Final Data from MAPS Flagship MDMA/PTSD Prepared for FDA Submission—
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On June 22, 2009, preliminary data from MAPS’ flagship US Phase 2 study of MDMA-assisted psychotherapy in the treatment of PTSD was submitted to the US Food and Drug Administration (FDA). The preparation of the preliminary data was the initial step in preparing MAPS’ first-ever Final Clinical Study Report. Over the next two months the study’s database will go through final review and analysis. From this, MAPS will produce the final clinical study report containing a summary and analysis of all safety and efficacy data collected during the study. Submission of the final study report to FDA is the culminating step in completing a clinical study – this will be a monumental achievement in MAPS history!

The purpose of this process is to create a report acceptable to all regulatory authorities. The document will combine the clinical and statistical description, presentations, and analyses of this study’s data into a single report.

The completion of this study is one small step toward MDMA becoming a prescription medicine for use in psychotherapy.

MAPS Holiday Auction

MAPS is accepting donations of items for our holiday auction to take place in November. If you have an item to donate please contact Randolph Hencken at Randolph@maps.org or at 831-429-6368.

Israeli Medical Marijuana Moves Toward Independence After Years of MAPS’ Support

Over the past few years, MAPS has given financial support to several Israeli medical marijuana production facilities. This project has been primarily supported with help of one anonymous MAPS donor. There are a few Ministry of Health-licensed production facilities that have permission to grow medical marijuana. The producers must give the marijuana away to approximately 500 patients who have been approved by the Ministry to use marijuana for a variety of medical reasons. The growers in Israel are not allowed to sell their product. However, the prospects of being able to eventually sell the medicine for profit has attracted investors and several growing operations have applied to the Ministry of Health for permits to sell the marijuana. Consequently, MAPS is reducing, and possibly eliminating, our financial support since it appears that the producers are likely to be able to sustain themselves through investments rather than donations.

On July 1, 2009, the first version of the Israel Medical Marijuana database (shared by all Ministry of Health-approved medical marijuana growers, distribution centers, and patients) was released and demonstrated to the Israeli Ministry of Health. The database was built from a collaboration between Shlomi Vakin of Tel Aviv, Mimi Peleg of Wo/Men’s Alliance for Medical Marijuana (WAMM), and MAPS (with significant help from MAPS staff member Joshua Sonstroem) and was originally hosted on the MAPS website. The database has now been transferred to a server operated by the Israeli Ministry of Health.

The database is designed to collect information for the use of medical marijuana patients. The data will be used for future research into medical marijuana’s efficacy, benefits and risks, and the cost of medicines replaced by medical marijuana. This cost information is designed to determine whether there would be cost savings to the Israeli national health care system if marijuana is made available as a legal prescription medicine. The database is based on Open-EMR, an open source Electronic Medical Records software used in clinics worldwide for both clinic and patient management, and for collecting statistical medical information. The customized version of this program will be stored in English on the MAPS server for other medical marijuana projects to download, use, and modify.