

Dr. John Halpern Reports on Various Psychedelic Research Projects

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I wish I could report that our FDA-approved study, “Phase II Dose-Response Pilot Study of (+/-)-3,4-Methylenedioxyamphetamine (MDMA) Assisted Psychotherapy in Subjects with Anxiety Associated with Advanced-Stage Cancer,” is an active study by now. Certainly the way the press buoyed up our work as a news item in early 2005, one could easily have been left with the impression that we were but mere moments away from starting. My earlier predictions of Spring '05 were far off the mark, but I don't expect to report another round of delays by the next MAPS Bulletin.

On September 28, 2005, the McLean Hospital IRB re-approved our protocol, which was re-submitted to them in its entirety earlier in the month. This re-review helped identify where the informed consent should be modified as well as a few other procedural issues regarding discharge, the HIV testing form, and the use of videotapes.

On October 14, we hosted investigators of the DEA Boston Field Office once again. This was actually their first opportunity to fully test the alarms on the safes we will use at McLean Hospital. We are confident that the DEA completed their investigation with this visit, and, if favorable, a Schedule I Registration for the research use of MDMA in our study could be sent to us sometime in the following two months. I really do believe this meeting is the turning point we've all been waiting for and hopefully we will be recruiting subjects before the New Year.

LSD and Psilocybin in the Treatment of Cluster Headache

MAPS is also backing our efforts to evaluate whether LSD and psilocybin have important medicinal properties for the treatment of cluster headaches. R. Andrew Sewell, M.D. continues to work and collaborate with me here at McLean Hospital in addition to his other work as a research fellow in drug and alcohol abuse research. He spearheaded the data collection of 384 people with cluster headache who claim their condition improved after personal experimentation with these substances. We requested medical records to confirm diagnosis and standard medication trials, which then pared down our cases available for review to 53. The positive reports we obtained from these 53 cases have been written up, and we intend to soon submit it for publication. In the meantime, we are discussing the design of a protocol for a randomized, controlled pilot study, which is the best way to tell for sure if the intriguing results implied by the case series are valid and observable. Many steps still remain before any type of research begins, but we look forward to reporting our progress to you in the months ahead.

Neurocognitive Functioning of Members of the Native American Church

Grants from MAPS contributed to completing my multi-year study of neurocognitive functioning of Navajo Native Americans. The paper that summarizes our primary findings, “Psychological and Cognitive Effects of Long-Term Peyote Use Among Native Americans,” is slated for publication in the mid-October issue of the journal *Biological Psychiatry*. With data on 176 participants, we believe this is the largest neuroscience study of this important under-represented minority to be published in the peer-reviewed

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medical literature, is the largest study of groups of relatively exclusive users, and offers the first quantified data-set on the cognitive and psychological functioning of participants in the legitimate ceremonies of the Native American Church. The conclusion of the abstract states, “We found no evidence of psychological or cognitive deficits among Native Americans using peyote regularly in a religious setting. It should be recognized, however, that these findings may not generalize to illicit hallucinogen users.” The abstract can be found online: <http://journals.elsevierhealth.com/periodicals/bps/content/59434abs>

Review of Hallucinogenic Botanicals of America

MAPS support is also acknowledged in a forthcoming paper co-authored with Dr. Sewell that is in press with *Life Sciences*, “(Minireview) Hallucinogenic Botanicals of America: A Growing Need for Focused Drug Education and Research.” The paper was developed from a talk I gave at a NIDA-sponsored workshop, “Natureceuticals (Natural Products), Nutraceuticals, Herbal Botanicals, and Psychoactives: Drug Discovery and Drug-Drug Interactions” that was held in Baltimore late last year. The paper reviews DMT, psilocybin, mescaline, salvinorin A, lysergic acid amide, atropine and scopolamine, ibotenic acid and muscimol, kava lactones, examples of abuse, and a description of the current religious use of some of these compounds. An in press version of this paper can be obtained at: <http://dx.doi.org/10.1016/j.lfs.2005.09.005>

Both of the above papers may be of importance in the coming Supreme Court case reviewing the right of Uniao do Vegetal (UDV) members to practice their religion in the United States. The UDV won a preliminary injunction in federal court against the Department of Justice and in particular the DEA. This injunction protects the UDV’s religious use of ayahuasca as their sacrament even though it contains Schedule I DMT. Oral arguments are slated for November 1st. The UDV has created a website of all the friend of the court briefs that have been filed. I joined one, currently listed as #8 on their list: <http://www.udvusa.com/amicus.php>

Neurocognition Study of MDMA Users

Finally, my MDMA-neurocognition study remains active, and we are aggressively continuing to recruit users and non-users who reside in Utah, New Mexico, and Idaho (people from these States can call and see if they qualify: 1-800-444-0601). Neurocognitive performance is assessed in a variety of domains using a wide range of standardized tests. Participants should have an extensive history of attendance at all-night parties and report a history of MDMA (“Ecstasy”) use as their primary drug of choice or report a history of little to no drug experimentation. It is our ambition that this study will help inform the ongoing debate about MDMA’s impact on mental health and cognitive performance. Especially because of the seed-money provided by MAPS to help in the collection of pilot data, we were ultimately able to obtain a 5-year \$1.8 million grant from NIDA for this project. This achievement is a shining example of how research sponsored by MAPS can also gain mainstream recognition and collaborative support.