Animal data demonstrates administration of Prozac completely blocks MDMA's neurotoxic effect, even when a single dose of Prozac is taken up to 6 hours after MDMA.

Conclusions of MDMA Neurotoxicity Researchers

Drs. Lewis Seiden and George Ricaurte expressed a deep reluctance to support the human use of MDMA in any patient population due to the uncertain and very narrow range of doses that would be both low enough to produce no neurotoxicity and high enough to produce a therapeutically desired outcome. The threshold level of MDMA in primates needed to cause some neurotoxicity was in the range of a single oral dose of2.5 - 5.00 mg/kg. Due to the wide range of variability of response in humans, it is therefore possible that doses of 1.5 mg/kg (around the therapeutic dose) will cause some neurotoxicity in humans, however slight.

Dr. Ricaurte was also concerned by new evidence demonstrating that the previously observed recovery of damaged serotonin nerve terminals was only a temporary phenomenon, with gains in serotonin levels plateauing after four months and dissipating over the next year or so. Even though evidence demonstrates administration of fluoxetine (Prozac) completely blocks MDMA's neurotoxic effect, Dr. Ricaurte was generally uncomfortable with polypharmacy, especially in research contexts.

Drs. Lewis Seiden and George Ricaurte expressed a deepened understanding of the range and number of the anecdotal reports of MDMA's therapeutic potential and suggested a vigorous research effort to find compounds that lacked MDMA's neurotoxic potential yet retained its therapeutic qualities. Balancing the risks and benefits, Drs. Seiden and Ricaurte expressed fewer reservations about well designed human studies with patients with terminal illness. They recognized that there are still no cases in the literature of any individuals suffering from significant observable adverse neurological consequences from possible MDMA neurotoxicity. Non-subtle consequences of neurotoxicity, if there actually are going to be any, might take at least fifteen or twenty years of use to develop. They indicated a strong possibility they would support a well designed study in terminal patients that limited MDMA to oral doses around 1.5 mg/kg and limited number and frequency to four or five exposures with two weeks or more between sessions.

Purpose of Protocol Review Committee

This volunteer group will be composed of psychiatrists, neurologists, brain researchers, psychologists, and past government regulators not all from the community of previous supporters of psychedelic research. This group would ideally but not necessarily convene in one location. They would evaluate the MDMA protocol for methodological shortcomings, suggest improvements, suggest outcome measures that were valid cross-culturally, and assist in the political process of securing permission to conduct such studies.

Since the FDA would probably assemble a similar advisory committee to review the protocol, it would be beneficial to have a committee of equal reputation review and improve the experimental design before submission. With a committee of sufficient expertise and reputation, the FDA may feel comfortable approving the protocol without the need of convening their own advisory committee. If this occurs, the use of MDMA in human studies may be able to begin up to a year sooner.

Since it is hoped that this area of research will grow substantially over the years, creating an expert committee experienced in reviewing protocols might also improve the overall quality of subsequent research and ensure the wise use of MAPS resources in the future. In the development of MDMA into an approved medicine, fiscal efficiency is of utmost importance.

Overall, the conference was successful beyond the expectations of most participants. A new-found sense of cautious optimism regarding the development of this field is at hand.