

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of
MDMA SCHEDULING

)
) Docket No. 84-48
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6/13/86

GOVERNMENT'S EXCEPTIONS TO THE OPINION AND RECOMMENDED RULING,
FINDINGS OF FACT, CONCLUSIONS OF LAW AND DECISION OF
THE ADMINISTRATIVE LAW JUDGE

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INTRODUCTION

The Administrative Law Judge has recommended that the Administrator of the Drug Enforcement Administration (DEA) find that the drug, 3,4-methylenedioxymethamphetamine (MDMA) be placed in Schedule III of the Controlled Substances Act (CSA). The Administrative Law Judge reached this conclusion after finding that MDMA has a currently accepted medical use in treatment in the United States, based upon its use by a few psychiatrists; that MDMA does not lack accepted safety for use under medical supervision, again based upon the observations of a few psychiatrists; and that MDMA has less than a high potential for abuse.

There are five parties in this proceeding. The record, which consists of affidavits of direct testimony, transcripts of cross examination, and documents introduced by the parties is extensive. Of the 34 witnesses who offered testimony by affidavit and/or cross-examination, 14 were presented by the Government. The Government also introduced over 30 documentary exhibits into the record. The Administrative Law Judge gave little, if any, consideration or weight to the testimony and documents proffered by the Agency.

The Administrative Law Judge has systematically disregarded the evidence and arguments presented by the Government in preparing his Opinion and Recommended Ruling, Findings of Fact, Conclusion of Law and Decision, hereinafter referred to as Opinion. With regard to the six issues under consideration in

the Opinion, the Administrative Law Judge found against the Government on each issue. The Administrative Law Judge's unbalanced analysis of the record before him is indicative of his bias.

The Agency will demonstrate, in the pages that follow, the areas in which the Administrative Law Judge's faulty reasoning, failure to understand the materials presented, and bias led him to arrive at the erroneous conclusion that MDMA should be placed in Schedule III. While the Agency is hesitant to reiterate arguments made in prior filings in this case, it may be necessary since it appears the Administrative Law Judge chose not to consider them.

THE ADMINISTRATIVE LAW JUDGE'S CONCLUSION THAT "ACCEPTED MEDICAL USE IN TREATMENT IN THE UNITED STATES" MEANS "WHAT IS ACTUALLY GOING ON WITHIN THE HEALTH CARE COMMUNITY" IS A VAGUE, UNACCEPTABLE CONCLUSION WHICH IS UNSUPPORTED BY SOUND LEGAL ANALYSIS.

The Administrative Law Judge rejects the position advanced by counsel for the Drug Enforcement Administration and the Food and Drug Administration (FDA) that "currently accepted medical use in treatment in the United States" means approved for marketing in the United States under the Federal Food, Drug and Cosmetic Act. In concluding that "currently accepted medical use in treatment in the United States means "what is actually going on within the health care community," the Administrative Law Judge places great weight on court decisions and statements by FDA officials relating to the Food and Drug Administration's lack of authority to regulate the practice of medicine. The

Administrative Law Judge has completely misconstrued the interpretation of the Federal Food, Drug and Cosmetic Act, and the courts' interpretation of what constitutes regulation of the practice of medicine.

Regulation of the practice of medicine is not relevant to the issue of what constitutes accepted medical use, nor is it relevant to the definition of approval for marketing under the Food, Drug and Cosmetic Act. The Food and Drug Administration does not regulate the practice of medicine by approving drugs for marketing in the United States any more than the Administrator of the Drug Enforcement Administration regulates the practice of medicine by scheduling drugs under the Controlled Substances Act. It is clear, however, that both the Commissioner of the Food and Drug Administration and the Administrator of the Drug Enforcement Administration impact upon the medical profession by approving drugs for marketing and scheduling drugs. In referring to the Federal Food, Drug and Cosmetic Act, the United States Court of Appeals for the Fifth Circuit stated in United States v. Evers, 643 F. 2d 1043, 1048 (1981):

Of course, while the act was not intended to regulate the practice of medicine, it was obviously intended to control the availability of drugs for prescribing by physicians.

Careful reading of the quotations from court cases and statements made by officials of the Food and Drug Administration provided in the Opinion demonstrates that the courts and FDA interpret FDA's lack of authority to regulate the practice of medicine as a prohibition from requiring a physician to use a drug only as specified in its approved labeling. This is

commonly referred to as unapproved uses of approved drugs. A sentence from a quotation utilized by the Administrative Law Judge on page 11 of his Opinion clearly illustrates this point:

Once a drug product has been approved for marketing, a physician may, in treating patients, prescribe a drug for a use not included in the drug's approved labeling. (48 Fed. Reg. 2673 (June 9, 1983))

There is a vast difference between not interfering with a physician's unapproved uses of drugs already approved for some use by the Food and Drug Administration, and finding that use of a drug not approved for any purpose lacks a "currently accepted medical use." The Agency made this argument in its Response to the Findings of Fact, Conclusions of Law and Argument submitted by Drs. Greer and Grinspoon, et. al, Lyn B. Ehrnstein, and Hoffmann-La Roche, Inc. (See pages 7-11 of that document) The Administrative Law Judge clearly chose not to consider this material in arriving at his conclusion.

The matter at issue is what is a reasonable definition of the term "currently accepted medical use in treatment in the United States," not what authority the Food and Drug Administration may or may not have over the practice of medicine. The standards provided in the Federal Food, Drug and Cosmetic Act provide a reasonable and scientific basis for such a definition. Section 201(p), 21 U.S.C. 321(p), of the Food, Drug and Cosmetic Act provides that a substance is a "new drug" if it is not "generally recognized" by "qualified" experts to be safe and effective for use under the conditions prescribed, recommended or suggested in its labeling. A drug that is "generally recognized"

as safe and effective by experts based upon controlled studies and publicly available scientific information is an "old drug" which is approved for marketing on that basis. The Supreme Court further explained the meaning of the term "new drug" in Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973), by saying at page 652:

Whether a particular drug is a "new drug" depends in part on the expert knowledge and experience of scientists based on controlled clinical experimentation and backed by substantial support in scientific literature.

The opinions of a handful of physicians, working in the absence of any reliable clinical or pharmacological information regarding the safety and effectiveness of a drug are immaterial in determining whether a drug is "generally recognized" and are equally immaterial to the determination of whether a drug has a "currently accepted medical use in treatment in the United States." The Supreme Court in Weinberger v. Hynson, Westcott and Dunning, Inc., 412 U.S. 609, 619 (1973), upheld the regulations of the Food and Drug Administration requiring adequate and controlled clinical investigations in support of safety and efficacy of "new drugs" by saying:

Moreover, their strict and demanding standards, barring anecdotal evidence indicating that doctors "believe" in the efficacy of a drug are amply justified by the legislative history. The hearings underlying the 1962 Act show a marked concern that impression or beliefs of physicians, no matter how fervently held, are treacherous.

Impressions and beliefs, not controlled studies, are what the psychiatrists testifying on behalf of MDMA in this proceeding relied upon, and what the Administrative Law Judge relied upon in

determining that MDMA had a currently accepted medical use in treatment in the United States. If the Congress and the Supreme Court, as well as the Food and Drug Administration, find that anecdotal evidence, opinions and beliefs of physicians, and uncontrolled studies are not sufficient to determine that a drug is "generally recognized", then how can they be sufficient for the Administrator to determine that a drug has an "accepted medical use in treatment in the United States?"

The psychiatrists who have used MDMA themselves, and administered it to patients stated in their testimony in these hearings that their studies were not controlled, scientific studies. For example Dr. Richard Ingrasci stated:

I really want to emphasize that point. I am not a researcher. I don't pretend to be a researcher. I see myself as a psychiatrist, clinician, trying to do---alleviate suffering in a psychiatric manner.

(Tr-7, p. 33)

Dr. Ingrasci went on to say that before giving MDMA to patients, "I took it first several times . . ." and that he did this "given the fuzzy nature of our knowledge at this point." (Tr-7, p. 42)

Dr. Greer, one of the parties in this matter, who is a psychiatrist, prepared an article or study involving 29 individuals to whom he had administered MDMA. This paper is entitled, "MDMA: A New Psychotropic Compound and Its Effects in Humans." This document is an exhibit in this proceeding, GG-14. In the introduction to the study, Dr. Greer states:

The information gathered here is limited because the primary purpose of the sessions conducted with MDMA was therapeutic rather than investigative. Consequently, only the therapist's observations and the subjects' reports are available for analysis.

This study was never submitted for publication to any scientific journal or any other publication.

Dr. Downing, a psychiatrist in San Francisco, participated in a study with 21 individuals in California. The results of this study have been entered as exhibits in this proceeding, GG-8. This is entitled, "MDMA Pilot Study-Physiological, Psychological and Sociological Summary of paper being prepared for publication." The introduction to the study states:

The planned data collection was incomplete due to unanticipated experimental workload and hemolization of the blood samples. This study and findings are presented as preliminary and suggestive rather than definitive.

In this "study" the individual participants took MDMA which they had obtained themselves. The substance that they took was not tested to verify whether it was MDMA, or what the strength was. The physicians did not know what dose each patient took. Dr. Joel Kleinman, a psychiatrist and neuropharmacologist who appeared on behalf of the Agency testified regarding these studies by Drs. Greer and Downing:

It is my professional opinion that the studies described in the direct testimony of Drs. Downing and Greer have little or no scientific merit...The physicians who conducted these studies may be conscientious and concerned physicians, but they lack any serious academic or scientific standing in the psychiatric community.

The standard which is used by the Food and Drug Administration to approve new drugs for marketing, or permit the marketing of drugs which have been found to be "generally recognized," among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as

safe and effective. . ." (21 U.S.C. 321(p)(1)), is the same standard which the Administrator should use to determine if a substance has a "currently accepted medical use in treatment in the United States." Therefore, when a drug is approved for marketing in the United States by the Food and Drug Administration it acquires a "currently accepted medical use in treatment in the United States," and not before.

The Administrative Law Judge has declared the Agency's position that "currently accepted medical use in treatment in the United States" means approved for marketing under the Federal Food, Drug and Cosmetic Act to be "wrong." Further, the Administrative Law Judge stated that since the Government's position would allow the Food and Drug Administration to regulate the practice of medicine, the standard proposed by the Government is not within the Agency's "authority." The Administrative Law Judge also concluded that Congressional acceptance of the Agency's standard is "wrong."

In 1984 the Congress enacted Public Law 98-329 in which the Congress ordered the Attorney General to place methaqualone in Schedule I, and ordered the Secretary of the Department of Health and Human Services to withdraw the approval of the new drug application (NDA) for methaqualone which had been previously issued under Section 505 of the Food, Drug and Cosmetic Act. There is a statement in the legislative history of this Act, specifically, the Report of the Committee on Energy and Commerce of the House of Representatives, which the Administrative Law Judge chose to quote in his Opinion and claims is incorrect. The

statement, which was quoted by the Agency in previous filings in this matter is:

However, the Drug Enforcement Administration does not have authority to impose Schedule I controls on a drug which has been approved by the Food and Drug Administration for medical use.

The paragraph continues by saying:

The statutory findings required for agency scheduling decisions clearly state that the agency may not, in the absence of Congressional action, subject drugs with a currently accepted medical use in the United States to Schedule I controls. (page 4 of House Report)

The Administrative Law Judge agrees with the Committee's second statement, but not with the first. Certainly, Congressional interpretation of a statute which they have passed is worthy of deference by the Administrative Law Judge. Since it is the statute which is being interpreted, Congressional interpretation should carry the greatest weight. The Agency pointed this out earlier in this proceeding by indicating that the Congress of the United States interprets "accepted medical use" to mean "approved by the Food and Drug Administration for medical use."

The Administrative Law Judge places great weight on the fact that Congress ordered the Secretary of Health and Human Services to withdraw approval of the new drug application for methaqualone thirty days after the drug was placed in Schedule I. Congress provided no explanation of its timing; its intent, however, was clear. The statute does not permit the Administrator of the Drug Enforcement Administration to place a substance which had been approved by the Food and Drug Administration into Schedule I, therefore, the New Drug Application approval was required to be withdrawn by the Food and Drug Administration.

The evidence presented in this proceeding, a careful reading of the Food, Drug and Cosmetic Act, the Controlled Substances Act, their legislative histories, and court interpretations of those Acts, as well as sound and rational reasoning all support the Agency's definition of "currently accepted medical use in treatment in the United States." The use of a vague definition, such as that proposed by the Administrative Law Judge provides no clarification of the issue, nor can it be considered a rational conclusion to be reached from the information available.

Application of the definition of "accepted medical use" proposed by the Administrative Law Judge could lead to extremely undesirable results. As the Administrator is aware, within the large population of medical professionals, including over 600,000 practitioners registered by the Drug Enforcement Administration to handle controlled substances, there are small numbers who abuse their registration with DEA to divert and personally use controlled substances for other than legitimate medical purposes. Using the Administrative Law Judge's definition, a small group of such physicians could synthesize any compound they wished, take it themselves, provide it to individuals who appreciate its effects, and by pronouncing the substance to have an accepted medical use, prevent its placement in Schedule I. Clearly the administration of a controlled substance by a practitioner registered by DEA to an individual to help them be more creative, such as the reason given by Dr. Greer to administer MDMA to five

of the subjects in his study 1/, would be considered "outside the scope of professional practice" and "not for a legitimate medical purpose." The Administrator should not create the opportunity for such a situation to occur. In his responsibility to protect the health and safety of the American public, the Administrator would be derelict in allowing a substance which has not been found by the Food and Drug Administration to be safe and effective for use, and which is not available through commercial, legitimate, channels to the medical community, to have an "accepted medical use in treatment in the United States," merely because a handful of physicians are of the opinion that it may have therapeutic usefulness.

THE ADMINISTRATIVE LAW JUDGE'S CONCLUSION THAT MDMA HAS A CURRENTLY ACCEPTED MEDICAL USE IN TREATMENT IN THE UNITED STATES IS BASED UPON THE FAULTY PREMISE THAT MDMA IS ACCEPTED BY THE MEDICAL COMMUNITY FOR USE IN TREATMENT IN THE UNITED STATES.

The Administrative Law Judge adopted the legal malpractice standard to determine whether MDMA has been accepted by the "medical community" within the United States. In other words, if it is not malpractice for a physician to administer MDMA to a patient, then it has a "currently accepted medical use in treatment in the United States." The Administrative Law Judge has based his conclusion on a faulty foundation.

Careful review of the Administrative Law Judge's Opinion will show the flaws in his analysis. The Administrative Law Judge relies heavily on a 1976 court case from the Texas Court of Civil Appeals. This case, as quoted in the Administrative Law Judge's Opinion, rejected the rule of "generally recognized
1/ See Tr-3, p.17.

treatment" and adopted as the rule treatment recognized by a "respectable minority of physicians." The Administrative Law Judge then appears to adopt as his standard for determining whether a drug has a "currently accepted medical use in treatment in the United States," whether a respectable minority of physicians indicate that a drug has accepted medical use. The Agency has no intention of arguing standards of medical malpractice. It is irrelevant to the issues arising in this proceeding. Using a malpractice standard to determine what constitutes accepted medical use is wholly inappropriate. There is no liability at issue in determining what constitutes accepted medical use. There is no fault at issue in determining whether a drug has an accepted medical use. Accepted medical use is a criteria for scheduling of a substance and is not intended to provide the basis for a penalty against an individual physician. Accepted medical use has no relationship to malpractice. The concept of "generally recognized" use and approved for marketing under the Food, Drug and Cosmetic Act is a more appropriate standard.

In previous filings in this matter, counsel for the Agency has overlooked the obvious, but would like to bring it to the Administrator's attention in light of the Administrative Law Judge's conclusions. Webster's Third New International Dictionary, Unabridged, p. 11 (1976), defines the word "accepted" as follows:

accepted - generally approved: widely used or found:
generally agreed upon: unchallenged,
conventional.

If the meaning of a statute cannot be ascertained by any other method, the plain meaning of the statute is a proper determination of the language. The dictionary definition of "accepted" is in accord with the Agency's proposed meaning of what constitutes "currently accepted medical use in treatment in the United States." It is not in accord with the Administrative Law Judge's standard of malpractice, based upon the opinions of a "respectable minority." Can a physician who gives a patient a drug which has not been shown safe for administration to humans be considered "respectable?"

The Administrative Law Judge, in his findings of fact with regard to accepted medical use, quotes several of the psychiatrists who testified on behalf of Drs. Greer and Grinspoon, et. al. The Administrative Law Judge does not state in his opinion that these psychiatrists constitute a "respectable minority" of the medical community, and the Agency does not feel it is necessary to argue such a point. It should be noted, however, that the Administrative Law Judge chose not to refer to or mention the testimony of the two psychiatrists who testified for the Government, nor to the conclusions regarding MDMA reached by the Assistant Secretary of Health, himself a physician. Rather, the Administrative Law Judge stated at page 30 of his Opinion that:

No testimony to the contrary by any witness is brought to the attention of the administrative law judge by the Agency or any other participant.

While the Agency questions an individual psychiatrist's capacity to conclude that a drug has a "currently accepted medical use in

treatment in the United States," especially in a proceeding where the meaning of that term is at issue, Dr. Kleinman testified in this proceeding to the contrary. Dr. Kleinman stated in his rebuttal testimony:

MDMA is an interesting but potentially dangerous compound which should not be administered to humans without extensive further trials with animals. (Kleinman, rebuttal, p. 4)

This statement is inconsistent with the belief that MDMA has a currently accepted medical use in treatment in the United States. The Administrative Law Judge also did not consider the findings of the Assistant Secretary of Health which were outlined in a letter to then-DEA Administrator Francis M. Mullen, Jr., dated June 6, 1984:

As a result of our evaluation, we believe that MDMA has a high potential for abuse and presents a significant risk of harm to the public health. It is our recommendation that MDMA be placed in Schedule I of the CSA. (Agency Exhibit B3)

In the evaluation attached to the letter from the Assistant Secretary for Health, is the statement, "There is no known legitimate use of MDMA in humans." (Agency Exhibit B4)

Dr. Edward Tocus, who has a Ph.D. in pharmacology and is employed by the Food and Drug Administration, testified for the Government in this proceeding. He prepared the evaluation for the Assistant Secretary of Health. Dr. Tocus testified that before preparation of this document he:

reviewed the data contained in the DEA document and searched the files of the Food and Drug Administration for information concerning the drug 3,4-methylenedioxymethamphetamine (MDMA). I found no reference in the files of the Food and Drug Administration to this drug. There were

no investigational new drug applications or approvals, and there was no indication that any sponsor had informed FDA that such submission would be forthcoming. Based on the review of the files of the Food and Drug Administration, I was able to conclude that the substance or drug 3,4-methylenedioxymethamphetamine had not been approved for human research studies, or for marketing in the United States. (Tocus, direct, p. 6)

There is no evidence in the record that MDMA is a "generally recognized" drug utilized by the medical profession. What is clear is that the Food and Drug Administration has not approved MDMA for marketing in the United States, and that physicians consider it to be a harmful drug which should not be given to humans without further testing. The Agency submits that the evidence in the record supports a finding that MDMA does not have a currently accepted medical use in treatment in the United States because it is not approved for marketing in the United States by the Food and Drug Administration.

THE ADMINISTRATIVE LAW JUDGE'S CONCLUSION THAT THERE IS AN "ACCEPTED SAFETY FOR USE . . . UNDER MEDICAL SUPERVISION" FOR MDMA BECAUSE IN THE JUDGMENT OF "REPUTABLE" PHYSICIANS MDMA IS SAFE, AND THAT "NO EVIDENT HARM RESULTED" FROM PERSONS USING MDMA UNDER MEDICAL SUPERVISION, IS AN UNACCEPTABLE STANDARD NOT BASED UPON SOUND SCIENTIFIC EVIDENCE AND REASONING.

The Administrative Law Judge has chosen to totally disregard the opinion and standards developed by the agency designated by Congress to determine safety of drugs. He has instead substituted the judgment and observations of a handful of physicians who have administered MDMA to willing subjects in uncontrolled, non-research "studies." The Administrative Law Judge has chosen to disregard scientific, controlled studies conducted by scientific researchers which have shown MDMA to be

neurotoxic when administered to rats, and instead substituted the anecdotal judgments of physicians who observed the behavior of human animals under the influence of MDMA. In the Administrative Law Judge's findings of fact, he states:

37. Although single injections of MDMA may be slightly less neurotoxic than MDA, chronic use of MDMA appears to be more neurotoxic than MDA. The relevance and materiality of this conclusion to the report of the study on which this conclusion was based indicates only that the MDMA was injected into rats. The route of injection, which will make a vast difference in the meaning of the results noted, is not given in the report. Humans are known to take MDMA orally, not by injection. This difference is of great importance, and renders the test results meaningless for our purposes.

Dr. Lewis S. Seiden, a Ph.D. in biopsychology, has conducted extensive research in the fields of psychopharmacology and neuropharmacology at the University of Chicago. He has conducted research on MDA and MDMA in rats and found that these drugs destroy neurons in the brain that release serotonin. Dr. Seiden provided testimony on behalf of the Agency in this proceeding.

Dr. Seiden found:

Based upon the evidence available I would predict that MDA and MDMA will have the same neurotoxic effects in other mammalian species, including humans. . .MDMA has a neurotoxic potential in humans, yet to the best of my knowledge, this compound has not been systematically screened for efficacy for the treatment of mood or behavioral disorders... The claim that MDMA has beneficial effects is suspect. . .(Seiden, direct, p.4-5)

Dr. Edward C. Tocus, a Ph.D. in pharmacology and Chief of the Drug Abuse Staff, Division of Neuropharmacological Drug Products of the Food and Drug Administration, also provided testimony on behalf of the Government in this proceeding. He stated:

A substance cannot be deemed safe unless FDA has determined that there is scientific data which demonstrates that a substance can be given to humans without irreversible harm. . . .A review of the available scientific literature on MDMA does not support the safety of the drug for use under medical supervision. (Tocus, direct, p. 9)

Instead of relying on scientific data, or the opinion of the Food and Drug Administration, the Administrative Law Judge chose to rely upon the "world of health care practitioners." The Administrative Law Judge discusses the studies, using human subjects, conducted by Drs. Greer, Ingrassi, and Downing. He notes that none of the individuals who participated in the studies "suffered apparent harm." The Administrative Law Judge apparently believes that humans should be used, instead of rats, to decide if a drug is safe. If it appears that the patient suffers no ill effects after taking the drug, then it must be safe. This is an irrational conclusion based upon opinion and not scientific evidence. As Dr. Seiden stated in his testimony, neurotoxic tests in humans cannot be conducted unless the subject is sacrificed to provide samples of brain tissue which are necessary for evaluation. This statement explains why animal tests are vital to such determinations.

In considering the testimony of the "world of health care practitioners," the Administrative Law Judge did not consider the testimony of the two psychiatrists presented by the Agency. Dr. John Docherty, formerly Chief of the Psychosocial Treatments Research Branch of the National Institute of Mental Health, a psychiatrist, testified that based on his knowledge of MDMA, adequate safety for the drug had not been established. He also

testified that as a psychiatrist, he would not have administered MDMA to a patient. (Tr-7, p. 142) As previously noted, Dr. Kleinman, a psychiatrist and neuropharmacologist, testified that he would not give MDMA to humans without further study, he stated, "With a drug such as MDMA, we don't have that wealth of experience as to how safe it is in human beings." He also stated, "We don't really know what would happen in a large population of individuals that we gave this drug to." (Tr-5, p. 208-209) The Assistant Secretary of Health concluded in his letter to then-Administrator Mullen that his agency believed that MDMA, "presents a significant risk of harm to the public health." Certainly the opinions of these health care professionals were worthy of the Administrative Law Judge's consideration.

As a result of the human testing which occurred in World War II, standards of testing were developed by Western Countries in the "Declaration of Helsinki." These standards are entitled, "Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects." They are quoted in 21 CFR 312.20, and were attached to the Government's Findings of Fact, Conclusions of Law and Argument. The first paragraph reads:

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

The document continues under the section entitled, " Medical Research Combined with Professional Care" to say:

6. The doctor can combine medical research with professional care, the objective being the acquisition

of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient. [Emphasis added]

A review of the "studies" conducted by Drs. Greer, Downing and Ingrasci does not stand up under such scrutiny. Dr. John Docherty, an experienced researcher in the psychiatric area, characterized Dr. Greer's study as, "inadequate to establish the therapeutic efficacy of MDMA as an adjunct to psychotherapeutic treatment." He further stated that the study was "an uncontrolled investigation." He criticized the entire methodology of the study and concluded:

the methodological problems noted above make any reasonable inference regarding the efficacy of MDMA for enhancing the therapeutic efficacy of psychotherapy impossible and form no reasonable basis for such an assertion in my opinion. (Docherty, direct, p. 5)

Dr. Joel Kleinman, also a psychiatrist with a research background stated in his direct testimony:

It is my professional opinion that the studies described in the direct testimony of Drs. Downing and Greer have little or no scientific merit. I base that conclusion on the fact that (1) there were not adequate descriptions of the patients or subjects of the studies; (2) these were not blind or double blind studies: the purpose of using blind studies is to ensure that clinical ratings of effectiveness are not biased by the experimenter's expectation of the drug's action; (3) there were no objective outcome criteria: these criteria serve as measurement standards which allow the researcher to objectively test whether or not the drug significantly improves the patient's condition; (4) the studies appear to be heavily biased; and (5) the reports are almost entirely anecdotal and thus largely subjective in nature. Although these reports make interesting reading, their lack of scientific design, methodology and controls make them scientifically unsound. (Kleinman, rebuttal, p. 2)

And Dr. Lewis S. Seiden, who has done significant research in the area of neuropharmacology concluded:

In a drug trial the preliminary case for efficacy must be weighed against the potential for harmful side effects. the case to date that MDMA is an effective drug seems weak; furthermore, there is evidence to suggest that the drug could harm 5HT cells in the brain. . . It would follow from the above evidence that clinical scientists should conduct trials of MDMA in humans with the utmost caution. They should ensure that the potential benefits to the person is(sic) great enough to outweigh the risks, and they should collect data in a systematic and well controlled manner as is usually done under an Investigational New Drug Permit. (Seiden, direct, p. 5)

The Administrative Law Judge's conclusion that since none of the subjects "suffered apparent harm," MDMA is safe, is without merit. A drug must be proven safe. There is no evidence in the record to support the Administrative Law Judge's conclusion that MDMA is safe for use under medical supervision.

The Administrative Law Judge was incorrect when he stated that ~~the Agency's position~~ regarding "accepted safety for use under medical supervision," would reduce the question to one of economic benefit. Under FDA procedures, a drug may not be tested in humans until an Investigational New Drug (IND) application has been submitted and approved. Part of the IND approval process requires a showing that "the chemical in a biological system is not likely to produce irreversible damage at the doses proposed for human use." (Tocus, direct, p. 2) To make this showing animal tests are required, as well as data concerning the chemistry of the drug. An IND may be applied for by anyone, including an individual physician. The testimony offered by the psychiatrists who administered MDMA verifies that they had not applied for an IND with the Food and Drug Administration, as Dr. Tocus, of the FDA had testified.

It is clear that the only evidence in the record to support the Administrative Law Judge's conclusion that MDMA has "accepted safety for use under medical supervision" is observations of physicians who have administered MDMA to patients in a therapeutic setting. In some cases the physicians "tested" the MDMA before giving it to patients by self-administration.

The two psychiatrists who testified on behalf of the Government in this proceeding concluded that MDMA was not safe for human consumption. The Assistant Secretary for Health found that MDMA posed a public health risk. There is no scientific evidence which provides a basis for concluding that MDMA has accepted safety for use under medical supervision. MDMA lacks accepted safety for use under medical supervision.

THE CONCLUSION OF THE ADMINISTRATIVE LAW JUDGE THAT MDMA DOES NOT HAVE A "HIGH POTENTIAL FOR ABUSE" IS NOT SUPPORTED BY THE WEIGHT OF THE EVIDENCE.

The Administrative Law Judge made 100 findings of fact relating to MDMA in his Opinion, and then concluded that MDMA has a "potential for abuse less than the drugs or other substances in Schedules I and II," and that MDMA "may lead to moderate or low physical dependence or high psychological dependence." The Administrative Law Judge misinterpreted the scientific data and failed to apply it properly in determining MDMA's relative potential for abuse.

In the legislative history of the Controlled Substances Act there is extensive discussion of the phrase "potential for abuse." This was highlighted by the Agency in their Proposed

Findings of Fact, Conclusions of Law and Argument. See pages 8-10 of that document. The portion of the findings made by Congress which the Agency relies upon in these proceedings originated in regulations promulgated to the Drug Abuse Control Amendments of 1965. One of the factors listed as defining potential for abuse was:

(4) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be a significant diversion from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or the safety of the community. ([1970] U.S. Code Cong. & Admin. News 4602)

Although, the Administrative Law Judge found that there is a similarity between MDMA and MDA, a Schedule I substance, he concluded that this similarity was not relevant since MDMA and MDA were also similar to other drugs, "which have not been found to have any abuse potential and which are not scheduled at all." Although it is unclear exactly which other drugs the Administrative Law Judge is referring to, the Administrative Law Judge's analysis is severely flawed.

First of all, it should be noted that the Administrative Law Judge did find, based upon the evidence, that MDMA did have sufficient potential for abuse to be placed in Schedule III of the Controlled Substances Act. In addition he found the following similarities between MDMA and MDA:

1. Similarity in chemical structure (Findings 10-12)

2. "MDMA produces pharmacological effects in common with both central nervous stimulants like amphetamine, and hallucinogens like MDA, in animals." (Finding 14)
3. "MDA and MDMA both produce central nervous system stimulation in animals as measured by increased locomotor activity in mice." (Finding 15)
4. "MDA and MDMA produce similar centrally mediated analgesic effects in mice as determined by the hot-plate test, the tail flick test and the stretch test." (Finding 20)
5. "Both MDA and MDMA have potent releasers of serotonin or 5-hydroxytryptamine, a neurotransmitter which has a widely accepted role in the activity of hallucinogens." (Finding 24)
6. "In mice, dogs and monkeys, MDA and MDMA produce the same spectrum of pharmacological effects when observed during toxicity studies. These effects include hyperactivity, excitability, emesis, apprehension or fright, aggressive behavior, bizarre body attitudes, apparent hallucinations, dyspnea and hypernea. Motor activity effects include convulsions, muscular rigidity and tremors and the autonomic activity includes mydriasis, piloerection, salivation and vascular flushing. These effects are part of what is described as the classical pharmacological response of the dog to intravenous mescaline." (Finding 26)
7. "The LD50's for MDMA and MDA were substantially the same with the LD50 for MDA equalling 90.0 mg./kg. and the LD50 for MDMA equalling 106.5 mg./kg. . . Davis also found that both MDA and MDMA showed the amphetamine-like property of increased lethality under aggravated housing conditions compared to isolated housing conditions." (Finding 29)
8. "MDMA, MDA, amphetamine and methamphetamine produce effects that are neurotoxic, i.e., nerve destructive, when administered to animals. MDMA and MDA are neurotoxic in rats at doses which are very low compared to the neurotoxic doses of amphetamine and methamphetamine." (Finding 34)
9. "MDMA and MDA both produce long term reduction in serotonin levels and uptake sites in the rat brain." (Finding 35)
10. "MDMA shares discriminative stimulus properties in common with amphetamine and MDA in drug discrimination studies in rats." (Finding 43)

11. Rats trained to recognize amphetamine recognized MDA and MDMA in drug discrimination studies. (Finding 44)
12. Rats trained to recognize MDA recognized MDMA as having properties similar to MDA. (Finding 45)

The above similarities are taken from scientific, published tests conducted on animals. This is the most reliable data available on the subject. The Administrative Law Judge pointed out the differences between MDMA and MDA in relationship to observations from the human "studies" which have been conducted. When human anecdotal data may support the position of the Agency the Administrative Law Judge stated, "[t]here are no results of controlled scientific experiments in the record establishing MDMA to be a hallucinogen in humans." (Finding 47) However, when the Administrative Law Judge concluded that, "[t]he uncontradicted evidence in the record is that there are qualitative differences in humans between MDA and MDMA," (Finding 58) it appears that it is not worthy of mentioning that this data comes from uncontrolled, nonscientific studies in humans. The reason that the record is uncontradicted is simple. There are no controlled, scientific studies involving the substances MDA and MDMA in humans. Dr. Harlan E. Shannon, a pharmacologist at the National Institute on Drug Abuse, Addiction Research Center in Baltimore, Maryland, testified for the Agency in this proceeding. In his position as Acting Chief of the Neuropsychopharmacology Laboratory at the Addiction Research Center, he is well versed in the meaning of research data on psychoactive drugs such as MDMA. Dr. Shannon testified that:

[I]t has become well established that clinical descriptions of psychoactive drugs are valid only when both the practitioner or scientist and the client or subject are unaware of whether a drug or placebo has been given. Such studies are termed "double-blind, placebo controlled." To date, no such studies or clinical experiences have been reported for MDMA, even though there has been ample opportunity. Thus, there are no valid clinical descriptions of the effects of MDMA to date. Therefore, we must rely solely on the available animal data. [Emphasis added] (Shannon, rebuttal, p. 2)

In reaching his conclusion, the Administrative Law Judge considered each similarity between MDA and MDMA separately. He failed to make the comparison in a comprehensive fashion, choosing instead, to view each fact in a vacuum. When all the previously listed factors are considered together, they support the conclusion that MDA and MDMA are so related, due to their similar chemical structure and pharmacology, that it is likely they will have the same potential for abuse. The similarities of MDMA to other drugs such as MDA, amphetamine, and mescaline, which are controlled substances in Schedules I or II, with a known high potential for abuse, further supports the conclusion that MDMA has a high potential for abuse.

Evidence of actual abuse of MDMA merely reinforces the finding that MDMA has a high potential for abuse based upon its pharmacological similarity to MDA. The Administrative Law Judge based his conclusion that MDMA has less than a high potential for abuse on several quantitative criteria. For example, he stated on page 58 of the Opinion that, "The few mentions here of MDMA are far less than those of such Schedule I drugs as heroin, marijuana, and LSD." Nowhere does Congress indicate that

relative potential for abuse is a quantitative measurement. As the Administrator is aware, trends in drug abuse may shift dramatically based upon what is "popular" at the moment. Thus a drug that has a "high potential for abuse" may not become "popular" until it receives media attention or recognition in the drug abuse community. This phenomenon is shown by the Administrative Law Judge's findings of fact 67 and 68. In 13 years, DEA laboratories identified 41 exhibits of MDMA totalling approximately 60,000 dosage units. From July 1, 1985 to early October, 1985, DEA laboratories have identified MDMA in at least 14 exhibits totalling over 35,000 dosage units from Texas alone. This clearly indicates the speed with which a shift can occur.

In addition to finding that a drug is pharmacologically related to a substance with known potential for abuse, two of the other findings which Congress listed in defining potential for abuse are:

- (1) There is evidence that individuals are taking the drug or drugs in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community;
- (2) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice;
([1970] U.S. Code Cong. & Admin. News 4602)

There is evidence in the record that individuals are seeking treatment for abuse of MDMA, that there have been mentions of MDMA in the Drug Abuse Warning Network (DAWN) and that two overdose deaths have been associated with MDMA. There is also

evidence in the record to indicate that MDMA is trafficked much like any other controlled substance. (See direct testimony of S/A Chester).

The Administrative Law Judge arrived at several erroneous conclusions in formulating his findings of fact in this proceeding. One of the most blatant is found in his findings of fact numbered 31 to 33. In these findings, the Administrative Law Judge found that there is a "comparatively large margin of safety in the use of MDMA in humans - the LD50 is 160 times the ED50." The Administrative Law Judge's error occurred when he attempted to calculate the therapeutic index for MDMA, the LD50 divided by the ED50. First, he extrapolated data in order to arrive at what he termed an ED50, or the effective dose of MDMA, in humans. Second, and most fatal, was that he compared the LD50 from rats to the ED50 in humans. No witness in this proceeding made such a comparison. Making an inter-species comparison is a violation of basic scientific principles. The therapeutic index is not calculated from the LD50 from one species of animal and the ED50 of another species of animal. Dr. Harold F. Hardman, a pharmacologist and toxicologist who testified on behalf of the Agency stated in his testimony:

[I]n addition to the LD50, there's another term that I'd like to introduce. It's called the effective dose 50 and the ratio of the LD50 to the effective dose 50 is what we call the therapeutic index, and it gives you an understanding of the relative safety in using this drug to produce an effect versus one that may produce toxic effects. (Tr-6, p. 19)

Dr. Hardman continued by saying:

I think you have to establish first of all, that the drug is effective in doing something. That's what effective dose 50 means. If you establish an effective dose, you have to define what you mean by effective. You can do an LD50 without having any idea of an effective dose 50.

(Tr-6, p. 20)

Later in his testimony, Dr. Hardman compared the LD50's for MDMA in different animal species:

All right, we want the LD50 in milligrams per kilogram. Under those circumstances, the rat was the most sensitive, with an LD50 of 49 milligrams per kilo, and the mouse and guinea pig were approximately the same with values of 97 and 98 milligrams per kilo.

(Tr-6, p. 39)

It is obvious, if the LD50 is so different between the rat and the mouse, that it would be different between the rat and a human being. Comparing the LD50 in rats to the ED50 in humans is ——— absurd, and of absolutely no relevance or value. The Administrative Law Judge's conclusion that "there appears to be a comparatively large margin of safety in the use of MDMA in humans" is based upon misapplication of the data presented in this proceeding and is not supported by any evidence in the record.

There is substantial evidence in the record to support a finding that MDMA has a high potential for abuse. The fact that MDMA is pharmacologically similar to the Schedule I controlled substance MDA, as well as similar to amphetamine and methamphetamine, both Schedule II controlled substances with high potentials for abuse, clearly supports the conclusion that MDMA has a high potential for abuse. The reports of actual abuse of MDMA act to reinforce the finding of high potential for abuse.

MDMA is clandestinely manufactured, it is trafficked on the street like other Schedule I and II controlled substances, and it has been associated with drug abuse and medical emergencies. Thus, the record clearly supports the conclusion that MDMA has a high potential for abuse.

THE ADMINISTRATIVE LAW JUDGE DID NOT CONSIDER THE RECOMMENDATION BY THE WORLD HEALTH ORGANIZATION THAT MDMA BE PLACED IN SCHEDULE I OF THE CONVENTION ON PSYCHOTROPIC SUBSTANCES, 1971, NOR DID HE CONSIDER THAT THE COMMISSION ON NARCOTIC DRUGS VOTED TO PLACE MDMA IN SCHEDULE I OF THE PSYCHOTROPIC CONVENTION.

While the Administrative Law Judge makes reference to the 28 phenethylamines which were under consideration by the World Health Organization for control under the Convention on Psychotropic Substances, 1971 (finding of fact 11 on page 41 of the Opinion), and the fact that not all were recommended for scheduling under the Psychotropic Convention, he failed to consider what findings were made by the World Health Organization concerning MDMA. The World Health Organization recommended that MDMA be placed in Schedule I of the Convention on Psychotropic Substances, 1971, based upon its review of the findings of the Twenty-Second WHO Expert Committee on Drug Dependence. The Administrative Law Judge also failed to consider that the Commission on Narcotic Drugs voted to place MDMA in Schedule I of the Convention on Psychotropic Substances, 1971. This last matter was brought to the attention of the Administrative Law Judge in oral arguments conducted on February 14, 1986, (Tr-10, p. 21) and was not entered into the record of this proceeding because the action occurred after the record was closed. The Administrator has been independently advised of this fact by the

United States State Department. (See appendix 1) While the fact that MDMA has been placed in Schedule I of the Convention on Psychotropic Substances is not dispositive of the instant scheduling issue, the Controlled Substances Act makes scheduling under the Convention on Psychotropic Substances a matter for consideration by the Secretary of HHS and the Attorney General. See 21 U.S.C. 811(d)(3).

In its recommendation for scheduling, the World Health Organization (WHO) concluded that MDMA should be added to Schedule I of the Convention on Psychotropic Substances, 1971. (Agency Exhibit B-20, Annex I, p. 6) The WHO Twenty-Second Expert Committee on Drug Dependence stated as part of its findings on MDMA:

This substance is commonly known as MDMA. In mice MDMA increased locomotor activity and produced analgesia. In dogs and monkeys the substance has a pharmacological profile similar to other substances already controlled under the Convention on Psychotropic Substances. Reports in man are contradictory as to whether MDMA has hallucinogenic activity. The substance is a potent serotonin releaser in rat whole brain synaptosomes. The toxicological properties in animals have been studied extensively. The acute toxicity of MDMA is about twice that of mescaline. No pharmacokinetic data is available . . .

On the basis of the data outlined above, it was the consensus of the Committee that 3,4-Methylenedioxy-methamphetamine met the criteria of Article 2, para. 4 for control under the Convention on Psychotropic Substances. Since there is insufficient evidence to indicate that the substance has therapeutic usefulness, the Committee recommended that it be placed in Schedule I. (Agency Exhibit B-20, Annex II, p. 8)

The fact that the Commission on Narcotic Drugs has placed MDMA in Schedule I of the Convention on Psychotropic Substances, 1971, is not dispositive of any issue raised in these proceedings. The Government suggests, however, that the findings of the WHO Expert

Committee and the Commission on Narcotic Drugs are certainly worthy of consideration by the Administrator. The restrictions placed on substances under Schedule I of the Psychotropic Convention, require placement in Schedule I or II of the Controlled Substances Act to provide the control required by the Convention. International scheduling of a substance which is being considered for domestic control is an important matter for consideration, even if the Administrative Law Judge chooses to ignore it.

THE ADMINISTRATIVE LAW JUDGE'S OPINION IS BIASED AGAINST THE GOVERNMENT IN THAT HE CONSISTENTLY FAILED TO CONSIDER THE EVIDENCE PRESENTED BY THE GOVERNMENT, AND GAVE EXCESSIVE WEIGHT AND CREDIBILITY TO THE TESTIMONY OF WITNESSES OF DRs. GREER AND GRINSPOON, ET. AL.

The Administrative Law Judge's 68 page Opinion is almost devoid of reference to testimony and other evidence presented by the Government. While quoting extensively from witnesses presented by Drs. Greer and Grinspoon, et. al, listing their education, background and experience, the Administrative Law Judge has failed to mention or quote the witnesses provided by the Agency. In discussing the observations and conclusions proffered by the witnesses of Drs. Greer and Grinspoon, et. al, the Administrative Law Judge appears to ignore criticism of these witnesses' "studies" presented by the Government's witnesses. The Government presented two psychiatrists to testify concerning the "studies" conducted by the psychiatrists presented by Drs. Greer and Grinspoon, et. al, and use of a drug such as MDMA in psychiatric practice. Dr. Joel E. Kleinman is a psychiatrist

who has a Ph.D. in neuropharmacology and is currently a resident in neurology. He practices neurology and psychiatry at George Washington University Hospital in Washington, D.C., and conducts research at St. Elizabeth's Hospital as Chief of the Clinical Brain Studies Section. Dr. John Docherty is a psychiatrist and former Chief of the Psychosocial Research Branch at the National Institute of Mental Health in Rockville, Maryland. The Administrative Law Judge does not mention either witness, nor does he make reference to any of their testimony in his Opinion.

In addition, after naming the psychiatrists presented by Drs. Greer and Grinspoon, et. al, and indicating that these individuals testified that MDMA had a currently accepted medical use in psychotherapy, the Administrative Law Judge states at page 30 of his Opinion:

No testimony to the contrary by any witness is brought to the attention of the administrative law judge by the Agency or any other participant.

As has been referred to previously in this document, there is testimony in the record that contradicts the Administrative Law Judge's conclusion.

The Administrative Law Judge dismissed the letter and evaluation of the Assistant Secretary of Health, Department of Health and Human Services, and stated that "it appears to be deserving of very little weight." (Opinion, p. 65) The Administrative Law Judge based this conclusion on the fact that the evaluation stated, "there is no known legitimate use of MDMA in humans." The Administrative Law Judge further stated that the Assistant Secretary's conclusion is an incorrect factual

statement. In his finding of fact 98, the Administrative Law Judge points out that the Acting Commissioner of Food and Drugs concluded that "MDMA has a significant potential for abuse," rather than a "high potential for abuse." In the Administrative Law Judge's opinion this statement apparently renders the Acting Commissioner's opinion meaningless. The Administrative Law Judge defined the difference between "significant" and "high" a "quantum increase." It should be noted at this point that the Acting Commissioner of the Food and Drug Administration at that time was Mark Novitch, who, in addition to being the Acting Commissioner, is a medical doctor. Dr. Novitch's conclusion that MDMA has a "significant" potential for abuse is clearly entitled to weight in this proceeding concerning MDMA's potential for abuse.

In addition to disregarding the evidence presented by the Agency and the Department of Health and Human Services, the Administrative Law Judge failed to consider the fact that several of the psychiatrists who testified on behalf of Drs. Greer and Grinspoon, et. al had themselves taken MDMA, many on their own initiative. It is obvious that this fact would tend to impact on the credibility of the witnesses to objectively and scientifically evaluate the effect of the drug in others. This fact was noted by both Dr. Docherty and Dr. Kleinman in their criticisms of the clinical "studies." Dr. Docherty stated:

The report noted a potentially very troublesome variation in the procedure wherein MDMA was administered. It is noted on page 5 of an attachment to the report entitled "The Legal, Safe, and Effective Use of MDMA" by George Greer, M.D., Santa Fe, New Mexico, that "in

special cases, facilitators may want to take MDMA with clients, but at least one facilitator should not take any in order to maintain appropriate social judgment." It is not clear whether the facilitator took MDMA on some occasions or not. We might expect that it certainly would make a difference whether or not the facilitator in the project was also using the substance at the same time as the "patient." (Docherty, direct, p. 5)

Dr. Grinspoon, who has personally used MDMA, but has not administered it to patients, described his experience with MDMA as follows:

Well, the reason I took it twice goes like this. I was very interested in -- from what I understood of this drug, various people had urged me to do this and I had said to them, if this is as you describe it, there is only one person in the world I would be willing to do it with, and that is my wife.

However, my wife was reluctant, ~~she is even more~~ drug naive than I am in terms of experience and I said well, suppose I take it once and if we're both persuaded that it's a harmless experience and an interesting experience, as we have been told it will be, then you can decide whether we will do it together. . . .

She spent the afternoon with me the first time I did it, we were both satisfied that it was certainly something we wanted to try so we did it the second time together. (Tr-6, p. 68-69)

In spite of the criticism of the "studies" done by Drs. Greer, Downing, Ingrasci, and Wolfson with MDMA, and despite the fact that they administered MDMA to themselves, and that they administered MDMA to humans without obtaining FDA approval in the form of an investigational new drug application, the Administrative Law Judge characterized these physicians, in his finding of fact 64, as, "wholly legitimate and highly regarded."

The Administrative Law Judge failed to consider much of the Government's evidence, and when he did consider it, declared it immaterial. In his finding of fact 51, the Administrative Law Judge found that Agency Exhibit B-21, the preliminary report of a study of the reinforcing properties of MDMA in the baboon, lacked "sufficient indicia of reliability to be given any weight." In order to obtain as much evidence as possible for the record, the Agency requested Dr. Roland R. Griffiths, an Associate Professor of Behavioral Biology and Associate Professor of Neuroscience at the Johns Hopkins University School of Medicine to submit a preliminary report of his study utilizing MDMA with baboons. He submitted his preliminary results which were introduced by the Government into the record. Dr. Griffiths concluded:

As discussed elsewhere, the abuse liability of a compound is a positive interactive function of 1. the reinforcing efficacy, and 2. the adverse effects (appended reprint: Griffiths, et al 1985) If MDMA does indeed have hallucinogenic activity as has been suggested in clinical trials (a significant adverse effect), then the moderate to high reinforcing efficacy revealed in the present data would suggest that MDMA should be considered to be a compound having high abuse liability.
(Agency Exhibit B-21)

The Administrative Law Judge did not consider Dr. Griffiths' opinion.

The Administrative Law Judge's consistent failure to consider evidence presented by the Agency from well-respected academic researchers and articles published in refereed scientific journals, or to consider the evidence presented, and summarily dismiss it as immaterial, indicates the Administrative Law Judge's bias in this proceeding. In preparing his Opinion,

the Administrative Law Judge relied on his own judgment and that of a few psychiatrists who tested MDMA on patients and themselves, rather than the scientific evidence presented by the Agency.

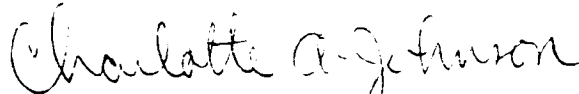
The Administrator of DEA would be failing to consider the public interest, and neglecting his responsibility as an impartial decision-maker, if he chooses to accept the biased conclusions of the Administrative Law Judge. The Agency strongly urges the Administrator to consider the all the evidence in the record, and to evaluate the credibility of the witnesses presented by all parties in this proceeding. The Agency is sure that such a review will result in a well-reasoned and even-handed decision.

CONCLUSION

Counsel for the Agency urges the Administrator to reject the Opinion of the Administrative Law Judge in this matter and find, based upon the substantial evidence in the record, that the substance MDMA is most properly placed in Schedule I of the Controlled Substances Act because it has no currently accepted medical use in treatment in the United States, it lacks accepted safety for use under medical supervision, and it has a high potential for abuse.

Respectfully submitted,

Stephen E. Stone
Associate Chief Counsel



Charlotte A. Johnson
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Dated: June 13, 1986

CERTIFICATE OF SERVICE

On June 13, 1986, I caused a copy of the foregoing to be mailed, postage prepaid, to the following:

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NAR/CL.2/1986

REFERENCE: DND 421/12(1-12/28)

The Secretary-General of the United Nations presents his compliments to the Secretary of State of the United States of America and, in accordance with article 2, paragraph 7, of the 1971
..... Convention on Psychotropic Substances, has the honour to communicate hereby the text of decisions 1 (S-IX) through 17 (S-IX) of the Commission on Narcotic Drugs taken at its ninth special session.

By decisions 1 (S-IX) through 7 (S-IX), the Commission included the seven substances cathinone, 2,5-dimethoxyamphetamine (DMA), paramethoxyamphetamine (PMA), 3,4,5-trimethoxyamphetamine (TMA), 2,5-dimethoxy-4-ethylamphetamine (DOET), 5-methoxy-3,4-methylenedioxyamphetamine (MMDA) and 3,4-methylenedioxymethamphetamine (MDMA) in Schedule I of the Convention on Psychotropic Substances; by decisions 8 (S-IX) through 10 (S-IX), the Commission included the three substances fenetylline, levamphetamine and levomethamphetamine in Schedule II of that Convention; by decision 11 (S-IX), the Commission included the substance cathine in Schedule III of that Convention; and by decisions 12 (S-IX) through 17 (S-IX), the Commission included the six substances N-ethylamphetamine, fencamfamin, fenproporex, mefenorex, propylhexedrine and pyrovalerone in Schedule IV of that Convention.

In accordance with article 2, paragraph 7, of the Convention, the decisions "shall become fully effective with respect to each Party 180 days after the date of [the present] communication", except for any Party which may have given notice under the relevant provision of that article.

28 February 1986

A handwritten signature in black ink, appearing to be 'NAR' or similar, located at the bottom right of the page.

ANNEX

Commission on Narcotic Drugs

Decisions 1 (S-IX) - 17 (S-IX)

1 (S-IX)

INCLUSION OF CATHINONE IN SCHEDULE I OF THE 1971 CONVENTION
ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that (-)-alpha-aminopropiophenone (also referred to as cathinone) should be included in Schedule I of that Convention.

2 (S-IX)

INCLUSION OF 2,5-DIMETHOXYAMPHETAMINE (DMA) IN SCHEDULE I
OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-2,5-dimethoxy-alpha-methylphenylethylamine (also referred to as 2,5-dimethoxyamphetamine or DMA) should be included in Schedule I of that Convention.

3 (S-IX)

INCLUSION OF PARAMETHOXYAMPHETAMINE (PMA) IN SCHEDULE I
OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that 4-~~methoxy~~-alpha-methylphenylethylamine (also referred to as paramethoxyamphetamine (PMA)) should be included in Schedule I of that Convention.

4 (S-IX)

INCLUSION OF 3,4,5-TRIMETHOXYAMPHETAMINE (TMA) IN SCHEDULE I
OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-3,4,5-trimethoxy-alpha-methylphenylethylamine (also referred to as 3,4,5-trimethoxyamphetamine or TMA) should be included in Schedule I of that Convention.

5 (S-IX)

INCLUSION OF 2,5-DIMETHOXY-4-ETHYLAMPHETAMINE (DOET) IN SCHEDULE I
OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-2,5-dimethoxy-4-ethyl-alpha-methylphenylethylamine (also referred to as 2,5-dimethoxy-4-ethylamphetamine or DOET) should be included in Schedule I of that Convention.

6 (S-IX)

INCLUSION OF 5-METHOXY-3,4-METHYLENEDIOXYAMPHETAMINE (MMDA)
IN SCHEDULE I OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-5-methoxy-3,4-methylenedioxy-alpha-methylphenylethylamine (also referred to as 5-methoxy-3,4-methylenedioxyamphetamine or MMDA) should be included in Schedule I of that Convention.

7 (S-IX)

INCLUSION OF 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) IN SCHEDULE I
OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-3,4-methylenedioxy-N-alpha-dimethylphenylethylamine (also referred to as 3,4-methylenedioxymethamphetamine or MDMA) should be included in Schedule I of that Convention.

8 (S-IX)

INCLUSION OF FENETYLLINE IN SCHEDULE II OF THE
1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-3,7-dihydro-1,3-dimethyl-7-(2-[(1-methyl-2-phenylethyl)amino]ethyl)-1H-purine-2,6-dione (also referred to as fenetylline) should be included in Schedule II of that Convention.

9 (S-IX)

INCLUSION OF LEVAMPHETAMINE IN SCHEDULE II OF THE
1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that l-alpha-methylphenethylamine (also referred to as levamphetamine) should be included in Schedule II of that Convention.

10 (S-IX)

INCLUSION OF LEVOMETHAMPHETAMINE IN SCHEDULE II
OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that l-N, alpha-dimethylphenethylamine (also referred to as levomethamphetamine) should be included in Schedule II of that Convention.

11 (S-IX)

INCLUSION OF CATHINE IN SCHEDULE III
OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided d-threo-2-amino-1-hydroxy-1-phenylpropane (also referred to as cathine) should be included in Schedule III of that Convention.

12 (S-IX)

INCLUSION OF N-ETHYLAMPHETAMINE IN SCHEDULE IV OF THE
1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-N-ethyl-alpha-methylphenylethylamine (also referred to as N-ethylamphetamine) should be included in Schedule IV of that Convention.

13 (S-IX)

INCLUSION OF FENCAMFAMIN IN SCHEDULE IV
OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-N-ethyl-3-phenylbicyclo(2,2,1)-heptan-2-amine (also referred to as fencamfamin) should be included in Schedule IV of that Convention.

14 (S-IX)

INCLUSION OF FENPROPOREX IN SCHEDULE IV
OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-3-[(alpha-methylphenethyl)amino]propionitrile (also referred to as fenproporex) should be included in Schedule IV of that Convention.

15 (S-IX)

INCLUSION OF MEFENOREX IN SCHEDULE IV OF THE
1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-N-(3-chloropropyl)-alpha-methylphenethylamine (also referred to as mefenorex) should be included in Schedule IV of that Convention.

16 (S-IX)

INCLUSION OF PROPYLHEXEDRINE IN SCHEDULE IV OF THE
1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-1-cyclohexyl-2-methylaminopropane (also referred to as propylhexedrine) should be included in Schedule IV of that Convention.

17 (S-IX)

INCLUSION OF PYROVALERONE IN SCHEDULE IV
OF THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

At its 969th meeting on 11 February 1986, the Commission on Narcotic Drugs, in accordance with article 2, paragraph 5, of the 1971 Convention on Psychotropic Substances, decided that dl-1-(4-methylphenyl)-2-(1-pyrrolidinyl)-1-pentanone (also referred to as pyrovalerone) should be included in Schedule IV of that Convention.