

MAPS-Sponsored Cancer Anxiety Research

Dr. John Halpern's Study of MDMA-Assisted Psychotherapy in Subjects with Anxiety Associated with Advanced-Stage Cancer

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OVER the last five years, MAPS has donated over \$94,000 to Harvard Medical School-affiliated McLean Hospital in a long-term effort to sponsor Dr. John Halpern's proposed research into the use of MDMA-assisted psychotherapy in advanced-stage cancer patients. This MDMA-assisted psychotherapy study is part of MAPS' overall strategy to become the leader in sponsoring research into both the risks and the benefits of MDMA (Ecstasy). In terms of studies into the risks of Ecstasy, one fruit of MAPS' support of Dr. Halpern over the years has been the initiation of the most methodologically well-designed study of the neurocognitive effects of MDMA, to take place in a population of subjects who had used Ecstasy numerous times with minimal use of other drugs. MAPS had brought information about and access to this population to the attention of Dr. Halpern and had donated in excess of \$15,000 to McLean Hospital for an initial pilot study in these subjects. The results of the pilot study were so promising that Dr. Halpern applied for and received a \$1.8 million, five-year grant from the National Institute on Drug Abuse (NIDA), with the grant application containing an acknowledgement of MAPS' support for the pilot study.

On January 19, 2006, we learned that the Drug Enforcement Administration (DEA) had issued the necessary license for Dr. Halpern's study of MDMA-assisted psychotherapy in advanced-stage cancer patients. This meant that final regulatory approval was in hand and the study could begin since additional approvals had previously been obtained in December 2004 from the Food and Drug Administration (FDA) and prior to that from the McLean Hospital's Institutional Review

Board (IRB), the IRB at the Lahey Clinic (where Dr. Todd Shuster, the oncologist who will refer subjects to the study, works) and the Massachusetts Department of Public Health. Yet just when it seemed that MAPS had achieved its long-sought goal of starting this study, it became necessary for MAPS to withdraw from further direct sponsorship of Dr. Halpern's research and from MAPS' parallel effort to sponsor research at McLean Hospital into the use of LSD and psilocybin in the treatment of people suffering from cluster headaches.

Immediately after DEA approval was obtained, I learned that the McLean Hospital administration felt that MAPS' long-term advocacy for MDMA psychotherapy research and general opposition to Prohibition would cause the results of the study to be challenged as biased if MAPS were to sponsor the study and that they did not want McLean to be involved in a study funded by MAPS. Therefore, I decided that it would be best for MAPS to offer to withdraw from further direct financial sponsorship of Dr. Halpern's research so that the study, which we had all labored so long to start, could proceed. Sacrifices sometimes need to be made. Instead of funding the study, MAPS plans to assist Dr. Halpern in contacting donors interested in giving support directly to McLean Hospital. We believe that this financial distance from MAPS, and more so the rigor of the methodological design of the study itself, will enable the results of the research to be viewed by skeptics as more objective. If the results of the pilot study are promising, MAPS will again explore options for the support of research at McLean Hospital. •

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