# From the Desk of Rick Doblin, Ph.D.

**After 29½ years, we're sending** out yet another year-end Bulletin, and I'm sensing something new in the air: a deeper sense of hope. MAPS now feels to me like a caterpillar—our U.S. Food and Drug Administration (FDA) Phase 2 MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) research—about to wrap itself into a chrysalis—our upcoming End of Phase 2 meeting with the FDA—in order to transform into a butterfly (our Phase 3 MDMA-assisted psychotherapy for PTSD research).

MAPS is approaching the end of our international series of Phase 2 pilot studies investigating the use of MDMA-assisted psychotherapy in people with chronic, treatment-resistant PTSD. Our first PTSD study began in Spain in 2000. Before the end of 2015, we'll have gathered primary outcome data from about 100 PTSD patients. This process of sponsoring exploratory pilot studies to gather data is roughly equivalent to a caterpillar's youthful larva stage working hard to find enough food and get ready to start the next stage.

Once we have all of our primary outcome data from our pilot studies in Spain, two locations in the U.S., Switzerland, Israel, and Canada, MAPS' next stage is to cease gathering data from further Phase 2 clinical trials. We are preparing to shift from gathering to analyzing data, turning our focus inward as we wrap ourselves up in statistical analysis and prepare for our End of Phase 2 meeting with the FDA. Like the caterpillar, we'll begin our metamorphosis from conducting the preliminary Phase 2 pilot studies to our decisive multi-site Phase 3 studies, we estimate with 400 subjects. We will continue moving forward with our planned additional Phase 2 PTSD studies with U.S. Department of Veterans Affairs-affiliated researchers, blending MDMA with existing, evidence-based, non-drug psychotherapies for PTSD. These studies are not part of our direct drug development research, since they will explore a different form of psychotherapy than in our standardized *Treatment Manual*.

During this process of data analysis, the various elements of our Phase 2 protocol designs will be broken down into their constituent parts as we try to understand which of those elements were most helpful in empowering people to integrate their traumatic memories and move forward with their lives. We will also work to determine the costs of each element of the protocol design, so that we can build a Phase 3 protocol that will be both effective and efficient. We will gather and analyze all of our data, write some scientific papers, gather safety data from other MDMA researchers willing to share, consult with our consultants, design our ideal Phase 3 protocol, and submit that to FDA to start our End of Phase 2 meeting.

The process of negotiating with the FDA regarding the methodological design for our Phase 3 studies is the next stage of our transformation. Once we come to an agreement with the FDA, we're ready to emerge from our cocoon and initiate our Phase 3 trials with a clear view of what we have to do and what is at stake. Our Phase 3 protocol design is our gorgeous set of wings: refined, pilot-tested, and ready to propel us toward the magic moment of the MDMA drug development process, the New Drug Application (NDA).

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I have taken this metaphor about as far as it will go. I hope that it highlights the magnitude of the transition that MAPS is preparing for in the process of moving from Phase 2 pilot studies to our pivotal Phase 3 studies. These are exciting times building on work of many decades. With the continued support of current MAPS members, and with additional support from new MAPS members, and with the skill and compassion of therapists committed to helping people integrate their trauma and heal from PTSD, and with the PTSD patients courageous enough to face their suffering directly, we have the real potential to make transformative progress not just within our own lifetimes, but in the near future.

Rick Doblin

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