



# MAPS

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**From celebration to frustration, and back again.** MAPS' major accomplishments at the end of last year led me to believe that our goal of developing psychedelics and marijuana into FDA-approved prescription medicines was moving from distant vision to realistic possibility. Yet immediately after celebrating our achievements, new resistance blocked further progress and for a time our initial excitement was replaced by frustration. Now, after more than half a year of difficult, slow work, we've made significant progress overcoming some obstacles and have energetically responded to others.

On November 2, 2001, after fifteen years of struggle, FDA approved a MAPS-funded MDMA psychotherapy protocol, specifically Dr. Michael Mithoefer's study of MDMA-assisted psychotherapy in the treatment of posttraumatic stress disorder (PTSD) (p.4). By November 7, however, senior administrators at the Medical University of South Carolina (MUSC), where we expected to conduct the study, reacted with alarm to the media attention generated by FDA's approval of the protocol (see [www.maps.org/media/](http://www.maps.org/media/)). We tried for five months to address their fears and concerns, but were unable to obtain permission to submit the protocol for review to the MUSC's Institutional Review Board (IRB). We then started negotiating with FDA to move the study to a new location. On June 14, FDA informed us that our request was approved. We're now in the midst of an independent IRB review, and with luck will be able to begin the study in several months.

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

We also experienced a roller coaster ride in our four-year effort to obtain a license to produce our own supply of FDA-approved marijuana, necessary in order to proceed in a professional manner with a medical marijuana research program. MAPS has partnered with Prof. Lyle Craker, UMass Amherst Dept. of Plant and Soil Sciences, and has pledged a grant to fund all production expenses (p. 3). On December 3, 2001, after reviewing our application for six months, the Massachusetts Department of Public Health informed me that it had no objections in principle to the UMass Amherst facility, as long as the Drug Enforcement Administration (DEA) first approved the project. This major milestone moved the application to the federal level.

Progress soon stalled. On December 5, DEA informed me that it had lost our application, which we had submitted six months before. We subsequently faxed a copy to DEA, waited over a month and then were told the application was rejected because it only had a photocopied signature (DEA had lost the application with the original signature). Realizing that we were in for a major struggle, we decided to seek outside support before resubmitting. These last six months have been focused on obtaining two supporting documents; a letter to DEA Administrator Asa Hutchinson from several Congressional Representatives endorsing the licensing of private facilities to produce marijuana for medical research (see back cover), and a legal analysis by the American Civil Liberties Union and Covington & Burling explaining why US international treaty obligations do not prevent DEA from licensing the facility. We anticipate filing our application in early July.

In December 2001, as a result of a generous grant from a new donor, MAPS and CaNORML were able to start planning for a new round of marijuana vaporizer research. Our intent is to have a vaporizer approved by FDA for use in clinical trials, following the recommendation of the Institute of Medicine for the development of a non-smoking delivery device. Unfortunately, our search for vaporizers that had a reasonable chance of being approved by the FDA ended up taking longer than anticipated. We've recently chosen two promising models, the Volcano ([www.vapormed.com](http://www.vapormed.com)), and the Vapir ([www.air-2.com](http://www.air-2.com)), and have finally started a new \$35,000 marijuana vaporizer research project, with results to be reported in the next Bulletin.

During these difficult times, I've been encouraged by the stories I've been reading to my kids, particularly about the tortoise and the hare. If anything characterizes MAPS' track record, it's slow and steady! With your continued support, I'm confident we can win the race, eventually.

— Rick Doblin, Ph.D., MAPS President