

Update on the **MDMA-Assisted Psychotherapy Study** for Treatment-Resistant Anxiety Disorders Secondary to Advanced Stage Cancer

WE HAVE BEEN WORKING for three years plus now to get this study active. MAPS was instrumental in the crucial initial phases of this project as long-standing MAPS members well know from our prior updates to the *MAPS Bulletin*. Though MAPS no longer has any direct role in this study or connections to my institution, this work remains of great interest (of course!) so I am delighted to provide MAPS with our latest news. This study, for those that aren't aware of it, is a pilot-study to evaluate whether MDMA-assisted psychotherapy can help treatment-resistant patients with an anxiety disorder secondary to their diagnosis of advanced stage cancer. If participation is complete, all subjects will receive MDMA on two separate occasions with eight of 12 (total) subjects receiving nearly-full to full doses of MDMA and the remaining four receiving very low doses that should then function as a control group.

We've made a lot of predictions already about timing, and the surprises to "speed bumps" that we've encountered along the way have pushed our start date into the future much further than I could ever have anticipated. But I will offer yet another prediction in this *Bulletin* and it is that we should see our first subjects enrolled in this study around the beginning of 2007, and should start the MDMA-assisted psychotherapy sessions in early 2007. Why so? Well, all government approvals are in place and remaining IRB items are few and minor. Before getting to this stage with our IRB, the review process has been (and continues to be) extremely careful and cautious: patient protections must be as perfect as possible and therefore many additional revisions required re-evaluation by a full IRB committee. The next anticipated review by a full committee should occur after five subjects complete their participation. Ongoing concern to ensure patient safety does result in many layers of careful scrutiny and over-

sight! In addition to myself, up to 10 other physicians are involved in conducting or monitoring this study.

From a clinical research perspective, this small pilot study could prove to be a fundamental building block for a line of research into clinical utilities for a drug that most Americans are only familiar with because of its illicit use as "ecstasy." The oversight issues therefore can be quite complicated and easily can result in periods of slow progression to study activation. But the need for this type of research is clear and especially so for patients who are further debilitated from clinical anxiety associated with end-of-life issues. We intend to find out if MDMA-assisted psychotherapy helps the dying in fundamental ways not achieved with standard approved treatments. With meaningful improvements to quality of remaining life, we have great hope for the promise of this therapy. Though substances like MDMA may be controversial because of their abuse liability and/or illicit use, research like we are attempting in this study should not be considered controversial. Why? Because the study is held to the best standards and methodology, FDA approval indicates as well that this work is in the public interest, and because physicians have an obligation to seek improvements in the care of patients. I am happy to report that our assembled research team will now face the greatest challenge of all because we will soon start to find out if we do, in fact, have something of compelling use for patients who struggle with anxiety as they face their mortality. When we publish our data, no matter the outcome, our efforts will, we hope, lead to improved options for these patients to choose from. Many thanks to MAPS for past direct support, continued "moral" support, and your continued advocacy and interest in realizing important clinical research that others might label impossible. 2007 is shaping up quite nicely. •



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