WORLDS OF CONSCIOUSNESS RESEARCHERS

by Rick Doblin, MAPS President

The ECSC is the unifying organization in Europe for psychedelic researchers

IN MY CAPACITY as president of MAPS, I had the pleasure of attending the first international conference of the European College for the Study of Consciousness (ECSC) in late September, 1992. The conference was held in the small University town of Gottingen with its ancient churchs and elevated walls and wooded paths encircling the inner city. Rather than describe the conference itself (see related story on page 14), I will discuss instead what came out of the conference for MAPS.

To distribute to the conference attendees, I brought 500 copies of the latest MAPS newsletter reporting the good news that the FDA Drug Abuse Advisory Committee had specifically recommended that MDMA research in humans be approved and that psychedelic research in general be resumed. This news, I hoped, might help researchers around the world to negotiate successfully with their governments for the resumption of comprehensive psychedelic research.

In a series of conversations I had with Dr. Hanscarl Leuner and Michael Schlichting, conference organizers and founders of the European College, it became clear to me that government regulators in most of Europe were unwilling to approve MDMA research until the FDA had approved human studies in the US. In the only country where limited psychiatric use of MDMA research is approved, Switzerland, political support is weak (see pages 21-23). It also became clear to me that the ECSC is indeed the unifying organization in Europe for psychedelic researchers and that Michael Schlichting and Dr. Leuner had both the depth of experience and the well-earned respect of their colleagues to successfully coordinate the conference as well as the efforts of the researchers to get back into their laboratories to study how psychedelic research could help in understanding the human mind and soul.

Because the FDA has finally permitted human studies with MDMA (see protocol on pages 2-3), MAPS is now in a position to make a uniquely valuable contribution to members of the ECSC interested in securing their government's permission to conduct MDMA research. MAPS' contribution is one that only a non-profit organization would consider, since it involves giving away its most valuable asset in the attempt to stimulate MDMA research in other countries. Because MAPS is not a profit-making corporation with proprietary interests to protect, and because MDMA research in other countries will help to build the data base necessary to eventually secure FDA approval for prescription access to MDMA, MAPS gains by giving away monopoly ownership of its MDMA toxicity studies.

For those of you new to MAPS, or for those who don't recall what I am talking about, I am referring to the 28-day multiple dose MDMA toxicity studies in the dog and the rat that MAPS used in 1986 to open an FDA Drug Master File for MDMA. Today, the studies would cost about $100,000 to duplicate. Data from the studies is owned exclusively by MAPS and only those researchers who specifically get MAPS' permission may use the data as part of their applications to the FDA to conduct human trials.

THESE STUDIES were a prerequisite to the FDA's consideration of Phase 1 studies (preliminary evaluation of safety in humans) and Phase 2 studies (preliminary evaluation of efficacy in humans). Because of FDA's concerns over neurotoxicity, MAPS' toxicity studies were not sufficient to secure FDA approval for human studies even though they showed no evidence of neurotoxicity. It took seven years of MDMA neurotoxicity research, funded by millions of government dollars, and an additional, strategically directed $100,000 from MAPS, before the FDA was willing to approve the first study of MDMA in humans. MAPS' toxicity studies were neccesary but not sufficient to secure FDA approval for MDMA research. In many countries, regulators require similar data.

A very important decision for MAPS emerged from the conference. Once I finally understood the role of the ECSC, and saw what a remarkable organization it was, I decided to give it an FDA-certified copy of the contents of the data in the MAPS Drug Master File as well as

legal rights to the use of that data. The ECSC is being assisted by MAPS to catalyze MDMA research in Europe and is given a head-start in developing a data base that it might use to have MDMA declared a prescription drug in Europe. In return, the ECSC is asked to inform MAPS about data generated by European studies. As soon as MAPS receives from the FDA a certified copy of the contents of our Drug Master File, I will forward the paperwork to Dr. Leuner and Michael Shlichting and they will begin the attempt to assist scientists to conduct MDMA research in Europe.

The researchers in Germany who seem most likely to conduct MDMA research are Drs. Euphrosyne Gouzoulis of the Department of Psychiatry on the Medical Faculty of the RWTH in Aachen and Dr. Leo Hermle of the Department of Psychiatry at Christophsbad in Goppingen. They have conducted rigorous studies into the physiological and psychological effects of MDE, the results of which will be reported in the next MAPS newsletter. Their studies were conducted before MDE was scheduled in Germany. Now that MDE is scheduled, the lack of preclinical animal studies hinders further research. Sasha Shulgin and I suggested to them that MDMA is subtlely but profoundly different than MDE, and therapeutically more useful, and we encouraged them to seek approval to investigate it.

Dr. Franz Vollenweider of the University of Zurich is a Swiss medical researcher who spoke at the ECSC about his work conducting PET scans of people under the influence of ketamine and psilocybin (see page 18-20). Hopefully, he will eventually get permission to conduct PET research with MDMA. Also in attendence was Dr. Hans-Jorg Helmlin, a researcher at the University of Bern who was planning to conduct an MDMA pharmacokinetics study in two patients in mid- October. Dr. Helmlin had previously looked for MDMA metabolites in human urine and was going to follow up that research with an investigation of blood samples. Dr. Helmlin's research will help guide Dr. Grob's Phase 1 MDMA study in that we will take blood samples at the time of the peak concentration of MDMA metabolites, as first determined by Dr. Helmlin. I also met Ulrike Drews, a Swiss Ph.D. student in clinical psychology who is considering doing her dissertation on the use of MDMA and LSD by Swiss psychiatrists (see story on pages 21-23). I gave Ulrike a copy of the MAPS protocol for the use of MDMA in the treatment of pain and distress in end-stage cancer patient; we hope to confer on research design and methodology issues.

TWO observations about terminology. The Europeans seem to have wholeheartedly adopted the idea that MDMA and MDE are part of a new class of drugs and that the word to describe that class is "entactogen", created by Dr. David Nichols of Purdue University to mean "to touch within." Personally, I applaud this idea. I prefer "entactogen" to the alternate term "entheogen", meaning "to reveal the god within", which ignores the role of set and setting in creating the drug experience and the potential of these drugs to catalyze problematical, unpleasant experiences. I also prefer "entactogen" to "empathogen" which is too positively loaded to be scientifically precise. The second linguistic issue was that the European researchers often spoke about psychedelic experiences as "model psychosis," a term that deserves abandonment along with the term "hallucinogen", since however politically expedient those terms may be they both imply that psychedelic experiences can be discounted as crazy and distorted. The word "psychedelic", meaning "mind-manifesting", is still the best.

Above all, the ECSC conference demonstrated the critical importance of international cooperation in psychedelic research. The conference was extraordinarily successful and may be followed next year by a smaller meeting on research methodology. ■

MAPS is giving the ECSC legal rights to its FDA MDMA Drug Master File