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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 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obtained final approval for MDMA research at Harvard in advanced-stage cancer patients with anxiety, though MAPS has withdrawn from formal sponsorship of that study (p.11).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 one of Timothy Leary's wiser sayings, "If you want to be a bridge, you have to get used to being stepped on." 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 US Drug Czar John Walters. Haif Messing, the Director of the Anti-Drug Authority, reported that about 20 million doses of MDMA are smuggled into Israel each year, and "everyone is a hand grenade." In contrast, Mr. Messing had previously written and sent a formal letter of support for MAPS' MDMA/PTSD pilot study to the Israeli Ministry of Health, at its request. Over the past seven years, MAPS has built relationships and offered educational seminars about MDMA research to members of the Israeli Ministry of Health and the Anti-Drug Authority, and this work bore fruit in the letter of support from Messing. Similarly, a letter of support for the MDMA/cancer anxiety pilot study to senior administrators at Harvard Medical School's McLean Hospital, from a former senior official at the US White House Office of National Drug Control Policy with whom I've built a dialogue over the past eleven years, was instrumental in obtaining the final approval for that study.

Perhaps it will take the next twenty years for MAPS to complete its five-year, $5 million plan to obtain FDA approval for the prescription use MDMA. Perhaps it will just take five years. Either way, it's a worthy struggle. It's my privilege to thank everyone who has supported MAPS since its inception, especially the MAPS staff members who have worked with us in our quixotic quest. I'm thrilled to contemplate what we can accomplish together over the next twenty years!

Rick Doblin, Ph.D., MAPS President

Lyle Craker's DEA Lawsuit for a MAPS-Sponsored Medical Marijuana Production Facility: An Update

The courtroom drama is over. 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 from DEA Administrator Karen Tandy to DEA Administrative Law Judge Mary Ellen Bittner, expected by summer 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 38 members of the House of Representatives (35 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's (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(e)(1); 21 C.F.R. § 1301.35(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 1 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 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 exclusively for use in federally approved research. Prof. Craker's facility would have been funded by a grant from MAPS. Yet the DEA has refused to issue a Schedule I manufacturing license to Prof. Craker for over four and a half years. 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 2003, Prof. Craker's lawyers established through the 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 uses (see Allen Hopper's update in the Fall 2005 Bulletin at http://www.maps.org/news-letters/v13n5-htm/dea.html).

During the second weeklong trial 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 DEA's lawyer, DEA Hearing Administrator Karen Tandy requested a recommendation for a DEA license after being "edified" by the witnesses. Tandy noted theínhanced safety and efficacy of marijuana over tobacco and the importance of conductmg a serious study with similar THC levels. This erroneous claim later hurt the DEA's case once it was contradicted by the DEA's own witnesses.

The third day, the DEA called on Steve Gust, Assistant Director of NIDA, and our lawyers obtained several very important admissions from him under oath. First, he said that after the FDA has approved a protocol, the PHS/NIDA review takes an additional three to six months. Gust stated that the process would go out of its way to encourage the DEA to approve marijuana into a prescription medicine, since time delays in pharmaceutical drug development are expensive and substantially important.

Nobody in the courtroom said a word for more than a minute. It was clear that Bayly was struggling to figure out how to respond. Gust added: "In personal communications I have remained for so long that Judge Bittner was compelled to speak again, asking him once more if he had any objections. Bayly shook it off. His testimony and cross-examination continued without protocol submissions. The context then led to admitting the letter in its entirety. We now had Prof. Elsohly on record saying that NIDA marijuana can't possibly be as bad as it is really, and we had photos and witnesses to prove that it is indeed that bad.

The DEA 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.

Then, Gust said that there is no formal appeal process, but that if an appeal is made, it would take another three to six months. He also said that since approving marijuana under such circumstances, the DEA has just 30 days to respond to protocol submissions.
other inaccurate claims about the addictive nature of marijuana and its link with mental illness. This enabled us to request that a chapter from Lester Grinspoon’s Marijuana: The Forbidden Medicine, “Measuring the Risks,” be entered into evidence as a rebuttal. Even though Judge Bittner had previously upheld a DEA request to block the text since the risks and benefits of marijuana weren’t an issue in this case, in this instance she agreed to our request. Thus, Grinspoon’s chapter was finally entered as evidence, contradicting Voth’s testimony in numerous ways.

The primary thrust of Voth’s testimony was that marijuana has so many ingredients that it can’t possibly be made into a medicine. He said that it is difficult to standardize marijuana because various strains have significantly different chemical compositions, implying that blocking us from doing marijuana research doesn’t matter since there is no way that the FDA would accept the marijuana plant as a prescription medicine. This argument was more persuasive until about 30 years ago, when the FDA developed guidelines for investigation of botanical medicines. This argument also fundamentally contradicted Prof. El Sohly’s testimony that research could be conducted with a strain of marijuana provided by NIDA and then the sponsor of research could easily obtain FDA permission to market a different strain since NIDA can’t legally provide marijuana for prescription use.

Later in the day, over strenuous DEA objections, we entered into evidence FDA statements saying that the FDA welcomes research protocols evaluating whether the marijuana plant deserves to be available as a legal prescription drug. Once again, the FDA’s willingness to place science over politics was a major assistance to our efforts.

The DEA’s final witness was David E. Auslander, M.D., an expert in pharmaceutical drug development. His entire testimony substantially helped our case by reinforcing Dr. Voth’s view that it is extremely difficult to standardize a plant because different strains have significantly different chemical “fingerprints”.

Most importantly, at the end of Auslander’s testimony, we asked him if the FDA would be concerned about the variation in chemical “fingerprints” of different marijuana strains. He said yes, definitely. We then asked him if it would be problematic for a pharmaceutical company if it did research with one strain of a plant, got FDA approval to market it, but then tried to market a different strain with a different fingerprint. He said this would matter since FDA regulations require the same strain and chemical composition.

While we can’t predict how Judge Bittner will interpret the evidence presented over the two weekend trial proceedings, we are satisfied that our key arguments were presented thoroughly and accurately in this landmark struggle for scientific freedom.

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. The DSMB reported that they did not have any concerns about the safety of the study, and recommended that it continue without modification. The DSMB is comprised of an MD, a PsyD, and a PharmD who are not otherwise involved in the study.

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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.

http://www.maps.org/mmj/DEAlawsuit.html

To read transcripts of the court proceedings, media coverage, or background information on the case, see MAPS’ DEA lawsuit page on the Internet at: http://www.maps.org/mmj/DEAlawsuit.html