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.

Right now, in the 30th year of the Multidisciplinary Association for Psychedelic Studies (MAPS), we're preparing for the most important reality check of our entire history. We're analyzing our Phase 2 data from our international series of pilot studies into the use of MDMA-assisted psychotherapy in people suffering from chronic, treatment-resistant posttraumatic stress disorder (PTSD), studies which we began in Spain in 2000 and continued in the U.S., Switzerland, Israel, and Canada. We're also busy designing the protocols for our two multi-site Phase 3 clinical trials. These are required to prove safety and efficacy of MDMA-assisted psychotherapy for PTSD prior to the U.S. Food and Drug Administration (FDA)'s approval of prescription use.

We are preparing to submit our Phase 2 data and proposed Phase 3 protocols to the FDA for our End of Phase 2 meeting, the purpose of which is to come to agreement with the FDA on the design of our Phase 3 studies. If our assumptions are accurate, we project the approval of MDMA-assisted psychotherapy for PTSD in 2021 by both the FDA and the European Medicines Agency (EMA). Whether our Phase 2 data is sufficient, and our proposed Phase 3 designs are accepted, is the reality check we're eagerly anticipating.

We currently estimating that our Phase 3 costs will total about $25 million, of which we've raised or been pledged over $10 million. Over the next five years, we have a major fundraising challenge ahead of us, but it is attainable. We also have a major challenge ahead training over 100 therapists to work in co-therapist teams to treat approximately 450 participants with PTSD in our Phase 3 studies. That challenge is also attainable.

We must rise to these challenges—and together we will—because the need is so great for new treatments for PTSD, to break the cycles of multi-generational trauma that perpetuate conflicts, fear, and hatred through time. A recent commentary by Stanford neuroscience researchers Boris Heifets and Rob Malenka, published July 14, 2016, in the mainstream journal Cell, concluded by saying: "The world's populations need more compassion and empathy for one another. The study of MDMA provides one small but potentially important step toward reaching that goal."

This 30th year of MAPS' existence is also a major reality check for our efforts to sponsor FDA-approved medical marijuana drug development research, as we've finally obtained all the regulatory approvals we need to start our first medical marijuana drug development study. We'll evaluate four different potencies of marijuana with varying ratios of THC and CBD to treat 76 U.S. veterans with chronic, treatment-resistant PTSD. We'll enroll subjects in two locations, at Johns Hopkins University in Baltimore, Maryland, and at a research facility in Phoenix, Arizona. The study is being funded by a $2.15 million grant to MAPS from the Colorado Department of Public Health and Environment (CDPHE), the first government grant MAPS has ever received.

The marijuana for the study is being produced at the University of Mississippi, which has grown marijuana for research

since 1968. We are purchasing the marijuana at cost from the National Institute on Drug Abuse (NIDA), which has a Drug Enforcement Administration (DEA)-enforced monopoly on the federally legal marijuana required for FDA drug development research. This is first time NIDA has been willing to sell us marijuana since 1992, when MAPS was working with Dr. Donald Abrams at the University of California, San Francisco, for a study of marijuana for nausea control and appetite stimulation in HIV patients with AIDS wasting syndrome. We obtained FDA and Institutional Review Board (IRB) approvals for that study, but NIDA refused to sell us the marijuana, preventing the study from starting. Sadly, it's taken 24 of our 30 years to persuade NIDA to sell us marijuana for our drug development research!

We'll be getting another reality check soon in MAPS' efforts to end the obstructive NIDA monopoly. Starting in 2000, MAPS began partnering with Prof. Lyle Craker at the University of Massachusetts-Amherst to obtain a DEA license to grow marijuana for drug development research. In 2005, after the DEA rejected his application, Prof. Craker sued the DEA in an internal DEA Administrative Law Judge (ALJ) hearing. In February 2007, Prof. Craker won the case when the ALJ recommended to the DEA Administrator that it would be in the public interest for the NIDA monopoly to end. The DEA Administrator did not respond to the recommendation for almost two years, finally rejecting it a week before the inauguration of President Obama. In 2013, Prof. Craker disappointingly lost his U.S. Court of Appeals case against the DEA when the judges ruled that NIDA had an adequate supply for researchers.

Still undeterred, Prof. Craker is now within weeks of submitting a new application to the DEA for a license to grow marijuana and produce marijuana extracts for FDA-regulated medical research. We're trying again now with optimism because we can more clearly demonstrate that NIDA does not have an adequate supply, a position supported by a new pro bono legal analysis by the major Washington, D.C., law firm Covington & Burling. NIDA has not been able to provide MAPS with the strains and potencies of marijuana we requested. Furthermore, NIDA marijuana can only be used for research, not for prescription sale, and cannot be used in FDA-approved Phase 3 studies. Before the Obama Administration leaves office, there is a very good chance it will order the DEA to end the NIDA monopoly and issue a license to Prof. Craker, and to other private producers as well.

With the continued support of our members, MAPS will proceed with confidence to our upcoming reality checks, further refine our strategies, and continue our work to mainstream the therapeutic uses of psychedelics and marijuana.

With appreciation,

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 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.

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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