

Pursuant to the February 8, 1985, Memorandum and Order of the Administrative Law Judge, the Drug Enforcement Administration hereby submits the following Prehearing Statement.

ISSUES

The Drug Enforcement Administration accepts the five potential issues identified by the Administrative Law Judge in his Memorandum and Order of February 8, 1985.

In addition to the five issues listed, the Drug Enforcement Administration proposes the following additional issue:

6. What is the potential for abuse of MDMA relative to substances currently controlled under the Controlled Substances Act?

The Government's position on the five previously identified issues and the additional proposed issue is as follows:

1. The phrase "currently accepted medical use in treatment in the United States," as used in 21 U.S.C. § 812 (b) means that the drug or other substance being considered for scheduling is lawfully marketed under the Federal Food, Drug and Cosmetic Act. (21 U.S.C. § 301 et seq.) In most instances lawfully marketed in the United States under the Federal Food, Drug and Cosmetic Act means that the drug or other substance has an approved new drug

*our case
is
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strong*

application (NDA) from the Food and Drug Administration (FDA).

2. 21 U.S.C. §811, which is the authority and criteria for classification of substances under the Controlled Substances Act, states in paragraph (b) that, "The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters . . ." Although the finding as to whether a drug or other substance has a currently accepted medical use in treatment in the United States is to be made by the Attorney General, the evidence upon which such a finding would be made is a scientific and medical matter which would be within the purview of the Secretary's recommendations. Therefore, the finding or conclusion of the Secretary that a substance has no currently accepted medical use in treatment in the United States would be binding upon the Attorney General.

3. "Accepted safety for use under medical supervision," as used in the criteria listed in 21 U.S.C. § 812 (b) means that a drug product has qualified to be lawfully marketed under the Food, Drug and Cosmetic Act. The Food and Drug Administration requires evidence of a drug's safety and efficacy prior to granting approval for

marketing. FDA considers "safe" to mean that the therapeutic benefits derived from the drug outweigh known or potential risks. A drug which has not been approved for marketing has not been subject to the extensive clinical and preclinical testing and exhaustive scientific scrutiny required before a drug may be approved by FDA for marketing. A drug not approved for marketing has therefore not been "accepted" as safe for use under medical supervision.

4. A drug or other substance can be placed in no schedule other than Schedule I under the Controlled Substances Act if it has "no currently accepted medical use in treatment in the United States." Any other conclusion would disregard the intent and structure of the Controlled Substances Act. Unless one of the exceptions specifically listed in the Act applies, a drug or other substance must comply with the criteria established in Section 812 of the Act for the schedule into which the drug will be placed.

5. If it is determined that MDMA has "a currently accepted medical use in treatment in the United States," and that there is no "lack of accepted safety for use of [MDMA] under medical supervision," MDMA should be placed in Schedule II of the controlled substances act because it has a high potential for abuse.

6. The potential for abuse of MDMA is equivalent to that of other drugs and substances controlled in Schedules I and II of the Controlled Substances Act.

Issue number four, as to whether a substance having no currently accepted medical use in treatment in the United States can be placed in any schedule other than Schedule I of the Act, is a purely legal issue which requires no documentary or testimonial evidence. In addition, this issue is an essential question in this scheduling matter.

A preliminary ruling on this issue after the submission of legal briefs by all parties, would expedite the remainder of the proceeding by possibly eliminating the need to present extensive evidence on the relative potential for abuse of MDMA in relation to other drugs and substances controlled under the CSA.

WITNESSES

John Docherty, M.D., Chief
Psychosocial Treatments Research Branch
National Institute of Mental Health
Bethesda, Maryland

Dr. Docherty is a psychiatrist with extensive experience in the combined use of psychopharmacological and psychosocial treatments. He will testify regarding the usefulness of MDMA as a psychotherapeutic adjunct. Dr. Docherty's testimony will focus on the current and potential clinical

usefulness of MDMA. He will testify that the use of MDMA as an effective clinical treatment adjunct has not been established.

Paul Fishbein (or another individual from the Foundation)
Phoenix House Foundation
164 West 74th Street
New York, New York 10023

Mr. Fishbein will testify that he has conducted surveys of the use of hallucinogens by individuals who seek treatment in one of the centers of the Phoenix House Foundation. He will testify regarding information which he has received in the course of his duties about the street use of MDMA in New York and California.

Richard A. Glennon, Ph.D.
Professor
Department of Medicinal Chemistry
Medical College of Virginia
Virginia Commonwealth University
P.O. Box 581
Richmond, Virginia 23298-0001

Dr. Glennon will testify that he has investigated the discriminative stimulus properties in rats of MDA and MDMA. He will testify that administration of racemic MDMA to MDA-trained animals resulted in stimulus generalization. In (+)-amphetamine trained animals stimulus generalization occurred with racemic MDA and racemic MDMA.

Harold Hardman, Ph.D.
Department of Pharmacology/Toxicology
Medical College of Wisconsin
P.O. Box 26509
Milwaukee, Wisconsin 53226

Dr. Hardman will testify regarding the toxicity of MDMA, MDA and related compounds in animals based upon studies which he has conducted in five animal species. He will describe the behavioral effects related to the motor, autonomic and central nervous system functions of dogs and monkeys after administration of MDA, MDMA, and mescaline. Dr. Hardman will further testify that these substances produce similar qualitative effects in the dog and monkey after administration of adequate doses of the substances.

Daryl Inaba, Pharm.D., Director
Haight-Ashbury Free Medical Clinic
409 Clayton Street
San Francisco, California 94117

Dr. Inaba will testify that he is the Director of the Haight-Ashbury Free Medical Clinic in San Francisco, California. He will further testify that he sees about three patients a month at the clinic who say that they have taken MDA, ADM, MDMA or Ecstasy. Although Dr. Inaba cannot be certain how many patients actually took MDMA, he will testify that users of MDA, ADM and MDMA are treated by the clinic in the same manner. Dr. Inaba will describe the symptoms and characteristics evidenced by those who use substances of this type. He will describe the type of

individuals who he sees at the clinic who claim that they are users of MDMA. Dr. Inaba will also testify about the use of MDMA in the treatment of various types of drug dependencies.

Frank L. Sapienza, M.S.
Drug Control Section
Drug Enforcement Administration
1405 I Street, N.W.
Washington, D.C. 20537

Mr. Sapienza will testify concerning the data which he has collected regarding the analysis of samples of MDMA by DEA and other forensic laboratories. He will also testify about the clandestine manufacture of MDMA and information regarding clandestine laboratories which he has received from state and local law enforcement agencies. Mr. Sapienza will testify concerning the document, "Schedule I Control Recommendation under the CSA for 3, 4 - methylenedioxymethamphetamine." He will also testify about reports of trafficking of MDMA which he has received from authorities of foreign governments.

Ron Siegel, Ph.D.
Department of Psychiatry and Biobehavioral Science
University of California at Los Angeles
Los Angeles, California 90073

Dr. Siegel will testify regarding his knowledge of the manufacture, distribution and use of MDMA as a street drug of abuse. Based upon interviews which he has conducted with users of MDMA, Dr. Siegel will discuss the adverse

reactions, acute effects and psychological problems associated with the abuse of MDMA. Dr. Siegel will also testify regarding his view of the usefulness of MDMA as an adjunct to psychotherapy.

Edward Tocus, Ph.D., Chief
Drug Abuse Staff
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

Dr. Tocus will testify that he reviewed data submitted to the Department of Health and Human Services by the Drug Enforcement Administration concerning MDMA; that the files of the Food and Drug Administration then contained no data on this substance; and that MDMA is not currently approved by FDA to be marketed in the United States. Dr. Tocus will further testify that no Investigational New Drug Application (INDA) has been submitted to the Food and Drug Administration for 3,4-methylenedioxymethamphetamine. Based upon his scientific and medical evaluation of the data concerning MDMA submitted by the Drug Enforcement Administration, Dr. Tocus will testify that MDMA meets the criteria found in 21 U.S.C. § 812 (b) for placement in Schedule I. Dr. Tocus will also discuss the requirements for submissions of INDA'S and NDA'S to the Food and Drug Administration and the reviews which are conducted by the agency prior to approval of such submissions.

Special Agent
Drug Enforcement Administration
Dallas Field Division
1880 Regal Row
Dallas, Texas 75235

A DEA Special Agent assigned to the DEA Dallas Division Office will testify about the distribution and use of MDMA in the Dallas, Texas area. His testimony will be based on information obtained from confidential sources of information, purchases of MDMA, known as Ecstasy on the street, and subsequent laboratory analyses of the substances. The agent will discuss street trafficking patterns of MDMA and their similarity to the trafficking patterns of other controlled substances in the illicit market.

DOCUMENTS

A. Scientific Literature

1. Anderson, G.M., Braun, G., Braun, U., Nichols, D.E., Shulgin, A.T., Absolute Configurations and Psychotomimetic Activity, In QUASAR Research Monograph 22, G. Barnett, M. Trsie, R. Willette, eds., National Institute on Drug Abuse, 8-15 (1978). (eight pages)
[In humans, the effective dose of racemic MDMA is 75 to 160 mg. while the effective dose of the "s" isomer is 80 to 120 mg. MDMA produces a nominal intoxication in individuals at these dosages.]

2. Bailey, K., By, A.W., Legault, D., Verner, D., Identifications of the N-Methylated Analogs of the Hallucinogenic Amphetamines and Some Isomers, JAOAC 58, 62-69 (1975). (eight pages) [MDMA has been encountered on

the illicit market and analytical data were developed to assist the forensic chemist in the identification of MDMA and other substituted amphetamines.]

3. Braun, U., Shulgin, A.T., Braun, G., Centrally Active N-Substituted Analogs of 3,4-Methylenedioxyamphetamine (3,4-Methylenedioxyphenylisopropylamine), J. Pharm. Sci 69, 2, 192-195 (1980). (four pages) [MDMA produces analgesic effects and increased motor activity similar to those produced by MDA.]

4. Braun, U., Shulgin, A.T., Braun, G., Study of the Central Nervous System Activity and Analgesia of the N-Substituted Analogs of the Amphetamine Derivative 3,4-Methylenedioxyphenylisopropylamine, Arzneim.-Forsch./Drug Res. 30 (I), No. 5, 825-830 (1980). (eighteen pages) [Both MDA and MDMA increase motor-activity in mice and produce psychotomimetic effects in man.]

5. Davis, W.M. and Borne, R.F., Pharmacological Investigation of Compounds Related to 3,4-Methylenedioxyamphetamine (MDA), Sub. Alc. Act/Mis 5, 105-110 (1984). (six pages) [MDMA and MDA show the amphetamine-like feature of enhanced lethality in mice after aggregation.]

6. Glennon, R.A. and Young, R., Further Investigation of the Discriminative Stimulus Properties of MDA, Pharmacol. Biochem. Behav. 20, 501-505 (1984). (five pages) [Racemic MDMA has discriminative stimulus effects in common with d-amphetamine, racemic MDA and s(+)-MDA in rats.]

7. Hardman, H.F., Haavik, C.O., Seevers, M.H., Relationship of the Structure of Mescaline and Seven Analogs to Toxicity and Behavior in Five Species of Laboratory Animals, Toxicol. Appl. Pharmac. 25, 299-309 (1973). (eleven pages) [Toxicity studies in five animal species showed that MDMA was more toxic than mescaline, but less toxic than MDA. In dogs and monkeys MDMA, MDA and mescaline produced similar effects related to motor activity, autonomic activity and central nervous system activity.]

B. Other Documents

(1) Letter dated March 13, 1984 from Mr. Francis M. Mullen, Jr., Administrator of the Drug Enforcement

Administration to Dr. Edward Brandt, Assistant Secretary for Health. (two pages)
[DEA requests a scientific and medical evaluation of MDMA and a scheduling recommendation.]

(2) Document entitled Schedule I Control Recommendation Under the CSA for 3, 4-Methylenedioxymethamphetamine, prepared by the Drug Control Section, Office of Diversion Control, DEA, January 19, 1984 (23 pages)
[Document contains data gathered by DEA regarding abuse potential, abuse, trafficking and clandestine production of MDMA.]

(3) Letter dated June 6, 1984 from Dr. Edward Brandt, Assistant Secretary for Health to Mr. Francis M. Mullen, DEA Administrator (one page). [Dr. Brandt recommends that MDMA be placed into Schedule I of the Controlled Substances Act.]

(4) Document entitled Evaluation of the DEA Recommendation to Control 3, 4-Methylenedioxymethamphetamine (MDMA) in Schedule I of the CSA (two pages)
[Document describes the basis for Dr. Brandt's Schedule I control recommendation for MDMA.]

(5) Excerpts from a document entitled Critical Review of Information on 28 Uncontrolled Phenethylamines for the 22nd Expert Committee on Drug Dependence, prepared by James H. Woods, Ph.D., Yng-Shiuh Sheu, Ph.D. and Inayat Khan, M.B., B.S., Ph.D., pp. 159-163. (World Health Organization Document MNH/PAD/84.13 - Restricted Document) (five pages)
[Document contains data from countries signatory to the Psychotropic Convention relevant to a determination of the abuse potential and need for international scheduling of MDMA.]

(6) Pamphlet entitled Ecstasy: 21st Century Entheogen, author unknown. (28 pages) [Pamphlet obtained from a "street" distributor of MDMA (Ecstasy) and which describes the use, effects, legality, etc. of MDMA.]

(7) Circular entitled Ecstasy - Everything Looks Wonderful When You're Young and on Drugs, author unknown (one page). [Circular obtained from user of MDMA; it describes ecstasy and its effects in relation to other hallucinogens such as LSD.]

(8) Letter dated January 23, 1985 from Edward P.

O'Brien, J.D., Chairman, California Research Advisory Panel to Mr. Stephen E. Stone, Associate Chief Counsel, DEA (two pages). [Letter supports DEA's proposal to place MDMA into Schedule I of the CSA.]

(9) Letter dated May 9, 1983, and attachments from Mr. Henry Hudson, Arlington County, Virginia Commonwealth's Attorney to Mr. Francis Mullen, DEA Administrator (three pages). [Letter notifies DEA of a new hazardous substance, Ecstasy (MDMA), found in the illicit drug traffic. Mr. Hudson requests that DEA take appropriate action.]

(11) One (1) page each entitled Trans-High Market Quotations, from the January, 1985 and February, 1985 issues of High Times magazine (two pages). [These pages list the street price for ADM (XTC) which is believed to be MDMA.]

(11) Letters from the following individuals to Mr. Howard McClain or Mr. Frank Sapienza, DEA Drug Control Section regarding the identification of MDMA in drug evidence samples submitted to their forensic laboratories:

a) 5-8-79 - Captain Roger H. Dingeman, State Director, Crime Laboratory Division, Oregon Department of State Police. (1 page)

b) 5-9-79 - 2nd Lieutenant Charles H. Vaughan, Crime Laboratory Director, Oregon Department of State Police. (1 page)

c) 5-11-79 - Nicholas P. Stumbaugh, Criminalist, Office of the Sheriff, County of San Mateo, California (1 page).

d) 5-24-79 - L. Herald Smith, Laboratory Supervisor, State of Tennessee, Department of Safety. (1 page)

e) 6-20-79 - Jerry M. Dismukes, Drug Laboratory Supervisor, North Carolina State Bureau of Investigation (1 page).

f) 6-20-79 - C. M. Johnston, Supervising Drug Chemist, Texas Department of Public Safety (1 page).

g) 7-7-79 - Vernon P. Koziatek, Supervisory Chemist, United States Army Criminal Investigation

Laboratory -CONUS (1 page).

h) 7-14-82 - Celia Hartnet, Criminalist, State of California, Department of Justice (1 page).

i) 8-20-82 - Robert D. Burris, Criminalist, Criminalistics Laboratory, City of Fort Worth, Texas (1 page).

j) 12-28-82 - Don C. Taylor, Supervisor of Toxicology Lab, Texas Department of Public Safety (1 page).

k) 10-13-83 - James R. Zimmerman and Robert E. Shark, Northern Regional Forensic Laboratory, Commonwealth of Virginia (1 page).

l) 12-15-83 - Richard P. Gervasoni, Chief Chemist, Montgomery County, Maryland (16 pages, including attachment)

(12) Correspondence postmarked July 5, 1983 from Mr. Dan Barnes, Altamonte Springs, Florida to Georgia Lab Supply, Atlanta, Georgia (4 pages). [Letter and attachments suggest that MDMA will be produced in an attempt to circumvent the Controlled Substances Act.]

(13) Letter dated June 6, 1979, from K. Bailey, Ph.D., Chief, Drug Identification Division, Health and Welfare, Ontario, Canada, to Mr. Frank Sapienza, DEA Drug Control Section (1 page). [Letter describes the control of MDMA in Canada.]

(14) Excerpt from Federal Register entitled, "Proposed Recommendations to the Drug Enforcement Administration Regarding the Scheduling Status of Marihuana and Its Components and Notice of a Public Hearing." 47 F.R. 28141-28153 (June 29, 1982), (13 pages)

C. Audio-Visual Evidence

(1) Videotape of investigative report on Ecstasy aired during the February 21 and 22, 1985, 10 p.m. newscasts on Channel 36, KTVV in Austin, Texas (viewing time less than 15 minutes). [Program describes the abuse of MDMA (Ecstasy) on the University of Texas campus at Austin, Texas and contains interviews with two students who were then using MDMA.]

OTHER MATTERS

Although it may not directly impact upon this proceeding, the National Institute on Drug Abuse (NIDA) has undertaken additional animal studies with respect to the abuse liability of MDMA. If these studies are completed within the time frame of this proceedings, the Government may present the results of the studies.

Respectfully submitted,

Stephen E. Stone

Stephen E. Stone
Associate Chief Counsel

Charlotte A. Johnson

Charlotte A. Johnson
Attorney

Date: MAR 11 1985

Certificate of Service

On March 11, 1985, I caused a copy of the foregoing to be delivered to Francis L. Young, Administrative Law Judge, Drug Enforcement Administration, 1405 I Street, N.W., Washington, D.C. 20537, and a copy mailed to each of the following:

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