U.S. DEPARTMENT OF JUSTICE
Drug Enforcement Administration

In the Matter of MDMA Scheduling	Docket No. 84-48

OPENING MEMORANDUM ON BEHALF OF
DRS. GREER AND GRINSPOON, PROFESSORS BAKALAR AND ROBERTS

This memorandum is submitted in response to the February 8, 1985 Memorandum and Order requesting participants in this matter to set out their positions on certain matters and to provide initial lists of witnesses and documents. We address each of the six areas requested -- numbered as they appear in Judge Young's memorandum and order of February 8, 1985. To understand our responses to Judge Young's specific inquiries, it is necessary to understand our overall position in this proceeding. Therefore, before turning to the specific questions raised by Judge Young, we summarize our basic position on the scheduling of MDMA.

Summary of Position

Participants Greer, Grinspoon, Bakalar, and Roberts (hereinafter "Greer, et al.") recognize that this proceeding involves issues that are at the frontiers of both research and treatment in the field of psychotherapy as well as legal issues of first impression. It is therefore impor-

tant to emphasize that our position has three separable components.

First, we embrace a proposition with respect to MDMA that we believe is beyond dispute:

- MDMA does not have a "high potential for abuse." At most it has a low or moderate potential.

This proposition will be a matter for proof during the hearing. But it is important to recognize, at the outset, what follows from this proposition alone. If MDMA does not have a "high" potential for abuse, it cannot be placed in either Schedule I or Schedule II. Both Schedule I and Schedule II are limited to substances that have a high potential for abuse. If MDMA is to be scheduled at all, it can only be placed in Schedule III, IV, or V.

Second, we will argue that current use of MDMA by practicing psychiatrists in their professional practice demonstrates (1) that MDMA can be safely used under medical supervision and (2) that MDMA has a currently accepted medical use in treatment in the U.S. We recognize that these positions raise difficult questions of statutory interpretation. We will argue that under the proper interpretation of the Controlled Substances Act, the evidence will demonstrate that MDMA does have an accepted medical use, that it can be safely used under medical supervision, and that for these reasons, as well as the fact that MDMA does not have a high

abuse potential, MDMA cannot properly be placed in Schedule I.

Much more important than the narrow legal arguments over the interpretation of "accepted medical use" under the CSA, however, is the clear fact that MDMA has, at a minimum, demonstrated significant therapeutic potential which deserves to be further researched and explored. To avoid stifling research on a drug that has only low to moderate abuse potential, MDMA should not be placed in Schedule I or II and should be placed in a lower schedule.

Third, we will argue that MDMA must either be scheduled in Schedule III, IV, or V or it cannot be scheduled at all. We believe that, even if MDMA does not have a "currently accepted medical use in treatment in the U.S.," the Drug Enforcement Administration has the authority and discretion under the Controlled Substances Act to place MDMA in Schedule III, IV, or V. Schedule I is limited to drugs of "high" abuse potential which have no medical use. Schedule II is limited to drugs of "high" abuse potential with an accepted medical use. Schedule III, Schedule IV, and Schedule V are the only schedules available for substances with moderate or low abuse potential. It makes no sense for Congress to have given DEA the authority to control drugs of moderate or low abuse potential which do have medical use (in Schedules III, IV, and V), but not to have given DEA the authority to impose controls on drugs with low or moderate abuse potential which do not have a medical use. On the

other hand, if substances with no accepted medical use cannot be placed in Schedules III, IV, and V, then MDMA cannot be scheduled at all.

In summary, MDMA cannot be placed in Schedule I because it plainly does not have a high potential for abuse. In addition, it does not meet the other two criteria for Schedule I because the evidence will show that it can safely be used under medical supervision and that it has an accepted medical use in treatment in the U.S. Under these circumstances, it cannot be placed in Schedule I and is appropriately placed in either Schedule III, IV or V. Even if MDMA does not have an accepted medical use in the U.S., the only Schedules in which DEA has the authority to place MDMA are Schedules III, IV, or V. If MDMA cannot be placed in one of these three Schedules, it cannot be scheduled at all.

We now turn to the six areas identified in Judge Young's Memorandum and Order.

Responses to Questions Raised

1. Five Legal Issues

We agree that these proceedings raise all five of the issues identified in Judge Young's memorandum, but we believe that other issues are raised as well.

We emphasize, however, that the primary issue in these proceedings will be the abuse potential of MDMA. It is only because it is the assumption of all parties to this proceeding that the evidence will show that the abuse poten-

tial of MDMA is moderate to low, that the issues identified in Judge Young's memorandum arise.

2. Succinct Statement of Proposed Additional Issues

In addition to the legal issues identified by Judge Young's memorandum, we believe the following evidentiary issues will need to be considered specifically with respect to MDMA:

(a) the abuse potential of MDMA;

(b) the dependence causing potential of MDMA (statutory criterion for placement of substance in Schedule III, IV, or V);

(c) the extent to which MDMA has a currently accepted medical use in treatment in the United States;

(d) the extent to which MDMA has "accepted safety for use under medical supervision";

3. Brief Statement of Position on Each Issue

Our position on each of the issues identified is as follows:

1. What constitutes "currently accepted medical use and treatment in the United States" within the purview to Z1 U.S.C. § 812(b)?

Any one of the following constitutes currently accepted medical use in treatment in the United States:

(a) IND approval issued to any physician in the United States by the Food and Drug Administration for use of a substance in humans; or

(b) FDA approval of a new drug application (NDA or ANDA) or other FDA approval for interstate shipment and sale of any

substance for any medical use in the United States; or

(c) Recognized grandfathering under the Food, Drug and Cosmetic Act of any substance for interstate shipment and sale for medical use (over-the-counter or prescription); or

(d) Approval of any substance for intrastate shipment and sale for medical use by any appropriate State authority; or

(e) Actual therapeutic use of a substance by practicing physicians in the United States accepted as appropriate by the medical community within which they practice.

2. Is a finding by the Secretary of Health and Human Services that a substance such as MDMA has "no currently accepted medical use and treatment in the United States" binding on the Attorney General (Administrator of the Drug Enforcement Administration, UEA) within the purview of the provisions 21 U.S.C. § 812?

Such a finding is not binding in the context of a hearing on the scheduling of a substance under the CSA. Any other position would be wholly inconsistent with the statutory provision for decisions concerning scheduling to be made on the basis of a hearing on the record. All issues relevant to scheduling must be subject to the hearing requirement. The Secretary of Health and Human Services has not made any finding concerning "currently accepted medical use" on the record after a hearing. Therefore, no such finding can foreclose the hearing mandated under the Controlled Substances Act from considering and arriving at a conclusion on this issue based on the evidence adduced at the hearing.

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

Any of the following constitutes currently accepted medical use and treatment in the United States:

(a) IND approval issued to any physician in the United States by the Food and Drug Administration for use of a substance in humans; or

(b) FDA approval of a new drug application (NDA or ANDA) or other FDA approval for interstate shipment and sale of any substance for any medical use in the United States; or

(c) Recognized grandfathering of any substance for interstate shipment and sale for medical use (over-the-counter or prescription); or

(d) Approval of any substance for intrastate shipment and sale for medical use by any appropriate State authority; or

(e) Actual therapeutic use of a substance by practicing physicians in the United States accepted as appropriate by the medical community within which they practice.

(f) Use of a substance clinically under the supervision and approval of an Institutional Review Board.

4. Can a substance, such as MDMA be placed in any schedule other than Schedule I if it is determined that the substance has a potential for abuse and that it has "no currently accepted medical use and treatment in the United States"?

Our position is, first, that such a substance can properly be placed in a schedule other than Schedule I, and second, that such a substance cannot legally be placed in Schedule I because it only has "a potential for abuse" and not a "high" potential for abuse.

5. If it should be determined (1) that there is "a currently accepted medical use and treatment in the United States" for MDMA, and (2) that there is no "lack of accepted safety for use of [MDMA] under medical supervision," but that (3) MDMA has a potential for abuse, in which of the schedules, II through V should MDMA be placed?

MDMA plainly cannot be placed in Schedule I or Schedule II because both Schedule I and II require a "high potential for abuse." At this time, we express no view on which of Schedules III through V MDMA should be placed in. Once we have had a chance to review the Government's evidence as well as consult in more detail with our own expert witnesses, we will be in a position to take a more definitive position on this issue.

6. What is the abuse potential and dependence causing potential of MDMA?

Based on evidence currently available, it is our position that MDMA has a low potential for abuse and a low dependence causing potential.

4. Statement whether issue No. 4 is a strictly legal question

It is our position that issue No. 4 is a strictly legal issue requiring no evidence for decision. Indeed, while we are prepared to present an extended legal argument based on legislative history, the logic of the statutory scheme and relevant case law, we believe the question essentially answers itself. Schedule I requires that a substance must have a "high" potential for abuse. For those substances without a high potential for abuse, Schedules III,

IV and V are available. It is inconceivable -- given the Congressional directive to DEA to control substances with abuse potential ranging from low to moderate to high, that Congress would have intended to have DEA control substances with a low or moderate abuse potential only when they have an accepted medical use. Such an interpretation would leave an enormous hole in DEA's regulatory authority. It is simply plain from the intent of the statute and the basic statutory scheme that it is within DEA's authority to control substances with a low to moderate abuse potential which have no medical use as well as those that have a medical use. To be consistent with the statutory scheme, these substances would have to be placed in Schedule III, IV, or V depending on findings to be made about their abuse potential and dependence causing characteristics.

5. List of Witnesses

At this time we intend to call the witnesses listed below. In some instances, however, the ability of the witnesses to attend the hearing will depend on the location in which the hearing is scheduled. If the hearing locations are such that our witnesses cannot attend, we will delete the names at a later date:

Professor Lester Grinspoon, M.D.
Harvard Medical School
Department of Psychiatry
Cambridge, MA

George Greer, M.D.
3 Azul Drive
Santa Fe, NM 87505

Lance Wright, M.D.
3901 Market Street
Box 1952
Philadelphia, PA 19104

Norman Zinberg, M.D.
11 Scott Street
Cambridge, MA 02138

Rodney Houghton, M.D.
P.O. Box 1147
Bernalillo, NM 87004

Richard Ingrasci, M.D.
Turning Point
173 Mount Auburn Street
Watertown, MA 02172

Jack Downing, M.D.
59 Kittredge
San Francisco, CA 94118

Professor Thomas B. Roberts, Ph.D.
Northern Illinois University
Department of Learning, Development
and Special Education
DeKalb, IL 60115

Richard Seymour
Haight-Ashbury Physican Training and
Education Project
409 Clayton
San Francisco, CA 94117

June Reidlinger, R.Ph.
8514 Parkview Avenue
Brookfield, IL. 60513

Attached as Appendix A is a compilation of a brief summary of the nature of the testimony expected from each witness.

Furthermore, we will almost certainly name additional witnesses once we have examined the witnesses the government intends to call. We emphasize that the above list is our initial list of witnesses. Based on our anticipation of the government's case, we think it likely we will

have two additional witnesses from the East Coast, one additional from the Midwest and one from California.

6. List of Documents

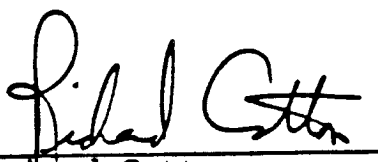
Attached at Appendix B is our initial list of documents.

Procedural Issues

We request that hearings be held, at a minimum, in Washington and San Francisco. We also request that hearing sessions be held in Chicago and Santa Fe, New Mexico if the government seeks cross-examination of our witnesses from the Midwest or from New Mexico.

In addition, we urgently make another procedural request. The DEA is the initiating party and has the burden of proof in this case. Therefore, we request that our direct testimony be submitted 45 days after we have received the direct testimony of DEA witnesses. In that way, our witnesses will be able to respond to the direct testimony of the agency's witnesses.

Respectfully submitted,



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Date: March 11, 1985

APPENDIX A -- WITNESS SUMMARIES

TESTIMONY OF LESTER GRINSPOON, M.D.

Dr. Grinspoon's testimony will discuss the following:

(1) Potential for MDMA abuse is low. Tolerance develops so quickly that the experience cannot be repeated frequently, and the experience is too intense to be treated casually or recreationally. For similar reasons, we believe that the dependence producing potential of MDMA is low. In addition, we have heard no reports of craving or withdrawal symptoms.

(2) We believe that MDMA can be safely used under a physician's supervision. There are no effects so disturbing, disorienting, or physically dangerous that this would be impossible.

(3) Because MDMA is a relatively new drug, there are few published reports and no controlled studies that we know of. However, it has been used for therapeutic purposes by physicians and psychotherapists. We have heard from a number of mental health professionals who have found MDMA useful as a catalyst of self-exploration. It belongs to a group of drugs that have been described as "feeling enhancers," and which apparently produce a hightened capacity for introspection and emotional intimacy without distracting changes in perception and body image. It may have value in

diagnostic interviews, in marital counselling, as an occasional adjunct to insight oriented therapy, and in other ways as yet undiscovered. Unless properly controlled human research becomes possible, we will have no way of learning the potential of this and other related drugs, which could be significant for both psycotherapy and experimental psychology.

TESTIMONY OF GEORGE GREER, M.D.

Dr. Greer's testimony will discuss:

(1) his clinical use of MDMA in his professional practice;

(2) his professional opinion, based on his experience with his patients, that MDMA has a low abuse potential;

(3) his professional opinion, based on his clinical experience with his patients, that MDMA can be safely used under medical supervision;

(4) his professional opinion that MDMA has important therapeutic use based on his clinical experience in using MDMA with patients in his practice;

(5) his professional judgment that he has not detected any dependence-causing potential of MDMA in his practice; and

(6) the adverse impact that placement of MDMA in Schedule I or II would have on his medical practice.

TESTIMONY OF LANCE WRIGHT, M.D.

Dr. Wright's testimony will cover the following points:

(1) Based on his professional experience and observations as a practicing psychiatrist and in the drug and alcohol treatment unit of the Philadelphia VA Medical Center, Dr. Wright will discuss his views that MDMA does not have a high abuse potential;

(2) Based on his professional experience and observations, Dr. Wright will also discuss his professional opinion that MDMA can be safely used under medical supervision.

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March 8, 1985

In 1968, conducting the first controlled experiments giving marihuana to human subjects with Dr. Andrew Weil proved that it was safe and experimentally reasonable to work with a drug previously so feared as to be virtually barred from research with human subjects. In 1972, under the sponsorship of The Drug Abuse Council, (DAC) Inc., I conducted a phenomenological study of the subjective experience of several illicit drugs, including MDA and heroin, which was published as a DAC monograph entitled "'High' States: A Beginning Study."* It is my impression that my uncontrolled study and others similarly indicate that psychedelic drugs can also be safely worked with experimentally.

It is important to note that the psychedelic drug experiences I studied and mentioned above were with MDA, a, so to speak, full-strength psychedelic with the typical intense psychedelic experience lasting 8 to 12 hours, accompanied by various mild neurological symptoms. MDMA is a far milder drug with effects lasting from 2 to 4 hours, few, if any, secondary neurological symptoms, and much less consciousness change. So far I have personally interviewed only one subject who has taken MDMA once a month as part of a formal psychotherapy with another established therapist. My aim in this and other planned interviews is to determine both the safety and the efficacy of MDMA as a therapeutic aid. So far, there is little doubt about the safety of the procedure. The patient shows no increased anxiety, depression, or other untoward reaction. Her response to the drug lasts 2 to 3 hours, and after 6 episodes she seemed to be developing tolerance to the consciousness-changing effects. The patient has felt the experience to be useful to her greater understanding of herself, but I have doubts as to whether over time actual benefit will have occurred. Only continued monitoring can provide even a subjective answer to that question.

The work just now with MDMA seems to be following the course of interest in other psychedelic drugs. As long ago as the late fifties

*Reprinted in Shaffer H, Burglass ME, eds. Classic contributions in the addictions. New York: Brunner/Mazel, 1981:241-276.

there were high hopes that the psychedelic experience would help psychiatric residents understand their patients better and in turn allow patients to experience certain of their inner states more fully. Also, there was particular hope, buttressed by the success of these drugs in helping dying patients deal with the pain and desecration of death, that the capacity of these drugs to allow a person some inner distance from his/her own painful experience would make that person careful with the painful cravings from addiction to drugs and alcohol.

Because of the notoriety accorded the illicit use of psychedelic drugs, the power of these drugs that frequently induced negative responses, and their brief duration of action that made them unwieldy to work with, virtually all experimental efforts were abandoned before the degree of success or failure could be determined. There is a fresh chance for such studies and experiments with MDMA. MDMA is not notorious, is not as hard to work with, nor as powerful. It would seem to me that prematurely putting the drug into Schedule I with little or no evidence that it belongs there, again cuts off the possibility of scientific advance.

TESTIMONY OF RODNEY HOUGHTON, M.D.

Dr. Houghton's testimony will cover the following points:

(1) Based on his professional experience and observations, MDMA has only a low abuse potential and little tendency to cause dependence;

(2) Based on his professional experience and observations, MDMA can be safely used under medical supervision;

(3) Based on his professional experience and observations, MDMA has important therapeutic potential which deserves to be researched;

(4) As a member of the peer review board for the work of Dr. George Greer, Dr. Houghton will describe his professional view of Dr. Greer's work.

TESTIMONY OF RICHARD INGRASCI, M.D.

Dr. Ingrasci's testimony will cover the following points:

(1) He will discuss his professional clinical experience in using MDMA with patients in his medical practice;

(2) Based on his professional experience and observations, he will discuss his view that MDMA does not have a high abuse potential, but has at most a low to moderate abuse potential;

(3) Based on his professional experience and observations, he will discuss his professional opinion that MDMA can be safely used under the supervision of a physician;

(4) Based on his professional experience and observations, he will discuss his views concerning the medical use of MDMA in treatment in the United States.

TESTIMONY OF JACK DOWNING, M.D.

Dr. Downing's testimony will present the results of certain studies on the physiological effects of MDMA.

TESTIMONY OF THOMAS ROBERTS, Ph.D.

Professor Robert's testimony will cover the following points:

(1) His experience as a patient in psychotherapy receiving MDMA under the supervision of a physician;

(2) His professional opinion that MDMA has a very low potential for abuse, based on his own experience and on his professional background as an educational psychologist who runs training programs for mental health professionals;

(3) His professional opinion that MDMA can safely be used under medical supervision; and

(4) His professional opinion that MDMA has an important potential for beneficial therapeutic effects as an adjunct to psychotherapy.

TESTIMONY OF RICHARD SEYMOUR

Mr. Seymour's testimony will cover the following:

(1) As Director of the Haight-Ashbury physician training project of the Haight-Ashbury Free Medical Clinic, he will discuss the clinic's experience as a major drug abuse treatment facility which indicates that MDMA does not have a high abuse potential.

TESTIMONY OF JUNE RIEDLINGER, R.Ph.

June Riedlinger's testimony will cover the following points:

(1) MDMA has has a low potential for abuse. In standard effective doses, its effect is mild and of brief duration. This effect is not enhanced by increasing the dosage. In fact, higher doses of MDMA only increase its harmless but unpleasant side effects -- blurred vision, for example. This fact limits substantially its "recreational" value and thus its abuse potential.

(2) The psychoactive properties of MDMA apparently are based on a different active isomer than that of MDA, a drug regarded as having abuse potential. MDMA's isomer seems to help affect serotonin levels in the brain.

(3) MDMA can be safely used under a physician's supervision. It appears to be safer than other drugs currently used to treat depression and other psychological problems.

(4) MDMA does have a clearly significant therapeutic potential deserving further research. This potential is especially marked, in her opinion, with respect to its possible use as an antidepressant in conjunction with psychotherapy. The drug's biologically-active

positive isomer activity induces the release of serotonin in the brain. Serotonin deficiencies seem to play a part in possibly all forms of depressions, so increasing serotonin levels might well have the opposite effect.

APPENDIX B - INITIAL LIST OF DOCUMENTS

1. Shulgin, A.T. and Nichols, D.E., Characterization of Three New Psychotomimetics, The Pharmacology of Hallucinogens, Eds. R.C. Stillman and R.,E. Willette, Pergamon Press, New York. (1978).

2. Anderson III, G.M., Braun, G., Braun, U., Nichols, D.E. and Shulgin, A.T., Absolute Configuration and Psychotomimetic Activity, NIDA Research Monograph #22, pp 8-15 (1978).

3. Braun, U., Shulgin, A.T. and Braun, G., Centrally Active N-Substituted Analogs of 3,4-Methylenedioxypphenylisopropylamine (3,4-Methylenedioxyamphetamine), J. Pharm. Sci., 69 pp 192-195 (1980).

4. Kueny, S., Report on a Study to Examine the Feasibility of Using 3,4-Methylenedioxymethaphetamine (MDMA) to Facilitate Psycho-therapy. Term Report, Psychopharmacology 641, Pacific Graduate School of Psychology, Menlo Park, CA. March, 1980.

5. Nichols, D.E., Lloyd, D.H., Hoffman, A.J., Nichols, M.B. and Yim, G.K.W., Effects of Certain Hallucinogenic Amphetamine Analogues on the Release of (3H) Serotonin from Rat Brain Synaptosomes. J. Med. Chem. 25, pp 530-535 (1982).

6. Glennon, R.A., Young, R., Rosecranes, J.A. and Anderson, G.M., Discriminative Stimulus Properties of MDA and Related Agents. Biol. Psychiat. 17, 807-814 (1982).

7. Greer, G., MDMA; A New Psychotropic Compound and its Effects in Humans. Copyright 1983, 333 Rosario Hill, Sante Fe, NM 87501. (1983).

8. Letter from Legislative Counsel of California to Honorable John R. Garamendi, May 26, 1981, re Sherman Food, Drug, and Cosmetic Law - #8182.

9. Opinion of Evelle J. Younger, Attorney Genreal, State of California, CV 76/212, CV 77/236, dated May 2, 1978.