

Letter from Rick Doblin, Ph.D., MAPS President

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TOGETHER, WE'VE SUCCEEDED against all odds. After twenty-two years of difficult struggles since MAPS was founded in 1986, we've overcome enormous obstacles and, finally, have successfully concluded our first MDMA-assisted psychotherapy study. We've demonstrated that we can provide clinically and statistically significant relief to subjects with treatment-resistant posttraumatic stress disorder (PTSD). A tantalizingly promising new world of opportunity now lies ahead for MAPS.

Our pioneering U.S. MDMA/PTSD pilot study has outperformed the pharmaceutical industry in the quest to develop effective treatments for PTSD. To do so, we've had to overcome aggressive suppression of research, and massively exaggerated estimates of the risks of MDMA put forth by anti-drug authorities around the globe—seeking to block research into the beneficial uses of MDMA. I can now see the next ten years laid out ahead of us, during which we'll transform MDMA--and perhaps other psychedelics and marijuana—into approved prescription medicines.

To paraphrase Winston Churchill, while we're not yet at the beginning of the end (of integrating the medical uses of psychedelics and marijuana into our culture), we are at the end of the beginning. In our rigorous, methodologically well-designed MDMA/PTSD Phase 2 study, we've produced data demonstrating safety and efficacy that even the most skeptical of critics will need to acknowledge.

This October, like the Phoenix rising from the ashes, partial results from MAPS' Spanish MDMA/PTSD dose-response pilot study will appear in the 40th anniversary edition of the *Journal of Psychoactive Drugs* (originally called the *Journal of Psychedelic Drugs*). We began the study in 2000, only to heartbreakingly and helplessly watch as it was prematurely aborted in 2002 before completion by Spanish and U.S. anti-drug forces, who were politically opposed to the world's first controlled, clinical study of the therapeutic use of MDMA. At present, there are over 3000 scientific papers indexed in Medline about MDMA and/or Ecstasy. Yet this paper about MAPS' Spanish MDMA/PTSD study will be the first paper ever published in the scientific literature presenting evidence from a controlled, clinical trial about the use of MDMA-assisted psychotherapy. Sometime in 2009, a paper about our U.S. MDMA/PTSD study will appear in the scientific literature, marking an historic achievement.

We've now passed a critical turning point. MAPS has completed our U.S. MDMA/PTSD pilot study and is currently sponsoring additional ongoing MDMA/PTSD studies in Switzerland and Israel. We're working to obtain permission for further Phase 2 MDMA/PTSD studies in Canada, Spain, France, Jordan, and the U.S., and we catalyzed and arranged for the funding of a study at Harvard Medical School into the use of MDMA-assisted psychotherapy in treating anxiety in advanced-stage cancer patients. We're refining our MDMA/PTSD treatment manual that describes our method of MDMA-assisted psychotherapy for PTSD patients. We're also developing a therapist training program for the twenty to thirty

male/female co-therapist teams who will eventually conduct our large-scale, multisite Phase 3 studies, that will be required by the FDA and the European Medicines Agency (EMA) to prove safety and efficacy prior to approval of MDMA for prescription use.

The challenge ahead is daunting. For the next two years, we'll be conducting and completing several additional Phase 2 studies, designed to gather data necessary for an "End of Phase 2" meeting with the FDA to determine the design of our two, large Phase 3 multisite studies, with perhaps six hundred subjects. These Phase 3 studies will take an additional three to five years, followed by

FDA and EMA review of the data lasting another year or two.

For the last ten years, I've spoken and written about a five million dollar, five-year plan to develop MDMA into a prescription medicine. Based on the last decade of experience, I'm now thinking in terms of a \$10 million, 10-year plan which, if we're lucky, may end up as a \$7 million, 7-year plan. In any case, what's a few years and a few million dollars either way, when the goal is so tremendous?

MAPS is also involved in LSD and MDMA and, eventually, psilocybin research, in people with anxiety associated with end-of-life issues. We plan to expand our research into the use of ibogaine in the treatment of substance abuse. If we can break the federal monopoly on the supply of marijuana for legal research, we'll also work to start developing marijuana into a prescription medicine.

Together, we can work wonders and make a positive and lasting contribution to this magnificent yet hugely suffering world.

Rick Doblin, MAPS President.

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