WESTERN INSTITUTIONAL REVIEW BOARD ®
WESTERN INTERNATIONAL REVIEW BOARD ®
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September 6, 2002

Michael C. Mithoefer, M.D.
208 Scott Street
Mt. Pleasant, SC 29464

Dear Dr. Mithoefer:

SUBJECT: BOARD DISAPPROVAL OF RESEARCH
Multidisciplinary Association for Psychedelic Studies (MAPS) Protocol #63-384
WIRB #20021019/1040339

At the meeting of September 4, 2002, Western Institutional Review Board (WIRB) considered the above-referenced research (approved July 10, 2002) at the request of a WIRB-affiliated Board member physician.

The purpose of this letter is to inform you of the action taken by the Board.

Upon reconsideration of its prior approval, WIRB voted **to withdraw approval** for the research.

The Board considered the information presented at its September 4 meeting as representing a significant change in the information the Board had relied upon in making its prior decision. This information included the following:

1) The investigator's brochure (IB) was compiled by three authors about whom there is insufficient or no information to assess their professional expertise and qualifications regarding the research. The IB minimizes the known toxicity of MDMA reported by other sources.

2) The IB inappropriately references the study as coming out of the Medical University of South Carolina (MUSC). Neither this study nor any other studies involving MDMA have been submitted for review through the MUSC IRB. Dr. Mark T. Wagner is identified as a sub-investigator in the study. By the MUSC's own research regulations, the study is therefore subject to MUSC IRB oversight and would need to go through review with the MUSC IRB.

3) In a contact with Dr. Bryan Roth, project director of the National Institute of Mental Health's Psychoactive Drug Screening Program, he stated that he is opposed to any further human studies using MDMA. In addition to known neurotoxic effects, research on MDMA by Dr. Roth and others is discovering evidence of adverse cardiac valve effects.

4) Work by Dr. Una McCann out of Johns Hopkins University is referenced in the study IB. In a contact with Dr. McCann, she revealed her reservations about subject safety if MDMA research were to be conducted out of a private office as submitted for this study. Dr. McCann reiterated that MDMA, as an amphetamine derivative, is the only psychedelic with neurotoxic effects. She further stated that there is no scientific evidence that MDMA has therapeutic effects—there are only unsubstantiated anecdotal reports.

5) Dr. David Nichols at Purdue University was designated the supply source for MDMA; however, information about this source of MDMA was not provided with the IB. A DEA Form 222 is required before Dr. Nichols can release the MDMA for this research. As the principal investigator, you cannot perform this research until you have been issued a DEA Schedule I license.

The Board concluded that MAPS appears to have presented information about MDMA for purposes of this research in a manner that omits significant facts and that uses information in ways that are overly reassuring regarding the risk/benefit analysis. Based on the additional information considered at the September 4 meeting, the Board concluded that both the sponsor and yourself appear to lack the scientific objectivity and rigor required to carry out this research and that the research presents unacceptable risks to subjects. The Board's decision derives from its responsibilities to protect "the rights and welfare of human subjects"; to ensure that the "risks to subjects are reasonable in relation to anticipated benefits"; to conduct ongoing review; and, when appropriate, to terminate approval of research. See 21 CFR 56.101(a), 56.111(a)(2), and 56.113.

You are directed to immediately terminate all research activities based on WIRB's July 10, 2002, approval of this study, including, without limitation, any subject recruitment or enrollment. To expedite communication this letter is being sent by facsimile with original to follow.

You may address WIRB in person or in writing regarding its actions. If you wish to address the Board in person or if you have questions, please contact WIRB's Executive Director, James R. Baldwin, Ph.D.

Sincerely,

Ronald Glass for

William C. Jacobs
Chairman

WCJ:MC:slh
W:\Documents\Correspondence\withdraw\mithoefer 20021019
By fax to 843-884-3010
By Airborne Express - #3070 945 2211
cc: Richard E. Doblin, Multidisciplinary Association for Psychedelic Studies
Division of Scientific Investigations, CDER/FDA
Theodore D. Schultz, WIRB Panel Three Chair – via e-mail