September 14, 2011

Rick Doblin, Ph.D.
Multidisciplinary Association for Psychedelic Studies (MAPS)
3 Francis Street
Belmont, MA 02478

Dear Dr. Doblin:

The United States Department of Health and Human Services conducted a scientific review of your proposed study, "Placebo-Controlled, Triple-Blind, Randomized Crossover Pilot Study of the Safety and Efficacy of Five Different Potencies of Smoked or Vaporized Marijuana in 50 Veterans with Chronic, Treatment-Resistant Posttraumatic Stress Disorder (PTSD)." This review was to determine whether the proposed study meets prevailing scientific standards and whether the data obtained from the study are likely to be helpful in the evaluation of marijuana or marijuana-based medications. It is understood that you are not seeking funding from the Federal government, but rather are requesting a supply of research-grade marijuana to use in the study.

An important need is addressed through the proposed study: improved treatment for veterans with post-traumatic stress disorder (PTSD). However, a number of concerns were identified related to the proposal's approach, feasibility, and documentation of human subjects' protection. Some of these issues are presented below and they must be satisfactorily addressed in writing before approval can be provided for the research-grade marijuana you requested. Please note that the comments below are not exhaustive and that a re-review of the proposal by the review committee is not limited to these issues. More detailed information about the identified issues can be found on the attached copies of the reviewers' comments.

1. There was substantial concern about the research expertise and research support to perform this study. No principal or co-investigators with substantial research experience are mentioned. While Dr. Sisley's CV indicates that she is an experienced clinician, she lacks sufficient research expertise. Specific expertise in PTSD is also needed. There is no evidence of institutional support for the research or availability of an independent entity for data collection, management, and analysis.

2. The review panel had a number of concerns about the study design. The theoretical framework and justification for the complex study design need additional explanation. A simpler design might be preferable for this pilot study. There was concern about whether the study is adequately powered.

3. The study does not provide a basis for determining individual differences in efficacy, precluding predictive capacity for favorable responses. An analytic plan to assess individual differences would strengthen the potential value.

4. A number of safety concerns were raised. Some reviewers were concerned about the use of drug-naïve participants. Documentation of an IRB review was not submitted.

If you plan to submit a revised proposal, please forward it to my office for review. In addition, please contact me with any questions at sarah.wattenberg@hhs.gov.

Sincerely,

Sarah A. Wattenberg, MSW
Sr. Advisor and Review Committee Chairperson

Cc: Suzanne Sisley, M.D.