

UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

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In The Matter Of
MDMA SCHEDULING

Docket No. 84-48

OPINION AND RECOMMENDED RULING, FINDINGS OF
FACT, CONCLUSIONS OF LAW AND DECISION
OF ADMINISTRATIVE LAW JUDGE

ON ISSUES TWO THROUGH SEVEN

FRANCIS L. YOUNG, Administrative Law Judge

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Dated: MAY 22 1986

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I.

Introduction

This is a rulemaking proceeding pursuant to the Controlled Substances Act as amended¹ (the Act or the CSA) to determine in which schedule, if any, of the five schedules established by the Act, the substance 3, 4-methylene-dioxymethamphetamine, also known as MDMA, should be placed. The proceeding is being conducted pursuant to Subchapter II of Chapter 5 of Title 5, United States Code, the Administrative Procedure Act, after opportunity for a hearing.²

The Act itself placed a great many substances in one schedule or another. It vested the Attorney General with the authority, after considering several prescribed factors, to place other substances in appropriate schedules, to move substances from one schedule to another, and to de-schedule them. That authority has been delegated to the Administrator of the Drug Enforcement Administration (DEA).³

¹ P.L. 91-513, 84 Stat. 1242, 21 U.S.C. §§ 801, et seq.

² 21 U.S.C. § 811(a).

³ 28 C.F.R. § 0.100.

At the commencement of this proceeding in July 1984 MDMA was not listed in any schedule. At that time DEA published in the Federal Register⁴ a notice of proposed rulemaking to place the substance in Schedule I. A number of persons filed comments and objections and requested a hearing. This administrative law judge was requested by the then-Deputy Administrator to preside and to provide the Administrator with a certified record and recommended findings of fact, conclusions of law and decision.

At a preliminary prehearing conference of participants on February 1, 1985 it was suggested that one of the issues identified presented a purely legal question which might be decided without the need of any evidence and in advance of the other issues in the case. (The Deputy Administrator had specified this issue as one on which a recommended conclusion was to be prepared for the Administrator.) After considering memoranda submitted by the participants the administrative law judge agreed and accepted the suggestion. The judge called for briefs from the parties on that issue. It was designated issue number 1, and was stated thus:

1. Assuming that a substance has a potential for abuse and has no currently accepted medical use in treatment in the United States, can the substance be placed in any schedule other than Schedule I?

After studying the briefs the judge issued a recommended decision on that issue, dated June 1, 1985. He recommended, first, that the language of the Act was such that a substance with a potential for abuse less than a "high" potential, and having no currently accepted medical use in treatment, cannot be placed in any of the five schedules. (Clearly, a substance with a "high" abuse potential and no accepted medical use in treatment, must be placed in Schedule I.) Alternatively the judge recommended, based upon court decisions interpreting the Act, actions of the Congress, legislative history and DEA's own past

⁴ 49 F.R. 30210 (1984).

actions, that such a substance should be placed in either Schedule III, IV or V depending upon its degree of potential for abuse. In a letter to the administrative law judge dated October 7, 1985 the Administrator advised that he had decided not to issue a final agency ruling on that initial issue until he had received the entire record at the conclusion of the case.

Meanwhile, the proceeding continued with respect to the remaining issues. Direct examination testimony of all witnesses was submitted in written narrative form. Exhibits were identified and submitted. Hearing sessions for cross-examination of witnesses were held in Los Angeles, California, Kansas City, Missouri and Washington, D.C. on June 10, July 10 and 11, October 8, 9, 10 and 11 and November 1, 1985. The participants⁵ submitted briefs and proposed findings and conclusions, and oral argument was heard in Washington, D.C. on February 14, 1986.⁶

The administrative law judge has carefully considered all the evidence of record and the arguments of the participants, as well as the written comments received during the comments period early on in the proceeding. He submits herein to the Administrator his recommended findings, conclusions and decision with respect to the issues other than Issue 1.

⁵ The participants are the Agency staff (DEA or the Agency); George Greer, M.D., Lester Grinspoon, M.D., Thomas B. Roberts, Ph.D. and James Bakalar (Greer-Grinspoon); McNeilab, Inc. and Hoffmann-La Roche, Inc. (McNeilab); Lyn B. Ehrnstein, Esq., (Ehrnstein); and David E. Joranson (Joranson). See Memorandum to Counsel dated March 22, 1985.

⁶ There are ten volumes of transcript. The first contains the preliminary session on February 1, 1985. The remainder contain the testimony on cross examination and the oral argument. They have been numbered 1 through 10, and are cited herein as follows:

February 1, 1985	Tr 1	October 9, 1985	Tr 6
June 10, 1985	Tr 2	October 11, 1985	Tr 7
July 10, 1985	Tr 3	October 11, 1985	Tr 8
July 11, 1985	Tr 4	November 1, 1985	Tr 9
October 8, 1985	Tr 5	February 14, 1986	Tr 10

II.

Recommended Ruling

The administrative law judge recommends that the proposed findings and conclusions submitted by the participants be rejected by the Administrator, except to the extent they are included in the judge's recommendations, for the reason that they are irrelevant, unduly repetitious or not supported by substantial evidence. The judge's recommended findings and conclusions are contained in the text of this opinion.

III.

Issues

The issues yet to be disposed of are as follows:

2. What constitutes "currently accepted medical use in treatment in the United States" within the purview of 21 U.S.C. § 812(b)?

3. What constitutes "accepted safety for use . . . under medical supervision" within the purview of 21 U.S.C. § 812(b)?

4. Is a finding by the Secretary of Health and Human Services that a substance has "no currently accepted medical use in treatment in the United States" or a finding that a substance has no "accepted safety for use . . . under medical supervision" binding on the Attorney General (the Administrator of the Drug Enforcement Administration, DEA) within the purview of the provisions of 21 U.S.C. § 812?

5. Does MDMA have a "currently accepted medical use in treatment in the United States" within the purview of 21 U.S.C. § 812(b)?

6. Is there a lack of "accepted safety for use [of MDMA] under medical supervision" within the purview of 21 U.S.C. § 812(b)?

7. If, on the basis of the resolution of the above issues [including issue 1], MDMA can lawfully be scheduled in a schedule other than Schedule I, in which schedule should it be placed?

"Currently Accepted Medical Use
In Treatment In The United States"

Introduction

Section 812(b) of Title 21 U.S.C. provides that, aside from actions mandated by certain international agreements, which are not applicable here, and except in the case of an immediate precursor, with which we are not concerned, "a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance." It is the responsibility of the Administrator of DEA to make these findings after receiving an evaluation and recommendation from the Secretary of the Department of Health and Human Services (HHS)⁷ pursuant to § 811(b). After making his findings, the Administrator is to place the drug or substance in question in the appropriate schedule of the five schedules established by the Act.

The findings required for placement in each schedule are set out in Section 812(b) as follows:

(1) Schedule I.-

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II.-

(A) The drug or other substance has a high potential for abuse.

⁷ The Secretary's input into the matter comes to the Administrator from the Assistant Secretary of Health, HHS.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III.-

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV.-

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V.-

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(Emphasis added).

Thus a finding must be made for each drug or other substance to be

scheduled as to whether or not it has a "currently accepted medical use in treatment in the United States".

What constitutes such use? What does this phrase mean? How is the Administrator to ascertain whether or not a drug has a currently accepted medical use in treatment in this country? This is essentially a legal issue of statutory interpretation. No findings of fact are called for.

To the Agency staff the answer is simple. They assert that "accepted medical use" means approval by the Food and Drug Administration (FDA) of HHS pursuant to the procedures established by Section 505 of the Federal Food, Drug and Cosmetic Act of 1938 (FDCA), 21 U.S.C. § 355. DEA need only ask FDA whether the drug or substance in question has received FDA approval under the FDCA in order to ascertain the existence, vel non, of "accepted medical use".

There is no denying that such a situation would greatly simplify the scheduling task of the DEA staff. It provides a quick solution to the problem for DEA. It provides a certain answer. But it is wrong.

The FDCA

The FDCA was enacted in 1938. It established procedures which a person must follow, and approvals he must obtain, before he may "introduce or deliver for introduction into interstate commerce any new drug". 21 U.S.C. § 355(a). In a word the FDCA, as amended, requires that FDA must approve a new drug as being safe and as being effective for a stated purpose - before it may be introduced into interstate commerce in the United States. There is nothing in that statute authorizing FDA to approve a new drug for use in the practice of

medicine by a licensed physician. The power to grant or withhold such approval would constitute regulation of the practice of medicine. The FDCA does not empower the FDA to do this. The FDA itself has repeatedly stated that it is not empowered to attempt such regulation.

The question of FDA's authority in this regard has arisen when that agency has considered the practice of physicians using marketed drugs for purposes which the FDA has not approved.⁸ In 1972, FDA summed up its view on this subject when, in the preamble to a proposed rule on drug labeling, it stated:

If an approved new drug is shipped in interstate commerce with the approved package insert and neither the shipper nor the recipient intends it be used for an unapproved purpose, the requirements of section 505 of the Act are satisfied.

Once the new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration.

This interpretation of the Act is consistent with congressional intent as indicated in the legislative history of the 1938 Act and the drug amendments of 1962. Throughout the debate leading to enactment, there were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice and references to the understanding that the bill did not purport to regulate the practice of medicine as between the physician and the patient. Congress recognized a patient's

⁸ Under the FDCA, the labeling of any prescription drug, whether subject to approval or not, must be adequate for the drug's intended purposes. In the case of prescription drugs (as opposed to "over-the-counter" drugs available without a prescription), the requirements are met by conditioning availability on a practitioner's prescription, and on there being labeling directions for physicians and pharmacists (as opposed to laymen) as to the prescribing, dispensing, and administration of the drug. 21 C.F.R. § 201.100.

right to seek civil damages in the courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession.

37 Fed. Reg. 16503 (1972).

Subsequently, in 1975, five years after enactment of the Controlled Substances Act, the Food and Drug Administration wrote as follows:

The comments recommended that the proposed regulations be revised to require an appropriate statement in package inserts that, in addition to the conditions of use which the manufacturer may recommend to physicians in compliance with the law and Food and Drug Administration regulations, there are other conditions of use for which the drug may be regarded as safe and effective on the basis of the experience of critical physicians using the drug in the practice of medicine over a period of years.

The Commissioner stated in a separate notice of proposed rulemaking published in the Federal Register of August 15, 1972 (37 Fed. Reg. 16503)⁹, concerning the use of a drug for conditions not included in its labeling, that the labeling does not intend either to preclude the physician's use of his best judgment in the interest of the patient or to impose liability if he does not follow the package insert. The Commissioner clearly recognizes that the labeling of a marketed drug does not always contain all the most current information available to physicians relating to the proper use of the drug in good medical practice. Advances in medical knowledge and practice inevitably precede the labeling revision by the manufacturer and formal labeling approval by the Food and Drug Administration. Good medical practice and patient interest thus require that physicians be free to use drugs according to their best knowledge and judgment. Certainly where a physician uses a drug for a use not in the approved labeling, he has the responsibility to be well informed about the drug and to base such use on a firm scientific rationale or on sound medical evidence, and to maintain

⁹ Quoted immediately above.

adequate medical records of the drug's use and effects, but such usage in the practice of medicine is not in violation of the Federal Food, Drug and Cosmetic Act.

40 Fed. Reg. 15393-94 (1975) (emphasis added).

In 1979, the Food and Drug Administration once more reiterated this view:

Good medical practice and patient welfare require that physicians remain free to use drugs according to their best knowledge and judgment

44 Fed. Reg. 37435-36 (1979).

Once again, in June 1983, the FDA repeated its view that it does not have the authority to regulate the practice of medicine:

Although no final rule has been issued on this subject, the Agency has continued to apply the principle set forth in the preamble to the 1972 proposal. In FDA's Drug Bulletin of April 1982, the Agency sought to clarify and reiterate the position that the Act does not regulate the "practice of medicine." Once a drug product has been approved for marketing, a physician may, in treating patients, prescribe the drug for use not included in the drug's approved labeling. The primary legal constraints in that situation are State laws on medical practice and products liability law. The IND Rewrite proposal would codify the Agency's longstanding position that the regulations do not apply to the "practice of medicine," though the proposal does not purport to define with specificity such practice in terms of the Act.

48 Fed. Reg. 2673 (June 9, 1983).

Finally, the Food and Drug Administration reemphasized this position in a filing with the United States Court of Appeals for the District of Columbia Circuit in 1983. In the course of its argument in the 1983 case, the FDA emphasized the

commonly recognized exception to the Act's broad and protective coverage: the 'practice-of-medicine' exemption. FDCA's legislative history expresses a specific intent to prohibit FDA from regulating physicians' practice of medicine. According to the Commissioner, FDCA does not regulate physicians in their practice because physicians are licensed by the states. Letter from the Commissioner at 3, JA 88.

Chaney v. Heckler, 718 F.2d 1174, 1179 (D.C. Cir. 1983), rev'd,
____ U.S. _____, 84 L. Ed. 714 (1985). (Footnotes omitted).

A word of caution is called for. In the penultimate quotation above, the phrase "approved for marketing" appears. This term is frequently used as a substitute for the statutory language "introduced into interstate commerce". Agency counsel slipped into this inaccuracy in oral argument on February 14, 1986. (Tr 10, p.6) It is important to keep clearly in mind what Congress was doing when it enacted the FDCA in 1938 - it was regulating the interstate commerce of substances. It was not undertaking to define the acceptable practice of medicine. It was not attempting to provide a yardstick for "accepted medical use".

The above-quoted statements by the FDA, which carries out the provisions of the FDCA, provide no basis for turning to that statute for a determination of what does or does not constitute "accepted medical use". Indeed, the FDA's own pronouncements are clearly to the contrary.

DEA's brief in this proceeding points to another statement by FDA, in 1982, prompted by efforts to "legalize" marihuana. In its published proposed recommendations to DEA on the scheduling status of that substance and its components, FDA said, referring to the language of § 812(b):

FDA interprets the term "accepted medical use" to mean lawfully marketed under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301, et seq. . . . A drug may be marketed lawfully under the Federal Food, Drug, and Cosmetic Act after approval of a new drug application (NDA) for that drug. There are, theoretically other ways in which a drug could be marketed legally. The drug could satisfy either the requirements for exemption from the definition of "new drug"

in 21 U.S.C. 321(p) or the requirements for a "grandfather clause" from the new drug approval provision. (47 Fed. Reg. 28150)

The Commissioner of FDA continued at page 28151 by saying:

The mechanism set up by Congress for lawful marketing of a new drug requires submission of an NDA to FDA and FDA approval of that application before marketing. Before FDA can approve an NDA, however, the drug sponsor must submit data from an extensive battery of experimental testing on both animals and humans to establish the drug's safety and effectiveness for its proposed uses. In addition, the sponsor must submit data and manufacturing controls demonstrating that standards of identity, strength, quality, and purity will be met.

He concludes by saying:

Thus, the lack of an approved NDA for a drug substance leads FDA to find that a substance lacks "an accepted medical use in treatment" for two reasons. First, if use of the drug is unlawful whenever interstate commerce is involved, medical use of the drug cannot be classified as accepted. Second, in the absence of the data necessary for approval of the NDA, the agency has no basis for concluding that medical use of the drug in treatment can be considered acceptable by medical standards.

The last quotation flies directly in the face of the preceding statements of statutory interpretation by FDA, issued over a period of eleven years. It represents a complete reversal of position with no stated basis whatsoever. One can only conclude that, in the context of the battle over marihuana, FDA temporarily lost sight of its long-acknowledged lack of statutory authority to regulate the practice of medicine. Perhaps it failed to realize the full effect of its statement. FDA is not charged with forming a conclusion, binding on the medical profession, "that medical use of the drug in treatment can be considered acceptable by medical standards." FDA is to pass on the safety and efficacy of a drug simply and solely in connection with approving it for "introduction into interstate commerce."

FDA is acting properly if it attempts to ascertain whether or not the medical profession has accepted use of a drug in treatment as the agency determines whether or not to allow the drug's introduction into interstate commerce. Acceptance of use in treatment, with other factors, is certainly an appropriate consideration. But nowhere in either statute, the FDCA or the CSA, is it provided that FDA's fiat will be binding on the medical profession with respect to what is, or is not, accepted medical practice or accepted medical use.

There can be a very simple reason why there exists no NDA for a particular drug and why FDA has not approved it for introduction into interstate commerce: no one may have sought such approval from FDA. The fact no one has sought approval does not necessarily mean that no one is using the drug and that such use is not accepted by the profession. There are very real economic factors affecting whether an NDA is sought for a drug.

The Controlled Substances Act

The Controlled Substances Act (CSA) was enacted in 1970, 32 years after the Food, Drug and Cosmetic Act. In 1970 the Congress was well aware of its 1938 handiwork. There are several specific references to the 1938 statute in the 1970 enactment. Thus we find in the CSA that "drug" is defined by specific reference to a section of the FDCA; see 21 U.S.C. § 802(12). Congress excluded from the Attorney General's scheduling power any substance permitted by the FDCA to be sold "over the counter and without a prescription"; see 21 U.S.C. § 811(g)(1). Congress specifically referred to the investigational new drug provisions of the FDCA in the CSA; see 21 U.S.C. §§ 827(c)(2)(A), 827(f). Other references to provisions of the FDCA are found in the CSA at 21 U.S.C. §§ 825(a), 825(b), 829(a) and 829(d). Congress could easily have linked the phrase "accepted medical use in treatment" in the CSA to some provision of the FDCA, and FDA's authority thereunder, had it desired to do so. It did not do so.

The Agency's reply brief¹⁰ refers to the "somewhat sparse legislative history of the Controlled Substances Act relating to 'accepted medical use'." No participant quotes any comment on the meaning of this phrase from a committee report or floor manager. However, there were references to the phrase in the testimony of several witnesses.

Dr. John Jennings, then Acting Director of the Bureau of Drugs, FDA, testified as follows at one point:

Q: Let me ask one question: when a drug is under investigation pursuant to investigational new drug applications, is the drug considered to have an accepted medical use?

Dr. Jennings: Usually not, although it might.

Q: Could you enlarge on that?

Dr. Jennings: Yes, sir. The exemption for investigational use is usually granted for a drug for which the medical use has not been established so in most cases that would be so, there would not be an accepted medical use.

However, drugs that have one or maybe several accepted medical uses might be under investigation for additional medical uses.

Q: But in the great majority of cases —

Dr. Jennings: It would be true that the accepted medical use would not have been established.

House Hearings, at 343 (emphasis added).

The subject came up also during the testimony of Michael R. Sonnenreich, Deputy Chief Counsel of the Bureau of Narcotics and Dangerous Drugs (BNDD), DEA's predecessor agency, of John Ingersoll, Director of BNDD, and of Dr. Roger Egeberg, Assistant Secretary of HEW. They testified as follows:

¹⁰ Government's Response To The Findings, etc., Submitted by Drs. Greer and Grinspoon, et al., etc., p. 13.

Mr. Sonnenreich: [Criterion] Two [no accepted medical use] is a factual determination and normally where we get such information is through the AMA or WHO. You don't have to be a doctor to find out whether or not it has an accepted medical use in the United States or not. So the fact that you are asking whether it has got accepted medical use is something that a lawyer can find out as well as a doctor.

House Hearings, at 165 (emphasis added).

Mr. Rogers: Under Schedule I drugs. Would HEW or the Department of Justice be able to determine on a drug a lack of accepted safety for use under medical supervision?

Dr. Egeberg: I would think that HEW would expect to have a good deal to say on that.

Mr. Rogers: All right. HEW would have the competence there. I think this would be admitted. What about no accepted medical use in the United States?

Dr. Egeberg: Well, I would think that HEW would be the primary source, through its various agencies and its contacts, for information on that subject.

House Hearings, at 194 (emphasis added).

Mr. Ingersoll: I must also point out that this review [prior to registration of researchers by the Department of Justice] is only required for Schedule I substances which the medical profession has already determined have no legitimate medical use in the United States.

House Hearings, at 678 (emphasis added).

Mr. Rogers: So the only category of [Schedule] I is simply for research?

Mr. Sonnenreich: Yes, sir, and that is because they have no medical use as determined by the medical community.

House Hearings, at 696 (emphasis added).

Mr. Sonnenreich: Mainly, our feeling is that the trigger on your Schedule I drugs which are really different from your II, III and IV drugs. It is this basic determination that is not made by any part of the federal government. It is made by the medical community as to whether or not the drug has medical use or doesn't.

Mr. Rogers: If it has medical use, Food and Drug probably would have authorized it, wouldn't they?

Mr. Sonnenreich: I assume so, sir.

House Hearings, at 718 (emphasis added).

From the foregoing exchanges it clearly appears that the spokesmen for BNDD and FDA were of the view in 1970 that one should turn to "the medical community" to ascertain the existence of accepted medical use in treatment, and that "a lawyer can find out as well as a doctor" whether such acceptance exists, and that "this basic determination is not made by any part of the federal government".¹¹

This interpretation, provided to the Congress by Administration witnesses, contemporaneously with enactment, is reasonable and authoritative. The Congress has given no indication of having rejected it or of adopting another. It is in accord with the plain meaning of the language in the statute. The Congress had every opportunity to tie "accepted medical use" to FDA actions under the FDCA. It did not do so. The only rational conclusion is that it did not intend to do so.

¹¹ In their Reply Brief, at page 16, Agency counsel quote a sentence from a written statement submitted to the Congress on another occasion by Director Ingersoll in justification of the Schedule I placement of a particular substance. This one, isolated sentence appears directly to contradict Mr. Ingersoll's oral testimony to the Committee quoted above. To that extent it is inconsistent also with the quoted oral statements of Mr. Sonnenreich, Mr. Ingersoll's deputy chief counsel. In the circumstances, and being uninformed as to the full context of the written sentence, it would seem that the oral statements, made when the phrase was being specifically discussed, should be accepted as accurately expressing BNDD's opinion on the point. The only alternative is to conclude that Mr. Ingersoll was not a reliable witness at all and that none of his statements can be accepted.

Court Decisions

Court decisions have agreed with the FDA itself, and the BNDD spokesmen in 1970, that the FDA is not empowered to decree what is or is not proper medical practice.

Congress did not intend the Food and Drug Administration to interfere with medical practice as between the physician and the patient. Congress recognized the patient's right to seek civil damages in the courts if there should be evidence of malpractice and declined to provide any legislative restrictions upon the medical profession. . . . Congressional intent set out in 37 Fed. Reg. 16503 (1972) indicates the Congress did not intend the Food and Drug Administration to interfere with medical practice and that the bill did not purport to regulate the practice of medicine as between the physician and the patient.

* * *

". . . the physician can ascertain from medical literature and from medical meetings new and interesting proposed uses for drugs marketed under package inserts not including the new proposed usages . . . New uses for drugs are often discovered, reported in medical journals and at medical meetings, and subsequently may be widely used by the medical profession. . . . The manufacturer may not have sufficient commercial interests or financial wherewithal to warrant following the necessary procedures to obtain FDA approval for the additional use of the drug. When physicians go beyond the directions given in the package insert it does not mean they are acting illegally or unethically and Congress does not intend to empower the FDA to interfere with medical practice by limiting the ability of physicians to prescribe according to their best judgment.

United States v. Evers, 453 F. Supp. 1141, 1149, 1150 (M.D. Ala. 1978),

aff'd 643 F.2d 1043 (5th Cir. 1981). (Emphasis added.)

In its opinion affirming the District Court in Evers, the Fifth Circuit observed:

***[T]he [FDCA] was intended to regulate the distribution of drugs in interstate commerce, not to restrain physicians from public advocacy of medical opinions not shared by the FDA.

United States v. Evers, 643 F.2d 1043, 1053, n. (1981).

Agency counsel's quote from the Fifth Circuit opinion in Evers (Reply Brief, p. 9) simply expresses recognition of the FDA's lack of power to regulate medical practice with reference to the specific facts of that case which centered on the use of a non-prescription drug for a purpose other than that stated in the package insert. The quotation in no way detracts from the court's recognition of the basic principle. It reinforces it.

Uniform Controlled Substances Act

The plebiscite conducted by participant Joranson of state regulatory officials is wholly irrelevant and immaterial. He asked them to express their interpretations, as regulators, of language in the Uniform Controlled Substances Act, not the language in the Federal statute with which we are concerned. It is the medical community which is to be consulted on the Federal statutory question, not state regulators working with different statutes.

Classification Of Alphacetylmethadol

The Agency's discussion of Congress' treatment of alphacetylmethadol has no relevance here. The Agency submitted a statement to the Congress about that substance, that "since the current use of alphacetylmethadol is limited to research, it has no currently accepted medical use. . . ." Whatever else was said about that substance was surplusage with respect to its accepted medical use.

Congressional Rescheduling of Methaqualone

In 1984 Congress enacted special legislation effectively placing the substance methaqualone in Schedule I.¹² Agency counsel now point to one sentence in a House Report concerning that legislation as evidencing an understanding by the Congress that "accepted medical use in treatment" was equated by the Committee with FDA "approval". Counsel's reliance on the quoted statement is misplaced.

To begin with, the statement is wrong. The Committee Report says: "[T]he 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". There is no such bar in the CSA. The CSA does provide, in 21 U.S.C. § 811(b) that "if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance". But there is no language having the effect of the quoted statement in the House Report.

The very next sentence in the House Report, not quoted in the Agency's brief, is correct and does show the necessity for Congressional action to outlaw methaqualone at that time. The sentence says:

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.

The Report continues:

There are circumstances when public health considerations require the Congress to exercise its responsibility to determine whether the adverse health effects caused by diversion of a drug outweigh its therapeutic usefulness and therefore warrant impositions of Schedule I controls.

¹² P.L. 98-329, 98 Stat 280, June 29, 1984. See Appendix.

. . . Although methaqualone currently has an accepted medical use, there is a consensus of medical opinion that it has no unique therapeutic advantages over other available drugs and has a significantly higher incidence of and potential for abuse.

* * *

Should future research discover a new use for methaqualone or if it can be clinically demonstrated that methaqualone possesses therapeutic advantages not possessed by other sedative-hypnotic drugs, the Controlled Substances Act specifies procedures for administratively removing the drug from Schedule I and placing it in an appropriate schedule of the Act.¹³

The House committee was not focusing on the problem which concerns us at the moment. But implicit in the above language is recognition that what the medical profession is actually doing is not to be equated with an approval action by the FDA. Indeed, the Report shows that the Committee listened to the medical community. At least one physician is quoted in the Report, as is a report adopted by the House of Delegates of the American Medical Association.

The Agency brief states, p. 20:

*** By ordering the Secretary to withdraw the NDA for methaqualone, Congress ensured that the drug then met all the criteria for control in Schedule I, particularly that it had "no currently accepted medical use in treatment in the United States".

Counsel are mistaken. A careful reading of the statute enacted reveals that the Attorney General was directed to transfer the substance from Schedule II to Schedule I first, and thirty days thereafter the Secretary (FDA) is directed to withdraw the NDA. See Appendix.

Clearly, Congress was exercising its prerogative, which only it possesses, to enact legislation. DEA and FDA must operate within the procedural scheme

¹³ H.R. Rep. No. 98-534, 98th Cong., 1st Sess. 4(1983)

established for them by the Congress, but Congress is not so constrained. Congress, as it has the power to do, directed DEA to outlaw methaqualone regardless of the fact that it had an accepted medical use and regardless of the fact that the NDA had not yet been withdrawn by FDA.

Conclusion

The administrative law judge concludes that "accepted medical use in treatment in the United States" is not determined by NDA approvals or dis-approvals by FDA. It is determined, rather, by what is actually going on within the health care community.

"Currently Accepted Medical Use"
Of MDMA

Let us, then, in the words of Deputy Chief Counsel Sonnenreich, consult "the medical community as to whether or not [MDMA] has medical use or doesn't." In this instance, as in many others, it is instructive for this tribunal to look to the courts for guidance.

Most court decisions are dealing with suits for medical malpractice. But the basic inquiry is the same as that in which we are presently engaged. Was the doctor's action acceptable, or is he to be considered culpable for taking it? How large a segment of the medical community must accept a mode of treatment before the courts will accept it and find no culpability in the doctor following it?

In Hood v. Philips, 537 S.W. 2d 291 (1976) the Texas Court of Civil Appeals found itself dealing with a claim of medical malpractice arising from a surgical procedure claimed to have been unnecessary. The court noted that the usual treatment for emphysema by the majority of the medical profession is non-surgical. The defendant doctor, however, resorted to surgery. The court said:

***This is a highly controversial procedure, but there is evidence that carotid body surgery is performed by at least one other doctor in Texas, a doctor in Boston, Massachusetts, and doctors in Japan, Poland and Italy. Until his retirement in 1967, defendant was apparently the only physician in the Houston area who employed this procedure. The defendant stated that eighty-five percent of some 1,200 persons on whom he has operated derived some benefit, but there is medical evidence in the record that the procedure is generally recognized as having no value in treating emphysema and in some cases may be detrimental to the patient's health.

537 S.W. 2d at 292. Noting that some courts had adopted a rule of "generally recognized treatment", the Texas court observed that courts have also enunciated a corollary to the rule that one should follow the better method, viz.:

where there are several possible methods of treatment, a doctor will not be liable for a patient's injuries as long as the treatment is one followed by a respectable minority of the medical profession and his care under that treatment conforms with the general practice of reasonable physicians utilizing the same treatment.

Ibid. at 293. The Texas court quoted from an Arizona court decision, holding that

a method of treatment, as espoused and used by . . . a respectable minority of physicians in the United States, cannot be said to be an inappropriate method of treatment or to be malpractice as a matter of law even though it has not been accepted as a proper method of treatment by the medical profession generally.

Ibid. at 294. Noting that the Federal District court in the Arizona case found a "respectable minority" composed of sixty-five physicians throughout the United States, the Texas court adopted as "the better rule" to apply in its case, that

a physician is not guilty of malpractice where the method of treatment used is supported by a respectable minority of physicians.

. . . .

Ibid. The court sent the case back to the trial court for a determination applying that rule. One judge dissented, believing that the evidence in the particular case was insufficient to raise an issue of malpractice for the jury.

He observed:

. . . I fear the long term effect [will] discourage new procedures and techniques, so necessary to improve health care.

Ibid. at 297.

In Chumbler v. McClure, 505 F.2d 489 (6th Cir. 1974) the Federal courts were dealing with a medical malpractice case under their diversity jurisdiction, applying Tennessee law. The Court of Appeals said:

. . .The most favorable interpretation that may be placed on the testimony adduced at trial below is that there is a division of opinion in the medical profession regarding the use of Premarin in the treatment of cerebral vascular insufficiency, and that Dr. McClure was alone among neurosurgeons in Nashville in using such therapy. The test for malpractice and for community standards is not to be determined solely by a plebiscite. Where two or more schools of thought exist among competent members of the medical profession concerning proper medical treatment for a given ailment, each of which is supported by responsible medical authority, it is not malpractice to be among the minority in a given city who follow one of the accepted schools.

505 F.2d at 492. (Emphasis added).

How do we ascertain whether there exists a school of thought supported by responsible medical authority, and thus accepted? We listen to the physicians.

The court and jury must have a standard measure which they are to use in measuring the acts of a doctor to determine whether he exercised a reasonable degree of care and skill; they are not permitted to set up and use any arbitrary or artificial standard of measurement that the jury may wish to apply. The proper standard of measurement is to be established by testimony of physicians, for it is a medical question.

Hayes v. Brown, 133 S.E. 2d. 102(Ga., 1963) at 105.

The courts and former Deputy Chief Counsel Sonnenreich are in accord.

Findings Of Fact

There is testimony in this record from reputable physicians, i.e., responsible medical authorities who constitute a respectable minority, that the use of MDMA is acceptable in the treatment of certain kinds of patients.

Dr. George Greer is a psychiatrist in private practice in New Mexico. He is Board Certified. He is also a part-time consultant psychiatrist at the penitentiary in New Mexico where he treats inmates. Prior to July 1, 1985 Dr. Greer had been doing clinical work with MDMA for four and one-half years. He had administered it to 76 patients. He found MDMA to be helpful as an adjunct to psychotherapy in certain cases. He considers himself a clinician, not a researcher. He has studied extensively in the field of using altered states of consciousness to facilitate psychotherapy and personal development.

In January 1983 Dr. Greer learned that MDMA was being used recreationally. He became concerned that its legitimate medical use might be challenged, so he wrote a paper describing his work with the substance. In this paper Dr. Greer intended simply to present the results of his experience using MDMA with patients. It was not his intention there to report on a formal, controlled testing program for MDMA to present a convincing argument definitely establishing the efficacy of MDMA. He believes that MDMA should be scheduled and subjected to some controls by DEA. He desires to see it placed in Schedule III. He desires to see formal research undertaken with the drug and funding made available for such research. He has informally sought such funding from at least two pharmaceutical companies, but they were not interested. The drug cannot be patented. He made informal contact with officials at FDA, suggesting that FDA provide funding for studies and promote research in the use of the drug. So far no one has made such funding available.

Dr. Rick J. Strassman is Assistant Professor of Psychiatry, University of New Mexico School of Medicine, in Albuquerque. He is medical director and principal investigator of a program in which marihuana or THC is being used to combat cancer chemotherapy-induced nausea and vomiting. This project is funded by the State of New Mexico with approval of FDA and the National Institute of Drug Abuse (NIDA). Previously he was Assistant Professor of Psychiatry at the University of California, Davis Medical Center. He has served as a psychiatrist at mental health centers in California and Alaska. He is board certified by the American Board of Psychiatry and Neurology.

Dr. Strassman is a member of the peer review committee which had been overseeing Dr. Greer's work with MDMA. Dr. Strassman testified:

As a member of [Dr. Greer's] peer review board in New Mexico, I have reviewed his inclusionary and exclusionary criteria for entrance into the protocol, informed consent forms, protocol for administration of MDMA, the setting in which sessions occur, his results of follow-up, etc. In my opinion, he has included appropriate safeguards and has not experienced significant adverse reactions to this form of treatment, and that all individuals have experienced significant benefit. Therefore, within the standards of practice set forth by the physicians' community, MDMA has a currently accepted medical use in the hands of a qualified clinician (e.g., Dr. Greer).

Strassman Rebuttal Testimony, at 1-2.

Dr. Rodney A. Houghton was another member of Dr. Greer's peer review committee. He is a former Chief Resident in the Department of Psychiatry at the University of New Mexico and has conducted psychiatric clinics in four rural New Mexico counties. In this connection among other things he provided in-service training on various aspects of clinical psychiatry for law enforcement agencies including policemen, jailors and local sheriffs. He has served as an expert on

psychiatric care to the New Mexico State Department of Health and Environment concerning the State Mental Health Programs. As a psychiatrist he has been medical consultant to the Social Security Administration, HHS, reviewing psychiatric disability cases for the Disability Determination Unit of New Mexico. He has served as a member of the committee reporting to the State agency responsible for funding and maintaining standards for community mental health programs. He is a Clinical Assistant Professor of the University of New Mexico Department of Psychiatry. He is a member of the medical staffs of two psychiatric hospitals in Albuquerque. Dr. Houghton is in contact with and has worked with psychiatrists and other mental health care professionals throughout New Mexico. Dr. Houghton testified in this proceeding as follows:

In summary, during the nine years of practicing psychiatry in New Mexico, I have become well acquainted with the academic community, rural and private practice standards of psychiatric evaluation and treatment. I have been involved at all levels of developing and maintaining quality medical treatment of psychiatric patients in this state — in the political and government agency area, in the grassroots community level, and in the private profit and not-for-profit hospitals.

* * *

In my expert opinion, as one who is familiar with the accepted standards of psychiatric practice in New Mexico, indeed, having established many of those standards for five rural communities and community programs throughout the state, I believe Dr. Greer's use of MDMA is an accepted and safe medical practice. I base this opinion not only on my own experience and what I believe to be

acceptable, but also on my conversations with teachers and colleagues about his work.

Houghton Rebuttal Testimony, at 3-5.

Dr. Will L. MacHendrie was another member of Dr. Greer's peer review committee. In his testimony in this proceeding, given in April 1985, Dr. MacHendrie said:

I am a Board Certified psychiatrist and for the past five years I have been working in community mental health and private practice in New Mexico.

For the past two and one-half years, I have been on the Peer Review Committee for Dr. George Greer's use of MDMA. In that capacity, I have extensively reviewed his methodology and his results regarding therapeutic use of MDMA. I feel that there is definitely a medically accepted use of this drug in treatment, and that there is acceptable safety for use under medical supervision.

MacHendrie Rebuttal Testimony, at 1.

Dr. MacHendrie has served as Assistant Clinical Professor of Psychiatry at the University of California, Davis, and as Staff Psychiatrist for Sangre de Cristo Mental Health Service in New Mexico. He is now in private practice in Santa Fe.

Neither Dr. MacHendrie nor Dr. Houghton appears to have used MDMA in his treatment of patients. However, three California psychiatrists have done so. Dr. Philip Wolfson and Dr. Joseph Downing are in private practice in San Francisco. Each has used MDMA as an adjunct to therapy with certain patients. Each of them considers it to be an accepted medical use to do so.

Dr. Robert DuBois Lynch is a psychiatrist in private practice in La Jolla, California. He is also statewide psychiatric consultant to the Department of Rehabilitation of the State of California. He has not used MDMA in his practice although he would like to conduct research with it. He believes that in the area in which he lives, and in California generally, a psychiatrist using

MDMA for particular therapeutic purposes would be considered to be doing pioneering good medical practice by his colleagues.

This testimony, of course, as with the testimony of many of the witnesses, was given before the temporary Schedule I placement of MDMA on July 1, 1985 and is to be read in that context.

Four additional psychiatrists testified in these proceedings that, before its being placed in Schedule I on July 1, 1985, MDMA had a currently accepted medical use in psychotherapy for certain purposes and under certain conditions. They were Dr. Morris Lipton, professor of psychiatry at the University of North Carolina, Chapel Hill, and Deputy Editor of the American Journal of Psychiatry of the American Psychiatric Association; Dr. Norman Zinberg, clinical professor of psychiatry, Harvard Medical School; Dr. Lance Wright, practicing psychiatrist and Assistant Clinical Professor of Psychiatry, University of Pennsylvania and Associate Professor of Child Psychiatry, Hahnemann Medical College; and Dr. Richard Ingrassi, a psychiatrist in private practice in Watertown, Massachusetts.

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.

Conclusion

The administrative law judge finds and concludes that, prior to its being proscribed effective July 1, 1985, MDMA did have "a currently accepted medical use in treatment in the United States." It is not presently being used in treatment because it has been proscribed.

VI

"Accepted Safety For Use"
Of MDMA

Section 812(b)(1) provides that, in order to place a substance in Schedule I, the Administrator is "required" to find that, with respect to the substance, "[t]here is a lack of accepted safety for use . . . under medical supervision." Stated issues numbered 3. and 6. in this proceeding are as follows:

3. What constitutes "accepted safety for use . . . under medical supervision" within the purview of 21 U.S.C. § 812(b)?

6. Is there "a lack of accepted safety for use [of MDMA] under medical supervision" within the purview of 21 U.S.C. § 812(b)?

These issues will now be considered.

The Agency staff takes the same position with respect to "accepted safety for use" generally, i.e., issue 3., as it took with respect to "accepted medical use in treatment." It asserts that "accepted safety for use" under the CSA is to be equated with approval by FDA under a different statute, the FDCA, as safe and effective, pursuant to 21 U.S.C. § 355(d). The appeal of this position, as providing a clear basis for a ruling with minimum effort to ascertain it, is as readily apparent here as it was with respect to "accepted medical use in treatment". This position cannot be accepted here for the same reasons that it cannot be accepted there:

- There is no basis in the text of the CSA for the Agency's position.
- Had the Congress intended this interpretation, it could easily have so provided in the CSA. It specifically referred back to

the previously enacted FDCA in other sections of the CSA, but it did do so here. This can only mean that Congress did not here intend to refer back.

- There is nothing in the legislative history to this effect.

- The only comment in testimony before Congress on this issue brought to light by the parties is the exchange between Congressman Rogers and FDA's Dr. Egeberg, quoted above on page 16.

It is to be noted that Dr. Egeberg did not say that the question of "accepted safety" for CSA purposes would be bindingly determined by FDA, utilizing the authority granted FDA 38 years earlier for FDCA purposes. The Assistant Secretary said that he "would think that HEW would expect to have a good deal to say on that". (Emphasis added.) Assuredly so. One would hope and expect FDA to have an informed opinion on the question, and make it available to DEA's Administrator for consideration together with all the other evidence received on the record after opportunity for a hearing. But the determinative "findings prescribed by subsection (b) of section 812", including accepted safety for use vel non, are to be made by the Administrator of DEA and by no one else. The statutory language is perfectly clear. 21 U.S.C. § 811(a)

The impossible situation to which the Agency position here would bring us is well pointed up by proposed finding number 6. on page 28 of its brief: "There is no legitimate commercial manufacturer of MDMA in the United States". If this is the criterion, "accepted safety" for use by physicians is reduced to

being determined by, and therefore equated with, a businessman's or corporation's determination of the economic feasibility of mass production. Congress has not given the slightest hint of an intention to rely here on such judgments. That would, however, be the bottom line result of the Agency's position in many cases. It is wholly unacceptable. It ignores the reality that commercial pharmaceutical manufacturers base their production decisions on economic considerations. If they are commercially manufacturing a product, they have, no doubt, concluded that the pharmaceutical can be safely used. But the converse is not necessarily true. Pharmaceutical companies do not normally manufacture a substance just because it is safe. They manufacture it because they expect to make a profit by so doing.

As when determining "accepted medical use," the only logical source for relevant information on safety is the world of health care practitioners. We turn to the evidence of record in these proceedings.

Findings Of Fact

With respect to the safety of MDMA, the following facts are established in this record by the preponderance of the evidence.

MDMA has been utilized by some psychiatrists as an adjunct to psychotherapy. It is usually administered to the patient only once, or at most twice, at the beginning of a course of psychotherapy. It is administered by, or in the presence of, the treating psychotherapist. The psychiatrist remains with the patient, or is immediately available, during the period after ingesting of the substance when it might adversely affect normal functioning. All of this is in marked contrast to the manner of administering many other controlled drugs,

which patients self-administer at home or elsewhere with scant regard for possible immediate contact with the physician.

There are many other oral medications, controlled substances, that are not so restricted by the treating physician, i.e., to only one or two administrations and in such relatively low doses.

MDMA has been administered to animals in a number of different studies. The injection LD 50¹⁴ has been established and the oral LD 50 has been reliably estimated. The doses of MDMA administered therapeutically by psychiatrists to patients have been less than one percent of the LD 50. This indicates a very high margin of safety with MDMA when it is used in treatment.

Clinical trials with humans were reported in 1978 in a monograph, published by the National Institute on Drug Abuse. Dr. Greer has written a report on his clinical experiences administering MDMA to patients. Others interested in using MDMA in therapy had read copies of this report although it had not been published as of the time of the hearings in this proceeding. Dr. Ingrassi, a psychiatrist in private practice, has reported on his clinical observations in administering the drug to nearly 100 individuals over 5 years, from 1980 to 1985. No evident harm resulted to any of these persons from his use of the drug. Dr. Downing has reported on an informal study of the physiological effects of MDMA on some 20 human volunteers. None of them suffered apparent harm. Although there was no verification by scientific analysis, it is reasonable to accept, in the circumstances, that all these volunteers had ingested MDMA in the quantity assumed for purposes of the study.

In addition, other psychiatrists have been using MDMA in their practices over the past 10 years. Because MDMA cannot be patented, no pharmaceutical

¹⁴ See finding 27, page 45, below.

company has had the financial incentive to carry out the extensive animal and clinical tests required by the FDA for approval to market the drug on an interstate basis. Nevertheless, the overwhelming weight of medical opinion evidence received in this proceeding concurred that sufficient information on MDMA existed to support a judgment by reputable physicians that MDMA was safe to use under medical supervision. No evidence was produced of any instances where MDMA was used in therapy with less than wholly acceptable safety.

Conclusion

The administrative law judge finds and concludes that there is no "lack of accepted safety for use" of MDMA "under medical supervision." On the contrary, there is accepted safety for use.

VII

Effect Of Secretary's
Findings

Issue number 4 is stated:

4. Is a finding by the Secretary of Health and Human Services that a substance has "no currently accepted medical use in treatment in the United States" or a finding that a substance has no "accepted safety for use . . . under medical supervision" binding on the Attorney General (the Administrator of the Drug Enforcement Administration, DEA) within the purview of the provisions of 21 U.S.C. § 812(b)?

The Agency staff argues that the answer is in the affirmative, pointing to language which it asserts is in § 812 and to one sentence found in House Report No. 91, legislative history of the CSA.

The Agency's brief is in error where it says, on page 32:

The statutory language of 21 U.S.C.
§ 812 is clear that

The recommendation of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters

(Emphasis added.)

The quoted language is found in § 811, not in § 812.

A careful reading § 811(b) reveals that, before initiating proceedings to schedule a drug, and after gathering data, the Attorney General (i.e., DEA) is to request from the Secretary a scientific and medical evaluation and recommendations as to whether the drug should be controlled. Section 811 then continues:

In making such evaluation and recommendations, the Secretary shall consider the factors

listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters

It is only the scientific and medical factors specified in § 811(c)(2), (3), (6), (7) and (8), and any such considerations as are involved in § 811(c)(1), (4) and (5), on which the Secretary's recommendations are binding. "Currently accepted medical use in practice" and "accepted safety for use" are not mentioned in § 811(c). They appear in § 812, as matters with respect to which "findings" must be made by the Attorney General (DEA) when he is determining which of the five schedules is appropriate. Thus the provision in § 811 for certain recommendations of the Secretary to be binding has no reference at all to "currently accepted medical use" and "accepted safety for use."

The one broad-brush, general statement quoted in the Agency's brief from the Committee Report cannot be read so as to alter the clear language in the statute itself.

The anomalous situation in which the Agency's argument here would put us, i.e., according finality to the recommendation of the Secretary on any questions classifiable as scientific or medical, was pointed up by the Court of Appeals for the District of Columbia Circuit. In its recent opinion in the Buprenorphine scheduling case, the Court observed:

The intervenor's brief contends, and the Department of Justice agreed at oral argument, that the Administrator's conclusion that buprenorphine is a thebaine derivative can be upheld on an alternative ground. According to these parties, HHS's initial communication to

DEA stated that buprenorphine is a thebaine derivative, and the Act makes HHS's recommendations as to "scientific and medical matters" binding on the DEA. See 21 U.S.C. § 811(b) (1982). If that were so, it is difficult to see what purpose the agency's on-the-record hearing served in this case. Certainly the Administrator did not appear to regard his independent findings on "scientific and medical matters" as superfluous. While we entertain doubts about the soundness of the Justice Department's interpretation of the Act - Section 811(b) could be read to indicate only that the DEA must follow HHS's recommendations on the specified matters in deciding whether to initiate scheduling actions - our disposition of this case renders it unnecessary for us to decide the point.

Reckitt & Colman, Ltd. v. Administrator, etc. No. 85-1193, April 8, 1986, slip opinion, p. 9, n. (Emphasis added.)

The administrative law judge concludes that the recommendations of the Secretary on the questions of "accepted medical use in practice" and "accepted safety for use . . . under medical supervision," to the extent the Secretary addressed these issues, are not binding on the Administrator of DEA.

VIII

Proper Schedule For MDMA

Introduction

We come to the last of the stated original issues.

7. If, on the basis of the resolution of the above issues [including issue 1, the "preliminary issue"], MDMA can lawfully be scheduled in a schedule other than Schedule I, in which schedule should it be placed?

The findings and conclusions of the administrative law judge set out above resolve all the previous issues so as to permit, indeed to require, that MDMA be placed in a schedule other than Schedule I. In which one? We must now focus on the "findings required for each of the Schedules" II through V found in § 812.

Having found that there is a currently accepted medical use for MDMA, and that there is not a lack of accepted safety for use of it under medical supervision, the only matters still to be addressed are the extent of MDMA's potential for abuse, finding (A) for each of these schedules, and the extent of psychological or physical dependence resulting from abuse of it, finding (C) for each of them. The Administrator can place a substance in a schedule only if he "makes . . . the findings prescribed by subsection (b) of section 812 . . . for the schedule in which such drug is to be placed." 21 U.S.C. § 811(a)(1)(B).

Findings of Fact

1. MDMA, or 3,4-methylenedioxymethamphetamine, belongs to a class of compounds which can be termed phenethylamines or, narrowly defined, phenylisopropylamines or amphetamines.

2. MDA, or 3,4-methylenedioxyamphetamine, amphetamine and methamphetamine are also phenylisopropylamines.

3. MDA, or 3,4-methylenedioxyamphetamine, is formed by the addition of a methylenedioxy group to amphetamine.

4. MDMA is formed by the addition of a methylenedioxy group to methamphetamine.

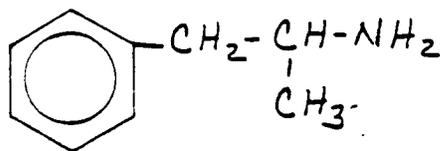
5. The addition of a methylenedioxy group to the aromatic nucleus of amphetamines produces compounds with psychotomimetic activity.

6. Psychotomimetic is a term used to describe a large class of compounds which change or modify a person's mood or mental state. The terms psychotomimetic and hallucinogenic are commonly used interchangeably.

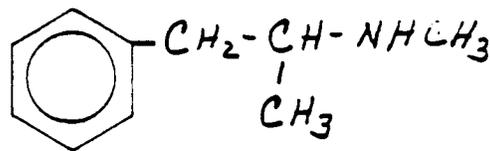
7. MDMA is the N-methyl analog of MDA. This means that MDMA differs structurally from MDA the same way that methamphetamine differs from amphetamine, by the addition of an N-methyl group.

8. N-methylation of amphetamine yields methamphetamine which retains the central nervous system activity of amphetamine.

9. The difference in structure between amphetamine and methamphetamine is illustrated by the following diagram:

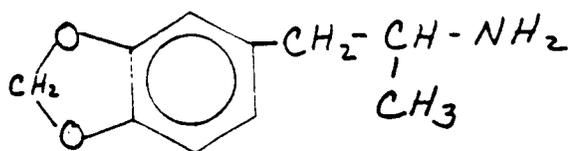


amphetamine

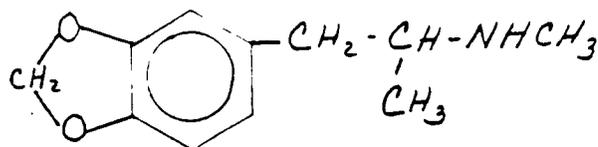


methamphetamine

10. The difference in structure between MDA and MDMA is illustrated by the following diagram:



MDA



MDMA

11. This similarity in chemical structure, although of some significance, does not establish that the two substances have identical, or even similar, abuse potential. Nor does the fact that MDMA can be classified as a phenethylamine establish similarity as to abuse potential. Of the 28 phenylethylamines recognized as such by HHS, there are eight which have neither been scheduled in the United States nor recommended for scheduling by the World Health Organization (WHO). Yet the Expert Committee on Drug Abuse of WHO has reviewed the abuse potential of all 28.

12. Research performed by Dr. Harold F. Hardman, an Agency witness, established that mescaline and seven other substances, analogs, have very similar structural formulas, shown below:

No.	MW	5	4	3	R	Name
I	247.4	OCH ₃	OCH ₃	OCH ₃	CH ₂ -CH ₂ -NH ₂	3,4,5-Trimethoxy-β-phenylethylamine HCl (mescaline HCl)
II	214.4	H	OCH ₃	OCH ₃	CH ₂ -CH ₂ -NH ₂	3,4-Dimethoxy-β-phenylethylamine HCl
III	200.0	H	O-CH ₂ -O		CH ₂ -CH ₂ -NH ₂	3,4-Methylenedioxy-β-phenylethylamine HCl
IV	215.5	H	O-CH ₂ -O		CH ₂ -CH-NH ₂	3,4-Methylenedioxy-α-methyl-β-phenylethylamine HCl
					 CH ₃	
V	229.0	H	O-CH ₂ -O		CH ₂ -CH-NH ₂	3,4-Methylenedioxy-α-ethyl-β-phenylethylamine HCl
					 CH ₂	
					 CH ₃	
VI	231.0	H	OCH ₃	OCH ₃	CH ₂ -CH-NH ₂	3,4-Dimethoxy-α-methyl-β-phenylethylamine HCl
					 CH ₃	
VII	261.4	OCH ₃	OCH ₃	OCH ₃	CH ₂ -CH-NH ₂	3,4,5-Trimethoxy-α-methyl-β-phenylethylamine HCl
					 CH ₃	
VIII	229.4	H	O-CH ₂ -O		CH ₂ -CH-NH-CH ₃	3,4-Methylenedioxy-N,α-dimethyl-β-phenylethylamine
					 CH ₃	

In the above listing, substance I is mescaline, substance IV is MDA and VIII is MDMA. From columns "4" and "3" we see that substances III, IV (MDA), V and VIII (MDMA) all have the methylenedioxy group added to amphetamine. Yet substances III and V are not scheduled drugs. DEA has not found them to have significant abuse potential, despite their close structural similarity to MDA and MDMA.

13. Chemical similarity may or may not be a good guide to the actual effects of a compound in the human body.

14. MDMA produces pharmacological effects in common with both central nervous system stimulants like amphetamine, and hallucinogens like MDA, in animals.

15. MDA and MDMA both produce central nervous system stimulation in animals as measured by increased locomotor activity in mice.

16. Tests conducted by Braun, Shulgin and Braun show that at an oral dose of 20mg./kg. in mice, MDA produced a significant increase in locomotor activity. At the same dose, MDMA produced approximately three times the motor activity of MDA during the first three hours after application. They concluded that MDA, MDMA and N-ethyl MDA caused the greatest stimulation and that this is consistent with results of tests in mice of amphetamine compounds with no ring substitution (e.g. amphetamine and methamphetamine). Braun, Shulgin and Braun further conclude that "compounds which cause a sharp increase in motor activity in animals generally prove to have a pronounced central nervous system effect on man."

17. A study conducted by Intox Laboratories reported significantly reduced body weights at 7 and 14 days following initiation of MDMA dosing in rats.

18. The Intox Laboratory study also reported that rats who had been administered MDMA showed hyperactivity, excitability, aggressive behavior and stereotypic behavior.

19. Studies conducted by Dr. Harris at the Medical College of Virginia compared the locomotor activity in mice using d-amphetamine and MDMA. Dr. Harris found that MDMA produces slightly less central nervous system stimulation than amphetamine at peak activity which is 1 1/2 hours after administration. However, at 5-15 minutes and 2-3 hours after administration, the maximum stimulating effect of MDMA is substantially greater than that produced by d-amphetamine.

20. 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. The tail-flick test and hot plate tests showed that MDMA produces an increased analgesic effect over that produced by MDA.

21. MDA and MDMA both produce an increase in body temperature when administered to rabbits at similar potencies. Hyperthermia in rabbits is reported to be a measure of central nervous system activity. Dr. Shulgin notes that there is a reasonably good parallel between the hyperthermia response in rabbits and some of the effects of LSD, and that these parallel quite closely the psychopharmacological potency in humans. He feels that it is probably the best animal test at present for estimating psychotomimetic potency.

22. The preceding eight findings demonstrate that it is appropriate to classify MDMA as a central nervous system (CNS) stimulant. Although MDMA may be so classified, there are many other substances which are CNS stimulants but which are not currently controlled in the United States nor have been recommended for control by WHO. Caffeine is one such substance. Others, whose abuse potential has been reviewed by WHO, are clobenzorex, fenbutrazate, furfenorex, morazone, para-oxyamphetamine, and N, N-dimethylamphetamine.

23. Categorizing a substance as a CNS stimulant is of little assistance in determining whether or not it has a potential for abuse or what relative degree of abuse potential it may have.

24. Both MDA and MDMA are potent releasers of serotonin or 5-hydroxytryptamine, a neurotransmitter which has a widely accepted role in the activity of hallucinogens.

25. Two substances classified by HHS as hallucinogens have not been scheduled in the United States nor have they been recommended by WHO, after

review, for scheduling. They are 4-bromo-2, 5-dimethoxyphenethylamine and N-ethyl-3, 4-methylenedioxyamphetamine. Thus, categorizing a substance as a hallucinogen is of little assistance in determining whether or not that substance has a potential for abuse or what relative degree of abuse potential it may have.

26. 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 hyperpnea. 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.

27. The lethality of a compound is reported as an LD50, which is the dose of a drug which will kill 50% of the animals receiving that dose.

28. The LD50's for mescaline, MDA and MDMA were determined by intravenous¹⁵ or intraperitoneal¹⁶ administration in five species of animals. MDMA had LD50's between 2 and 6 times less than those of mescaline and between 1.5 and 3 times more than MDA. This means that MDMA is more lethal than mescaline but less lethal than MDA.

29. Intraperitoneal LD50's for MDA and MDMA were determined in mice by Davis. The LD50's of 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. Dr. Hardman found the LD50 of MDA to be 92 mg./kg. Davis also found that both MDA and MDMA showed the amphetamine-like property of increased lethality under aggregated housing conditions compared to isolated housing conditions.

¹⁵ into a vein.

¹⁶ into the abdominal cavity.

30. In the study conducted by Intox Laboratories the oral LD50 for MDMA in rats was estimated to be approximately 325 mg./kg. No oral value was reported for MDA but based on the data from Intox Laboratories, Dr. Hardman estimated it to be approximately 150 mg./kg.

31. Every drug has an LD50. The preceding four findings as to LD50 have nothing to do with establishing the abuse potential of MDMA. A value that is of interest, however, is the therapeutic index, i.e., the ratio of the LD50 to the effective dose (ED50). How close is the dose which will kill 50% of the tested animals to the dose required for the desired effect in humans? If these two doses are very close to each other, then there is an obvious danger in using the drug with humans.

32. Most general anesthetics have a very low therapeutic index of two to one, i.e., just twice the quantity commonly used in medical practice is sufficient to kill. Yet these anesthetics are used by doctors all the time, under carefully controlled conditions.

33. The estimated oral LD50 for MDMA in rats, as noted above, is 325 mg./kg., i.e., 325 mg. of MDMA per kilogram of weight of the rat. The effective oral human dose is 2 mg./kg. of weight. Thus there appears to be a comparatively large margin of safety in the use of MDMA in humans - the LD50 is 160 times the ED50 in humans.

34. 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.

35. MDMA and MDA both produce long term reduction in serotonin levels and uptake sites in the rat brain. These neurochemical depletions are due to

the destruction of serotonin nerve terminals as determined by visual staining techniques.

36. In humans, serotonin nerve terminals are believed to play a major role in mood, emotion, pain perception, sleep and affect the regulation of aggressive and sexual behavior.

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 purpose.

38. The neurotoxicity of amphetamine and methamphetamine has been determined in rats, guinea pigs and monkeys.

39. MDMA and MDA are suspected of having the potential to produce the same neurotoxic effects to serotonergic nerves in humans, but there is very little evidence to support this suspicion.

40. On the other hand, the drug fenfluramine has been determined to produce the biochemical effects in rats of which MDMA is suspected, but at much lower dosage levels than in the case of MDMA. In fact, the proven dosage levels of fenfluramine causing these effects are merely 1.25 times its ED50 when used for anorexia in humans. Nonetheless, FDA has approved the daily use of fenfluramine in humans on a chronic basis. Fenfluramine is a controlled substance, but this proven neurotoxic substance is only in Schedule IV.

41. Drug discrimination studies in animals allow one to determine if a particular dose of a test substance produces in the animal effects which are recognized by the animal as the same as those produced by a particular dose of another substance. It is believed that the effects recognized by the animals in these studies are central nervous system effects and hence this paradigm is very useful in characterizing centrally acting compounds.

42. In drug discrimination paradigms, complete generalization indicates that the test compound is similar enough for the animal to recognize it as the training drug by responding on the appropriate drug lever at least 80% of the time. No generalization indicates that the test compound is unlike the training compound so that a low number of responses will be made on the drug lever. Partial generalization indicates that there may be pharmacological effects common to both test and training drug, but that some doses of the test and training drug are similar and at the tested doses another type of pharmacological effect may predominate.

43. MDMA shares discriminative stimulus properties in common with amphetamine and MDA in drug discrimination studies in rats.

44. In a drug discrimination test described by Dr. Glennon, rats trained to recognize amphetamine also recognized MDA and MDMA. MDMA was slightly more potent than MDA in being recognized as amphetamine. Other compounds which generalized to the amphetamine stimulus included methamphetamine, cocaine and para-methoxyamphetamine.

45. Rats trained to recognize MDA recognized MDMA, in drug discrimination studies conducted by Dr. Glennon, as having some properties similar to MDA.

46. MDA completely generalized (83% correct response) in rats trained to recognize 4-methyl-2, 5-dimethoxyamphetamine (DOM), a substance with known

hallucinogenic properties, but only within a very narrow dosage range.

47. MDA is unique among chemicals in being recognized by animals who are trained to recognize hallucinogens and also by animals trained to recognize stimulants. MDMA does not share this dual response characteristic of MDA. The overwhelming weight of the evidence in this record is that MDMA is not properly classified as a hallucinogen. One witness disagrees. His disagreement results from reports he has received from street users, who are widely regarded as an unreliable source of information as to specifics on any matter. There are no results of controlled scientific experiments in the record establishing MDMA to be a hallucinogen in humans. Animals trained to recognize MDA who also respond to MDMA are, more likely than not, responding to the CNS stimulant characteristic of MDMA rather than to any hallucinogenic properties.

48. The significance of animal discrimination test findings as to abuse potential in humans is far from certain. An Agency witness in this proceeding co-authored an article, published in 1984, which states that unless a particular compound has been tested in humans, one cannot be certain that structure-activity relationships will apply in the clinical situation, i.e., when used in humans. He cautioned that the most common error found in animal models is the identification of "false positives". That is, the animal models may indicate a compound to be active, whereas actual testing in humans reveals inactivity. The article also says that it is clear that no present animal models correlate with the qualitative differences between hallucinogens observed in humans.

49. In 1984 the National Institute of Drug Abuse (NIDA) reviewed DEA's initial proposal for the placing of MDMA in Schedule I. NIDA reported to

Dr. Edward Tocus of the FDA that: "The direct evidence that MDMA has any abuse potential in animals is not substantiated, based on the data DEA provided."

GG 55.17

50. A standard abuse liability test for assessing the reinforcing properties of a drug is the substitution procedure. It is the most common and reliable method for determining whether a drug will be self-administered. In this procedure new drugs are tested to determine whether or not they will maintain the responding of animals trained to lever press for intravenous delivery of a known drug reinforcer.

51. As our hearings were concluding it was learned that tests were being conducted with rhesus monkeys and baboons trained to self-administer cocaine to see if the monkeys and baboons would continue to self-administer when MDMA was substituted for the cocaine. Preliminary reports were obtained from those conducting these tests. These reports were placed in evidence by the Agency. Upon study of them, and of the Response to them dated November 4, 1985 by Drs. Grinspoon, et al., the administrative law judge finds that these preliminary reports lack sufficient indicia of reliability to be given any weight. They certainly fail to buttress the Agency's position that MDMA has "a high potential for abuse" in humans. They are immaterial.

52. Drs. Shulgin and Nichols first reported that MDMA produces psychotomimetic effects in man in 1976. These effects are described as intoxication, an easily controlled altered state of consciousness and sympathomimetic stimulation.

17/ "GG" = Drs. Grinspoon, et al., exhibit; "G" = Agency exhibit.

53. The racemic mixture of MDMA, which is a combination of both optical isomers, is the drug which is clandestinely produced, found in the illicit traffic and used by psychiatrists.

54. In a 1978 publication, Dr. Shulgin reported that racemic MDMA produced a high level of intoxication in man at doses of 100-160mg. Color enhancement as well physical symptoms of mydriasis and jaw clenching were noted. MDMA was described as maintaining the same potency as MDA but exhibiting subtle differences in the qualitative nature of the intoxication.

55. In a 1980 publication, Dr. Shulgin and others describe MDA and MDMA as having both stimulant and psychotomimetic properties in humans. Racemic MDA and MDMA were administered orally to five volunteers at doses up to 160mg. The effective dose of MDA was 60-120mg., while that of MDMA was 100-160mg. Dr. Shulgin and others noted a drive increasing effect, a change in expression and an apparent increase in the acoustic, visual and tactile sensory perceptions as well as a tension-decreasing, mood-lightening effect in the human subjects. A slight mydriasis and sympathomimetic stimulation were noted during the entire period. The effects of MDA and MDMA were apparent beginning 30 minutes after ingestion and continuing for approximately four hours, except that a slight increase in motor activity lasted several more hours. Shulgin concluded that the "psychopharmacological profiles" of MDA and MDMA and two other compounds are very similar. However, five years later Shulgin wrote: "There can be little validity in an argument that the psychopharmacology of MDMA can be predicted from that of MDA. The facts are otherwise." GG 30, p.3.

56. There are observed differences in humans between the effects of MDA and MDMA. Studies other than the one reported by Shulgin in 1980 have shown MDA to have duration of action in humans of 12 to 15 hours, as compared to four to six hours for MDMA. MDA has been found to produce a mild cognitive impairment in humans at the 75mg. dosage level, while MDMA did not impair cognition

even at 200mg. As MDA dosages increase from 75 to 200mg., the effects in humans become increasingly similar to the effects of LSD, including the presence of visions. As dosages of MDMA increase from 75 to 200mg., the intensity of the sense of wellbeing and inner flow of associations which characterize the experience increase only moderately while the ego functions remain intact, cognition is unimpaired and visions are notably absent. Large doses of MDA (200mg) produce significantly greater disorientation and an up-welling of visual images that are not characteristic of MDMA in similar dose range.

57. The dosage comparisons just referred to are those using the levo-rotary optical isomer of MDA. There are clear indications that this isomer of MDA is more active than either the racemic mixture or the dextro-rotary isomer. It was the racemic mixture of MDMA that was used in the studies referred to immediately above.

58. The uncontradicted evidence of record is that there are qualitative differences in humans between MDA and MDMA.

59. The Agency presented testimony from a staff member of only one of the many drug abuse clinics in the country, the Haight-Ashbury Free Medical Clinic in San Francisco. This clinic treats approximately three to four clients per month who seek help for problems arising from the use of one or more of a group of five or six different drugs which the clinic lumps together in its statistics. MDMA is one of these drugs. The clinic has no reliable figures on how many of these three to four patients per month have been reporting abuse of MDMA specifically. Even if the three or four clients mentioned all reported using MDMA, that would constitute less than one percent of the clinic's total of about 450 clients per month. The clinic has no way of knowing whether any of

its relatively small number of clients reporting MDMA use were actually using MDMA -no reliable testing has been done. Many of the drugs sold on the street to persons such as the clients of this clinic are not, in fact, what they are represented to be by the seller. The numbers, three to four clients per month reporting use of MDMA or any one of the other drugs lumped together with it statistically by this clinic, has remained fairly constant for the last 15 years: In that 15 year period there has been only one instance of a client reporting use of MDMA and producing a pill of the type he said he had been taking which was analyzed and was reliably reported to be MDMA. Two other pills, brought in by other clients reporting them to be samples of MDMA, turned out to be not MDMA but, rather, MDA.

60. During the year preceeding April 24, 1985 there were no reported incidents of abuse of MDMA, or of complications resulting from its use, in the Philadelphia, PA, area. No such instances in New York City or in Boston during that period were brought to the attention of a staff psychiatrist at a Veterans Administration Hospital drug abuse clinic in Philadelphia who has talked with colleagues in those cities.

61. In the Los Angeles area there was a noticeable increase in the street use of MDMA shortly before its becoming illegal on July 1, 1985. This coincided with the attention MDMA received in the news media at that time. There was also a significant increase in the manufacture of MDMA at that time, much of which was to permit stockpiling of supplies before the July 1, 1985 ban went into effect. This manufacturing was done by those who supplied the street market. It has been estimated that in all of 1976, 10,000 doses of MDMA were distributed in the United States for street use, as opposed to 30,000 doses per month in 1985. These estimates are based on information obtained from street users. Street users are notoriously unreliable in matters of specific information. No reliable conclusion as to number of users can be gleaned from these

estimated figures. In 1985 the most common patterns of non-medical use of MDMA found in Los Angeles were "experimental" (ten times or less in lifetime history) or "social-recreational" (one to four times per month).

62. Cocaine poses many more, and much more serious, social problems for this country than did MDMA before it was banned. Street drug users in Los Angeles did not find it as appealing as cocaine. Cocaine is very rewarding and produces pleasurable sensations in the brain that causes the brain to try to repeat the experience. Cocaine has the potential for producing a lot of repetitive drug taking. It produces tolerance and, in an effort to overcome the tolerance, people repeat the experience again and again. Substances considered to be similar to MDMA in their effects on humans have not been used in that way, according to studies of drug users made over the last 20 to 30 years.

63. The circumstances and surroundings in which MDMA is taken, or in which one who has recently ingested MDMA finds himself, has an effect on the reactions and perceptions of the subject while the drug is still effective within his system.

64. Low to moderate doses of MDMA have been given to individuals by wholly legitimate and highly regarded psychiatrists as an adjunct to psychotherapy. Some of the MDMA so administered was made by them under the supervision of Dr. Shulgin in his laboratory in California.

65. MDMA has been reported, by the psychiatrists administering it to themselves and others, and by other individuals, to produce at one time or another some or all of the following physical effects: jaw clenching, anorexia, insomnia, flight of ideas, increased heart and pulse rate, mydriasis, nystagmus, blurred vision, enhanced deep tendon reflexes, fatigue after use, ataxia, nausea, vomiting, headache and shakiness.

66. Psychological effects reported for low to moderate doses of MDMA, in various subjects at various times, include gentle euphoria, sense of well-being and peacefulness, increases in physical and emotional energy, focus on the here and now, impaired judgement, heightened sensual awareness, anxiety, brief short term memory loss, distortion in depth perception, brief hallucination, visual illusion, nervousness, mild depression, mental fatigue, confusion and altered state of consciousness.

67. MDMA was first identified by a DEA laboratory in 1972. Between 1972 and April 1985, DEA laboratories had identified 41 exhibits of MDMA consisting of over 60,000 dosage units.

68. Since its temporary placement into Schedule I on July 1, 1985, MDMA has been identified in at least 14 exhibits submitted to DEA laboratories from Texas alone. These 14 exhibits contained over 35,000 dosage units of MDMA.

69. MDMA is available in tablets, capsules and powders with recent analyses indicating approximately 110mg. of racemic MDMA per dosage unit. MDMA has been encountered in many sections of the United States and other countries.

70. Since 1978, nonfederal forensic laboratories have reported at least 41 exhibits of MDMA to DEA.

71. Pharm Chem Laboratories and Toxicology Testing Service are laboratories which provide confidential analysis of drug samples voluntarily submitted to them. Their data provides some useful information on the availability of street drugs and trends in drug abuse patterns.

72. Between 1973 and 1983, Pharm Chem Laboratories reported MDA and MDMA in the same category. The total number of submissions of MDA/MDMA between 1973 and 1983 was 610, ranging from 21 in 1974 to 88 in 1978. This evidence is of little help to us since we are not told how many of the 610 total submissions

were MDA and how many were MDMA. It is worth noting that the highest number of combined MDA/MDMA submissions to Pharm Chem was 88 in 1978. Only 22 such submissions were reported in 1983.

73. Pharm Chem reported 20 submissions of MDMA between May 1983 and May 1984 when it discontinued its testing service.

74. Toxicology Testing Service reported 15 submissions of MDMA between April 1, 1984 and March 31, 1985.

75. In its investigation of the clandestine manufacture of controlled substances, DEA has seized four clandestine laboratories producing, or possessing the necessary chemicals to produce, MDMA during the 13 year period 1972 through 1984. A total of about 2,400 clandestine laboratories were seized during that period. During the seven year period 1977 through 1983, 31 clandestine laboratories having the capacity to produce MDA were seized. Impurities found in the MDMA analyzed by forensic laboratories indicate that MDMA is produced in clandestine laboratories.

76. A DEA investigation conducted in June 1984, of a suspected cocaine distributor produced information that a drug known as "Ecstasy" was being sold in the Dallas, Texas area. Samples were obtained through undercover buys in that area in February and March 1985. Analysis revealed each tablet to contain 110mg. of MDMA. In April 1985 "Ecstasy" was widely available on the street in the Dallas area. It was reported to DEA agents in March 1985 that "Ecstasy" was being shipped to the Dallas area in cases containing 100 tablet bottles from California. It was at that time being marketed in the Dallas area in a manner similar to that in which structured illicit drug trafficking

organizations operate. At that time it was not illegal to manufacture, sell or possess MDMA under the Federal CSA. The record is unclear as to whether or not these actions were illegal under Texas State law at that time.

77. Street prices for MDMA in 1984 were listed as \$70 per gram in New York and \$20 per capsule in New Hampshire in an underground flier.

78. Students at the University of Texas in Austin indicate that MDMA is easily available on campus at about \$5 to \$20 a tablet.

79. Dr. Richard P. Ingrasci has interviewed over 500 individuals who have used MDMA over the past seven to eight years. A little more than half of these individuals had used MDMA in a non-therapeutically motivated setting, out of curiosity or for recreation.

80. Dr. Joseph J. Downing, a practicing psychiatrist in San Francisco, CA, conducted a pilot study in 1984 into the effects in healthy humans of a single exposure to MDMA. The 21 subjects in Dr. Downing's MDMA study had all used MDMA previously. One had used MDMA 15 times, one 10 times, and one only once. The mean frequency of use of the 21 subjects was once every 2.2 months.

81. Dr. Lester Grinspoon reports that MDMA is being taken by a growing number of people, particularly students and young professionals. The text cited by Government counsel does not indicate to what extent this use is in a therapeutic setting or is in a casual or recreational manner.

82. Dr. George Greer, a practicing psychiatrist in Santa Fe, New Mexico, has used MDMA as an adjunct to psychotherapy in clinical work. He reported that one of his subjects, after taking the unusually high dosage of 350mg. of MDMA, reported a brief hallucination, a brief visual illusion, a mild

hearing impairment, a brief memory loss and a brief distortion in depth perception.

83. The National Institute on Drug Abuse (NIDA) publishes annually a compilation of drug abuse information collected through its Drug Abuse Warning Network (DAWN). This data collection system collects reports from selected (currently more than 700) hospital emergency rooms in the United States. The reports collected record all visits to those emergency rooms for medical problems associated with drug abuse. According to NIDA, the major objectives of the DAWN system include the following:

To monitor drug abuse patterns and trends and to detect new abuse entities and new combinations;

To assess health hazards associated with drug abuse.

84. The record reflects that from 1972 through September 15, 1983, there were only eight mentions of MDMA in the DAWN system. During the period 1972 through 1983, the DAWN system was reporting approximately 175,000 drug mentions each year. Thus, the eight mentions of MDMA occurred during a period during which DAWN reported roughly 2 million mentions of other drugs. The few mentions here of MDMA are far less than those of such Schedule I drugs as heroin, marijuana, and LSD. During the time period that MDMA was mentioned 8 times, MDA, a Schedule I drug, was mentioned 344 times -- more than 40 times as frequently. MDMA does not compare with the frequency with which Schedule II drugs appear in the DAWN reports, nor even with the mentions of Schedule III drugs or Schedule IV drugs found there. The FDA of the Department of HHS called the eight DAWN mentions of MDMA "not significant except to indicate the existence of human use of MDMA."

85. MDMA is reported to have been associated with two overdose deaths. One death occurred in Seattle, Washington in 1979. However, the evidence in the

record does not permit a finding that MDMA was, in fact, involved in that death. A careful reading of the toxicology report shows that the involvement of MDMA there is questionable. The second reported association, in Santa Monica, California, is even more questionable. There is no toxicology report at all in this record with regard to it. The evidence does not permit a finding that MDMA was, in fact, associated with that death, either.

86. The record of the FDA-HHS consideration of MDMA is as follows.

87. The relevant staff member at FDA, Dr. Edward Tocus, reviewed the DEA Control Recommendation proposing that MDMA be placed in Schedule I (G B-2). He subsequently prepared a one-and-one-half page document which included both a summary and an evaluation of the Recommendation.

88. Dr. Greer, practicing psychiatrist in New Mexico, had previously written to the Assistant Secretary for Health about Dr. Greer's therapeutic work with MDMA. Dr. Greer had also written to an FDA staff member (Mr. Contrera), a supervising pharmacologist who worked for Dr. Tocus, about Dr. Greer's work with MDMA, enclosing a copy of his report of his work with MDMA (GG 14). Dr. Tocus was not aware of these prior contacts between Dr. Greer and the FDA when Dr. Tocus wrote his MDMA control evaluation and prepared related papers for his superiors at HHS.

89. At the time Dr. Tocus reviewed the DEA recommendation and prepared the HHS documents for his superiors, he believed that the statutory phrase "accepted medical use in treatment in the United States" meant that a drug had to have been approved by the FDA for interstate shipment and sale pursuant to the FDCA. Further, Dr. Tocus believed that, based on his understanding of the law, if HHS came to the conclusion that a drug should be scheduled but it had not been approved for interstate shipment and sale, pursuant to the FDCA, "that

the only alternatives were Schedule I [if it had any abuse potential] or no schedule at all." (Tr 9, at 67)

90. Before formulating its recommendations on MDMA, the FDA and HHS did not consult any organization of medical professionals. Dr. Tocus testified that he did not take any action to make inquiries about medical opinion on MDMA even though he had been told on a hearsay basis that there was some therapeutic interest in the drug. The Department of HHS did not refer the issue of the appropriate scheduling of MDMA to the FDA's Drug Abuse Advisory Committee. This Committee is made up of authorities knowledgeable in the medical, behavioral and biological sciences as they apply to drug abuse. Its Charter, signed by the Secretary of HHS, states:

The Committee advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances and recommends actions to be taken by the Department of Health and Human Services with regard to marketing, investigations, and control of such drugs or other substances.

GG 62 (Emphasis added). No one at FDA had the benefit of any input from this Committee with respect to MDMA.

91. Dr. Tocus made six typographical corrections to the original DEA recommendation for Schedule I placement of MDMA. These corrections are set out in GG 59. Dr. Tocus then prepared his one-and-one-half page summary and analysis or evaluation of the DEA scheduling recommendation. (G B-4)

92. The recommendation Dr. Tocus prepared for his superiors does not mention that Dr. Tocus had been informed orally that there was therapeutic interest in MDMA, or that Dr. Greer had previously communicated his interest in

MDMA, and actual use of it in therapy, to the Assistant Secretary for Health and to the FDA.

93. The recommendation prepared by Dr. Tocus for his superiors never discusses or comments on "accepted medical use in treatment" or "accepted safety for use under medical supervision." It includes a single sentence asserting that: "There is no known legitimate use of MDMA in humans." (G B-4 at 2) This key statement was inaccurate.

94. Dr. Tocus testified that he forwarded his one-and-one-half page evaluation (G B-4) and the DEA's evaluation (GG 56) to the Acting Commissioner of FDA and thence to the Assistant Secretary for Health.

95. Before forwarding the papers Dr. Tocus requested comments on the DEA proposal to schedule MDMA in Schedule I from the National Institute on Drug Abuse (NIDA) — as he was required to do by HHS departmental procedures. The National Institute on Drug Abuse responded in memorandum form. GG 55. The NIDA memorandum states that: "The direct evidence that MDMA has any abuse potential in animals is not substantiated, based on the data DEA provided." That memorandum, noting that there have been some reports of MDMA use outside the medical context, concludes that "NIDA does not have any objection to placing MDMA under Schedule I of the CSA." But NIDA reaches no conclusion that MDMA has a "high" potential for abuse. The NIDA memorandum gives no indication of an opinion as to any level of potential for abuse in MDMA.

96. The NIDA memorandum was not forwarded to the Commissioner of the FDA and was not forwarded to the Assistant Secretary for Health. Dr. Tocus was aware of the views of NIDA prior to receiving the NIDA memorandum. He shared the NIDA view that the evidence did not substantiate abuse potential in animals. But those judgments were not reflected in the materials that Dr. Tocus

forwarded to the Acting Commissioner of Food and Drugs or to the Assistant Secretary for Health.

97. None of the underlying documents prepared at the Department of HHS ever reached the conclusion that MDMA had a "high" potential for abuse. The one-and-one-half page memorandum prepared by Dr. Tocus notes on page one that DEA has concluded that MDMA has a high potential for abuse. But the HHS evaluation itself never so concludes.

98. Based on this record, the Acting Commissioner of Food and Drugs forwarded the package on to the Assistant Secretary of Health. The Acting Commissioner stated his conclusion to be only that "MDMA has a significant potential for abuse." (GG 54) He made no mention of "a high potential for abuse," which is what the CSA requires for Schedule I or Schedule II placement.

99. The formal response to DEA from HHS, signed by the Assistant Secretary for Health, does state that: "We believe MDMA has a high potential for abuse" and recommends Schedule I placement. (G B-3) This difference as to degree of abuse potential between "significant" and "high" represents a quantum increase from the memorandum of the Acting Commissioner to the letter of the Assistant Secretary for which there is no basis in the record of HHS' consideration.

100. DEA was unaware of the therapeutic use to which MDMA had been put by Dr. Greer and other doctors when it prepared its initial recommendation for placing MDMA in Schedule I (G B-2) and sent it to HHS.

Discussion

The Agency staff has the burden here of establishing that MDMA has a "high" potential for abuse. It has not carried that burden. A "high" potential is required by the CSA for placement in either Schedule I or Schedule II.

The evidence as to the meaning of similarity of chemical structure between MDMA and other substances is inconclusive. There is similarity, for example, between MDMA and MDA, which is a CSA Schedule I substance. But there is comparable similarity between these two drugs and two others which have not been found to have any abuse potential and which are not scheduled at all. See finding 12, page 42. MDMA is classified as a phenethylamine. Some phenethylamines are scheduled under the CSA, but others are not. WHO has reviewed the abuse potential of 28 phenethylamines. It has recommended only some of those 28 for scheduling. Of those 28, there are eight which have neither been scheduled at all in the United States nor recommended for scheduling by WHO. See finding 11, page 41.

The great preponderance of the evidence in this record is to the effect that MDMA is not properly classified as a hallucinogen. There is some expression of opinion to the contrary. Even if it is classified as such, that fact would not establish a "high" potential for abuse in humans. There are at least two known hallucinogens which have not been scheduled at all in the United States. See finding 25, pages 44 and 45.

Animal tests have shown MDMA to be a central nervous system stimulant. MDA, a Schedule I substance, is a central nervous stimulant. But that fact does not establish that MDMA should also be placed in Schedule I. Many other substances

also act as central nervous stimulants which are not scheduled at all. See finding 22, page 44.

The other animal test results in the record are equally inconclusive as to abuse potential. See findings 37, 40, and 47, above.

There are reports of non-medical use of MDMA by humans. These reports do establish that MDMA has a potential for abuse. But before it can be said that, in the context of § 812, MDMA has a "high" potential for abuse, the known facts as to MDMA must be compared with the known facts as to human abuse of other substances. When these comparisons are made, it cannot be concluded that the facts show MDMA to have a "high" potential for abuse. See findings 59, 62, 72, and 84, above.

Upon close examination the material received from HHS is of little assistance to us in this case. No independent tests, studies or scientific examinations were made there. Relevant and material facts and opinions, within the knowledge of some at FDA, were not brought to the attention of higher officials, including the Assistant Secretary who signed the formal communication to the Administrator of DEA.

The staff person at FDA responsible in this matter had a misunderstanding of the law's requirements from the outset. He was of the misapprehension that a substance with any degree of potential for abuse had to be placed in Schedule I if it lacked an IND, or NDA, granted by FDA.

FDA did not see fit to consult its panel of experts created for the purpose, the Drug Abuse Advisory Committee. That group would undoubtedly have had helpful input for our consideration of the "acceptable medical use" issue, and the "degree of abuse potential" issue, among others.

There are no "binding" recommendations in the HHS letter of June 6, 1984 (G B-3) and its enclosure (G B-4) such as are contemplated by 21 U.S.C. § 811(b). The only recommendation stated is as to the schedule into which MDMA should be put. This is, of course, the ultimate question to be determined and the Secretary's recommendation on it, though entitled to consideration, is not made "binding" by the statute. For the rest, the response from HHS contains some factual recitals, largely repeating or summarizing the data initially sent to it by DEA, and some expressions of opinion - interesting in that they do not give much support to the one recommendation made. For instance, FDA observes on page 2 of G B-4 that the rate of MDMA mentions in the DAWN reports "is not significant except to indicate the existence of human use of MDMA." It is also there observed that the difference in numbers of DAWN mentions between MDMA and MDA "is considered to be more an indication of availability rather than degree of toxicity." The observation that "there is no known legitimate use of MDMA in humans" is incorrect as a factual statement. If it is intended to reflect an interpretation of the statute, it is entitled to consideration, which it has received, supra, but it is certainly not binding.

These critical observations are, regrettably, essential if we are to put the formal recommendation of the Assistant Secretary into proper focus and determine the weight of which it is deserving. In the circumstances, it appears to be deserving of very little weight.

Conclusion

The evidence of record does not establish that, in the context of § 812, MDMA has a "high potential for abuse." Accordingly, it cannot be placed in

Schedule II. (We have already seen that it cannot be placed in Schedule I, because it does have "a currently accepted medical use in treatment" and it does not "lack . . . accepted safety for use . . . under medical supervision.")

No one has argued here that the evidence establishes that MDMA "may lead to severe psychological or physical dependence," another requirement for Schedule II placement. The evidence does not so establish. For this reason, also, MDMA cannot be placed in Schedule II.

Mr. Ehrnstein argues that MDMA cannot be scheduled at all because HHS has not performed such a scientific and medical evaluation as the CSA calls for. He asserts that this failure deprives DEA of "jurisdiction" to schedule the drug. The administrative law judge rejects this argument. The statute requires DEA to "request" an evaluation from HHS. DEA did so. HHS did send a recommendation to DEA. DEA is considering that recommendation. The minimum statutory requirements have been met in this case.

Mr. Ehrnstein also argues that the evidence establishes no abuse potential sufficient to place MDMA in any of the five schedules. The administrative law judge agrees, and accepts this argument, as to Schedule II. The judge disagrees with, and rejects, the remainder of the argument. There is ample evidence of some abuse potential in the record.

Drs. Grinspoon, et al., argue that sufficient evidence of abuse potential has been shown to warrant placing of MDMA in Schedule III. The administrative law judge agrees, concluding that the evidence does establish MDMA to have "potential for abuse less than the drugs or other substances in Schedules I and II," and to establish that abuse of MDMA "may lead to moderate or low physical dependence or high psychological dependence." 21 U.S.C. § 812(b)(3).

The administrative law judge concludes that the evidence of record requires MDMA to be placed in Schedule III.

IX

Recommended Decision

Drs. Grinspoon, et al., assert that there are two courses of action open to the Administrator at this point: Either the Administrator can review all the evidence of record and reach a decision, based thereon, on all the issues, or the Administrator can send the record, together with the administrative law judge's findings and conclusions, to HHS for review and comment on the scientific and medical issues.

The administrative law judge finds neither authority nor merit for the second alternative.

The statute clearly provides that, in a situation such as ours, where DEA initiates a scheduling, DEA shall, "before initiating proceedings" and after gathering necessary data, request an evaluation and recommendations from HHS. 21 U.S.C. § 811(b). That was done. After HHS responded to the request, DEA initiated this proceeding. The statutory scheme clearly contemplates that at that point opportunity will be provided, in open hearings pursuant to the Administrative Procedure Act, for the presentation of further "data" or evidence on all issues. The Administrator is then to make the final Agency decision, which must be based on that record. The statute contemplates that the record may contain scientific and medical information not considered by HHS at the outset.

Referral of the matter at this point to HHS for a second time may well result in a record that could not pass muster under the Administrative Procedure Act.

The Administrator of DEA has no authority to direct the Secretary of HHS to take any action. The Administrator provided the Secretary with the opportunity the statute requires.

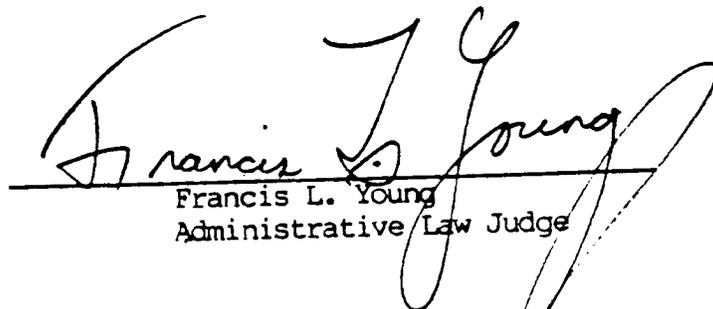
If the Administrator of DEA carefully considers the entire record now provided in this proceeding, there is no reason why he cannot come to the informed decision the law requires of him as the Agency head.

Needless to say, nothing in this opinion is to be taken as being in any way critical of the Agency's emergency scheduling of MDMA which became effective on July 1, 1985. That action was taken pursuant to certain statutory authority with which this proceeding is not concerned. That action was wholly unilateral, reflecting a view based on evidence then available to the Agency but without opportunity for the presentation of countervailing evidence or argument. This proceeding, a wholly separate process, has provided that opportunity. A complete record, with input from different perspectives, has now been assembled for the benefit of the Administrator, the head of the Agency.

The record now assembled contains much more material about MDMA than the Agency was aware of when it initiated this proceeding by publishing a notice almost two years ago.

Based upon this record it is the recommended decision of the administrative law judge that the substance 3, 4-methylenedioxymethamphetamine, also known as MDMA, should be placed in Schedule III.

Dated: MAY 22 1986


Francis L. Young
Administrative Law Judge

PUBLIC LAW 98-329 [H.R. 4201]; June 29, 1984

**CONTROLLED SUBSTANCES ACT; RESCHEDULING OF
METHAQUALONE**

For Legislative History of Act, see p. 540

An Act to provide for the rescheduling of methaqualone into schedule I of the Controlled Substances Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That, notwithstanding the schedule requirements of section 202(a) of the Controlled Substances Act (21 U.S.C. 812(a)) and the requirements of section 201 of such Act (21 U.S.C. 811) respecting the scheduling of controlled substances, the Attorney General shall, by order, transfer methaqualone from schedule II of such Act to schedule I of such Act. The transfer shall take effect not later than the expiration of ninety days from the date of the enactment of this Act.

SEC. 2. Effective thirty days after the date methaqualone is transferred to schedule I of the Controlled Substances Act, the Secretary of Health and Human Services shall by order withdraw the approval under section 505 of the Federal Food, Drug, and Cosmetic Act of the new drug application for methaqualone.

Approved June 29, 1984.