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

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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.

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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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 at issue in this case, in this instance she agreed to our request. Thus, Grinspoon’s chapter was officially 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 10 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 make matters a bit too the FDA and could require replication of some clinical studies, which are very expensive. It was the exact opposite of Prof. El Sohly’s testimony, in which he said we could conduct research with NIDA marijuana and then just switch to another plant. Prof. El Sohly was not presented to the Court as an expert in pharmaceutical drug development, so Auslander’s testimony therefore had more authority on these points.

Auslander supported one of our key arguments, that conducting research with NIDA marijuana from Prof. El Sohly isn’t reasonable since NIDA’s mission doesn’t permit it to provide marijuana for prescription sales, just research. Therefore, if we use NIDA marijuana in research and the FDA approves prescription use, we would have to apply to NIDA to obtain the same strain from Prof. El Sohly again. But, as we established earlier, Prof. El Sohly has fundamental conflicts of interest, since he has other marijuana-based products that would compete, plus he could charge anything he wanted because there would be no competition. The only other option would be to apply for FDA approval to market a different strain from a new manufacturer, which would present additional difficulties because of the differing chemical fingerprints of marijuana strains. In any case, there is currently no alternative supplier with a DEA license, and starting a new facility could take a year or more, a costly delay if millions of dollars had already been invested in research. In response to our final questions, Auslander helpfully testified that pharmaceutical companies must be assured of a reliable and consistent supply of any drug that could be used in research and made available for prescription sales.

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To read transcripts of the court proceedings, media coverage, or background information on the case, see MAPS’ DEA lawsuit page at: http://www.maps.org/mmj/DEAlawsuit.html
after the 1993 withdrawal of the licenses of five members of the Swiss Medical Association for Psycholytic Therapy (SaEPT), who practiced MDMA- and LSD-assisted psychotherapy for 5 years with few restrictions, we had to accept that future applications for licenses would be limited to the context of scientific research. In 2003, the Ethics Committee rejected a protocol developed by SAePT members to investigate the efficacy of psilocybin-assisted psychotherapy in recurrent depression.

In April 2005, my wife Verena Widmer and I visited MAPS President Rick Doblin, Ph.D., and MAPS-funded researchers John Halpern, M.D., and Michael Mojeiko, M.D., at MAPS and SaEPT, and in a short time we were able to adapt the MAPS standard protocol for MDMA/PTSD research to our study. The proposed pilot study will investigate the safety and efficacy of MDMA-assisted psychotherapy in 12 patients with treatment-resistant post-traumatic stress...