November 18, 2002

Dear Dr. James Baldwin,

I'm sending you this letter in advance of tomorrow's meeting of the WIRB's Executive Policy Committee (EPC), which you have informed me will decide whether or not the WIRB will continue to review protocols involving Schedule I drugs. I'd appreciate it if you could show this letter to the members of the EPC since the meeting was called as a result of MAPS' FDA-approved protocol for the use of MDMA in the treatment of posttraumatic stress disorder (PTSD), which the WIRB is in the midst of reviewing.

Israeli Ministry of Health Interest in EPC Decision

I've just returned earlier this morning from Israel, where MAPS had organized a seminar for members of the Israeli Ministry of Health, the Israeli Society of Addiction Medicine and the Israeli Anti-Drug Authority. The seminar focused on MDMA risk assessment, Ecstasy harm reduction, principles of MDMA-assisted psychotherapy in the treatment of PTSD, and protocol design for a proposed MAPS-supported pilot study to be conducted in Israel into the use of MDMA-assisted psychotherapy in the treatment of war and terrorism-related PTSD. I shared with the Israeli Ministry of Health the entire correspondence between MAPS and the WIRB, as well as the information about the WIRB's upcoming EPC meeting. I'd appreciate it if you could send a copy of the decision of the EPC via email to Dr. Jorge Gleser, Deputy Director Mental Health Services, Director Department for the Treatment of Substance Abuse, Israeli Ministry of Health, at: jorge.gleser@moh.health.gov.il

US and International Policy Regarding Schedule I Drug Research I received no guidance in response to my inquiries requesting information about the specific policy issues to be discussed by the EPC. As a result, I've not sent any letters of information/support regarding the value of research with Schedule I drugs in general and MDMA in particular. What follows instead is a very brief review of federal policy regarding research with Schedule I drugs which may be of some use to the EPC.

In 1992, FDA's Drug Abuse Advisory Committee met to evaluate FDA policy regarding research with Schedule I drugs. The Committee concluded that 1) drugs with an abuse potential could also offer significant therapeutic advantages when used in controlled medical contexts, 2) the risks of research with Schedule I drugs could be adequately evaluated and controlled by FDA's standard scientific review procedures, and 3) clinical research with Schedule I drugs should be permitted. The FDA adopted the recommendations of the Drug Abuse Advisory Committee and over the last decade has approved protocols with MDMA, psilocybin, mescaline, ibogaine, heroin and marijuana, among others. (More detailed information about the Committee's meeting and recommendations can be found in my 2001 Ph.D. dissertation for the Kennedy School of Government, Harvard University, at: http://www.maps.org/dissertation/).

In addition, research with Schedule I drugs is explicitly encouraged by the White House Office of Drug Control Policy, the Drug Enforcement Administration, the

National Institute on Drug Abuse, and all international drug control treaties to which the US is a party.

MAPS' Oct. 11 Submission to FDA of Dr. Bryan Roth's Unpublished Data

I understand that the EPC is not meeting to review any of the scientific issues related to MAPS' MDMA/PTSD protocol. Nevertheless, the EPC may still be interested in knowing that on October 11, 2002, I submitted Dr. Bryan Roth's unpublished data about MDMA's effect on heart tissue directly to FDA, as an addendum to MAPS' IND. Dr. Roth had previously tried to contact Dr. Russell Katz, Director of the Division of Neuropharmacologic Drug Products, to discuss his data but had received no reply. I submitted Dr. Roth's data along with a letter from Dr. John Mendelson, the NIDA-funded UC San Francisco researcher who has conducted the only study in the scientific literature in which echocardiograms were administered to frequent recreational users of MDMA (I also submitted Dr. Mendelson's letter to the WIRB on October 10). In my cover letter, I expressed a willingness to add echocardiograms to MAPS' protocol if the FDA decided to request it, but stated that neither Dr. Mendelson nor Dr. Mithoefer thought that adding echocardiograms was necessary. Five weeks have passed and FDA has not as of yet contacted me to request echocardiograms be added to the protocol.

Conclusion

It is my hope that the EPC will decide that there is no compelling reason why the WIRB should opt out of reviewing research with Schedule I drugs. If that is the decision of the EPC, Dr. Mithoefer and I would be available to come to meet with the WIRB panel at the earliest convenient date so that we can swiftly return to discussing the core scientific issues involved in MAPS' MDMA/PTSD protocol. The therapeutic potential of MDMA may be considerable, and deserves to be evaluated in the context of rigorous, double-blind, placebo-controlled studies, such as MAPS' FDA-approved protocol.

Sincerely,

Rick Doblin Ph.D.
MAPS President