

February 14, 2003

Dr. James Bauer  
Independent Review Consulting, Inc.  
100 Tamal Plaza # 158  
Corte Madera, CA 94925-1418  
Ph. 415 485-0717

Dear Dr. Bauer,

I've received the bid from PPD Development for monitoring the MDMA/PTSD project, although I thought I was hallucinating when I read the message. Loren Miller was clearly correct when he said that the bid would be more than \$20,000, since it turned out to be slightly more than \$175,000!

PPD Development indicated that it would assign one of its staff CRAs (Clinical Research Associate) to do the monitoring. According to PPD Development, they would have a CRA work full-time for 10 months (assuming a 6 month recruitment period), though they also indicate that the CRA would be on-site for only 3-4 days every two weeks.

Clinical Research Associate (CRA) is Amy Emerson's exact title at Chiron Corporation. According to Amy, with whom I've discussed the PPD Development bid, there is virtually no additional work other than the on-site monitoring that would need to be done at the office and, given that there are only 20 subjects, there is nowhere near that amount of on-site work on the project. She says that CRO's, like many companies, often submit high initial bids that can be reduced through negotiation.

Amy said that one factor contributing to the high bid maybe the length of our case report form. We have included in the case report form a place to record all data to be gathered about each patient, including data from screening and various physical tests that will not actually become analyzable data related to outcome measures but just serves as basic screening and safety checks. As a result, Amy speculated that PPD Development may have concluded that the amount of data to be analyzed for outcome measures is much larger than it is and that their system of monitoring was estimated to be larger than it needed to be.

I subsequently discussed this with Loren Miller and he confirmed that the amount of the bid was directly related to the length of the case report form. He says that we could look more closely at the case report form to see if there was some data that we didn't really need to gather, and that a reduction in the case report form of about 1/2 would reduce their bid by about 1/3. Loren reiterated that although PPD Development would appreciate our business, he didn't think the sort of monitoring that would be provided by PPD

Development was necessary until we reached the stage of Phase III trials. He also said that the system of data gathering and monitoring that we have proposed to be conducted by Dr. Mark Wagner and Amy Emerson seemed sufficient for this pilot study.

At present, there is one FDA-approved psychedelic pilot study being conducted in patients in the United States. This study is examining the use of psilocybin in Obsessive-Compulsive Disorder (OCD) patients, and is being conducted by Dr. Francisco Moreno, U. of Arizona, Tucson. MAPS is a co-sponsor of that study, with the Heffter Research Institute (HRI). Dr. Moreno's study is being conducted without the involvement of a CRO. A new psychedelic psychotherapy study, to be conducted by Dr. Charles Grob at Harbor-UCLA Medical Center, will involve the use of psilocybin in cancer patients with anxiety. This study has been approved by the FDA and is already in the second round of the IRB process. Dr. Grob has informed me that the IRB is nearing approval and has not asked for the involvement of a CRO for that study.

As outlined in more detail in the letter of Feb. 10 that MAPS submitted to the IRB, I propose that the IRB consider sufficient the independent and blinded screening and data gathering to be conducted by Dr. Mark Wagner and the professional monitoring to be provided by Amy Emerson on a volunteer basis (with only travel expenses to be covered by MAPS).

Sincerely,

Rick Doblin, Ph.D.  
MAPS President