

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of)
)
MDMA SCHEDULING) Docket No. 84-48
)
_____)

REBUTTAL TESTIMONY OF EDWARD CHARLES TOCUS, Ph.D.

I, Edward Charles Tocus make the following statement:

I have reviewed the direct testimony submitted by Robert DeBois Lynch, M.D., Joseph J. Downing, M.D., and Zofia Dziejwanowska, M.D., Ph.d. in the above captioned matter.

The Food and Drug Administration received the letter concerning application for an IND for MDMA from Dr. Lynch which he discusses in his testimony. On April 22, 1985, the Food and Drug Administration responded to Dr. Lynch (See Exhibit I.) This letter to Dr. Lynch explains the IND process and suggests that he consult with a firm that is familiar with the IND process and the data necessary for IND approval. Dr. Lynch was also provided with application forms for an IND. Although Dr. Lynch believes that MDMA is a potentially useful therapeutic agent, he provides no scientific data to demonstrate that MDMA has the effect that he and other investigators have alleged.

Dr. Joseph Downing indicated in his testimony that he supervised a "psychophysiological study of MDMA." Attached to his testimony was a paper entitled, "MDMA Pilot Study-Physiological, Psychological and Sociological Summary of

paper being prepared for publication," which represents itself as bearing upon the safety and effects of MDMA use in humans. This "study" presents no data or evidence to support a conclusion that the substance MDMA is safe or effective. The study protocol was not designed to allow conclusions of safety or effectiveness. There was no control group to compare with those who were ingesting the MDMA. Only previous MDMA users were asked to participate. The dose of MDMA was controlled by the participants in the study, and not by those conducting the study. The fact that the majority of the subjects were users of psychoactive drugs, including 49% who were current users of cocaine and 56% who were current users of marijuana distorted any results that may have been observed. The physical data that was gathered was not complete for all subjects. For example, complete blood chemistry and blood count samples were not obtained. No fasting from food or drink, or abstinence from drugs, preceded the administration of MDMA and subsequent blood chemistry. Complete blood cytology studies were not conducted because "delays in refrigeration rendered the specimens useless." Subjects were asked to evaluate the health effects of MDMA on themselves. Evaluation methods for the behavioral effects were not described.

This study does not provide any useful evidence concerning the safety or effectiveness of MDMA use. There was little if any valid scientific evidence obtained as a result of this study, only anecdotal remarks which have little scientific value. I concur with the experimenters closing remarks: "there is insufficient evidence to judge accurately either harm or benefit."

I have also reviewed the statement of Zofia Dziewanowska, M.D., Ph.D. concerning "currently accepted medical use in treatment in the United States." I agree that substances which are in the IND and pre-IND developmental stage may have a potential for medical use in treatment in the United States. These substances cannot be said to have an accepted medical use until they have been approved for marketing. The Food and Drug Administration generally does not recommend substances for scheduling until the completion of the NDA process. Benzodiazepines such as alprazolam and halazepam and anorectics such as mazindol, fenfluramine, and clortermine are examples of substances with abuse potential which were not recommended for control by the Department of Health and Human Services until the New Drug Application (NDAs) were approved. However, due to the United States treaty obligations, actual abuse of a substance, or the fact that a substance is controlled by virtue of its status in relation to a controlled substance, i.e. thebaine derivative, a

substance in the IND or pre-IND stage may be classified as a controlled substance. However, once the NDA for such a substance is approved, the substance is recommended for scheduling in Schedule II, III, IV or V depending upon its relative potential for abuse. An example would be the rescheduling of sufentanil from Schedule I to Schedule II in May, 1984. At the IND or pre-IND stage, a substance will not be recommended for control based solely upon its potential for abuse absent any actual abuse of the substance.

I declare under penalty of perjury that the foregoing statement is true and correct. Dated May 16, 1985.


Edward Charles Tocus, Ph.D.

APR 22 1985

EXHIBIT 1

Robert DuBois Lynch, M.D.
1030 Pearl Street
Suite One
La Jolla, California

Dear Dr. Lynch:

Your letter dated March 10, 1985, which was directed to the Division of Scientific Investigations requesting a Notice of Claimed Investigational Exemption for a New Drug (IND) to study MDHA (3,4-methylene-dioxymethamphetamine) has been referred to the Division of Neuropharmacological Drug Products.

In general, to apply for an IND you must complete the enclosed forms and submit a study protocol and chemistry information (as directed in Form FDA 1571). We also refer you to the enclosed brochure, "Clinical Testing for Safe and Effective Drugs", which may assist you in completing your application.

We regret that we are unable to design your protocol, train physicians, or participate in any phase of the investigation except for the review of your submission. We suggest you contact a consultant experienced in protocol design to assist you in these phases of your IND.

If you have any questions concerning the IND process, please contact Ms. Laurie Macturk, Consumer Safety Officer, at (301) 443-4020.

Sincerely yours,

JSP 4/19/85

John S. Purvis
Supervisory Consumer Safety Officer
Division of Neuropharmacological
Drug Products
Office of Drug Research and Review
Center for Drugs and Biologics

RECEIVED
MAY 14 5 19 PM '85
OFFICE OF DRUG RESEARCH AND REVIEW
DIVISION OF NEUROPHARMACOLOGY
CENTER FOR DRUGS AND BIOLOGICS