

MDMA-Assisted Psychotherapy in the Treatment of Posttraumatic Stress Disorder

a fourth update on the approval process and first report on study progress

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I said in my last update that one of these times my optimistic prediction was going to be right, and this is the time! I received my Schedule I Research Registration from the DEA on February 24, and have since received the MDMA. We have already created the MDMA and placebo capsules, as you may have seen on the ABC's *World News Tonight* feature story on our study that ran on the first of April. The DEA provided the final approval we needed to start the study. The other approvals have been the FDA approval (received in November 2001), the IRB approval (received in September 2003), and the South Carolina Drug Control approval (received in November 2003).

It has been a long process since I submitted my DEA application in early July 2002, but persistence finally paid off. Why it took so long for the DEA to process my application is not a trivial question. Whether from inefficiency or motivated by some agenda, inappropriate bureaucratic delay of legitimate research constitutes a serious interference with scientific inquiry. And this inquiry is, after all, directed at potentially relieving human suffering. In a free society, we should ideally be able to get an answer to this question. We may never have that answer; however, the regulatory system did work in the end, and for that I am grateful.

We have sent out letters to psychiatrists, psychologists, and other therapists in the area asking them to refer patients whom they think may qualify for the study. We have also had several inquiries from people who live in other areas and are willing to travel to Charleston to participate. We are finally under way!

Many of the final details have been completed. We have: assembled all the emergency drugs and medical equipment we need; furnished the room the subjects will stay in to make it a comfortable, welcoming, and aesthetically-pleasing place to be after an MDMA session; met with and trained the nurses who will act as attendants during the night after the experimental sessions; met with and oriented the emergency physicians and nurses who will be on duty for the first five hours of each session; and we will be meeting again with Amy Emerson who, as a volunteer, has helped us design the more than 50 different forms necessary for record keeping, and who will be coming to town periodically to monitor our compliance with documentation.

We've had a good response to our recruitment letters and from people who are either self-referred or referred by therapists from other parts of the country after hearing about the study in the media. As of this writing, we've done phone screening on over twenty people, many of whom are interested in participating.

THE FIRST SUBJECTS

Two subjects have been through the full medical and psychological screening process and have been enrolled in the study. They have both had their first experimental session during which they received either MDMA or placebo, with me and Annie present for eight hours. They subsequently had outcome measures repeated by the study psychologist (who is not involved in any of the treatment sessions and does not see the records from those sessions) four to five days after their experimental sessions. They also have been coming for weekly follow-up non-drug psychotherapy sessions with us as required in the protocol. Their second experimental session, during which they will receive the same substance they received in the first session (MDMA or placebo), will have occurred by the time this *Bulletin* is published. We have a third subject tentatively scheduled to start later this month, and several others who may participate but cannot start yet for various logistical reasons.

Because this is a double-blind study and because it is far too early to draw any conclusions from the data, I have nothing to report about the specifics of the sessions or the results of outcome measures. I can say that things are going smoothly with the study, and that the Data Safety Monitoring Board (two psychiatrists and a psychologist not otherwise involved in the study) met on April 28 to review the records of the first two subjects. The Board did not have any concerns about the safety of the subjects.

I am very pleased with the staff we've been able to assemble. The nurses are all people with high levels of compassion and experience. In particular, Amy has worked incredibly hard to bring her skills and experience from the pharmaceutical industry to bear on our study. Her participation has resulted in a level of documentation and monitoring exceeding that of much of the research done in academic centers. I have to admit that the number of forms boggled my mind at first, but now that we've gotten the hang of it they're extremely useful. And, of course, the MAPS staff is as tireless, dedicated, and effective as ever. I also want to acknowledge the people who volunteer for the study. I appreciate their willingness to go through the rigors of the evaluation process and all the other visits, knowing that it may or may not be helpful to them personally. Several have expressed their desire to contribute to research that could possibly help other people with PTSD in the future, regardless of the results for themselves.

Annie and I are very glad finally to have gotten started. There's still plenty of paper work and many logistical challenges involved, but now it all pertains to the experiences of actual people who are working to heal. The opportunity to support their efforts and to objectively evaluate a tool that may help us do that more effectively is a great privilege. •

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