George Greer, M.D.

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May 3, 1985

To: WITNESSES IN DEA HEARING ON SCHEDULING OF MDMA

Rick Cotton has asked me to send you all the enclosed testimonies of government witnesses. Any rebuttal testimony that we have is due May 20th. If you have a response to make, please send it to Rick this week so that he can discuss it with you if there need to be changes. Be sure to include the oath at the bottom: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct," and then date and sign.

I will outline below points I have thought of and discussed with Rick, but please add your own:

JOHN DOCHERTY - The main point here is that he does not address the point of my paper, which is that it is an anecdotal pilot study intended to indicate that MDMA has therapeutic potential that should be investigated further. No one can disagree that MDMA has not been scientifically proven to be effective for any use. But the issue for the hearing is "medically accepted use in treatment" and not proven use. If any of you can think of examples of treatment procedures that were widely accepted before they were proven in controlled studies, it would be useful to mention them. Rick thought of cardiac bypass surgery.

RONALD SIEGEL - This is the only testimony by an expert in drug abuse who has had contact with people taking MDMA that implies MDMA should be placed in Schedule I. The main criticism I have is that he does not say how he knows with certainty that the drug taken by people who have reported to him is actually MDMA. If it has not been chemically analyzed, it could be MDA or almost anything. He also says that the phenomenology of MDMA intoxication at higher doses is similar to LSD, but does not say in what way. Ron sent me a letter in January saying that the effects were rated similarly on "a global subjective rating scale, it does not reflect objective differences," and I will be sending a copy of this to Rick. He also says that MDMA is an hallucinogen, which is simply incorrect, unless he defines "hallucinogen" as any substance that induces an altered state. He does not say what he means by hallucinogen. He also does not say what he thinks the abuse potential of LSD, mescaline and other hallucinogens is, but that is more a legal and technical point than one that we should be addressing. Several points are actually made in our favor, like the lack of compulsive use and the fact that all use is not abuse. The estimate of

30,000 doses a month and the lack of reports of people being harmed by MDMA also seems to be favorable to me.

Daryl Inaba's testimony only said that some people came into the Haight-Ashbury Clinic with anxiety and physical symptoms and did not specifically address MDMA's abuse potential. I have not seen it, but Rick felt we did not need to respond to it. He was the only other drug abuse expert who testified, except for Dr. Tocus.

EDWARD TOCUS - The main point here is that it is not the FDA that sets standards of "accepted medical use." If you have anything to say about that, it would be helpful, especially if there are specific examples. Rick will be talking with some of you about finding an expert in standards of medical practice to offer testimony on this point. The other issue is the similarity of MDA to MDMA, which was more than adequately covered in the testimony of many of you, but can be mentioned here again.

I am enclosing the draft of my rebuttal testimony for those who are interested. Any comments, by phone or letter, will be appreciated. Because all of you have achieved greater recognition in your professions than I, it would be worth repeating any points I have made that you believe are valid. All in all, after reading the testimony of our 14 witnesses and 7 of their 8 witnesses, I feel optimistic. Of course, the DEA has a lot of leeway, but if we can show that MDMA's abuse potential is low, they will have a very hard time justifying putting it in Schedule I. It looks like they will have to concede that "lack of accepted medical use" and "lack of accepted safety" do not automatically mean that a substance must go into Schedule I, and that relative abuse potential is the primary determining factor. However, we have not heard their decision on that point yet. We still need to address all 3 issues, since they all will carry weight.

My clients and I want to thank all of you for your support in this hearing. It is certainly gratifying to come from feeling like I am the only one being open about using MDMA to having nationally respected scientists support the right to use it. I hope I have the opportunity to meet all of you and thank you in person before too long.

Sincerely,

George Greer, M.D.

George Greer, M.D.

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

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

DIRECT TESTIMONY OF JOHN P. DOCHERTY, M.D.

I, John P. Docherty, M.D., make the following statement:

I am a psychiatrist employed as Chief of the Psychosocial Treatments Research Branch, Division of Extramural Research Programs, National Institute of Mental Health, Rockville, Maryland. I received my M.D. degree from the University of Pennsylvania School of Medicine in 1970. I completed an internship at the Hospital of the University of Pennsylvania in 1971, and completed a psychiatric residency at Yale University in 1974. From 1974 to 1976, I served a clincial research fellowship at the National Institute of Mental Health, Intramural Research Program. During this time I was involved in conducting studies which involved the use of amphetamine to understand the biological basis and pharmacological treatment of schizophrenia and affective disorder. I have worked in the Psychosocial Treatments Research Branch of the National Institute of Mental Health since 1981 and currently am Chief of that Branch. A copy of my curriculum vitae is attached as Exhibit 1.

The Psychosocial Treatments Research Branch of the National Institute of Mental Health receives research protocols related to psychotherapy, which are approved by peer-review committees and the National Advisory Mental Health Council. After receiving these approved protocols, they are reviewed to determine whether they will be funded. The criteria for determining whether a

protocol will be funded includes the scientific quality of the proposal, the relevance of the proposed study to the field of study, and the public health significance. Very few of the protocols concerning psychotherapy involve drugs. The Psychosocial Treatments Research Branch also manages the grants that are made to clinical researchers. Technical assistance is provided to investigators, which includes conducting workshops and giving lectures concerning research in the area of psychotherapy. The Branch also conducts collaborative research.

During the course of my duties, I was contacted by Dr. George Geer concerning his activities with MDMA. This was approximately 8 months ago. I spoke with him briefly, and he also spoke with Dr. Levine in the Pharmacologic and Somatic Treatments Research Branch. I have recently reviewed the unpublished document entitled, "MDMA: A New Psychotropic Compound and Its Effects in Humans," by George Greer, M.D. Based upon my knowledge in the field of research in the area of psychotherapy I make the following observations:

The investigation reported in that paper is inadequate to establish the therapeutic efficacy of MDMA as an adjunct to psychotherapeutic treatment. This study suffers from numerous methodological problems and does not adequately control for possible errors of inference in the light of current state-of-the-art knowledge of clinical research methodology. Problems with this study include but are not limited to the following:

1. The study is an uncontrolled investigation. It does not provide for a comparison group which would allow us to determine whether or not MDMA adds appreciably to the psychotherapeutic treatment alone in terms of outcome. In order to make the inference that MDMA is therapeutically useful, it would be

necessary to have two groups of patients fully equivalent with regard to psychological problems. Both groups should receive a specific psychological treatment, one enhanced by MDMA and the other not. Only with such a comparison would we be able to determine whether MDMA appreciably enhances the efficacy of the psychological treatment. Furthermore, since we have good evidence that certain psychological treatments are themselves effective, as an initial study it would be important that the researcher utilize a psychotherapeutic approach of known efficacy in treating a specific psychological problem. Not a single one of these criteria or necessary conditions was met in the only published investigation regarding the therapeutic enhancement efficacy of MDMA.

2. Alluded to in the comments above is a necessity for clearly specifying the psychological problems for which treatment is thought to be effective. The group reported on in the investigation noted above is a heterogeneous group. Furthermore, of the 29 subjects, only 14 reported any psychological problems at all, and of those 14, only 9 had diagnosable psychiatric disorders. Of those with psychiatric disorders, all of the conditions were mild and included 2 cases of dysthymia, 1 case of simple phobia, 3 personality disorders, 2 adjustment disorders with depression, and 1 atypical depression. These are all very mild disorders which tend to be self-limiting. The small number of subjects in each of these different conditions makes it virtually impossible to determine the efficacy of an intervention since so many other variables could potentially be effecting the course of the illness.

3. Evaluation of the subjects was not reported to be carried out in a standardized manner which met necessary scientific standards. We have no

assurances that a rigorous, comprehensive, or adequate evaluation of the subjects which would allow for a comprehensive diagnosis was conducted. Furthermore, we have no assurances that the methods of assessment can be conducted in a reliable manner, that is, that more than one individual would agree upon the assessment made. This is an essential requisite for any credible investigation. In addition, no effort was made to assess the veridicality of the reports either by questioning other persons in the individual's life or by gathering sufficient information to ascertain whether the changes reported were simply changes in subjective state or reported behavior or actual changes in behavior.

4. The "therapeutic procedure" purportedly carried out in this study was not clearly specified. It is absolutely essential that the type of therapy which is provided each subject in an investigation like this be clearly defined. Furthermore, it is necessary that such a procedure be held constant across subjects. It is clear from this report that such was not the case and that important clinical variables may have varied widely and have thus contributed to variance in outcome. This makes it impossible to determine whether MDMA, even with a comparison group, would have been the effective agent in enhancing a therapeutic procedure. Simply stated, if you do not define the therapeutic procedure and conduct it in a stable manner, it is impossible to determine whether or not MDMA enhances it.

5. Additionally, in this investigation the setting was not held constant. Since we know that setting can influence responsiveness to treatment, it would be important in an investigation of this sort that setting was held constant. In this case, some subjects were seen in their home and other subjects were seen somewhere else not specified.

6. The report noted a potentially very troublesome variation in the procedure wherein MDMA was administered. It is noted on page 5 of an attachment to the report entitled "The Legal, Safe, and Effective Use of MDMA" by George Greer, M.D., Santa Fe, New Mexico, that "in special cases, facilitators may want to take MDMA with clients, but at least one facilitator should not take any in order to maintain appropriate social judgment." It is not clear in this investigation whether the faciliator took MDMA on some occasions or not. We might expect that it certainly would make a difference whether or not the facilitator in the project was also using the substance at the same time as the "patient."

In summary, the methodolgoical problems noted above make any reasonable inference regarding the efficacy of MDMA for enhancing the therapeutic efficacy of the psychotherapy impossible and form no reasonable basis for such an assertion in my opinion.

I declare under penalty of perjury that the foregoing statement is true and correct.

Executed on 4/24/91

Signature Jol C. Doctor, MD

RONALD K. SIEGEL, Ph.D.
Post Office Box 84358
Veterans Administration Branch
Los Angeles, California 90073

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

DECLARATION OF RONALD K. SIEGEL, Ph.D.

I, Ronald K. Siegel, declare and state as follows:

1. I am a psychopharmacologist, engaged in the research and study of the effects of drugs on human behavior. I am on the faculty of the Department of Psychiatry and Biobehavioral Sciences in the School of Medicine, University of California at Los Angeles, and in private practice. I have studied, lectured and conducted research at Brandeis University, Harvard Medical School, Dalhousie University and the Albert Einstein College of Medicine. I have been a consultant to the Canadian Government's Royal Commission on the Nonmedical Use of Drugs, the President's National Commission of Marihuana and Drug Abuse, the Pan American Health Organization and the World Health Organization. I am presently consulting with the President's Commission on Organized Crime. A summary of my professional qualifications is contained in my curriculum vitae which is attached to this declaration.

My research into the effects of drugs has included clinical studies in which I have administered a wide variety of drugs to human volunteers. These drugs have included the hallucinogens LSD, THC, marijuana, mescaline, psilocybin, ketamine, among many others. In addition, I have studied several populations of street drug users, including users of MDMA and related compounds. I also conduct research on street drug trends and utilize several methods including: testing and analysis of drugs and drug paraphernalia; interviews with manufacturers and distributors; monitoring the underground and alternative press; as well as longitudinal physical and psychiatric testing of users.

2. I am presently employing many of these techniques in a study of MDMA users. The formal research is still in progress and preliminary results are not expected until the end of 1985. However, interviews and examinations on a pilot group of subjects have been concluded and form part of the basis for my opinions. The full data and reasoning for these opinions is not given here due to the constraints of time.

3. The nonmedical street use of MDMA in the United States has escalated from an estimated 10,000 doses distributed in all of 1976 to 30,000 doses distributed per month in 1985. While the number of users cannot be calculated from these data, the most common patterns of current use are experimental (ten times or less in lifetime history) or social-recreational (one to four times per month). The three other patterns of nonmedical drug

use are either rare or absent with MDMA users. The pattern of circumstantial-situational use, whereby users try to work through personal problems, has been rare in past years but is escalating as users become aware of claims of medical use. Intensified or daily patterns of use have only been reported in users involved in illicit manufacture or distribution and sales. Compulsive patterns marked by escalating dose and frequency of use have not been reported with MDMA users.

4. The acute physical and psychological effects of MDMA do not differ substantially from mescaline, MDA and other hallucinogens. While street doses of MDMA are commonly low (less than 100 mg), generating reports of mild and unique intoxications, such reports are not significantly different from low doses of mescaline. The phenomenology and incidence of intoxication effects from higher doses (200 mg) are similar to effects from LSD. The long-term effects of MDMA use are unknown, although the relatively high incidence of acute toxic effects suggests caution.

5. Nonmedical street users of MDMA report positive effects, that maintain continued but infrequent use, as well as negative effects. Experienced street users report the ability to maximize positive effects through the manipulation of dose, set and setting, among other variables. Some negative effects can also be minimized but untoward and unsafe physical and psychological reactions cannot be readily controlled in nonmedical settings.

6. MDMA appears to have the same potential for abuse as mescaline, LSD and other hallucinogens in Schedule I. MDMA, like these other hallucinogens, has a potential for nonmedical use, but such use is not necessarily abuse when abuse is defined as dysfunction in physical, psychological or psychosocial assessments. While the semantics and logic of abuse vs. nonmedical use are not issues in this matter, MDMA remains a hallucinogen similar to others in Schedule I.

7. MDMA has no currently proven medical use in treatment in the United States. Thus far, case reports and clinical observations, albeit suggestive, are insufficient for demonstrating treatment effectiveness.

8. MDMA can be unsafe in nonmedical patterns of use. Since many of the untoward physical and psychological reactions contributing to this lack of street safety are also reported to occur in medical settings, it is doubtful that present medical and pharmacological knowledge can always supervise use with acceptable safety.

I declare under penalty of perjury that the foregoing statement is true and correct. Executed on April 13, 1985 at Los Angeles, California.

Ronald K. Siegel April 13, 1985

RONALD K. SIEGEL

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

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

DIRECT TESTIMONY OF EDWARD CHARLES TOCUS, Ph.D.

I, Edward Charles Tocus, make the following statement:

I am a pharmacologist employed as Chief of the Drug Abuse Staff, Division of Neuropharmacological Drug Products, Center for Drugs and Biologics, United States Food and Drug Administration. I received my doctoral degree in pharmacology from the University of Chicago in 1959. From 1960 through 1966, I was employed as a Research Pharmacologist at Lederle Laboratories, Pearl River, New York. Since 1966, I have worked in the Division of Neuropharmacological Drug Products, Food and Drug Administration. I have served as a Reviewing Pharmacologist, Supervisory Pharmacologist, and Chief of the Drug Abuse Staff. A copy of my curriculum vitae is attached as Exhibit 1.

The Division of Neuropharmacological Drug Products evaluates the safety and effectiveness of new human drugs which affect the central nervous system. The Drug Abuse Staff is responsible for the evaluation of the safety and efficacy of drugs that are analgesics, narcotic antagonists,

hallucinogens, and drugs which are used to treat some form of drug dependency. The Drug Abuse Staff evaluates all drugs with an abuse liability which are submitted to the Food and Drug Administration. Evaluation normally occurs upon submission of an investigational new drug application (IND) or a new drug application (NDA). Approval of an IND allows the sponsor of a drug to legally administer that drug to humans.

The IND process is a continual monitoring and approval process which continues during the course of the studies conducted by the the sponsor. The Food and Drug Administration may stop the process at any time. The initial or original application for an IND must satisfy three elements. The first element concerns the chemistry of the drug. The sponsor must show the sources and purity of substances used in the manufacture of the drug. He must show how the drug is synthesized and that such synthesis is reproducible. The sponsor must show the composition of the drug, and must determine its purity. Any impurities must be identified and quantified. The second element involves submission of the results of animal toxicity studies. These studies are required to obtain information concerning the safety of the drug. The studies must show that the chemical in a biological system is not likely to produce irreversible damage at the doses proposed for human use. The third

element is a description of the clinical studies which will be conducted on humans. The studies must be defined in specific terms and include such things as the procedure to be followed, a definition of the population to be used, the dosages to be administered, the variables to be measured, the control observations, the statistical analyses to be used and provisions to prevent harm to the patients. The scientific qualifications of the investigators must be documented as well. The results of the human studies must be submitted to the Food and Drug Administration on an ongoing basis. The studies continue until terminated by the sponsor, stopped by FDA, or until sufficient scientific data is available for the sponsor to prepare a new drug application (NDA).

An NDA must be approved by the Food and Drug Administration prior to marketing a drug in the United States. The NDA generally consists of data which has been collected as part of the investigational new drug (IND) process. The data in the new drug application must include carcinogenic studies in animals, reproductive studies in animals, stability determinations of the product, side effects in humans, samples of labeling, and sufficient results from controlled studies to show that the drug is safe and effective in humans for the therapeutic purpose advanced by the sponsor. If the drug which is the subject

of the NDA has any chemical or pharmacologic properties which indicate that it might have an abuse liability, the NDA submission must include specific drug abuse studies.

New drug applications have been required prior to drug marketing since 1938. The statutory requirements for new drug applications and procedures regarding submission, approval, withdrawal, and revocation are found in Section 505 of the Food, Drug and Cosmetic Act. 21 U.S.C. § 355. A copy of this section is attached as Exhibit 2.

The Drug Abuse Staff of the Food and Drug Administration evaluates data included in the NDA submission, the published literature and information received from other sources such as the Drug Enforcement Administration in order to determine whether a drug has an actual and/or relative potential for abuse. After evaluation of a compound for abuse potential, the Drug Abuse Staff makes a recommendation to the Division Director, then to the Commissioner of the Food and Drug Administration (FDA) and finally with concurrence of the National Institute on Drug Abuse, to the Assistant Secretary for Health of the Department of Health and Human Services as to the propriety and necessity of scheduling such a substance under the Controlled Substances Act. As part of my duties I initiate and prepare control recommendations to be submitted to the Drug Enforcement Administration by the Assistant Secretary

for Health for drugs which have been approved in the NDA process. There are occassions when drugs which have not been evaluated by the Drug Abuse Staff as part of the NDA process come to the attention of the staff. This occurs primarily when the Drug Enforcement Administration submits a control recommendation to the Assistant Secretary for Health for a scientific and medical evaluation and recommendation as required by the Controlled Substances Act. As part of my duties I evaluate control recommendations submitted to the Assistant Secretary for Health by the Drug Enforcement Administration and prepare the control recommendations which will be sent to the Administrator of DEA by the Assistant Secretary for Health.

In March, 1984 the then-Administrator of the Drug Enforcement Administration sent a letter and a document entitled, "Schedule I Control Recommendation Under the CSA for 3,4-Methylenedioxymethamphetamine (MDMA)" to the Assistant Secretary for Health. The DEA Administrator asked for a scientific and medical evaluation and a scheduling recommendation for MDMA in accordance with 21 U.S.C. § 811(b). The control document sent by DEA contained information concerning the abuse potential, references from the scientific literature and statistics on the illicit trafficking of MDMA which had been collected by DEA staff. The March 13, 1984 letter to the Assistant

Secretary for Health and the control document were forwarded to me for evaluation. Prior to the receipt of information from the Drug Enforcement Administration, I had had no specific knowledge or information concerning the drug MDMA. I reviewed the data contained in the DEA document, and searched the files of the Food and Drug Administration for information concerning the drug 3,4-methylenedioxymethamphetamine (MDMA). I found no reference in the files of the Food and Drug Abministration to this drug. There were no investigational new drug applications or approvals, there were no new drug applications or approvals, and there was no indication that any sponsor had informed FDA that such submission would be forthcoming. Based on the review of the files of the Food and Drug Administration, I was able to conclude that the substance or drug 3,4-methylenedioxymethamphetamine had not been approved for human research studies, or for marketing in the United States. I then applied the eight factor analysis required by the Controlled Substances Act using the data which had been submitted by the Drug Enforcement Administration in their control document. My conclusions based upon the application of the data supplied by DEA to the eight factor analysis are as follows:

1. The actual or relative potential for abuse of MDMA is evidenced by its chemical and pharmacological similarity

to the Schedule I controlled substance MDA. Actual abuse of MDMA has been shown by submissions of MDMA to DEA laboratories, seizures of MDMA, evidence of clandestine manufacture of MDMA, and mentions of MDMA in the Drug Abuse Warning Network. MDMA has been identified in 34 submissions to DEA laboratories from 12 states in an 11 year period. Clandestine laboratory seizures involving the manufacture of MDMA have been identified in four states. MDMA has received 8 Drug Abuse Warning Network (DAWN) mentions and one medical examiner report since 1972. These mentions indicate the existence of human use of MDMA.

2. Scientific studies have shown that the pharmacological effect of MDMA is similiar to that of MDA. MDMA and MDA both have analgesic activity in several procedures in mice, and both substances have been shown to produce increased motor activity or stimulant activity in mice. When tested in dogs and monkeys MDMA produced a spectrum of central nervous system, autonomic nervous system and motor activity similar to that obtained with MDA and mescaline, also a Schedule I controlled substance. Tests in humans have shown MDMA to be similar to MDA. Both substances produced a change in consciousness without hallucination, a decrease in tension, a heightening of mood, and an increase in acoustic, visual and tactile perception. Both MDMA and MDA cause increased heart rate and mydriasis.

3. The current scientific knowledge concerning MDMA is that it is chemically and pharmacologically related to the substance 3,4-methylenedioxyamphetamine (MDA) which is currently a Schedule I controlled substance under the Controlled Substances Act. This relationship is the same that amphetamine bears with methamphetamine, both Schedule II controlled substances, which is that there is a methyl group on the nitrogen of the amine. This difference is reflected in the chemical names of the substances - methamphetamine and 3,4-methylenedioxymethamphetamine, which contain "meth" for the methyl group. MDMA can be synthesized easily using readily available materials. Several alternative pathways for the synthesis of MDMA have been described in the scientific literature. Several synthetic methods of making MDMA have also been identified through the chemicals seized in clandestine laboratories.

4. The history and current pattern of abuse of MDMA was shown by DEA in its document describing laboratory submissions, seizures, clandestine laboratory operations, and DAWN mentions.

5. The scope, duration, and significance of abuse were shown in the DEA document by describing evidence of consistent illicit trafficking since 1970.

6. MDMA can produce harm to the public health. Studies in experimental animals which were included in the

DEA document indicate that MDMA is more toxic than mescaline and less toxic than MDA on a milligram basis.

7. There was no specific data available concerning the psychic or physiological dependence liability of MDMA.

8. MDMA is not an immediate precursor of a substance already controlled under the Controlled Substances Act.

After reviewing the eight factor analysis I concluded that MDMA satisfies the three criteria for Schedule I control. MDMA has a high potential for abuse. This is evidenced by its pharmacological similarity to the Schedule I substance MDA and evidence of its actual abuse. MDMA has no currently accepted medical use in treatment in the United States. This is because MDMA has not been approved by the FDA for marketing in this country. It is not a grandfathered drug, it does not have an approved NDA, and it has not been approved for over-the-counter use. MDMA lacks accepted safety for use under medical supervision. A substance cannot be deemed safe unless FDA has determined that there is scientific data which demonstrates that a substance can be given to humans without irreversible harm. No scientific data has been supplied to FDA which would demonstrate the safety of the drug, MDMA. A review of the available scientific literature on MDMA does not support the safety of the drug for use under medical supervision. If the safety of a drug cannot be established, then the drug lacks accepted safety.

After review and evaluation of the DEA document in conjunction with the eight factor analysis, finding that MDMA has not been approved by the Food and Drug Administration for marketing in the United States, and in the interest of preventing actual and significant harm to the public health, I concluded that MDMA should be controlled in Schedule I of the Controlled Substances Act.

I declare under penalty of perjury that the foregoing statement is true and correct.

Executed on April 22, 1985.

Edward Charles Tocus

Edward Charles Tocus, Ph.D.

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REBUTTAL TESTIMONY OF GEORGE GREER, M.D. IN DEA HEARING

ON SCHEDULING OF MDMA UNDER THE CONTROLLED SUBSTANCES ACT

REBUTTAL TO TESTIMONY OF DR. JOHN DOCHERTY

Dr. Docherty addresses my study as if it were an experiment to scientifically determine the efficacy of MDMA as an adjunct to psychotherapy for mental disorders. It is not and never was intended to be such a study. In the first paragraph of my report, "MDMA: A New Psychotropic Compound and Its Effects in Humans," I state, "The information gathered here is limited because the primary purpose of the sessions conducted with MDMA was therapeutic rather than investigative. Consequently, only the therapists' observations and the subjects' reports are available for analysis. Independent psychological evaluations with testing before and after sessions [Docherty's point #3] , control group data [point #1] with double-blind assessment, vital signs during sessions (except in 2 subjects), pre- and post-session laboratory testing of organ and metabolic functions, etc., were not done." Most people did not have diagnosable mental disorders [point #2] because this was a pilot study of the potential therapeutic use of MDMA in primarily normal and healthy subjects who simply wanted to learn from the experience. The procedure [point #4] and setting [point #5] was intentionally varied as was the involvement of the facilitators [point #6] for the purpose of examining the potential of using MDMA in various ways. Determining efficacy was never conceived to be an aspect of the study, only determining whether or not MDMA might have any potential therapeutic use that would warrant the kind of research Dr. Docherty describes. I conclude that my data supports the conclusion that MDMA does have therapeutic potential that is yet to be scientifically proven.

I would like to draw a distinction here between a scientifically proven effective treatment and a medically acceptable treatment. Many treatments, especially in psychiatry, are accepted by many practitioners, but have not been proven to be effective to the satisfaction of all scientists in the field. The efficacy of psychotherapy itself, with its myriad techniques, has yet to be scientifically proven to be effective to the satisfaction of many psychiatrists and psychologists. Yet it is considered to be medically accepted treatment. It is my clinical judgment, and that of my peer review committee, that, based on my clinical experience, the use of MDMA is a medically accepted part of the treatment approach I use.

The drug is not a treatment in itself, as is the case with most drugs used in psychiatry today, but is part of a treatment program. The condition for which this program is acceptable is a fear of emotional injury that prevents the person

from correctly judging unnecessarily self-limiting beliefs and from communicating to others certain thoughts and feelings in a direct and open way. This condition, in the people with whom I use MDMA, is rarely debilitating in terms of their being able to work and function socially, but it does restrict their potential for self-actualization and self-satisfaction. In the final analysis, their own reports stand as evidence that this conclusion is valid. Only they are in a position to determine what their goals for self-actualization and personal satisfaction are and, therefore, to what extent these goals are achieved. I do not use MDMA primarily to treat psychological symptoms, such as depression or anxiety, but to treat a fear-induced inhibition to learning how to achieve personal goals.

REBUTTAL TO TESTIMONY OF DR. RONALD SIEGEL

My primary criticism of Dr. Siegel's testimony is that he reports no method of determination of the identity of the drugs that his informants are taking. Street drugs often contain impurities as well as other psychoactive drugs. (See the enclosed letter from Dr. Alexander Shulgin.) Mr. Sapienza's testimony [on page 10] states that a sample of MDMA obtained in the Bronx also contained PCP, a powerful and dangerous hallucinogenic drug known to cause severe adverse psychotic reactions in some people. It is possible and even likely that the samples of MDMA that were reported by Dr. Siegel's subjects to cause effects "similar to effects from LSD" [point #4 on page 3] contained MDA or other substances. I say likely because the effects of samples proven to be pure MDMA have yet to be shown to be hallucinogenic, because MDA does cause hallucinations at high doses, and because samples reported to contain only MDMA have contained MDA [Shulgin letter]. Therefore, Dr. Siegel may well be basing all of his conclusions on the abuse potential of MDMA on data contaminated by the fact that some informants unknowingly took MDA or even PCP. This lack of certainty of the drug(s) actually ingested invalidates Dr. Siegels conclusions.

In point #2, Dr. Siegel states, "The full data and reasoning for these opinions is not given here due to the constraints of time." Given the above criticism, the data and reasoning is exactly what is needed in order to make a reasonable determination of MDMA's abuse potential. Without them, no rational assessment can be made.

In point #3, several facts about drugs purported to be MDMA are made which support a conclusion that MDMA has low abuse potential: use is most commonly four times per month to less than ten times in a lifetime, which indicates a lack of dependence-producing potential; "circumstantial-situational use, whereby users try to work through personal problems [this might be called unsupervised therapeutic use] is escalating as users become aware of claims of medical use," indicating that much of the MDMA taken is not taken to "get high" and escape from

personal problems or reality in an abusive way; daily use occurs only in dealers, and compulsive and continuous use, characteristic only of drugs with high abuse potential, has not been reported. Dr. Siegel is describing a drug with low abuse potential. And with his estimate of 30,000 doses a month distributed, there has been ample opportunity for any severe abuse to become manifest.

Point #6, coming after the description of the lack of serious abuse of MDMA, seems to say that mescaline, LSD and other hallucinogens also have a low abuse potential. He further supports this view by stating that "such use is not necessarily abuse when abuse is defined as dysfunction in physical, psychological or psychosocial assessments." He then states that MDMA is "a hallucinogen", but, again, has given no evidence for the basis of this opinion. Perhaps the enclosed letter to me from Dr. Siegel gives a clue to this reasoning. In it he states, "The comparison between MDMA and LSD was made by our subjects and respondents on a global subjective rating scale, it does not reflect objective differences." Such a "global" scale is not likely to determine whether or not a drug-induced altered state of consciousness involves hallucinations, a hallucination being the seeing of an object with eyes open that is not physically present. The relative intensity of such an experience, without regard to the specific qualities of the experience, may be comparable on a "global" scale, which may account for a similarity in responses by subjects taking LSD and subjects taking MDMA. But, again, there is no certainty as to what drugs any of Dr. Siegel's respondents are taking, so no definite conclusion can be made, only suggestions and rough probabilities.

In point #7, Dr. Siegel states MDMA has "no currently proven medical use in treatment." This is correct. However, it is not at all the same as saying that MDMA has no "accepted" use in treatment, which is the criteria for Schedule I. The difference between these two standards has been discussed above.

Finally, in point #8, Dr. Siegel mentions unspecified "untoward physical and psychological reactions ... reported to occur in medical settings." I do not know to which medical settings he is referring. All of the available written reports of the use of MDMA in medical settings has been submitted as part of the testimony of Dr's Downing, Ingrasci, Wolfson and myself. No significant or lasting untoward reactions have been reported in any of these settings. I also question Dr. Siegel's expertise in determining medical acceptable uses in treatment and safety because he is not a physician.

REBUTTAL TO TESTIMONY OF DR. EDWARD TOCUS

Dr. Tocus' main point is that because no Investigational New Drug Exemptions or New Drug Applications exist for MDMA, it has no accepted medical use in treatment. It is my understanding

that IND's and NDA's are filed for the purpose of getting a drug approved for marketing in interstate commerce, and not to establish medically accepted use. As mentioned in my original letter to the DEA in requesting a hearing on this matter, it is my understanding that the Food and Drug Administration has no jurisdiction over the practice of medicine. I have never seriously thought to attempt to gain marketing approval for MDMA because it is not patentable and does not qualify as an orphan drug. I cannot see how the millions of dollars required for research to gain marketing approval will be raised. Therefore, I have never seen it appropriate to apply for an IND. On page 2, Dr. Tocus states, "Approval of an IND allows the sponsor of a drug to legally administer that drug to humans." This is simply incorrect. The enclosed copy of a page from the FDA brochure on obtaining IND's states, "The FDA has no authority over the practice of medicine and cannot require a physician to prescribe or not to prescribe a drug for a particular illness." I am also not marketing MDMA, but using it only within a program of treatment in my medical practice.

On pages 6 and 7, in point #1, Dr. Tocus states, "The actual or relative potential for abuse of MDMA is evidenced by its chemical and pharmacological similarity to the Schedule I controlled substance MDA." The data included in Dr. Nichols' testimony and in the letter by Dr. Shulgin included with my original testimony clearly demonstrates that MDA and MDMA are quite different pharmacologically. This data was not available to Dr. Tocus when he made his assessment of the abuse potential of MDMA, and so his assessment cannot be valid. As I have pointed out, it is the hallucinogenic effect of MDA that gives it its primary potential for abuse rather than its stimulant effect. Hallucinogens are abused on an intermittent basis, and lead to problems because they distort perceptions of physical reality. Stimulants are abused on a continuous basis, but neither MDA nor MDMA have been abused in this pattern. Points #2 and #3 are also based on the erroneous comparison between MDA and MDMA.

Point #4 refers to the abuse pattern of MDMA. This pattern is one of low abuse given the paucity of DAWN mentions and lack of confirmed deaths, as described in my original testimony. Point #5 correlates illicit trafficking directly with abuse. As Dr. Siegel pointed out, all use is not abuse, so this correlation is not evidence for a valid assessment of abuse potential, but only of the potential for illicit use. What pattern of use would one expect of a drug with a high therapeutic potential and low abuse potential, which was unpatentable? It would have gone through little, if any, controlled scientific studies due to lack of funding from drug manufacturers; it would have increasing illicit use for therapeutic purposes in unsupervised settings (as described by Dr. Siegel); there would be few significant adverse reactions or deaths reported by DAWN emergency rooms; and there would be growing use under medical

supervision but outside FDA supervision. No other pattern of use for such an unpatentable drug is plausible.

Point #6 states, "MDMA can produce harm to the public health." If this is so, and if 30,000 doses are being distributed each month, why are not drug abuse treatment centers such the Haight-Ashbury Free Medical Clinic seeing large numbers of people having serious adverse reactions? There have only been 8 emergency room mentions by DAWN. Certainly MDMA can be toxic and even cause death if enough of it is taken, but this has simply not been happening after probably hundreds of thousands of doses have been taken.

Point #7 offers no evidence for a dependence liability of MDMA, which underscores its low abuse potential.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on May , 1985 in Santa Fe, New Mexico.

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George Greer. M.D.