MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

MAPS

VOLUME XIX NUMBER 2

From the desk of Rick Doblin, PhD

The renaissance in psychedelic research has been a satisfaction to work toward since I founded MAPS in 1986, and a delight to actually witness and celebrate. But eventually, like the bloom of youth, even a renaissance must either mature or stagnate and become irrelevant. We must grapple with and accept the end of the beginning, since when we started we just needed to assert claims of suppressed benefits to justify the renewal of research. Now, our research agenda has grown to include Phase 2 pilot studies in which we must generate preliminary data to support our claims of medical benefit. The outcome of all this work (whether or not we're able to achieve legal prescription use) will be largely determined by our actions these next several years. We now need to lay the foundations for larger Phase 3 research studies that are required to prove safety and efficacy, ideally with such transparency of methodology and outcomes that the next steps will be clear to everyone. What began as a mission to bring psychedelics (once again) to the attention of the scientific and psychotherapeutic communities, blossomed into something much larger and much more powerful.

Over the last several months, I've felt the time was approaching to shed my triumphant psychedelic renaissance language, once glittery and fresh with the imagery of renewal and birth. MAPS has recently achieved a psychedelic milestone that for me confirms that we've grown beyond the initial renaissance, beyond the return of the repressed, into the dissolving of the boundaries between culture and counterculture and the crafting of initial, tentative, complementary, and integrative mergings that can be so healing and are so deeply needed by all concerned.

This milestone was finally reached at the end of June, in the mountains of Austria. In an example of the increasing reach and professionalism of MAPS' staff, we gathered therapists from seven different countries (US, Canada, Switzerland, Germany, Spain, Israel, and Jordan) for a successful and emotionally nourishing debut of MAPS' first MDMA-assisted psychotherapy for the treatment of posttraumatic stress disorder (PTSD) therapist training program. The purpose of the training program is to prepare therapists to conduct MAPS-sponsored Phase 2 and Phase 3 psychotherapy studies in accordance with MAPS' MDMA/PTSD treatment manual. Over five days of programming, we featured progress reports and discussions of protocol designs, treatment methods, music for psychedelic sessions, and cultural considerations that can affect the therapeutic method.

Perhaps surprising to some, I believe that therapists who administer MDMA to PTSD patients can do so effectively without ever having taken MDMA themselves. MAPS will never require therapists working on our studies to experience MDMA. At the same time, I believe MDMA-naïve therapists who work with MDMA could become even more effective after they have had a personal experience of the subjective effects of MDMA when taken within a therapeutic context. The training program in Austria is preparing us for our next major milestone—to develop a program to legally administer MDMA to therapists as an integral part of their training. (I look forward to reporting positive news to you about this development sometime in the very near future.)

In Austria, two days were devoted to watching and discussing videotapes of therapeutic sessions from our US, Swiss, and Israeli MDMA/PTSD studies. Sitting and watching therapy sessions, stopping the tapes every few moments for commentary and critique from our diverse and experienced group, was to me our most moving and effective teaching method. However, the sheer diversity of comments from the assembled therapists about alternative interventions made me wonder whether we could ever refine our treatment manual so that the "best" therapeutic intervention flowed directly and obviously from the principles

of the method. Fortunately, the entire program was not rigorously analytical since on the middle day, we scheduled a Holotropic Breathwork session to give the group an experience of a non-ordinary state of consciousness and to provide experiential, emotional release.

Overall, the effort to teach made it even clearer that we ourselves have a lot to learn. Nevertheless, creating our first formal educational program for teaching the principles and practices of psychedelic psychotherapy, specifically MDMA-assisted psychotherapy for PTSD, was a milestone that took over two decades to attain and signifies a maturing movement.

I am excited to announce that on August 11, we received accreditation to provide continuing medical education credits at our conference in April 2010—a conference that will undoubtedly mark another milestone in our educational path.

In order for MAPS to continue to expand our research and educational activities, we need your support. Come join with us as we move beyond the renaissance, to the deeper integrations ahead.

Rick Doblin, PhD, MAPS President
rdoblin@maps.org

MAPS Conference: Psychedelic Science in the 21st Century

From April 15 to April 18, 2010, MAPS will be hosting "Psychedelic Science in the Twenty-First Century," an international psychedelic conference in the San Francisco Bay Area. We will have continuing medical education (CME) credits available for psychiatrists, other physicians, psychologists, social workers and nurses. The conference will also be open to the general public. There will be two tracks of presentations at the conference: the CME track will have leading researchers presenting their evidence-based findings from numerous studies that have recently, or are currently, taking place around the world, while the second track will have psychologists, artists, and other culturally intriguing presenters from the psychedelic community. There will be a special banquet on Saturday evening to honor the lifetime achievements of psychedelic luminaries Alexander "Sasha" and Ann Shulgin.

Confirmed speakers include: Stanislav Grof, MD; Alexander "Sasha" Shulgin MD; Ann Shulgin; Alex and Allyson Grey; Andrew Weil, MD; Michael Mithoefer, MD; Ann Mithoefer, BSN; Charles Grob, MD; Alicia Danforth, PhD candidate; David Nichols, PhD; Franz Vollenweider, MD; Torsten Passie, MD, PhD; Matt Baggott, PhD candidate; Jose Carlos Bouso, PhD candidate; Peter Gasser, MD; Julie Holland, MD; Sergio Marchevsky, MD; Francisco Moreno, MD; Peter Oehen, MD; Jordi Riba, MD; Michele Weitz, BA; John Harrison, PsyD candidate; Jeffery Kamlet, MD; Clare Wilkins; June May Ruse, PhD; Ingrid Pacey, MD; Rick Doblin, PhD; Valerie Mojeiko; Amanda Feilding; Ben Sessa, MD; Caroline "Mountain Girl" Garcia; and others.

Taking place at a lovely Holiday Inn (formerly a Hilton) near San Jose International Airport, the conference will start with a reception on Thursday evening and will have three days of programming through Sunday afternoon. The hotel was chosen for its reasonable prices and close proximity to the airport and public transit. Registration information will be available soon. To be placed on a registration list, please send an email to: conference2010@maps.org.

This will be a remarkable event that will be even more remarkable if you join us!

Therapist Training Protocol Leads to Positive Teleconference with FDA

On June 22, 2009, MAPS submitted a protocol to FDA requesting permission to administer a single MDMA-assisted psychotherapy session to therapists as part of their training to conduct MAPS' MDMA/PTSD research. On July 23, Rick Doblin, PhD, Michael Mithoefer, MD, and MAPS Clinical Program Manager Amy Emerson had a productive and positive teleconference with six members of FDA's Division of Psychiatry Products. The FDA officials made a series of suggestions about how, from their perspective, we could improve the protocol. They suggested that we write the protocol so that it would more closely resemble a Phase 1 safety study in normal (healthy) volunteers. The revised protocol will include more measures of the psychological effects of MDMA on healthy participants. We plan to submit the revised protocol in mid-August and should learn by mid-September if it's approved.

We learned that we could provide much in the way of educational experiences during our recent therapist training seminar that took place in Austria, with therapists from seven different countries. Nevertheless, we also believe it will benefit therapists who will be administering MDMA to patients to achieve a personal or subjective understanding of MDMA's effects when administered within a therapeutic setting. The only way such an MDMA experience can be legally provided to therapists is through an FDA protocol designed to gather safety information on the effects of MDMA. The protocol requires potential participants to have first successfully completed a non-drug therapist training program where they will watch video tapes and review our treatment manual. We believe this protocol will significantly enhance our ability to train therapists to work more effectively on our MDMA/PTSD studies.

While many people may doubt the feasibility of asking the FDA to approve the administration of a Schedule 1 drug to therapists in order to better understand the effects of that drug, we have thus far been greatly encouraged by FDA's suggestions and handling of this project. The FDA has so far shown us that developing MDMA into a prescription medicine is a matter of science, not of politics. As

long as we continue to operate with the highest standards of research and data collection and to follow the guidelines set forth by the FDA and the European Medicines Agency (EMEA), it will be the results of the research (and not ideology) that determines whether or not MDMA is approved as a prescription medicine.

MAPS Prepares for New MDMA/PTSD Study with War Veterans

MAPS is preparing a follow-up study to our US pilot study of MDMA-assisted psychotherapy for the treatment of PTSD, conducted under the direction of MAPS-sponsored researchers Michael Mithoefer, MD, and Ann Mithoefer, BSN. This new study will enroll eight US veterans with PTSD from the wars in Iraq or Afghanistan.

There are three purposes for conducting this study. The first purpose is to see if veterans respond any differently than those who suffer PTSD from sexual assault, sexual abuse, or victims of crime. Veterans made up a small minority of subjects in the Mithoefers' previous study (out of 21 subjects, only two were veterans). The EMEA has published guidelines for PTSD research that call for studies with homogenous subpopulations of people who suffer from PTSD from different causes. This is to determine if the same therapy can be administered across these subpopulations. It is possible that people with PTSD from different causes will require different therapeutic protocols for MDMA–assisted psychotherapy, or that some subpopulations could be unresponsive to MDMA-assisted psychotherapy. If people with PTSD from different causes are found to respond well to similarly designed protocols, then we can include all of these subpopulations in the larger Phase 3 multi-site studies. If we find that the treatments are different, we will have to take this into consideration when designing the Phase 3 studies.

The second purpose of this new study in veterans will be to gather methodological information about how different doses of MDMA succeed in creating an effective double-blind study. The researchers and subjects in our pilot study were often able to accurately guess when asked whether subjects had received an active dose of MDMA or an inactive placebo. The new study of veterans involves administering doses of 125 mg, 75 mg, or 25 mg (with four of the subjects randomized to receive 125 mg, two to 75 mg and two to 25 mg). We will see if the use of these three doses can be a successful double-blind study. We will also look to see if people who receive the higher doses showed a larger therapeutic effect than people who receive the lower doses.

The third and final purpose of the study is to enroll some subjects previously excluded for risk factors such as hepatitis C and hypertension. There is not strong evidence that MDMA poses greater risks to people with these health conditions, but we excluded these factors from our first pilot study in order to proceed cautiously and please our Institutional Review Board (IRB). The new protocol will involve special pre- and post-screening and monitoring plans to evaluate whether MDMA can be safely administered to people with previously excluded risk factors. If we can safely enroll these subjects, then recruitment into our Phase 3 studies will be faster since fewer subjects will be excluded for risk factors.

This protocol will be submitted to the FDA in September. After it is submitted and approved by the FDA, it will be submitted to our IRB. We hope to have the first subject enrolled before the end of November 2009.

On March 4, 2009, MAPS' MDMA/PTSD research was featured on military.com, a popular military website (read the full text of this article on the MAPS website: www.maps.org/media). Since then, numerous war veterans who wish to be in the study have contacted us. However, it is not clear whether all of them will pass the screening process and some may no longer be interested in participating by the time the study gets started. If you know, or are yourself, a war veteran suffering from PTSD who would be interested in participating in a study in Charleston, South Carolina, please contact MAPS at: askmaps@maps.org.

MAPS Podcasts

Have you heard a MAPS podcast recently? We are producing new podcasts regularly now and you can hear them on our website or by subscribing on iTunes.

12th and Final Patient Enrolled in Swiss MDMA Study

MAPS' Swiss MDMA/PTSD study has enrolled the 12th and final subject. Nine patients have completed the study; the 10th and 11th are currently in the treatment process. We estimate that the final treatments will take place between three and six months from now, depending upon whether the last subject gets placebo or MDMA. If a subject gets a placebo session, they will later have the option to participate in Stage 2, where they will go through the entire treatment process again but will receive the full dose of MDMA. This is called an "open -label" study. In this way, these subjects serve as their own controls, as well as being part of a matched control group.

The Swiss project is our second study of MDMA-assisted psychotherapy for the treatment of PTSD. While the Clinician Administered PTSD Scale (CAPS) scores in the Swiss research have not dropped as dramatically as they had in our US pilot study, a preliminary analysis suggests that we are likely to obtain statistically significant results. The completion of this study will be yet another major accomplishment for MAPS and for our supporters.

The Swiss study differed from our US pilot study in several ways. Instead of using an inactive placebo as we had in the US study, we used a low-dose active placebo of 25 mg of MDMA, followed by a 12.5 mg booster dose. The population in the Swiss study also differed from our US study in that the majority of subjects had PTSD resulting from accidents and natural causes, rather than from sexual or physical assault. The Swiss study is also smaller than our US study, which enrolled 21 subjects.

Canadian MDMA/PTSD Study Poised to Begin

Our Canadian MDMA/PTSD study will be ready to begin once we receive a license to import MDMA into Canada. We are not sure how long this will take–perhaps several more months. The principal investigators, Ingrid Pacey, MD, and Andrew Feldmar, MA, both participated in our MDMA/PTSD training seminar held in Austria in June. We have approval from Health Canada and a Canadian Institutional Review Board (IRB). The protocol and informed consent forms have been finalized. Our clinical monitoring team completed their pre-study visit and are currently preparing the other documents for the study, such as the case report forms, standard operating procedures, and other essential documents.

Our pharmacist in Canada has received an information packet from Health Canada with an application and instructions for a license to import a Schedule 1 substance. Unfortunately, the process of getting the importation license is taking longer than we had initially anticipated. Our pharmacist will become the first and only person to have a license to import MDMA into Canada for scientific research (or, for that matter, for any other purpose). We are hoping that we will be able to start the study by November 1 and are eager to begin this second North American study of MDMA-assisted psychotherapy for the treatment of PTSD.

We have received our first financial pledge for this study from supporter and Canadian drug harm reduction expert Mark Haden, in the amount of $800. We are seeking a Canadian nonprofit to partner with us so that Canadian donors can receive tax deductions. We are planning to have a fundraiser in Vancouver, Canada, on Saturday, October 24, where we will reach out to our Canadian supporters. MAPS President Rick Doblin, PhD, will be in Vancouver that weekend to speak at the Canadian Students for Sensible Drug Policy's national convention. If you are interested in attending the fundraiser, please contact Randolph@maps.org or call 831-429-6368 for more information.

MAPS supporters may recognize Ingrid from MAPS' educational *Psychedelic Crisis* video, which can be viewed on the MAPS website. Andrew made national headlines when the US Customs in Vancouver barred him from entering the US for having written about his own LSD use in the 1960s. Andrew was featured in a very funny *Colbert Report* segment, which can also be viewed online at: http://www.thedailytube.com/video/3768/colbert-nails-a-canadian-terrorist

MAPS Email Newsletter

Are you signed up to receive the MAPS email newsletter? Getting the monthly newsletter is the best way to stay informed about MAPS projects, activities, and other happenings. Signing up is easy at: www.maps.org

MDMA Projects in Jordan and Israel

MAPS is working with Jordanian psychiatrist Nasser Shuriquie, MD, to determine the best location for an MDMA/PTSD study in Jordan. Although we had originally thought that the research would take place at a Jordanian military hospital, Nasser recently retired from the Jordanian Royal Medical Services and has become the medical director of Jordan's only private psychiatric hospital. Nasser believes that our project may be more effectively conducted in the private hospital. Rick Doblin will be going to Israel and Jordan in August to meet with Nasser, see the psychiatrist hospital, and discuss the possibilities.

In Israel, a new psychiatrist has joined the therapist team. Tali Nachoni, MD, attended MAPS' MDMA/PTSD therapist training seminar in June along with her co-therapist Sergio Marchevsky, MD. Three out of 12 subjects have completed the study.

Swiss LSD Study Generates Positive Media Attention in Der Spiegel

On July 9, 2009, *Der Spiegel,* a respected and popular German news magazine, profiled a MAPS-sponsored clinical trial of LSD-assisted psychotherapy for people with anxiety associated with life-threatening illnesses. The LSD study is designed with an active dose of 200 mcg and an active placebo dose of 20 mcg.

Der Spiegel interviewed the principal investigator of the study, psychiatrist Peter Gasser, MD, and one of the subjects for the story. On July 24, 2009, the article was republished in English on *Spiegel Online* (this article is also archived on the MAPS website: www.maps.org/media). Peter and MAPS are pleased with the positive media coverage of the study. The study is still in the early stages of enrollment and we hope that the article will encourage people to apply to be subjects in the research. It is far too early for preliminary data analysis.

Ibogaine Project Expects to Enroll Final Subjects by End of 2009 or Early 2010

As of August 2009, 17 out of 30 subjects have been enrolled in the MAPS-sponsored observational case study of the long term efficacy of ibogaine-assisted therapy in the treatment of opiate addiction. Principal investigator and PsyD candidate John Harrison has been following patients who have undergone ibogaine therapy with Pangea Biomedics in Playas De Tijuana, Mexico. John expects that all subjects will enroll by the end of the year or by early next year. The study is designed to follow patients for one year after treatment and to administer the Addiction Severity Index (ASI) as well as some other measures related to life changes. This requires John to speak at length with each subject once a month in order to administer the ASI, and to make contact with a relative or close friend of the subject to confirm subjects' subjective reports. John notes that he is still in contact with almost all the patients, which in and of itself is remarkable considering the subject population and circumstances.

Israeli Medical Marijuana Moves Toward Independence After Years of MAPS' Support

Over the past few years, MAPS has given financial support to several Israeli medical marijuana production facilities. This project has been primarily supported with help of one anonymous MAPS donor. There are a few Ministry of Health-licensed production facilities that have permission to grow medical marijuana. The producers must give the marijuana away to approximately 500 patients who have been approved by the Ministry to use marijuana for a variety of medical reasons. The growers in Israel are not allowed to sell their product. However, the prospects of being able to eventually sell the medicine for profit has attracted investors and several growing operations have applied to the Ministry of Health for permits to sell the marijuana. Consequently, MAPS is reducing, and possibly eliminating, our financial support since it appears that the producers are likely to be able to sustain themselves through investments rather than donations.

On July 1, 2009, the first version of the Israel Medical Marijuana database (shared by all Ministry of Health-approved medical marijuana growers, distribution centers, and patients) was released and demonstrated to the Israeli Ministry of Health. The database was built from a collaboration between Shlomi Vakin of Tel Aviv, Mimi Peleg of Wo/Men's Alliance for Medical Marijuana (WAMM), and MAPS (with significant help from MAPS staff member Joshua Sonstroem) and was originally hosted on the MAPS website. The database has now been transferred to a server operated by the Israeli Ministry of Health.

The database is designed to collect information for the use of medical marijuana patients. The data will be used for future research into medical marijuana's efficacy, benefits and risks, and the cost of medicines replaced by medical marijuana. This cost information is designed to determine whether there would be cost savings to the Israeli national health care system if marijuana is made available as a legal prescription medicine. The database is based on OpenEMR, an open source Electronic Medical Records software used in clinics worldwide for both clinic and patient management, and for collecting statistical medical information. The customized version of this program will be stored in English on the MAPS server for other medical marijuana projects to download, use, and modify.

MAPS Holiday Auction

MAPS is accepting donations of items for our holiday auction to take place in November. If you have an item to donate please contact Randolph Hencken at Randolph@maps.org or at 831-429-6368.

Final Data from MAPS Flagship MDMA/PTSD Prepared for FDA Submission–

written by Amy Emerson

On June 22, 2009, preliminary data from MAPS' flagship US Phase 2 study of MDMA-assisted psychotherapy in the treatment of PTSD was submitted to the US Food and Drug Administration (FDA). The preparation of the preliminary data was the initial step in preparing MAPS' first-ever Final Clinical Study Report. Over the next two months the study's database will go through final review and analysis. From this, MAPS will produce the final clinical study report containing a summary and analysis of all safety and efficacy data collected during the study. Submission of the final study report to FDA is the culminating step in completing a clinical study – this will be a monumental achievement in MAPS history!

The purpose of this process is to create a report acceptable to all regulatory authorities. The document will combine the clinical and statistical description, presentations, and analyses of this study's data into a single report.

The completion of this study is one small step toward MDMA becoming a prescription medicine for use in psychotherapy.

Image: Seratonin of www.serotoninphotography.com

MAPS Welcomes Robert J. Barnhart to the Board of Directors!

On July 22, 2009, Robert J. Barnhart joined MAPS Board of Directors, replacing Marybeth Home, who has been on the board since 1986. Robert has been a long-time MAPS member and has been one of the primary funders of our Swiss LSD study as well as numerous other MAPS projects. Robert spends most of his time with his family. He says that the wisdom, love, and compassion that he learned through taking psychedelics has allowed him to make his four-year-old daughter the primary focus of his energy.

Born in Houston, Texas, Robert studied comparative religions at Emory University in Atlanta, Georgia. Through peak psychedelic experiences as a teenager, he became interested in beliefs that every living thing is part of one consciousness that is manifesting itself as individual beings. "I found it fascinating that ancient texts from Catholic mystics read as if the person had had a mind-opening psychedelic experience. Then I would see similar themes across all the religions."

In his early 30s, Robert directed most of his assets away from the petroleum industry and now continues to work to reallocate them into socially and environmentally conscious investments. With an understanding that was highlighted by positive affirmations with nature while on psychedelics, he wishes to support organizations that will leave the world healthy and livable for his children and grandchildren.

Robert is currently working on a documentary project about psychedelic psychotherapy that is intended to educate those who have not used psychedelics about their positive attributes. He is thrilled to be on the Board of Directors and thinks that all of the folks involved with MAPS are doing fantastic and ineffably important work.

Meet MAPS MDMA/PTSD researchers and other MAPS staff

Over the next several months we will be releasing numerous short video interviews on our website: www.maps.org

"Question" by Jewelfly, A.K.A. Marianne M. Bennett

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Rick Doblin, MAPS founder and President, earned his PhD in Public Policy from the Kennedy School of Government at Harvard University. Doblin was also in Stan and Christina Grof's first training group to receive certification as a Holotropic Breathwork practitioner.

Valerie Mojeiko, Director of Operations and Clinical Research Associate, coordinates projects at MAPS' headquarters and facilitates psychedelic research around the globe. Formally educated at New College of Florida and the California Insitute of Integral Sudies.

Josh Sonstroem, Accounting and Information Technology, earned his BA in Philosophy and Religion from New College of Florida and is a chef, musician, poet and technologist. He immensely enjoys the depths of existential experience.

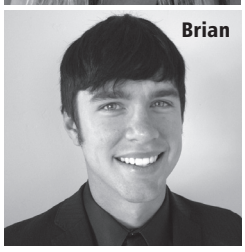
Randolph Hencken, MA, BS Communication and Marketing Director, earned his MA in Communication, and his BS in Business Administration from San Diego State University, where he focused all of his graduate studies on drug policy issues. He was the founder and president of the university's chapter of Students for Sensible Drug Policy, and he interned for the Drug Policy Alliance in San Diego. Formerly he was the program coordinator at the Ibogaine Association in Mexico.

Jalene Otto, Membership and Sales Coordinator, studied philosophy and sociology at Cabrillo College and the University of California, Santa Cruz. She is a story weaver and a mother.

Ilsa Jerome, Research and Information Specialist, earned a PhD in psychology from the University of Maryland. She helps MAPS and other researchers design studies, gathers information on study drugs by keeping abreast of the current literature and discussion with other researchers, creates and maintains documents related to some MAPS-supported studies, and helps support the MAPS psychedelic literature bibliography.

Amy Emerson, Clinical Program Manager, earned her BS in genetics and cell biology from Washington State University. She has worked in clinical development and research for the last 15 years in the fields of immunology, oncology and most recently in vaccine development. Amy has worked with MAPS as a volunteer since 2003 facilitating the development of the MDMA clinical program. She is currently working as the clinical program manager and is involved with creating the structure needed to support the growing needs of the clinical operations group and MAPS clinical research studies.

Brian Wallace, Events and Outreach Coordinator, studied neuroscience, philosophy, and medical sociology at a host of universities, the latest being UC Santa Cruz. As a longtime advocate for the dissemination of accurate, unbiased information with respect to psychoactive drugs and other medicines, Brian is right at home doing outreach and education on behalf of MAPS at music festivals and medical or policy conferences, and in the digital world through various Web 2.0 frameworks.



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, and anxiety and depression associated with end-of-life issues—by developing psychedelics and marijuana into prescription medicines; 2) to cure 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 2010 issue will be another special theme issue on psychedelics, death, and dying.

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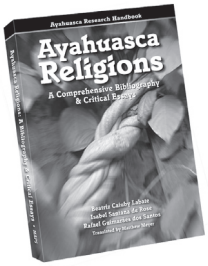

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