to attend our conference, Psychedelic Science in the 21st Century, and a post-conference workshop led by Stan Grof, M.D.

MDMA/PTSD Study in Israel Paused; Prospect of Revised Israeli Study Being Investigated

On March 26, 2010, we closed our Israeli MDMA/PTSD study to new subjects in order to provide more training to the therapeutic teams and to our independent rater, to improve our data collection processes, and to make several improvements to the protocol. There were no Serious Adverse Events (SAEs) and all patients had been treated without evidence of harm. We have conducted preliminary analysis of the data from the five subjects who were treated and found self-reports of healing, but quantitative measures did not correspond. Rick will visit Israel in October to discuss procedures for restarting the study with Principal Investigator Moshe Kotler, M.D. Though recruitment had been slow, an official at the Israeli Defense Forces indicated a willingness to refer soldiers with war-related PTSD once we restart the study. We have learned from the Israeli study that we need to provide all of our therapist teams with enhanced training about MDMA-assisted psychotherapy, protocol adherence, and data collection, prior to a study's initiation. We also have learned that we need a single, dedicated research coordinator for each site.

The screenshot shows the WebMD website interface. At the top, there are navigation tabs for Home & News, Health A-Z, Drugs & Supplements, Healthy Living, Eating & Diet, and Parents. Below the navigation is a search bar with the text "WebMD Better Information. Better Health." and a search button. The main content area displays a search result for "Ecstasy May Ease PTSD Symptoms" under the "Mental Health" category. The article title is "Designer Drug Ecstasy Combined With Therapy Successfully Treats Posttraumatic Stress Disorder, Study Says (continued)". The text below the title discusses the findings of a study, mentioning that MDMA elevates blood pressure and heart rate, which can be a risk to people with cardiovascular disease. It also notes that MDMA has been linked to death from heat stroke or excessive fluid in the substance of the brain (cerebral edema). The article mentions that the study was conducted at the University of California, San Diego, and was funded by the National Institute of Mental Health.

The screenshot shows the Fox News website. The main headline is "Study: Ecstasy Can Help Traumatized Soldiers". The article is dated Monday, July 19, 2010. The text of the article states: "The illegal party drug ecstasy is a potentially safe way of treating patients with post-traumatic stress disorder, according to a study published Monday in the Journal of Psychopharmacology. The drug, also known as MDMA seemed to reduce fear among long-term patients enabling them to get more out of their therapy sessions. The trial only studied 20 patients but the U.S. team has gained approval to complete a larger trial in military veterans. During the trial, which included patients with a history of psychosis or addiction, patients went through four psychotherapy sessions scheduled a few weeks apart. Eight of them were given a placebo and 12 of them were given a dose of ecstasy. Two months later, 10 of the 12 patients given ecstasy responded to the treatment, said the researchers led by Dr. Rick Doblin, president of the Multidisciplinary Association for Psychedelic Studies, in Santa Cruz, California. In contrast, just two out of eight patients offered a placebo showed an improvement. There were no adverse effects from the use of the drug in the study, which was funded by the Multidisciplinary Association for Psychedelic Studies. However, researchers will continue to follow up patients for long-term effects. Psychiatrist Dr. Michael Mithoefer, who led the study, said before ecstasy was used researchers used restraints and psychotherapists around the world often used it to boost therapy. He said the therapies for post-traumatic stress disorder involved revisiting trauma during the session and was an effective 30 percent in a clinical trial with restraints that was conducted in the U.S. in 2004." The article also includes a "HEALTHY LIVING" sidebar with various health-related links.

The screenshot shows the Military.com website. The main headline is "Study: Ecstasy Treats PTSD". The article is dated July 16, 2010. The text of the article states: "The drug Ecstasy shows positive results in the majority of patients when used to treat post-traumatic stress disorder, according to a report coming out Monday in the Journal of Psychopharmacology. The study, which focuses on 20 patients for whom previous drug and psychotherapy treatments were unsuccessful, is the first of its kind and a stepping stone for a follow-up that will focus entirely on U.S. military veterans, said Dr. Doblin, who founded the Multidisciplinary Association for Psychedelic Studies. 'We want most of the war veterans to get some relief from their PTSD, and we want some veterans to help people who have it.' The current study group was made up of 20 patients with PTSD. When the Association of Administration in 2007, the application specified application want to the U.S. The study was complete positive findings in 10 of 12 patients given ecstasy, and 2 out of 8 patients given a placebo. In the study, 12 of the 20 of MDMA and psychotherapy. According to Mithoefer, 10 of the 12 patients given ecstasy responded to the treatment, said the researchers. However, researchers will continue to follow up patients for long-term effects. Those in the trial group longer met the diagnosis included three patients unable to work. But after the study also found no adverse effects from the use of the drug in the study, which was funded by the Multidisciplinary Association for Psychedelic Studies. However, researchers will continue to follow up patients for long-term effects. Psychiatrist Dr. Michael Mithoefer, who led the study, said before ecstasy was used researchers used restraints and psychotherapists around the world often used it to boost therapy. He said the therapies for post-traumatic stress disorder involved revisiting trauma during the session and was an effective 30 percent in a clinical trial with restraints that was conducted in the U.S. in 2004." The article also includes a "Related" sidebar with links to other articles.

The screenshot shows the TIME magazine website. The main headline is "Ecstasy Shows Promise in Relieving PTSD". The article is dated Tuesday, Jul. 20, 2010. The text of the article states: "The drug Ecstasy shows positive results in the majority of patients when used to treat post-traumatic stress disorder, according to a report coming out Monday in the Journal of Psychopharmacology. The study, which focuses on 20 patients for whom previous drug and psychotherapy treatments were unsuccessful, is the first of its kind and a stepping stone for a follow-up that will focus entirely on U.S. military veterans, said Dr. Doblin, who founded the Multidisciplinary Association for Psychedelic Studies. 'We want most of the war veterans to get some relief from their PTSD, and we want some veterans to help people who have it.' The current study group was made up of 20 patients with PTSD. When the Association of Administration in 2007, the application specified application want to the U.S. The study was complete positive findings in 10 of 12 patients given ecstasy, and 2 out of 8 patients given a placebo. In the study, 12 of the 20 of MDMA and psychotherapy. According to Mithoefer, 10 of the 12 patients given ecstasy responded to the treatment, said the researchers. However, researchers will continue to follow up patients for long-term effects. Those in the trial group longer met the diagnosis included three patients unable to work. But after the study also found no adverse effects from the use of the drug in the study, which was funded by the Multidisciplinary Association for Psychedelic Studies. However, researchers will continue to follow up patients for long-term effects. Psychiatrist Dr. Michael Mithoefer, who led the study, said before ecstasy was used researchers used restraints and psychotherapists around the world often used it to boost therapy. He said the therapies for post-traumatic stress disorder involved revisiting trauma during the session and was an effective 30 percent in a clinical trial with restraints that was conducted in the U.S. in 2004." The article also includes a "Most Popular" sidebar with a list of trending articles.

MAPS' Autumn **Benefit Events**

MAPS is hosting several events this fall with the goal of generating funding for our clinical research projects and operational expenditures, and educating the public about our mission and the state of psychedelic psychotherapy research.

Twilight New York City Sept. 25, 2010

After the sun sets, at the Horizons: Perspectives on Psychedelics conference, doors will open nearby at Sullivan Hall for Twilight, a benefit party for MAPS. Twilight will be a very special event, with a keynote address by Rick. Several renowned electronic musicians, live bands, and combination acts will perform late into the night. The event is open to the public, and anyone is welcome to attend regardless of registration status for the Horizons conference.

Individuals wishing to support MAPS on a more personal level are invited to an intimate dinner before Twilight with Rick and other MAPS staff and colleagues. Space at the dinner is limited; please consider purchasing your ticket today to secure your seat at the table. Dinner patrons will enjoy expedited entry into Twilight, and access to a small, reserved area that includes beverages and fresh fruit throughout the night.

www.maps.org/twilight



Therapist Techniques for MDMA-Assisted Psychotherapy Workshop Boulder, Colorado Nov. 7, 2010

Rick and Marcela O'Alora G.L.P.C., (a co-therapist from our former MDMA-assisted psychotherapy for PTSD clinical study in Spain) will lead this workshop. Topics will revolve around therapist techniques utilized during MDMA-assisted psychotherapy, and will explore issues discussed in MAPS' MDMA/PTSD Treatment Manual, lessons learned from MAPS MDMA/PTSD pilot study, and theoretical applications of these techniques for use outside of MDMA-assisted psychotherapy. MAPS' MDMA/PTSD drug development program will also be discussed.

www.maps.org/colorado2010

An Evening with MAPS/SSDP Boulder, Colorado Nov. 7, 2010

MAPS' mission includes educating the public honestly about the risks and benefits of psychedelics and marijuana. Students for Sensible Drug Policy (SSDP) mobilizes and empowers young people to participate in the political process, pushing for sensible policies to achieve a safer and more just future, while fighting back against counterproductive Drug War policies. MAPS and SSDP share a mutual interest in rational, scientifically based education with respect to marijuana, MDMA, LSD, ibogaine, and other substances. Brought together by these shared values, MAPS and SSDP will co-host this benefit event with addresses by Rick and SSDP Executive Director Aaron Houston and Associate Director Jon Perri. Videos from both organizations will be aired throughout the evening, with music and dancing to follow late into the night. We recommend purchasing a ticket soon to guarantee your entrance to this extraordinary evening.

www.maps.org/colorado2010

**If you are a business owner or philanthropist
and are interested in sponsorship opportunities
for any of these events, please contact**

Brian Wallace,

MAPS Director of Field Development

at: brian@maps.org



**Lakeside Benefit
Oakland, CA
Nov. 12, 2010**

Enjoy a light dinner and drinks at the scenic Lake Chalet overlooking Lake Merritt in Oakland, CA. This will be a unique opportunity to meet Rick and members of MAPS' clinical research team and to hear firsthand about our various research projects. Plus there will be opportunities for attendees to go out on an intimate gondola ride around Lake Merritt!

www.maps.org/oakland2010

**Party at The Sanctuary for the Arts
Oakland, CA
Nov. 12, 2010**

After dinner at Lake Chalet, join MAPS for late night entertainment inside of a renovated church space at Oakland's Sanctuary for the Arts. We are partnering with several friends from the Burning Man community and beyond to bring attendees an outstanding night of music, artwork, performance and dance. Tickets are limited for this special event, so we advise you to purchase one before they sell out.

www.maps.org/oakland2010

These events will feature auctions of rare psychedelic memorabilia, including laboratory glassware from Sasha Shulgin's lab (Alexander "Sasha" Shulgin and his partner Ann documented the creation and exploration of MDMA, 2C-B, and hundreds of other psychedelic compounds in their books PIHKAL and TIHKAL), original visionary and limited edition artworks, signed Albert Hofmann collector's items (Albert Hofmann, Ph.D., is the late chemist who invented LSD in 1938), and one-of-a-kind jewelry and custom clothing.



**Reception at 99 High Art Collective
Venice, CA
Dec. 10, 2010**

At 6 PM at 99 High Art Collective (www.99collective.com) in Venice, join fellow MAPS members, new friends, and MAPS staff at a reception for Catalysts, our Los Angeles mini-conference. 99 High Art Collective is a one-of-a-kind visionary art gallery that organized a live mural painting at Psychedelic Science in the 21st Century. This reception is open to everyone and admission is free.

**Catalysts: The Impact of Psychedelics
on Culture, Cognition, & Creativity
Mini-conference
Los Angeles
Dec. 11, 2010**

This mini-conference will feature presentations on psychedelic science and clinical research, the impact of psychedelics on cognition and creativity, and presentations on psychedelic influences in art and culture. This event will take place at The Downtown Independent theatre in downtown Los Angeles. Presenters and topics will be announced on the MAPS website soon.

www.maps.org/la2010

**Critical Components on the Rooftop
Los Angeles
Dec. 11, 2010**

After Catalysts, MAPS will host an intimate evening benefit on the rooftop of The Downtown Independent. Attendees will enjoy a light dinner and drinks with Rick, members of MAPS' clinical research team, and other MAPS colleagues.

www.maps.org/la2010

**Flux: at Temple of Visions
Los Angeles
Dec. 11, 2010**

Temple of Visions' (www.templeofvisions.com) beautiful exhibition space in downtown's Gallery Row displays world-class contemporary mystical art and is hosting a late night benefit party for MAPS! The Downtown Independent Theatre is only a few blocks from Temple of Visions, so attendees of Catalysts will find it an easy walk or taxi ride from the day's earlier events. Flux will feature an incredible line-up of music and performance late into the night. This event is open to the public regardless of attendance at the day's earlier events; tickets will be available through the MAPS website this fall.

www.maps.org/la2010

New Marijuana-for-PTSD Protocol Close to Complete

MAPS is preparing a marijuana/PTSD pilot study in veterans of war to be conducted by Principal Investigator Sue Sisley, M.D. in Arizona. The protocol is close to being submitted to the FDA after having been reviewed, critiqued, and revised by several outside experts. The study is being developed in response to anecdotal reports of marijuana being used to alleviate PTSD symptoms. At present, there is no published data from a randomized, placebo-controlled, double-blind study of the risks and benefits of marijuana for chronic PTSD sufferers.

Forty subjects will be randomly allocated to one of four treatment groups. Each subject will be provided with two rolled cigarettes daily, each weighing 0.9 grams, the standard-size marijuana cigarette provided by the National Institute on Drug Abuse (NIDA). The cigarettes will contain either (1) 2% D9-tetrahydrocannabinol (THC), (2) 6% THC, (3) 6% THC and 6% cannabidiol (CBD), or (4) 12% THC. The subjects who receive 2% THC will serve as the low-dose/active placebo group; while an ideal placebo would not contain any potentially therapeutic action, previous research has shown completely inactive marijuana is rarely effective at producing an effective double-blind. Marijuana will be self-administered daily on an outpatient basis for four weeks, followed by two weeks of none. Within each treatment group, five of 10 subjects will smoke marijuana cigarettes; the other five are assigned to use a vaporizer.

In this groundbreaking study, marijuana will be used as a pharmacological medicine without associated psychotherapy. The primary outcome variable measuring the severity of PTSD will be the Clinician Administered PTSD Scale (CAPS), required by FDA and the European Medicines Agency (EMA).

At present, NIDA does not produce any marijuana with significant levels of CBD. We are specifically requesting NIDA produce such a strain for this study. NIDA has previously indicated that it could provide any marijuana strains requested by researchers. Should NIDA be unable to provide marijuana with CBD due to NIDA's monopoly on the supply of marijuana for FDA-regulated research we would have no other sources of supply and we would be forced to eliminate the 6% THC/6% CBD group from the protocol.

Swiss LSD/Life-Threatening Illness Study Amended and Progressing

On May 4, 2010, Peter Gasser, M.D. submitted an amendment to our Swiss LSD-assisted psychotherapy for the treatment of anxiety associated with life-threatening illness study to his Ethics Committee (EC). The EC met on May 25 and approved the amendment. The amendment (1) includes audio and video recording of the treatment sessions for later analysis, (2) adds interim data analysis in order to get a sense of the safety and effectiveness of treatments before the study is over, and (3) makes the protocol more flexible to meet the needs of the study population, which are people with advanced-stage cancer or other life-threatening diseases. Often these subjects have difficulties leaving home because of pain. As a result, we expanded some of the timelines from the former version of the protocol in order to be more flexible with the subjects.

On June 22, 2010, the eighth subject out of twelve received LSD in the subject's first experimental session. Dr. Gasser is in the recruitment process for the remaining subjects. Additionally, we added a new clinical study assistant to the staff, Katharina Kirchner, M.A., of Switzerland.

MAPS Intensifies Campaign for Craker's Marijuana Production License

MAPS has hired Chris Chiles and Stephen Morseman to coordinate a campaign to obtain a DEA license for Professor Lyle Craker of UMass Amherst to grow marijuana under contract to MAPS, and end the National Institute on Drug Abuse (NIDA) monopoly over the supply of marijuana available to the research community. Chiles and Morseman are attempting to have the issue brought up at the Senate Judiciary Committee's confirmation hearing for the new DEA Administrator. President Barack Obama has nominated DEA Deputy Administrator Michele Leonhart, but she is a holdover from President Bush and her track record does not bode well for medical marijuana and marijuana research.

On February 12, 2007, DEA Administrative Law Judge (ALJ) Mary Ellen Bittner ruled it is in the public interest for the DEA to license Craker. However, on January 12, 2009, Leonhart rejected this recommendation. On January 30, 2009, Craker's lawyers at the American Civil Liberties Union (ACLU) filed a Motion to Reconsider. The DEA has not responded. The ACLU has filed nine status updates (every 60 days) with the U.S. Court of Appeals, First Circuit, in case the DEA conclusively rejects the ALJ recommendation and a legal appeal is needed.

The goal of MAPS' campaign is to pressure three key senators—Senators Patrick Leahy (D-Vermont), Sheldon Whitehouse (D-Rhode Island) and Al Franken (D-Minnesota)—to ask Leonhart during the confirmation hearing to grant Craker's motion and accept the administrative law judge's recommendation to end the federal monopoly on the supply of marijuana for federally regulated research. **MAPS members are encouraged to contact these senators, using our sample letter and phone script available at: www.maps.org/mmj/campaign**

We Won the Guidestar/Great Nonprofits Nationwide Health Campaign! Mainstream Medical Acceptance Increases

On July 1, 2010, we won the Guidestar/Great Nonprofits Nationwide Health Campaign 2010, a one-month contest to collect the most reviews by an organization's supporters on the Great Nonprofits website. We have received a prize of \$5,000 along with increased credibility and visibility. On August 5, 2010, Guidestar sent an email out to more than one million people announcing our victory, which means many more people have become aware of us.

The success indicates our increasing mainstream acceptance as a health care related organization. More than 115 organizations entered the contest. Six hundred and three MAPS supporters submitted reviews between June 1 and June 30, while the two runner-ups had fewer than half our number of reviews. This is testimony to the strength of our community. As we strive to mainstream psychedelics as therapeutic medicines, we know our supporters are willing to provide us with the resources we need. Each small victory like this brings us closer to historic achievements.

upcoming events

with Rick Doblin, Ph.D.



Science and Nonduality Conference San Rafael, CA October 20-24, 2010

MAPS is collaborating with Neti Neti Media and over a dozen co-sponsors on the Science and Nonduality conference. The event, billed as part seminar, part festival, and part conference, will explore knowledge at the intersection of science and spirituality in a five-day series of talks, workshops, panels, and musical performances. The conference will address questions such as: How can science, art, psychedelics, and spiritual practices shed light on the deepest aspects of human experience? How can these and other fields help human beings rethink their most fundamental assumptions about time, selfhood, and reality? How can scientific and spiritual knowledge be reconciled, or is there a conflict at all?

Rick will be participating in a panel discussion on how advances in psychedelic science and struggles to bring psychedelic medicine back into the mainstream may help provide some fundamental answers to these questions. Matt Baggett, Ph.D., who has conducted research at UC San Francisco with MDMA, MDA, and LSD, and other speakers yet to be determined, will join Rick.

www.scienceandnonduality.com

Students for Sensible Drug Policy Mountain Plains Conference Boulder, CO November 6-7, 2010

Students for Sensible Drug Policy will hold its first annual Mountain Plains Regional Conference at the University of Colorado Boulder. Rick will give the keynote address for this event on the morning of November 6th, and MAPS staff members will be in attendance for the day's proceedings. The conference will include informational discussion forums on a wide range of drug policy issues. Attendees will be able to sign up for hands-on activism and campaign management workshops and trainings.

For more information on Students for Sensible Drug Policy, visit:

www.SchoolsNotPrisons.com

For more information about the Mountain Plains Conference, visit:

www.ssdp.org/conference/mountainplains

Entheogenesis Australis Psychedelic Symposium Melbourne, Australia December 4-5, 2010

The second indoor Entheogenesis Australis (EGA) Symposium will be held at the University of Melbourne. EGA will bring Rick to Australia to headline this year's Symposium. As a not-for-profit association, EGA creates a supportive environment fostering mature, open discussion about psychoactive plants and chemicals. EGA seeks to explore ways to assess societal impacts and examine the positive applications of plant-based psychoactives and empathogens. The conference aims to provide an unprecedented professional and engaging program in the field of psychedelic studies. EGA expects the 350 tickets to sell out quickly this year – if you will be in Australia, make your plans well in advance.

www.entheo.net



Mind Altering Science, an OPEN Foundation Conference Amsterdam October 23-23, 2010

The OPEN Foundation (translated from the Dutch Stichting OPEN), a Dutch institute working to encourage and legitimize research on psychedelics, will be hosting a conference on psychedelic science. "Mind Altering Science" will host two full days of talks. The list of speakers includes several researchers at the forefront of the current resurgence of psychedelic science. Representing MAPS will be Peter Oehen, M.D. who is currently completing a MAPS-sponsored study of the effects of MDMA-assisted psychotherapy for people with chronic, treatment-resistant PTSD. MAPS is pleased to support the OPEN Foundation conference and Dr. Oehen's work by sponsoring his travel to and from the conference. (*Rick Doblin will not be attending this event.*)

www.mindalteringscience.com



MAPS: Who We Are

MAPS' mission is 1) to treat conditions for which conventional medicines provide limited relief—such as posttraumatic stress disorder (PTSD), pain, drug dependence, anxiety and depression associated with end-of-life issues—by developing psychedelics and marijuana into prescription medicines; 2) to treat many thousands of people by building a network of clinics where treatments can be provided; and 3) to educate the public honestly about the risks and benefits of psychedelics and marijuana.

"Most of the things worth doing in the world had been declared impossible before they were done."

— Louis D. Brandeis

If you can even faintly imagine a cultural reintegration of the use of psychedelics and the states of mind they engender, please join MAPS in supporting the expansion of scientific knowledge in this area. Progress is possible with the support of those who care enough to take individual and collective action.

The MAPS Bulletin

This *MAPS Bulletin* has been reduced in size in order to reallocate funds to our expanding number of research projects. The *Winter Bulletin* will be a magazine-size publication and the Spring 2011 issue will be another special theme issue.

Multidisciplinary Association for Psychedelic Studies (MAPS) is an IRS approved 501 (c)(3) nonprofit corporation funded by tax deductible donations. Your participation, financial or otherwise, is welcome.

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Design/Build: Noah Juan Juneau
ISSN 1080-8981

Visit maps.org/catalog for information about donations and purchases. *MAPS Bulletin* is printed on 40% post-consumer recycled paper.

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Psychedelic Science in the 21st Century Conference a Huge Success

MAPS would like to thank its many members, colleagues, volunteers, and other friends for making Psychedelic Science in the 21st Century a huge success. The April conference drew more than 1200 scientists, therapists, medical professionals, and others from all over the world, many of whom received Continuing Medical Education (CME) or Continuing Education (CE) credit for their participation. It was the largest conference in the U.S. to focus specifically on psychedelics in 40 years—without a doubt a historic moment in the return of psychedelics to mainstream science and medicine. Renowned scientists shared the methods and results of the latest clinical and experimental studies into the physiological and psychological effects of psychedelics, therapists collaborated on innovative techniques for using psychedelics for treating a wide array of illnesses, and other scholars discussed what they know about the changing place of psychedelics in human culture. The mainstream media clearly recognized the significance of the conference, which received enthusiastic coverage from The New York Times, BBC, CBS, CNN, NPR, Scientific American, and many other local, national, and international media outlets. These and other media reports can be found on the MAPS website at: www.maps.org/media

Thanks to many generous donations from our members, MAPS is making videos of a large number of the presentations from the conference available for free viewing on the MAPS website.

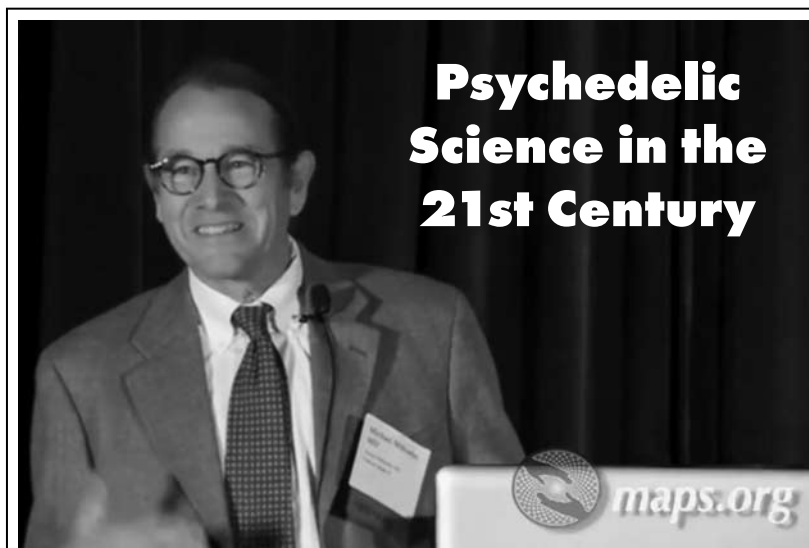
MAPS is thrilled to announce that we will be hosting another conference with the Heffter Research Institute, the Council on Spiritual Practices, and the Beckley Foundation on psychedelic science in April 2013. We have chosen to wait until 2013 to give researchers a chance to conduct more new studies and publish more results before presenting their latest findings to our audience. In the meantime, MAPS will continue to strengthen the bonds that unite the ever-growing psychedelic science community by hosting an array of events over the course of the next years, including a 25th anniversary celebration in 2011. We will provide a more in-depth and personal account of the conference in the year-end MAPS Bulletin.

New Ibogaine for Opiate Addiction Outcome Study Ready to Begin

MAPS is embarking on a new study investigating long-term outcomes of ibogaine-assisted therapy for people with opiate addiction. Our previous ibogaine pilot study led by John Harrison, Psy.D. candidate, concluded in December 2009, with sufficient suggestions of efficacy and safety to justify expanding our research to a new, more rigorous protocol. The new study is lead by MAPS Deputy Director Valerie Mojeiko, and co-lead by University of California, San Diego's Thomas Kingsley Brown, Ph.D., California Institute of Integral Studies' (CIIS) faculty member Meg Jordan, Ph.D., R.N., and CIIS graduate student Rishi Karim Gargour, M.A. The study follows patients at Pangea Biomedics, an ibogaine treatment center operated by Clare Wilkins in Playas de Tijuana, Mexico. CIIS' Human Research Review Committee (HRRC) is overseeing the safety of the project. The protocol will enroll 20 subjects, but if more funding is obtained an additional 10 subjects will be added. The study received HRRC approval on August 6, 2010, and will begin enrollment on August 23, 2010.

The new study investigates the effectiveness of ibogaine-assisted therapy in catalyzing opiate abstinence or reduced opiate use, and improving associated behaviors over 12 months following therapy. We will further investigate the correlation between lifestyle changes and the subjective intensity of the psychedelic ibogaine experience, and observe the severity of withdrawal symptoms associated with opiate detoxification. Subjects denied treatment due to medical problems found during admission (which happens about six times a year) will be asked to enroll in a control group for comparison with the treatment group. We have applied lessons learned from our Mexican pilot study by reducing the number of visits each subject will have with researchers and eliminating some measurements of craving and pain. We are considering adding urine or hair tests to verify if a subject is opiate-free.

Our ibogaine study was mentioned in Popular Science, which can be found on MAPS' website at: www.maps.org/media



Psychedelic Science in the 21st Century

free videos from the conference

www.maps.org/videos

Beginning September 15, 2010, online continuing medical education and continuing education credits will be available for a modest fee for physicians, other medical professionals, psychologists and social workers.

Michael Mithoefer, M.D.'s presentation about our U.S. MDMA/PTSD pilot study is now online, along with many other videos from the conference.