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Administrator  
Drug Enforcement Administration  
1405 I Street, N.W.  
Washington, D.C. 20537

Attn: DEA Federal Register Representative.

Dear Sir:

It has recently come to my attention that a proposal has been made (Federal Register 49 #146, July 27, 1984) to place 3,4-methylenedioxymethamphetamine (MDMA) into Schedule I of the Controlled Substances Act. This letter is in response to your request for comments.

This unusual compound was first brought to my attention some ten years ago as a possibly valuable tool for therapeutic use without appreciable hallucinogenic or "psychedelic" side-effects. Calling upon the early toxicology and pharmacology studies at the University of Michigan (Hardman et al., *Tox. and Appl. Pharmacology*, 25 299 (1973)), I collaborated with Dr. D.E. Nichols at Purdue University in the definition of additional pharmacological and preliminary psychopharmacological properties of MDMA. These studies appeared in The Psychopharmacology of Hallucinogens, Eds. Stillman and Willette, Pergamon Press, New York, (1978) pp. 74-83. We reported there that MDMA, lacking any hallucinogenic component, indeed resembled low levels of MDA. The differences between MDMA and MDA became striking at effective levels, where MDA presented its well-known "psychedelic" profile, while MDMA remained free of such side-effects. These properties were detailed in two papers which I co-authored with Drs. Braun and Braun, at Bonn University (Braun et al., *J. Pharm. Sci.*, 69 192 (1980) and Braun et al., *Arzn. Forsch.* 30 825 (1980).

I should like to comment upon the three findings that have been extended as the arguments for placing MDMA in Schedule I of the Controlled Substances Act.

(1) MDMA has a high potential for abuse. I cannot argue against the statement that there is the potential for abuse of MDMA. In the early clinical studies which had been relayed to me from psychiatrists and practitioners, I truly felt that this drug, being largely free of the sensory disturbances so characteristic of the known hallucinogenics, might not appeal to the sub-culture which sought recreational drug use. But in the last year or two, paralleling the expansion of use of MDMA in the medical community, there has been a growing misuse and abuse incidence. I feel that the potential for abuse, which may still be small, is nonetheless quite real.

(2) MDMA has no currently accepted medical use in treatment in the United States. This is simply not correct. I have been in direct communication with perhaps a score of physicians who have become sufficiently impressed with the value and safety of MDMA to have built much of their psychiatric practice about its use. From their comments, I might assume that the number of clinical environments that employ MDMA in some form in therapy, in the United States as well as in England and Germany, may well number a thousand at the present time. These are uses in proper medical practice, conducted within the framework of the accepted practice of medicine. And, the impressions that I received from therapists at a recent conference (The Association for Humanistic Psychology) at Boston, suggest that a tally of professional psychologists who have benefited from the use of MDMA in their own practice might swell this number to several times a thousand.

(3) There is a lack of accepted safety for the use of MDMA under medical supervision. This is a difficult comment to answer. One cannot accurately know the total extent of MDMA use, either clinically or recreationally. I would not be surprised if I were to learn that the person-exposure incidence exceeded one million examples. The risk factor is equally unavailable. There has been one death that clearly occurred within the time-frame of MDMA exposure. There have been as many as three others that may have been associated with MDMA use. I have not yet been able to collect sufficient facts to evaluate these statements. Further, I do not have sufficient experience to fairly evaluate the reward-to-risk ratio that justifies the continuing employment of an apparently valuable medicine. I can only say that I have heard of no immediate complications from the psychiatrists with whom I maintain some contact.

I truly hope that some hearings might be granted, to allow a balanced presentation to be made for the final disposition of MDMA. I believe that it should be scheduled, as it has been shown to have some real abuse potential. But it may best be scheduled in some intermediate category, perhaps Schedule 3, as it has unquestioned medical utility. An intermediate position

such as Schedule 3 would in no way impede the DEA in controlling and eliminating illicit laboratories and illegal trade in improper MDMA, but it would enormously simplify the tasks of the several medical researchers who are presently seeking out IND approvals and research protocols within the FDA.

It would be difficult for me to attend the proposed hearings on this matter during the forthcoming Fall semester, as I am committed to my classes at the University of California. Dr. Nichols might be available to attend any needed hearings. However, if I could provide any further information, I would make every effort to attend any forum where I might be able to present additional factual data.

Sincerely,



Alexander T. Shulgin, Ph.D.  
Scientific Consultant

CC: Dr. R. Ingrasci, Pres. AHP  
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