YEARS AGO, on April 8, 1986, I filed the necessary papers with the Florida Secretary of State to create the Multidisciplinary Association for Psychedelic Studies (MAPS). MAPS was initially created in response to DEA’s 1985 action making both the therapeutic and non-medical uses of MDMA illegal. I intended to use the non-profit structure primarily to build a membership-based research and educational organization that would develop MDMA into an FDA-approved prescription medicine. Through the sponsorship of scientific research, I planned for MAPS to serve as a scout into consciousness and culture, seeking to bring the psychedelic experiences and explorations that had been so beneficial to me and many others into wider, legal contexts.

Letter from Rick Doblin, MAPS President

I stumbled upon the underground MDMA psychotherapy community in 1982, when MDMA was still legal, and enthusiastically participated in a movement that felt profoundly healing, wonderfully freeing, and doomed. I was inspired to join hands with others to struggle against the slow, inexorable criminalization and demonization of MDMA. In 1984, we initiated a lawsuit against DEA seeking to protect MDMA’s therapeutic use. Despite our best efforts, we observed history repeat itself as hope was swallowed by fear, mirroring the prohibition of psychedelics in the 1960s. Yet even by 1986, I had benefited so much from my experiences with MDMA and other psychedelics that I felt I could work for these last twenty years, and for the next twenty as well, and still end up giving back to our culture just a fraction of what I had gained.

Twenty years after its founding, MAPS is where I thought it would take about five years to reach. However, considering the obstacles that we have overcome and our recent breakthroughs, I’m deeply satisfied. MAPS’ MDMA psychotherapy research studies in subjects with posttraumatic stress disorder (PTSD) have been approved in the US (p.7), Israel (p.10) and Switzerland (p.9). In addition, we’ve obtained final approval for MDMA research at Harvard in advanced-stage cancer patients with anxiety, though MAPS has withdrawn from formal sponsorship of that study (p. 11). MAPS is also involved in suing the DEA for obstruction of our medical marijuana production facility (p.3), bringing MAPS full circle.

MAPS’ work requires a successful balancing act that is as difficult as it is exciting. I’m frequently reminded of Timothy Leary’s wiser sayings, “If you want to be a bridge, you have to be prepared to be stepped on.” I recently attended a conference in Israel that illustrates the different worlds that MAPS is trying to bridge. The conference was sponsored by the Israeli Anti-Drug Authority and included a talk by Acting Prime Minister Ehud Olmert. The rhetoric was of the sort that would delight the political wrangling is in temporary respite. And, the possibility of MAPS-sponsored FDA-approved clinical trials with marijuana is now hinging on a recommendation to DEA Administrator Karen Tandy from DEA Administrative Law Judge Mary Ellen Bittner, expected by summer or fall of 2006.

Following two rounds of hearings and an aborted hearing in January, lawyers for the DEA and lawyers from the ACLU and the two Washington, DC, law firms working largely pro bono for Prof. Lyle Craker, Ph.D., are now preparing final legal briefings. The legal briefings, due April 27, will build legal arguments based on the evidence presented in court during oral arguments, but cannot introduce new evidence.

If Judge Bittner recommends that the DEA issue a Schedule I manufacturing license to Prof. Craker, it will be just that—a recommendation. The DEA could still reject the Judge’s ruling, leaving us with the unenviable option of suing the DEA in the Washington, DC, Circuit Court of Appeals on the grounds that their rationale for rejecting a favorable recommendation was flawed, a process that could delay the case for several more years. Therefore, if Judge Bittner makes a favorable recommendation, we will need to place political pressure on the DEA to follow it, even though we already have letters to the DEA urging it to issue the license from 36 members of the House of Representatives (36 Democrats and 2 Republicans), both US Senators from Massachusetts (Kennedy and Kerry), Republican strategist Grover Norquist, and organizations such as the California Medical Association, the Lymphoma Foundation of America, the United Methodist Church (UMC), and several state nurses’ associations.

The Background

Although Federal law requires adequate competition in the production of Schedule I drugs [21 U.S.C. § 823(a)(1); 21 C.F.R. § 1301.33(b)], at present, the federal government’s National Institute on Drug Abuse (NIDA) has a monopoly on the supply of marijuana, but no other Schedule I drug, that can be legally used in federally-approved research. This monopoly has been used to obstruct privately-funded research aimed at developing marijuana into an FDA-approved prescription medicine. For example, NIDA has refused to...
supply marijuana to two FDA-approved protocols sponsored by MAPS, preventing these studies from taking place. In addition, over the past several years, NIDA has refused to sell 10 grams of marijuana to a MAPS-sponsored laboratory study evaluating the effectiveness of a marijuana vaporizer, a non-smoking drug delivery device that eliminates the products of combustion that patients would inhale after burning marijuana. As NIDA well knows, sponsors will not invest millions of dollars into research studies until there is reliable access to a supply of high quality research material that can be used both in research and—if the research should prove successful—as an FDA-approved prescription medicine.

In June 2001, with support from MAPS, Prof. Craker, Director of the Medicinal Plant Program at the UMass-Amherst Department of Plant, Soil and Insect Sciences, applied to the DEA for a license to manufacture marijuana for research purposes. The DEA granted the license—subject to a condition that leaves the DEA with discretion to deny it at any time in the future. DEA licensing is the final regulatory hurdle in MAPS’ quest to create a privately-funded, federally-approved medical marijuana production facility, which would pave the way for a serious drug development effort aimed at developing marijuana into an FDA-approved prescription medicine. One of the DEA’s key legal arguments is that Prof. Craker’s facility is “not in the public interest”. During the first weeklong trial that took place in August 2005, Prof. Craker’s lawyers established through the deposition testimony of long-time California State Senator John Vasconcellos and former ONDCP senior policy analyst Barbara Roberts that there is an unmet demand for research that investigates the safety and efficacy of marijuana’s potential therapeutic use (see Allen Hopper’s update in the Fall 2005 Bulletin at http://www.maps.org/news-letters/v15n3/html/dea.html).

The DEA first called on Prof. Mahmoud El Sohly, Ph.D., NIDA’s marijuana grower at the University of Mississippi. During cross examination, Prof. El Sohly was asked to explain his commercial interests. He remained silent for over four minutes and then, after identifying marijuana-based products. This includes both his THC suppository and his new DEA license permitting him to grow marijuana to extract THC for sale to the pharmaceutical company, Mallinckrodt, to manufacture generic Marinol. We established that Prof. El Sohly would have a major conflict of interest if he were the sole supplier of marijuana to MAPS for prescription use, since marijuana would compete with products in which he has a personal financial interest.

Prof. El Sohly also claimed that he could provide marijuana of any potency and cannabidiol (CBD) content. When he later referred to a document that contained information on the THC and CBD content in the marijuana grown on NIDA’s property, Prof. Craker’s lawyers asked to see it, and it was introduced into evidence. As it turned out, there was nothing in the inventory that matched the THC and CBD content that the Dutch government is offering for sale for medical use.

After a day of cross-examination, Prof. El Sohly produced a statement that he hadn’t seen from Prof. El Sohly, and that he had no choice but to rely on the DEA’s case by defaulting on the issues and not providing any testimony. One of the DEA’s major legal arguments is that Prof. Craker’s facility is “not in the public interest”. During the first weeklong trial that took place in August 2005, Prof. Craker’s lawyers established through the deposition testimony of long-time California State Senator John Vasconcellos and former ONDCP senior policy analyst Barbara Roberts that there is an unmet demand for research that investigates the safety and efficacy of marijuana’s potential therapeutic use (see Allen Hopper’s update in the Fall 2005 Bulletin at http://www.maps.org/news-letters/v15n3/html/dea.html).

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During the second weeklong proceeding in December 2005, DEA lawyers called their witnesses to the stand. Amazingly, their testimony seemed to support MAPS’ case more than their own.

The possibility of MAPS-sponsored DEA-approved clinical trials with marijuana is now hinging on a recommendation to DEA Administrator Karen Tandy from DEA Administrative Law Judge Mary Ellen Bittner, expected by summer or fall of 2006. Nobody in the courtroom said a word for more than a minute. It was clear that Bayly was struggling to figure out how to object to this affidavit. He remained still for so long that Judge Bittner was compelled to speak again, asking him once more if he had any objections. Bayly shook off his paralysis and pored over the letter, paragraph for paragraph, line for line, trying to exclude any background information that wasn’t directly about the photographs itself. MAPS’ attorney, Julie Carpenter, skillfully argued that the background information was helpful in proving that marijuana can’t possibly be as bad as it really is, and we had photos and witnesses to prove that it is indeed that bad.

Then, in what seemed like an attempt to intimidate Byrne into withdrawing his affidavit, Mr. Bayly said that he wanted to cross-examine him under oath. The judge then ruled that Byrne would not withdrawn his affidavit, the DEA cancelled Byrne’s cross-examination.

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After Prof. El Sohly’s testimony, we contacted Al Byrne, who was present when Russo’s photograph was taken, to ask if he would testify to the unaltered nature of the photo. Byrne agreed to submit a signed affidavit, which we introduced into evidence on Friday, the last scheduled hearing. The affidavit was submitted to DEA by DEA lawyer Brian Bayly and it made the following points:

- DEA licensing is the final regulatory hurdle in MAPS’ quest to create a privately-funded, federally-approved medical marijuana production facility, which would pave the way for a serious drug development effort aimed at developing marijuana into an FDA-approved prescription medicine.

- The DEA first called on Prof. Mahmoud El Sohly, Ph.D., NIDA’s marijuana grower at the University of Mississippi. During cross examination, Prof. El Sohly was asked to explain his commercial interests. He remained silent for over four minutes and then, after identifying marijuana-based products. This includes both his THC suppository and his new DEA license permitting him to grow marijuana to extract THC for sale to the pharmaceutical company, Mallinckrodt, to manufacture generic Marinol. We established that Prof. El Sohly would have a major conflict of interest if he were the sole supplier of marijuana to MAPS for prescription use, since marijuana would compete with products in which he has a personal financial interest.

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MDMA-Assisted Psychotherapy in the Treatment of Posttraumatic Stress Disorder (PTSD): Seventh Update on Study Progress

Charleston, SC; USA

Seven years ago I began formal efforts with MAPS to pursue research investigating MDMA-assisted psychotherapy as a treatment for posttraumatic stress disorder (PTSD). As of February 2006, our study has now been underway for two full years. We enrolled the first subject in March 2004, more than three years after receiving Food and Drug Administration (FDA) approval and less than three weeks after approval from the Drug Enforcement Agency (DEA). Here’s where we are at the two-year mark:

- Eleven subjects have completed the study, and the twelfth subject is a month into the study.
- After receiving placebo in the first stage, two subjects have gone on to complete the open-label stage (which includes two MDMA-assisted psychotherapy sessions).
- A third subject who received placebo in Stage 1 is scheduled to return for the open-label stage in early March.
- We submitted our annual review report to the Institutional Review Board (IRB) in January 2006. The IRB subsequently granted approval for another year.
- On February 6, 2006 our Data Safety Monitoring Board (DSMB) met to review the records for all six subjects who have enrolled since their last meeting.
- While we can’t predict how Judge Bittner will interpret the evidence presented over the two weeklong trial proceedings, we are satisfied that our key arguments were presented thoroughly and accurately in this landmark struggle for scientific freedom.
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Michael Mithoefer, M.D.
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The study is moving along smoothly and our results continue to be very promising...

All the subjects who have received MDMA-assisted therapy thus far have experienced improvement in their PTSD symptoms.