



MAPS

MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

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IN MY 26 YEARS of work with MAPS, I've learned that psychedelic research must be conducted with state of the art scientific methodology, to withstand fierce yet justified critique from skeptics and allies alike.

The more scientific studies we design and conduct, the more time we spend negotiating with Institutional Review Boards (IRBs) over protocols, and the more journals that review our papers for publication, the more I see how unconscious and conscious bias, political pressure, and financial incentives can skew the implementation and rational review of studies and their results.

I've also learned how difficult it is to conduct research free of random factors, and have been surprised at how many sources of variance there can be even in our own rigorously designed studies. I've come to see effective scientific research not as a goal that can easily be attained, but as a process that we must always be working to improve.

From the desk of Rick Doblin, Ph.D.

This edition of the *MAPS Bulletin* provides an overview of current accomplishments and challenges in our psychedelic and medical marijuana research, with a special focus on our international series of Phase 2 MDMA-assisted psychotherapy for PTSD studies.

Replicating our impressive results from our two completed studies of MDMA-assisted psychotherapy in subjects with PTSD in additional locations with different research teams is essential for demonstrating the reliability of our data to the FDA and international regulatory agencies. Both of our completed studies—our initial U.S. Proof of Principle study (published in 2010 in the *Journal of Psychopharmacology*) and our Swiss study (with a paper about the results seemingly close to acceptance for publication)—have generated promising data about safety and efficacy that, if it had been from about 560 subjects rather than just 32, would justify approval for prescription use. Replicating results is also essential for showing potential donors to MAPS that the roughly \$15 million more we need to raise to complete Phase 2 and Phase 3 studies over the next seven or so years is a wise investment in our mission to create legal contexts for psychedelic psychotherapy.

We now are working to obtain similarly profound and lasting results in four new studies. Two are in the United States with one ongoing in veterans in Charleston, South Carolina and one about to begin in Boulder, Colorado. One study in Israel is about to begin, and one in Canada is still struggling to obtain approval from Health Canada for the security systems required to store the roughly \$1,500 worth of MDMA to be used in the study.

In addition to seeking to replicate our previous results, our new Phase 2 studies are also gathering information about how to conduct successful double-blind studies. The more uncertainty in the guesses of subjects and co-therapists about what dose was administered, the more convincing our results.

Our ongoing South Carolina study in veterans with co-therapists Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N., divides subjects into three groups, each receiving a different dose of MDMA together with psychotherapy: one receiving 30 mg, one receiving 75 mg, and one receiving 125 mg (all subjects also receive a supplementary half dose 1½ to 2½ hours after the first dose in order to prolong the therapeutic effects). Our other Phase 2 studies in Israel, Canada, and Colorado use only two groups and various lower dosages. Preliminary results suggest that raising the lower

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MAPS Mission and Vision

Mission

Founded in 1986, the Multi-disciplinary Association for Psychedelic Studies (MAPS) is a 501(c)(3) non-profit research and educational organization that develops medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana.

MAPS furthers its mission by:

Developing psychedelics and marijuana into prescription medicines.

Training therapists and working to establish a network of treatment centers.

Supporting scientific research into spirituality, creativity, and neuroscience.

Educating the public honestly about the risks and benefits of psychedelics and marijuana.

Vision

MAPS envisions a world where psychedelics and marijuana are safely and legally available for beneficial uses, and where research is governed by rigorous scientific evaluation of their risks and benefits.

From the Desk of Rick Doblin, Ph.D. *(continued from page 1)*

dose (for example, to 40 or 50 mg) could increase the success of the double blind. Unfortunately, increasing the low dose could lead to more beneficial therapeutic effects, making it more difficult to show a statistically significant difference in therapeutic outcomes between those receiving low doses and those receiving full doses. We're seeking to find a low dose that generates a successful double blind with the minimal amount of therapeutic efficacy.

Finding ways to reduce the cost of Phase 3 studies is another key challenge, and our new study of MDMA-assisted psychotherapy for PTSD in Boulder may help us find a way to do just that. In this new study we're experimenting with a new way of assembling our male-female co-therapist teams, with one member an older experienced professional psychotherapist and another an intern working for free. We're hopeful that teams of this composition will be successful since research has shown that younger therapists (perhaps due to enthusiasm or exposure to the newest therapeutic techniques) and older therapists (perhaps due to experience and accumulated wisdom) are often more effective than their mid-career peers. As our second trial site in the U.S., our Boulder study may help us find ways to conduct our studies more efficiently while still obtaining compelling results.

Our current series of Phase 2 MDMA-assisted psychotherapy for PTSD studies are also designed to learn more about whether subjects with war-related trauma respond to MDMA-assisted psychotherapy as well as subjects with PTSD from other factors, such as childhood sexual abuse, adult rape, or assault. We're also seeking to gather more information about possible cultural differences between U.S., Canadian, and Israeli subject populations.

With limited financial resources, we're trying to gather as much information as we can about the risks and benefits of MDMA-assisted psychotherapy for PTSD in as few studies as possible. We don't yet know whether we'll need additional data from further Phase 2 studies to properly design our Phase 3 studies. The beauty and the challenge of well-designed scientific research is that the results are unknown until the data is in—and only when the data is in do the next steps become clearer.

With your continued support, MAPS will be able to continue expanding our research program, getting unprecedented results, and transforming the culture and politics of psychedelic and medical marijuana research. Together, we can make psychedelics and marijuana into legally available prescription medicines within our very own lifetimes.



Psychedelically and scientifically yours,
Rick Doblin, Ph.D.
MAPS Executive Director



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