

TESTIMONY OF ROBERT DuBOIS LYNCH, M.D.

My name is Robert DuBois Lynch. I am currently a psychiatrist in private practice. I am currently statewide psychiatric consultant to the Department of Rehabilitation, State of California. I am in my fourth term of service with the Department of Rehabilitation and in my second term as statewide psychiatric consultant. A copy of my curriculum vitae is attached and incorporated into this testimony.

I have filed a request with the Federal Food and Drug Administration for the appropriate forms and application to apply for an IND (Investigational New Drug) with respect to MDMA. I have asked for a preliminary opinion by the Food and Drug Administration on the feasibility and legality of an MDMA-assisted motivational study for clients of the Department of Rehabilitation, State of California. I have not presented any formal proposal to the Department of Rehabilitation pending the response of the Food and Drug Administration. (The medical director of the department has approved my preliminary request to the FDA for the appropriate forms and for the FDA's opinion on this matter.) To date, I have had no answer to my request.

I desire to summarize my current best medical judgment about the potentially important medical use of MDMA in addition to those which appear as hypotheses in my proposal of March 18, 1985.

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I believe that MDMA is potentially the most important mind-exploring substance to become available in the last 20 years. MDMA plays no tricks on the subject as do other drugs. There is no loss of reality or of identity and the drug does not appear to be psychiatrically dangerous. The experience produced by MDMA is one in which the trans-personal experience becomes personal.

MDMA is not a pleasure "kick" drug. During the MDMA experience the subject's own higher mind is the therapist and the experience is highly motivational. The learning and the motivational experience of MDMA "sticks to the ribs" like a good meal rather than fading like short-term therapy or group weekend "highs".

The medical potential for the MDMA experience to assist and enhance individual psychotherapy, couple reconciliation, sexual awareness and affirmation, and for revelation of correct goals in spiritual growth should be investigated.

I believe that MDMA should not be considered as producing an experience like LSD. I believe that MDMA may be more useful at this time in history because what is needed is the possibility of a greater understanding by the individual of the purpose and potential of his life. An MDMA experience often gives the individual very explicit directions about what he should do in his life and relationships and this leads to a motivational experience which is not rapidly forgotten. Follow-up encouragement may be nec-

essary to sort out the aspirations and to act on the best goals supplied by the experience.

My knowledge of MDMA is based on two educational week-long seminars, review of scientific literature, review of subject protocols and reports. I have not yet conducted MDMA research. I have been the subject of one MDMA session in Dr. Greer's series.

As indicated in my proposal to the FDA which is attached and is incorporated by reference in this testimony, I had extensive experience in several LSD studies as assistant investigator and as investigator; in all studies I was the physician in charge of the actual clinical monitoring and support of the individual sessions. I also participated in subject selection and in preparation of scientific papers that resulted from these studies. My age is now 53 years. I have considerable experience in testimony as a forensic psychiatrist for twenty years (chiefly evaluation and treatment in work-stress injuries).

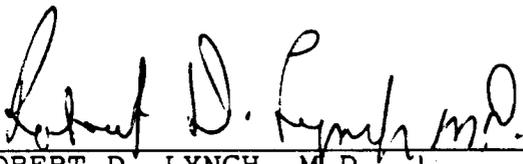
I believe that I am an objective observer of the substance MDMA. In my opinion, the small potential for abuse that this substance may have would not justify scheduling MDMA in such a way as to restrict or burden unnecessarily medical investigation of its use by persons not abuse-inclined. I believe that for enhancement of psychotherapy and for motivation, MDMA or some similar substance may be found to have a medical significance for certain persons of the order of the discover of insulin for diabet-

ics. I believe that extensive investigation of MDMA is justified at this time if toxicology is determined to be safe by animal studies. I have no economic interest in the outcome of the hearings or of the investigations with MDMA. I will abide by the decisions of the government in the classification of MDMA for my practice and in my recommendations to persons outside of my practice. I will not participate in statements to the media during the period of fact-finding and hearings as I have no desire for any personal publicity.

I believe that MDMA has medical potentialities which should not be overlooked by faulty comparison of MDMA with other classes of drugs.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on April 24, 1985.

  
ROBERT D. LYNCH, M.D.

**ROBERT DUBOIS LYNCH, M. D.**

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**March 18, 1985**

Division of Scientific Investigation HFN 340  
United States Food and Drug Administration  
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Rockville, MD 20857

I am writing to request an I and D for permission to study the benefits to their vocational rehabilitation for clients of the Department of Rehabilitation, State of California, of a voluntary MDMA (3,4-methylene-dioxymethamphetamine Assisted Motivational Experience of approximately four hours.

I am writing as the Statewide Psychiatric Consultant, Department of Rehabilitation, State of California. I am in my fourth term of service with Department of Rehabilitation and in my second term as Statewide Psychiatric consultant.

I desire to have your ruling on the Federal legality of my proposal before I recommend the study to the Department of Rehabilitation, seek volunteer physicians for training in accordance with standards you shall prescribe from among our approximately 600 physicians (civil service, hourly consultants and panel consultants) and obtain funding.

I would request that your agency supervise and take charge of as much of the protocol design, training of physicians for the study and evaluation of results as you require or desire to participate.

At this time I envision a MDMA-Assisted Motivational Experience of 4 hours with a trained staff person for randomly selected volunteer Rehabilitation clients along with an equal number of randomly selected volunteer Rehabilitation clients for controls using four one-hour Ritalin HCl-assisted sessions with a trained staff person, and a third equal number of randomly selected volunteer Rehabilitation clients for a non-drug assisted four hour motivational program with a trained staff person. A fourth group will have no motivational program.

My best medical presumption is that benefits to rehabilitation clients will reflect in statistically valid improvement in seeking and obtaining more appropriate jobs and in retaining these jobs. Such statistics are already obtained during and after successful case "closures" by the Department of Rehabilitation. I further presume that benefits from motivational

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programs will be greatest for MDMA-assisted clients, second most for Ritalin-assisted clients, third for non-drug-assisted motivated clients and least for clients provided no special motivational program. ("Hypothesis")

All clients will have been individually screened by the Medical Consultants and where required for a psychiatric disability by the Psychiatric Consultants. Clients with different disabilities will be evaluated but diagnosed schizophrenics, persons actively depressed, toxic from alcohol or drugs, and those medicated with problematical agents for drug interaction will be eliminated from all four groups in the study. No persons under 21 years of age will be included and all subjects will be required to volunteer with full knowledge of the study, of their random assignment to a group without discrimination and all 50,000 new clients will be equally eligible unless medically screened out. The size of each of the four groups will be determined by your statistical requirements for a minimum sample. Prior MDMA use will exclude one from participating in the study.

Training of volunteering physicians (including psychiatrists) will be supervised by you, by persons you designate or by a group of volunteer physicians provided by me for your certification.

I have read the literature on studies completed using MDMA with adult volunteers.

I understand that animal toxicity studies have been conducted for MDMA in the past. I have been told that studies of abuse potential for MDMA are currently being conducted on primates by an investigator for the Federal government.

My own research with LSD was conducted in the 1960's. I assisted bona fide researchers in studies of creativity enhancement by LSD, studies of treatment of alcoholics with LSD (both privately funded) and in an approximately five year study of 400 alcoholic subjects in a triple-blind LSD, Ritalin, and Valium research project jointly sponsored by National Institute of Mental Health, University of California at Los Angeles, Mesa Vista Foundation (San Diego) and Department of Corrections of San Diego County, all in the 1960's. This study was directed by Keith Ditman, M.D., as chief investigator. 14 papers resulted from the study, I believe. I have not used or possessed LSD or any other scheduled drug since the scheduling of these drugs and I have not recommended or prescribed LSD or any other scheduled drug since that NIMH study was concluded.

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My own personal experience with LSD was as a subject in Sidney Cohen, M.D.'s UCLA LSD study on three occasions, once each year, in 1958, 1959, and 1960. The accounts of these were appendices to a monograph titled, Speculation on Human States of De-Differentiation, accepted as a dissertation by the Menninger School of Psychiatry where I was graduated in 1961 and submitted for publication by the Menninger Foundation Monograph Series. I can make this study available to you.

I have not participated as subject or investigator in any investigational drug study since those studies reported above. I have taught alcohol and drug abuse courses in the Health Sciences Extension of several of the University of California campuses. I have been active in this teaching for approximately 20 of my 28 years out of medical school.

I have never violated a Federal or State law.

I have read literature provided by the National Clearinghouse and by medical and psychiatric journals on new developments in consciousness-altering drugs. I have not studied a consciousness-altering drug which I had interest in evaluating or felt confident in recommending until my knowledge of MDMA. I have not recommended this drug to anyone.

It is my best medical presumption that MDMA produces a relatively psychiatrically safe experience which makes transpersonal values very personal. The discoveries for the individual and for interpersonal relationship are clear and the motivation to change is reported to "stick to the ribs", unlike the discoveries of most drug-assisted experiences.

I understand that there are few reported psychiatric casualties. I understand that researchers have found no reason to expect MDMA to be an abuse-prone substance because the ingestion of the drug produces no significant experience for a number of weeks after a recent ingestion. I believe that the abuse potential is being investigated in primates at present.

I am aware of the physiological side effects of MDMA in its amphetamine-like physical effects. While these effects may be blocked by Inderol or other medication, I view with caution the effects of the drug on persons with cardiovascular disease or amphetamine-sensitivity-proneness.

Since this substance is reported to be in wide use in the United States, it must have some effect or benefit which recommends its use. It is not primarily a pleasure drug but has primarily learning, motivational and psychotherapy benefits as reported by its investigators. Self-motivation is provided by the subject's higher mind in a state of complete

control, clarity and rationality. Motivational plans are rapidly tested and integrated by the subject who comes out of the experience with transference to the therapist resolved and fears and apprehensions reduced and anxiety controlled to a degree that activity for rehability may begin. When subjects require a follow-up experience for clarification or resolution of unfinished self-motivation such additional experiences should be provided. In the study a rule would be made to either include or exclude subjects with extra MDMA assistance from the study. (No subjects would have prior MDMA use)

If you feel that my experience for administering such a study is not extensive enough, please state this but know that I am willing to yield my planned study to a physician of your designation to administer this study provided that he be positive in his interest in the study.

I have attended two week-long educational conferences on the use of MDMA in psychotherapy and it is my understanding that your agency possesses all available studies and reports of current professional investigation of MDMA. I shall make available a list of the studies which I have available and copies of any that you may need to determine the position which you will take on this proposed study.

I will welcome your complete participation in all phases of this investigation and I am available for questioning and you have my permission to investigate my personal and professional background in any manner necessary to comply with the duties of your Office.

I look forward to your preliminary decision on this matter.

Cordially



Robert D. Lynch, M.D.

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