MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

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Research Edition
BULLETIN

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From the Desk of Rick Doblin, Ph.D.

After 32 (and a half!) years, the Multidisciplinary Association for Psychedelic Studies (MAPS)' vision of U.S. Food and Drug Administration (FDA) approval of the prescription use of MDMA-assisted psychotherapy for a wide range of conditions is changing from a caterpillar into a chrysalis. As you read this edition of the *Bulletin,* our FDA Phase 3 multi-site studies will be in their very earliest stages, with screening for subjects underway and perhaps even the first subject enrolled at one of our 16 sites in the U.S., Canada, and Israel. We currently estimate that the studies will take about three years from the first enrollment until the end of 2021, when we project we'll obtain FDA approval for the prescription use of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD). This Phase 3 process is a massive $26.7 million experiment, which we have astonishingly raised all of thanks to donations from the psychedelic, cryptocurrency, and other communities, from individual gifts to foundation grants.

Right now is our opportunity to rigorously and scientifically demonstrate the value of MDMA-assisted psychotherapy.

Fortunately, FDA has a program called Expanded Access, also known as "compassionate use." We anticipate that by the end of Summer 2019, this program will allow some treatment-resistant PTSD patients to obtain MDMA-assisted psychotherapy from therapists MAPS has trained without a placebo control group as in the Phase 3 trials, with patients paying for their own treatments. Patients approved to participate in Expanded Access would need to be unable to enroll in our clinical trials, either because they live in areas without Phase 3 sites or where Phase 3 sites are full, or because they have exclusionary criteria that would prevent them from being enrolled. FDA won't consider data from the Expanded Access program for approval purposes, since the program is intended for compassionate use.

As we start our Phase 3 studies in the U.S., MAPS is laying the groundwork for conducting Phase 3 trials of MDMA-assisted psychotherapy for PTSD in Europe, for eventual approval by the European Medicines Agency (EMA) and individual countries in the European Union. This effort is still a caterpillar. MAPS has completed a six-month Scientific Advice Working Party (SAWP) process with EMA, and has reached agreements with EMA about accepting our FDA data and on the essential elements of the protocol design. These elements include the comparison of our manualized psychotherapy for PTSD with MDMA versus our manualized psychotherapy for PTSD with an inactive placebo; a geographic distribution of sites throughout Europe; and about 70 subjects in just one additional Phase 3 multi-site study, ideally including some migrants and refugees with PTSD.

From September 27–October 3, 2018, MAPS is organizing an MDMA Therapy Training Program near Amsterdam for 60 therapists, mostly from countries where we plan to have European Phase 3 sites (including the Netherlands, Czech Republic, Germany, Portugal, Finland, and England), as well as from other countries (like Australia, Afghanistan, Israel, Palestine, and China). We're also proceeding with the training of European therapists, and with regulatory submissions to EMA, EU countries (and the UK), made possible by the almost $400,000 in

donations we've already received for the European Phase 3 trials. When MAPS can proceed into actual Phase 3 clinical trials for EMA approval depends on how quickly we can raise $8.5 million—ideally by the end of 2018. That's a lot of money, but it's only about one-third the cost of our FDA Phase 3 studies, and could help a PTSD population in Europe even larger than that in the U.S.

MAPS is also reaching a major turning point in our efforts to bring the marijuana plant through the FDA drug development system. For the last 50 years, since 1968, there's been a federal monopoly on the production of federally legal marijuana, currently held by the National Institute on Drug Abuse (NIDA), which grows its marijuana at the University of Mississippi. The limitation of NIDA marijuana is that it can only be used in academic research, and could not be sold as a prescription medicine (even if anybody actually wanted to purchase its product, which is not known for its quality). Since drugs tested in Phase 3 trials must be the exact same drug that is proposed for marketing after FDA approval, FDA will not accept NIDA marijuana for use in Phase 3 trials, making such trials impossible. The NIDA monopoly can be ended either through DEA licensing of private domestic production and/or importation.

MAPS has worked since 2000 to assist Prof. Lyle Craker, Ph.D., of the University of Massachusetts-Amherst, to obtain a license from the U.S. Drug Enforcement Administration (DEA) to produce marijuana for FDA-regulated research. On July 25, 2018, eight U.S. Senators sent a letter to Attorney General Jeff Sessions, setting a deadline of August 11 for DEA to accept or deny for a cause all 26 applications to grow marijuana that DEA has received since August 11, 2016—two years previously—when the DEA under President Obama published a rule in the Federal Register announcing that it would license private producers and end the federal monopoly. MAPS is preparing a lawsuit against DEA, should the August 11 deadline pass without action, an outcome which seems likely at the time I'm writing this. By the time you're reading this, our lawsuit might even have been filed. We're also seeing signs that the federal marijuana monopoly has the potential to become a significant election-year issue.

Right now is our opportunity to rigorously and scientifically demonstrate the value of MDMA-assisted psychotherapy. The moment of truth is arriving soon, thanks to the generous support of MAPS donors, the hard work of MAPS staff, the inspiring courage of the patients who have volunteered for our studies, and the unique therapeutic properties of MDMA. With the continued support of MAPS donors, we can go together through Phase 3—and way beyond!

Psychedelically yours,

Rick Doblin

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

MAPS: Who We Are

Founded in 1986, the Multidisciplinary 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 establishing 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.

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.

MAPS relies on the generosity of individual donors to achieve our mission. Now that research into the beneficial potential of psychedelics is again being conducted under federal guidelines, the challenge has become one of funding. No funding is currently available for this research from federal governments, pharmaceutical companies, or major foundations. That means that the future of psychedelic and marijuana research is in the hands of individual donors. Please consider making a donation today. **maps.org/donate**

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