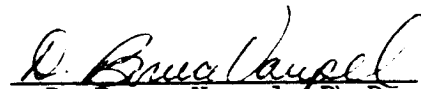


same type of psychedelic effects as seen with other drugs of this class, e.g. LSD and mescaline. Further, young drug users could not differentiate the effects of MDA from other psychedelics. Additional data provided by Richards suggests that MDA may have a relatively low safety factor since severe MDA responses were observed at dose levels only slightly greater than three times those administered in the clinical study of Naranjo, C., Shulgin, A.T. and Sargent, T. (Med. Pharmacol. Exp. 17:359-364, 1967 (exhibit 4)). These clinical data for racemic MDA have indicated a pharmacology characterized by sympathomimetic and, quite likely, LSD-type effects which vary according to the dose. In my opinion these data are consistent with the animal data presented in this deposition. Thus, although MDA may well represent a new class of drugs, it appears to possess attributes of both LSD and d-amphetamine, qualities which make it desirable as a drug of abuse or recreational use. Because MDMA represents only a relatively minor change in the structure of MDA, it is reasonable to be concerned that MDMA could share some pharmacologic actions in common with MDA. It is also reasonable based on the animal data, that the isomers of MDMA may have different pharmacologies.

Arguments for a specific and unique action of MDMA and particularly S(+) MDMA are based on clinical data which must be considered with circumspective interpretation. Evidence that S(+) and R(-) MDA elicit different subjective effects is available only as a personnel communication. Human data for the isomers of MDMA is presented in reference 19 of Dr. Nichols' statement, but the article presents no definitive data about subjective effects that can be assessed by scientific review; only levels of "intoxication" are shown. The statement concerning the lack of cross tolerance between MDA and MDMA (Nichols' reference 19) is not supported by one iota of data, details or other references. A demonstrable lack of cross tolerance between MDA and MDMA is critical evidence in ascribing different modes of action to these drugs. The statement concerning demonstrated cross tolerance almost amounts to hearsay evidence.

Succinctly stated, there does not appear to be adequate clinical dose-response data for either racemic MDMA or its isomers available to make a definitive conclusion concerning its pharmacologic classification, especially if it is not rigorous and seriously suffers from a lack of controls (i.e. placebo condition, standard or prototype drugs such as LSD, mescaline or amphetamine) as well as adequate techniques for measuring and quantitating subjective mood or feeling states. By analogy to MDA, there is the likelihood that the relative safety of MDMA in terms of doses producing the desired subjective effects to those which are toxic may be low and may present problems in the area of the recreational drug use of MDMA and to psychiatrists employing MDMA as a treatment adjunct. There is a need to schedule MDMA in my opinion, but I do not feel that the placement of MDMA in a less stringent schedule based on a unique pharmacology in humans is warranted by the evidence.

I declare under penalty of perjury that the foregoing statement is true and correct. Executed on May 17, 1985.


D. Bruce Vaupel, Ph.D.