maps • volume IX number 3 • 1999

MAPS

Bulletin of the Multidisciplinary Association for Psychedelic Studies

MAPS' long-standing efforts to conduct MDMA psychotherapy research have recently become much more difficult. You might expect that this is due to political obstacles restricting opportunities to conduct research. In the past, this has been the major source of difficulty MAPS has faced. However, after lengthy and persistent struggles, the FDA recently wrote to Dr. Charles Grob, Harbor-UCLA Medical Center, stating that it plans to approve a MAPS-sponsored protocol to investigate the use of MDMA-assisted psychotherapy in cancer patients, with the exact details of the protocol still to be determined and awaiting final FDA approval. Opportunities for MAPS-supported research into the use of MDMA psychotherapy in the treatment of post-traumatic stress disorder, though not approved, are looking promising in Spain and Israel.

Letter from Rick Doblin, MAPS President

MAPS' new difficulties result not from political obstructionism but rather from the success of the efforts to obtain FDA permission to conduct research! Now we have to address the inherent complexity of conducting rigorous scientific research into the specific methods by which MDMA can be used to treat clearly defined and meticulously measured aspects of psychological dysfunction. It is relatively easy to stand outside the scientific arena and proclaim that one has a wonder drug useful for this or that purpose, if only the powers that be would permit the necessary research. It is much harder to back up those claims with rigorously gathered scientific data when the doors to the laboratory are finally unlocked.

Naturally, it is a great relief to face these more difficult challenges after struggling for years and decades simply to obtain scientific freedom. Still, it is somewhat befuddling to be in such a position of opportunity. MAPS has been working since its founding in 1986 to obtain permission to study the therapeutic use of MDMA in cancer patients. On June 24, 1999, a teleconference took place between several FDA officials and a group working with MAPS. According to the memorandum of that teleconference prepared by the FDA, "The Center [FDA's Center for Drug Evaluation and Research, which is in charge of research on all new drugs for humans] has decided to allow the sponsor [MAPS] to undertake a proof of principle study..." Now we are faced with the exceedingly difficult question of how to measure exactly what MDMA can do to help cancer patients cope with their illness and impending death. Are we going to show change on standard measures of anxiety and depression, even though these tests have not been created to evaluate people facing death? How do we respond to the fact that the most appropriate measure of Quality of Life in terminal patients—the measure that explicitly evaluates a transcendent dimension related to changes in fear about and acceptance of death—is not yet scientifically validated for use in clinical research? Fortunately, the FDA is willing to let us start with a small pilot study with controls to determine what changes we are able to produce in a variety of measures.

Another promising development is that the FDA Office of Orphan Products Development approved MAPS' application to have marijuana declared an Orphan Drug for AIDS wasting (p. 19). As MAPS moves to initiate long-delayed research projects, your continued support will make all the difference. What a pleasure it will be to work together to address the difficulties that success has placed before us. — **Rick Doblin, MAPS President**

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