Progress Report: The Psilocybin/Obsessive-Compulsive Disorder (OCD) Study Obtains Final FDA Approval!

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On May 8, 2001, we learned that the FDA has approved the psilocybin for use in humans. This is the final approval we needed from FDA!

Update

Around April 20, 2001, we submitted additional analytical data to the FDA regarding the purity of the one gram of psilocybin that MAPS arranged to be synthesized and purchased for our experiment. On May 8, 2001, we learned from the FDA that the psilocybin was approved for human use. We now have final approval from FDA to begin the study! All we need to do now prior to beginning formal recruitment of subjects for the study is to obtain our DEA Schedule 1 licenses to handle the psilocybin, and obtain a DEA certificate of confidentiality (to protect the privacy of our subjects, who are required to have had prior experience with psychedelics). Now that we have final FDA approval for the study, we should be able to obtain our DEA licenses and certificate of confidentiality within a month or two.

History of the Protocol Approval Process

From late 1994 through the beginning of 1995, I treated, under Dr. Pedro Delgado's supervision, a patient who had difficult-to-treat Obsessive-Compulsive Disorder (OCD). Surprisingly, this patient reported that his symptoms had dramatically improved immediately after ingestion of dry psilocybin mushrooms (taken in a recreational context). After chronic exposure to these mushrooms, he noticed that his symptoms remained in remission even when he stopped using psilocybin.

After a brief discussion with Dr. Delgado, in which he indicated that he had heard of similar cases, we conducted a literature search and found minimal direct literature but several supportive reports. We wrote a case report and initiated contact with experienced hallucinogen researchers, including Dr. Rick Strassman, who was then in New Mexico and had expressed interest in collaborating in a prospective study to evaluate this phenomena under controlled circumstances. A number of other researchers including our supporters at MAPS were very enthusiastic about the plan and contributed ideas and feedback to the development of the current protocol.

Our initial task was to work closely with the University of Arizona Human Subjects Committee (HSC) in order to discuss the potential approval of our project. After repeated reviews and a visit by Dr. Delgado and myself with the HSC, we were able to satisfy their concerns and suggestions by November1997.

Earlier conversations with Dr. Strassman made it clear that obtaining permission from the FDA and the DEA would be the largest hurdles to overcome once the HSC had approved the protocol. In addition to FDA approval of our protocol for the use of an Investigational New Drug (IND), we need to obtain a DEA schedule I license that is psilocybin-specific. However, the DEA requires an FDA-sanctioned protocol with an approved IND in order to process the application for a DEA license.

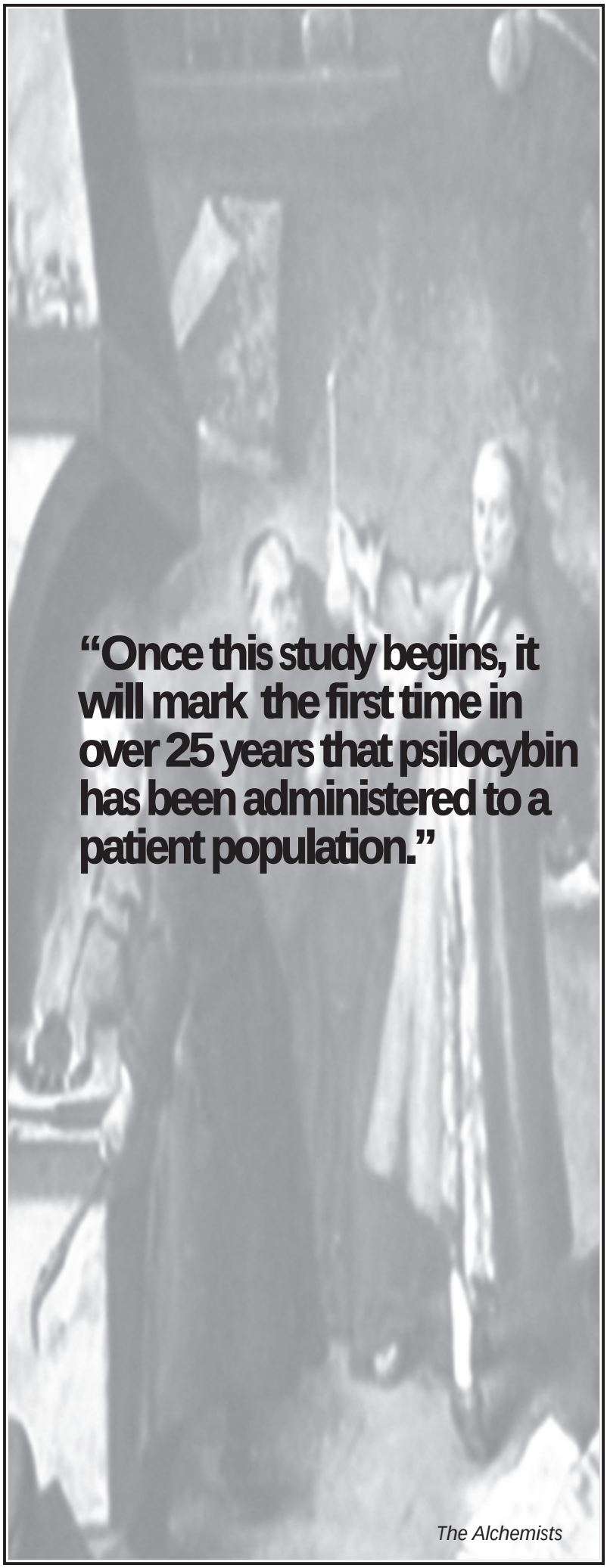
Although our protocol design was finally approved by the FDA on September 17, 1998, the FDA placed our IND on clinical hold pending clarification of the source of the drug. Part of the delay in the FDA process is the result of our lack of experience at preparing all the material that is required by the FDA. They accepted our application without a formal protocol written in the format that pharmaceutical companies usually compose. Mistakenly, we had provided the FDA with data on psilocybin existing at NIDA even though NIDA had not yet decided to make that psilocybin available to us. We made the decision to pursue obtaining the drug from NIDA through our in-house collaborators but were unable to do so after about one year of trying. We attempted to import psilocybin from Switzerland but were also unable to arrange for that option.

In October, 1999, Rick Doblin began searching for a potential non-governmental domestic source of psilocybin. He located Organix, a private company with the required DEA licenses and expertise in the synthesis of organic compounds, including psilocybin. He learned that Organix could synthesize our drug and provide the FDA with the required analytical data sufficient to characterize our drug source (the issue that resulted in the clinical hold FDA placed upon our protocol). A contract between MAPS and Organix for one gram of psilocybin was initially proposed for $7,500, but this amount was increased to $10,000 in a December 1999 contract after Organix had discussed directly with the FDA its needs for analytical data.

It then took almost six months to resolve lengthy discussions between Organix and the University of Arizona lawyers about what would be the safest legal process to obtain psilocybin from Organix. In May 2000, the University of Arizona received a grant of $10,527 from MAPS so that the University could purchase the substance directly from Organix. Two more months went by before the University of Arizona submitted a purchase order to Organix on August 1, 2000. By the end of September 2000, Organix had completed the synthesis and had provided us with the analytical data initially agreed upon. We, in turn, submitted this information to the FDA. On November 29, 2000, the FDA informed us that additional analysis, interpretation, and a written description of the synthetic process was required. Organix agreed to provide this additional information at an extra cost of $1,750 that MAPS agreed to pay directly to Organix. Organix subsequently provided us with the newly required data and we in turn resubmitted it to the FDA before April 20, 2001.

On May 8, 2001, we learned that the FDA has approved the psilocybin for use in humans. This is the final approval we needed from FDA! Now we will be able to obtain the necessary licenses from DEA. Once this study begins, it will mark the first time in over 25 years that psilocybin has been administered to a patient population in the context of a legal, FDA-approved protocol.

Partial funding for the operational cost of the study has been pledged by the Heffter Research Institute. Additional funding in the amount of $25,000 will be needed in order to complete the implementation of the entire project. Donations to MAPS can be restricted for our use, with 100% of the donation allocated to our study.



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The Alchemists