MDMA and the Treatment of Pain and Distress in Terminal Cancer Patients: A Preliminary Research Report

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WORK HAS BEGUN on the MDMA Phase II Protocol. The FDA has asked us to perform a preliminary assessment of our instruments with a small sample of terminal cancer patients. For this phase, it is our goal to test three or four subjects once a month for four months. Our first task was to select the maximum number of instruments already slated for the study while at the same time considering the physical and emotional stamina of this population.

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THIS PRESENTED an opportunity to scrutinize the instruments more carefully and with more specific questions in mind: How long would all these tests take? Do any of them overlap significantly in content? Are they accurate measures of the qualities we wish to assess? In the original protocol nine instruments were scheduled: four relating to pain (McGill Pain Questionnaire, Dallas Pain Questionnaire, Memorial Sloan Kettering Pain Card, Symptom Distress Scale) and five relating to psychological factors (Beck Depression Inventory, Brief Symptom Inventory, Brief Profile of Mood States -SR, Questionnaire Measure of Emotional Empathy, State-Trait Anxiety Inventory). As Jim McQuade, M.D. and I both have experience working with cancer patients, we were not only concerned about the feasibility of the testing but sensitive to the imposition of a test battery this extensive. Both Jim and Jeanne Achterberg, PhD. (our guided imagery consultant) strongly recommended we add an instrument which was not originally scheduled. The Functional Living Index: Cancer (FLIC) is a highly sensitive instrument for measuring quality of life specifically with cancer patients. Although there was a moderate degree of overlap among several of the pain questionnaires, it was ultimately decided to drop the Dallas Pain Questionnaire and replace it with the FLIC.

Among the psychological measures, we eliminated the Questionnaire Measure of Emotional Empathy (QMEE) because this index was essentially irrelevant to this preliminary investigation. In addition, upon re-evaluating the instrument, several of us concluded that it was not, in fact, measuring what we understood to be empathy, particularly in the context of MDMA research. In the *Journal of Personality* article describing its derivation, the authors (Albert Mehrabian and Norman Epstein) acknowledge two distinct definitions of empathy: the first a "cognitive role-taking approach" and the second a "vicarious emotional response". The QMEE was designed to measure the latter. Without either serious consideration or a careful examination of the specific questions in this instrument, a "vicarious emotional response" may appear to be a more profound experience of empathy than a mere "cognitive role-taking approach". Consider, however the following questions from the QMEE: "I become nervous if others around me seem to be nervous"; "I tend to lose control when I am bringing bad news to people"; "Seeing people cry upsets me"; " I cannot continue to feel ok if people around me are depressed". Is it *empathy* when we are engulfed by the emotions of others? How would a borderline personality score on this exam? Is the empathetic individual the →

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person who "loses control" or the person who can bear the other's pain with compassion and equanimity? As an MFCC Intern working with both individual clients and co-facilitating groups with cancer patients, this inquiry is both provocative and on-going. Our ultimate rejection of the QMEE led me to consult our research specialist, David Lukoff Ph.D., for a more meaningful instrument. He reported that one of his graduate students at Saybrook was also unable to find an appropriate scale and was forced to create his own instrument in measuring differences between an MDMA group and a shamanic drumming group and kindly forwarded that scale to us. (see page 25)

Having selected and formatted the eight chosen instruments, I first ran the battery on Charles Grob M.D., the principal author of the study while he was recuperating from minor surgery. We were both surprised to discover it took him only twenty-five minutes to complete the entire battery of tests. Even doubling that time, an hour or so of testing seemed like a reasonable expectation. Thus updated and optimistic we were ready, at last, to begin the actual testing.

On March 6, 1993, we began what continues to be an arduous search for subjects. Not only are there relatively few terminal cancer patients as a subject pool, participation in this phase of the study is an act of pure altruism. These subjects will not only fail to be exposed to MDMA, they are generally unfamiliar with its therapeutic potential. They are frequently grappling with physical pain, depression and dramatically reduced vitality. Consequently, they are agreeing to participate in a study based on a researcher's or psychiatrist's recommendation that this substance may benefit cancer patients somewhere down the line. Also, we inform them that their participation is making possible a study that is on the cutting edge of psycho-social support for cancer patients and has implications for further consciousness research.

Our first subject, a remarkable seventy-five year old woman with adrenal carcinoma came to us through a friend. Sarah (name changed) agreed to participate in the study out of pure altruism, an attribute I encounter frequently among cancer patients at my internship. It has been enriching spending time with her at this phase of her life where she is unwilling to squander her energy on the trivial or the superficial.

Shortly after Sarah's first round of testing we received a tape of guided imagery from Jeanne Achterberg, Ph.D. and Frank Lawlis, Ph.D. designed specifically for cancer patients. We decided to offer the tape to our subjects at the second round of testing and monitor its impact on the test results. After Sarah's second visit, however, she became quite depressed and physically uncomfortable. She passed the tape on to her cancer group at the Wellness Community and dramatically curtailed all her activities. When I called her to arrange our third meeting, she reported apologetically that she had neglected to fill out the daily pain card and had listened to the tape only once. She also asked that we postpone our next visit, hoping that her spirits and condition might improve. Sarah has reached the outside limit of her physician's prognosis and hopes that surpassing her "death sentence" will restore hope.

Our second subject was an equally remarkable young woman of thirty-seven suffering from metastic colon cancer. During our first visit she already appeared weak and emaciated but nonetheless felt quite determined to tackle the entire battery of tests. I believe in "Julie"'s case the motivation to participate in the study was as much intellectual curiosity and a desire to stay connected to the world as it was altruism. It took Julie approximately an hour and a half to complete six of the eight tests at which point we decided she had worked hard enough. When I called to arrange our second meeting I was informed that Julie was in the hospital. I called her there to say hello and she also reported, apologetically, that she was unable to fill out the daily pain card. A few days ago I received a phone call informing me that she had died.

From only these two subjects it becomes imminently clear how fragile this population is. Though I am happy to offer them an opportunity to be of service, I feel it is equally important to respond as quickly and as sensitively as possible to the very particular needs and considerations of individuals who are fighting to live or

coming to terms with death. Although Sarah was able to complete the daily pain card for the first forty days, I recommend that it be dropped from this phase of testing. No matter how many assurances I offer to the contrary I believe these subjects will feel they have let us down if they are unable to complete it. It seems appropriate to obviate that unnecessary guilt.

Upon this writing, Rick Doblin, MAPS President and coordinator of this study, informs me that the FDA has responded favorably to our concerns regarding this initial phase of preliminary testing. FDA has indicated a willingness to accept a shorter term follow-through with the terminal subjects as well as broadening the subject pool to include cancer patients with a year or two to live, rather than those already on death's door. We are all encouraged at this demonstration of flexibility and willingness to accommodate our needs even at this fledgling stage of investigation. •••

"Normal" Volunteers Needed for MDMA Research

No spinal taps but, sadly, no MDMA either. Subjects who volunteer for this study will be given preference to participate in subsequent studies in which MDMA may be administered.

Investigators at Harbor Hospital-UCLA Medical Center are interested in studying subjects with a history of past use of MDMA and/or LSD for possible evidence of MDMA neurotoxicity. This study is a very important investigation of the possible risks of MDMA. Data from this study will provide important evidence to compare to data from studies also being undertaken at Harbor Hospital-UCLA Medical Center in which small amounts of MDMA will be given to six medical professionals.

This study is formally known as a *challenge test.* Subjects will be administered either the drug fenfluramine or placebo in a randomized double-blind procedure and their blood will be sampled for evidence of the functioning of their neuro-hormone system, principally serotonin. Psychiatric interviews will also be conducted.

The challenge test takes between four to six hours and requires that subjects have a small needle inserted into an arm vein for about 4 hours. Small amounts of blood will be drawn intermittently throughout the challenge test. Subjects will need to participate in two tests, separated by about two to four weeks. Subjects must abstain from all drug use during the interim period. Subjects may volunteer to participate on weekends or weekdays, whichever is more convenient.

Three groups of volunteers are required with each group to consist of 20-30 subjects.

Group 1... people who have used MDMA at least 3-4 times.

Group 2... people who have used LSD, but not MDMA.

Group 3... people who have virtually no history of non-medical drug use other than alcohol or tobacco or caffeine. Note: This is a great opportunity for all the non-drug using readers of the MAPS newsletter to participate in MDMA research!

Anyone interested in possible participation in this research investigation of the long-term effects of MDMA should call Carla at (310) 222-1663.

Volunteering for this study is an excellent way to help MDMA research.

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Volunteers Needed for Study of Birth Trauma

I am a doctoral student at the Institute of Transpersonal Psychology conducting research in the area of birth trauma. I am seeking people who have personal experience with the resolution of their own birth trauma using any means (breathwork, psychedelics, ritual, etc.). If you would like to participate in an anonymous study utilizing a questionnaire and/or an interview, both phenomenological in format, please contact Anne at (510) 535-1534. Collect calls will be accepted. Copies of the completed dissertation will be given to the participants.