

## MDMA/PTSD RESEARCH IN SPAIN: AN UPDATE

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On February 17, 2000, our research team, whose members are located at the Universidad Autónoma de Madrid and at the Hospital Psiquiátrico de Madrid, Spain, received approval from the Agencia Española del Medicamento (the Spanish Medical Agency, equivalent to the US FDA) for an MDMA psychotherapy study. The study, funded by MAPS, is designed to assess the safety of different doses of MDMA in a population with posttraumatic stress disorder (PTSD) in a psychotherapeutic setting. So far, we have treated just six patients. All patients tolerated the treatment well, and there were neither physical complications nor remarkable side effects during the experimental sessions. None of them developed any psychological disturbance or distress associated with the effects of the drug nor suffered any psychopathological reaction, and we had no drop-outs during the treatment phase.



Unfortunately, we are having some problems with the continuation of the study. I have always been reluctant to discuss this project with the media — at least until it was finished — because some politicians tend to think that any discussion of the therapeutic potential of illegal drugs diminishes the risk perception of casual users. They tend to view illegal drugs as

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necessarily more dangerous than prescription drugs, basing their ideas on unscientific notions. It is obvious that the risks of a drug are not defined by its legal status but by its pharmacological properties. Hence, no drug is free from risks, whatever its legal status. In fact, prescription drugs have higher indices of mortality than illegal drugs, which represent only about 20 per cent of all drug-related deaths. The key when we propose clinical trials is to have a good balance between risks and benefits, and in the case of MDMA treatment it is quite clear that one or two doses of MDMA administered in a clinical setting would have a very low health risk while the benefits for patients may be quite high. The abuse potential of one or two doses of MDMA is also very low.

But last May, the Spanish media reported the news that we were conducting a study in which we administered MDMA to treat PTSD. The next day, we suffered a rude and unexpected inspection from the Health Department of the State of Madrid. Though the Spanish Ministry of Health is responsible for approving clinical trials in Spain, the inspections are carried out by the health departments of each state, with prior notice being given to the researchers. We received no such notice. They also have one month to submit a report from the inspection, but it too was never sent. Obviously, the inspection was meant to intimidate us.

The day after the inspection, the manager of the Psychiatric Hospital of Madrid met me to say that he received pressure from the Vice President of the Health Department to stop the study. As we

were using the facilities of that hospital, the manager told us that they could not lend the facilities anymore. Nobody ever gave us a reasonable explanation about why the study should be stopped, but it seems that the Madrid Anti-drug Agency pressured the Vice President of the Health Department to stop the study saying that it is not in accord with their prevention campaigns, that there is no reason to think that MDMA has therapeutic properties, and that it can produce neurological damage. Obviously, they did not take into account the opinions of the Ethics Committee, which is quite capable of making a scientific and ethical decision. We sent letters to the Vice President of the Health Department asking for explanation, and phoned him several times,

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the Vice President of Health Department will not change his mind. I think that it is very worrying that politicians have stopped a well-designed project which had been approved by the scientific committees legally designated for that purpose. We are now working hard to resume the study, as we also look for ways of asking for political accountability. ■

but he never answered our letters or calls. Finally, the Rector of my University sent him a letter and the Vice President of the Health Department answered that the study could not continue — but without giving any rational explanation.

Though we still have all the permits in order, we have no place to finish the study, and I am afraid that



'Galileo facing the Roman Inquisition', by Cristiano Banti (1857)