From the Desk of Rick Doblin, Ph.D.

As I write this, we're approaching the most important reality check in the Multidisciplinary Association for Psychedelic Studies (MAPS)' 30-year history: our End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA), taking place on November 29, 2016, at FDA headquarters in Silver Spring, Maryland. At this meeting, we will review the data gathered from our international series of Phase 2 pilot studies of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) in the U.S., Canada, Switzerland, and Israel. These studies have investigated the use of MDMA-assisted psychotherapy in 107 people suffering from chronic, treatment-resistant PTSD.

It is tremendously exciting to finally present our promising data to the FDA. We began Phase 2 clinical trials of MDMA-assisted psychotherapy for PTSD in Spain in 2000. The Spanish study was prematurely—and heartbreakingly—halted for political reasons by the Madrid Anti-Drug Authority after it received favorable media attention. We have come a long way since then.

The primary purpose of the November 29 meeting is to come to an agreement with the FDA on the design of our multi-site Phase 3 clinical trials, which the FDA requires prior to deciding whether to make MDMA-assisted psychotherapy a legally available treatment option. The meeting is also an opportunity to determine whether additional human or animal toxicity studies will be required prior to obtaining prescription approval. While our 90-minute meeting on November 29 may not resolve all of these issues, it will clarify what steps need to be taken to come to a full agreement. Once we have received feedback from the FDA, we will start discussions with the European Medicines Agency (EMA) as the first step to making MDMA-assisted psychotherapy legally accessible for PTSD in Europe.

I'm proud to report that in October 2016, just a week before we submitted our End of Phase 2 packet to the FDA, we had the opportunity to significantly improve our strategy. We had been working on our presentation for several months, wisely guided by three former officials from the FDA's Division of Psychiatry Products who have been providing consulting services to MAPS. As we prepared our submission and carefully reviewed our results, these consultants grew increasingly impressed with the data that we have gathered. With their advice in mind, before submitting our proposal, we modified our proposal in two ways.

First, we were advised submit a request to file a full application for Breakthrough Therapy Designation, the most important program that the FDA has for expediting the development of new medications that represent "breakthroughs" over existing treatments. We had initially decided not to submit the request. Previously, we had been advised that due to the large effect sizes we have seen in our Phase 2 studies, and the controversial (but increasingly less so) nature of MDMA research, our application would probably result in greater attention from senior FDA officials anyway, the main benefit of Breakthrough Therapy Designation. However, after our consultants closely reviewed our Phase 2 data, they suggested that it is compelling enough to make it worthwhile to ask the FDA for approval to apply for Breakthrough status. We submitted our request on October 18, and the FDA scheduled a teleconference with us in mid-December to discuss our request.

The second modification to our strategy suggested by our consultants is potentially even more consequential. Generally, the FDA requires two large multi-site Phase 3 studies to prove safety and efficacy. Given the serious and life-threatening nature of PTSD, and the enormous number of people for whom existing PTSD treatments are not fully helpful—for example, there are currently over 868,000 U.S. veterans receiving PTSD disability payments from the Department of Veterans Affairs at an estimated cost of $17 billion per year—we have proposed to the FDA that we conduct just one large multi-site Phase 3 study, with our meta-analysis of the 107 subjects in our Phase 2 studies serving as the second confirmatory study.

The support of our donors and the work of our staff over the last three decades have brought us to this historic point, with our End of Phase 2 meeting on the horizon.

While we're not sure how to estimate the chances that the FDA will accept our two modifications—for Breakthrough Therapy Designation and to conduct one rather than two Phase 3 trials—we're asking for the best outcome possible.

The support of our donors and the work of our staff over the last three decades have brought us to this historic point, with our End of Phase 2 meeting on the horizon. The road to approval for the prescription use of MDMA in psychotherapy is getting clearer, and our fundraising needs are growing along with our research. Together, MAPS donors and MAPS staff will integrate psychedelic-assisted psychotherapy into medicine, and introduce new approaches to healing, spirituality, compassion, and empathy into our culture.

Rick Doblin

Rick Doblin, Ph.D.
MAPS Founder and Executive Director