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 clinical 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 I have recently reviewed the unpublished document entitled, "MDMA: A New Psychotropic Compound and Its Effects in Humans," by George Greer, M.D. Based upon my knowledge in the field of research in the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 facilitator took MDMA on some occasions or not. We might expect that it certainly would make a difference whether or not the facilitator in the project was also using the substance at the same time as the "patient."

In summary, the methodological 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 2/4/81

Signature [Signature]
CURRICULUM VITAE

Name: John P. Docherty, M.D.

Address: 7401 Westlake Terrace, #1404
Bethesda, Maryland 20817

Telephone: 301/469-8529 (Home)
301/443-4527 (Work)

Date and Place of Birth: September 8, 1944
Brooklyn, New York, U.S.A.

Education:

Regis High School
New York, New York 9/58 - 6/62

Boston College
A.B. - Magna Cum Laude
Chestnut Hill, Massachusetts 9/62 - 6/66

University of Pennsylvania
School of Medicine - M.D.
Philadelphia, Pennsylvania 9/66 - 5/70

Internship

Hospital of the University of Pennsylvania
Philadelphia, Pennsylvania 6/70 - 6/71

Psychiatry Residency

Yale University
New Haven, Connecticut 7/71 - 7/74

Clinical Research Fellowship

National Institute of Mental Health, Intramural Research Program
Bethesda, Maryland 7/74 - 7/76

Licensure:
Connecticut
New York
Maryland

Specialty Board Certification:
Diplomate American Board of Psychiatry and Neurology - 1977

Positions:

1983 Chief, Psychosocial Treatments Research Branch, Division of Extramural Research Programs, National Institute of Mental Health, Rockville, Maryland

1982-83 Acting Chief, Psychosocial Treatments Research Branch, Division of Extramural Research Programs, NIMH, Rockville, Maryland
John P. Docherty, M.D.  

CURRICULUM VITAE

1981  Chief, Special Studies Section, Psychosocial Treatments Research Branch, Division of Extramural Research Programs, NIMH, Rockville, Maryland

1979-81  Chief, Adolescent Unit, Yale Psychiatric Institute, New Haven, Connecticut

1978-79  Chief, Schizophrenia Unit, Yale Psychiatric Institute, New Haven, Connecticut

1978-81  Director of Education, Yale Psychiatric Institute, New Haven, Connecticut

1976-78  Director, Continuing Care Division and Director of Psychiatric Research, Psychiatry Service, West Haven Veterans Hospital, West Haven, Connecticut

1974-76  Clinical Associate and Unit Administrator, Section on Neuropsychopharmacology, Adult Psychiatry Branch, National Institute of Mental Health, Bethesda, Maryland

1973-74  Chief Resident, Psychiatric Outpatient Clinic, Veterans Hospital West Haven, Connecticut

1971-74  Fellow, Clinical Research and Teaching Track, Yale Department of Psychiatry, New Haven, Connecticut

Adjunct Positions:

1985  Editorial Board, Journal of Personality Disorders

1983-  Clinical Research Consultant, Sheppard-Pratt Hospital, Baltimore, Maryland

1982  Co-Director, Medical Studies Program, Washington School of Psychiatry, Washington, D.C.

1981-  Private Practice, 5413 West Cedar Lane, Bethesda, Maryland 20814

1979  Consultant, Veterans Administration Cooperative Study Project Development Committee: Intermittent vs. Continuous Phenothiazine Maintenance Treatment in Schizophrenia

1979  Clinical Assistant Professor in the School for Social Work, Smith College, Northampton, Massachusetts

1979  Consultant, Veterans Administration Cooperative Study Project Development Committee: Therapeutic Efficacy of Hemodialysis for Schizophrenics

1979  Consultant, Walter Reed Army Institute of Research, Division of Neuropsychiatry
1978  Consultant and Site Visitor, Psychiatry Education Branch, National Institute of Mental Health
1978  Ad hoc Site Visitor, Clinical Projects Research Review Committee, Division of Extramural Research Programs, National Institute of Mental Health, Rockville, Maryland
1978  Keynote Speaker, Annual AMEDD, Behavioral Sciences Division Seminar (September 26-28)
1978-79 Consultant, United States Army, AMEDD, Behavioral Sciences Division
1978  Consulting Psychiatrist, Regis Multi-Health Center, New Haven, Connecticut
1978  Consulting Psychiatrist (Research), West Haven Veterans Hospital, West Haven, Connecticut
1976  Consulting Psychiatrist, Depression Research Unit, Yale University, New Haven, Connecticut
1975-76 Faculty, Senior Instructor, Graduate Program of the National Institutes of Health
1975-76 Faculty, Washington School of Psychiatry
1969-70 Instructor in Psychology, Manor Junior College, Jenkintown, Pennsylvania
1969  Summer Research Fellow, Department of Psychiatry, University of Pennsylvania, Philadelphia, Pennsylvania
1968  Summer Research Fellow, Department of Psychiatry, University of Pennsylvania
1967  Co-Step Officer, OSPHS, Clearinghouse for Mental Health Information, Chevy Chase, Maryland
1965-66 Research Assistant, Bereavement Project, Harvard Laboratory of Community Psychiatry

Honors and Awards:

A. College:

Graduate Magna Cum Laude

Elected to Alpha Sigma Nu, National Honor Fraternity

Elected Marshall in the Order of the Cross and Crown, College Honor Fraternity
Hamilton Watch Award for Interdisciplinary Study, 1966 ("For the student who has demonstrated excellence in and done most to integrate the natural and social sciences")

B. Medical School:

Kenneth E. Appel Award for Psychiatry, 1970 ("To that student who, through his work in the Department of Psychiatry, has shown highest devotion to the care and treatment of his patients, and constructive originality in his thinking about human behavior")

C. Residency:

Seymour Lustman Award for Psychiatric Research, 1974

D. Post-Residency

1. Thesis supervisor for medical student theses:

("Natural History and Clinical Course in Male Schizophrenics: New Perspectives on Chronicity") receiving the 1977 Yale School of Medicine Louis Welt Award and the Yale Department of Psychiatry Lidz Award

("The Process of Recovery from Schizophrenic Psychosis") which received the 1978 Yale Department of Psychiatry Lidz Award

("Clinical Staging in a Relapsing Disorder: Study of Fifty Schizophrenics") receiving the 1980 Yale Department of Psychiatry Sandoz Award

("Platelet Monoamine Oxidase Activity, Sensation Seeking, Judgment, and Color Preference in Normals") which received the 1970 Yale Medical School Nicholas J. Giarman Award

2. Thesis supervisor for psychiatric resident thesis:

("Dopamine Receptor Supersensitivity in Schizophrenia") which received the Yale Department of Psychiatry Lustman Award, 1978

3. Outstanding Teacher Award - Yale Psychiatry Residents, 1981

4. Visiting Professor, University of Hawaii School of Medicine, 1984

5. Fellow, American College of Psychiatrists, 1985

6. President-Elect, Association for Clinical Psychosocial Research, 1984-1985

Publications:

A. Undergraduate:

1. Docherty JP: Psychological implications of the general adaptation syndrome: Cosmos, Fall 1965. (Undergraduate Science Journal)
B. Residency:


C. Post-Residency:


28. Siris SG, Docherty JP, Roose SP: An experience with patient role-
playing in psychiatric education. Journal of Medical Education

Yale Psychiatric Quarterly 3(3), Fall 1980.

in the last two decades. American Journal of Psychiatry, 138(5):623-628,
1981.

31. Langer DH, Brown GL, Docherty JP: Dopamine receptor supersensitivity
and schizophrenia: a review. Schizophrenia Bulletin 7(2):208-224,
1981.

32. Prusoff BA, Weissman MM, Charney J, Docherty JP, Kleber H, Rounsaville BJ,
Sholomskas AJ, Sholomkas D: Speed of symptom reduction in depressed
outpatients treated with amoxapine and amitriptyline. Current Thera-

33. van Kammen DP, Docherty JP, Marder SR, Bunney WE: Acute amphetamine
response predicts antidepressant and antipsychotic response to lithium
carbonate in schizophrenic patients. Psychiatry Research 4:318-325,
1981.

34. van Kammen DP, Docherty JP, Bunney WE: Prediction of early relapse
after pimozide discontinuation by response to d-amphetamine during

35. Bialos D, Giller E, Jatlow P, Docherty JP, Harkness L: Recurrence of
depression after discontinuance of long-term amitriptyline treatment.

36. van Kammen DP, Docherty JP, Marder SR, Shulz SC, Dalton L, Bunney WE Jr:
Antipsychotic effects of pimozide in schizophrenia: treatment response
prediction with acute dextroamphetamine response. Archives of General

37. van Kammen DP, Docherty JP, Marder SR, Bayner JN, Bunney WE Jr: Long-
term pimozide pretreatment differentially affects behavioral responses
to dextroamphetamine in schizophrenia: further exploration of the
dopamine hypothesis of schizophrenia. Archives of General Psychiatry

in schizophrenia: a preliminary double-blind trial. American Journal

39. van Kammen DP, Bunney WE, Docherty JP, Marder SR, Ebert MH, Rosenblatt
JE, Rayner JN: d-Amphetamine induces heterogeneous changes in
psychotic behavior in schizophrenia. American Journal of Psychiatry


47. van Kammen DP, Docherty JP, Marder SR: Lithium attenuates the activation but not the induction of psychosis with amphetamine in schizophrenia. Psychopharmacology, in press.


Letters:


Audio-Visual Publications:


Book Reviews:


Publications (Submitted):


van Kammen DP, Docherty JP, Marder SR, Rosenblatt JE, Bunney WE: Lithium attenuates the activation but not the induction of psychosis with amphetamine in schizophrenia. Submitted to American Journal of Psychiatry.

Docherty JP, Fiester SJ: Clinical predictors of differential response to antipsychotic drug treatment in schizophrenia. Submitted to International Drug Therapy Newsletter.


Abstracts:


Publications:


