Lysergic Acid Diethylamide (LSD), Clinical Use and Research: A Proposal for Legislative Change

I. INTRODUCTION

Recent federal laws have discouraged medical research with LSD. The asserted rationale for the laws are that LSD has a high potential for abuse, that it has no accepted medical use and that it cannot be used safely even under medical supervision. Since the first justification is descriptive of most drugs, including those available without a prescription, the rationality of the laws hinges on the latter two justifications. This article spotlights the weakness of these justifications by describing the beneficial research and clinical use of LSD with terminally ill, mentally ill, alcoholic and schizophrenic patients prior to the restrictive laws of the mid-1960's. This article also describes the burdensome administrative procedure presently controlling the experimental use of LSD and demonstrates that the inhibiting effect of the laws are disproportionate to the dangers anticipated. The author proposes specific changes in these laws to allow wider research and clinical use. It is the thesis of this article that the possibility of LSD aiding gravely ill people would more than compensate for difficulties resulting from relaxation of existing laws.

II. THE DRUG, HOW IT WORKS, WHAT IT DOES

LSD is a man-made substance first synthesized in 1938 by two scientists in Basle, Switzerland, as an intermediate step in the production of the ergot compound ergonovine.[1] In 1943, while looking for an effective psycho-stimulant, Dr. Albert Hoffman accidentally ingested a small amount of LSD and experienced hallucinations. Realizing that the LSD may have caused the deep psychological effects, he purposely ingested a larger amount of the drug, which produced a more profound result.[2] Other investigations followed, including one

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[1]Levine, *LSD — A Clinical Overview*, in DRUGS AND THE BRAIN 301 (P. Black ed. 1969).

[2]Hofmann, *Psychotomimetics: Chemical, Pharmacological and Clinical Aspects*,

by Dr. W. Stoll, who first administered the drug to mentally ill patients.[3] By 1951 six reports on the use of LSD had been published, and by 1957 the number swelled to over 275.[4]

LSD is categorized as an hallucinogenic drug along with psilocybin, mescaline, dimethyltryptamine (DMT) and psilocin. These drugs are further divided as psychotomimetic or psychedelic,[5] depending primarily on their time-course of action. LSD and mescaline have a time-course of approximately eight hours, while psilosybin and DMT have two to three hour course of action. The drugs also differ in some side effects; mescaline, for example, usually causes more autonomic changes and nausea than does LSD. However, the psychological changes produced by all the compounds are similar.[6]

Researchers have yet to determine how LSD works. Scientists have determined the course of the drug after ingestion but not its interaction with the different parts of the body.[7] For the purposes of this article, however, the biochemistry of the drug is not important. The focus of this article is on the psychological effects of LSD and how these effects change human beings.

III. RESEARCH AND CLINICAL USE OF LSD IN THE 1950's AND EARLY 1960's

The Drug Abuse Control Amendments of 1965 signalled the beginning of federal control of LSD. Hallucinogenic drugs were brought within the scope of these laws in 1966 by the Secretary of Health, Education, and Welfare, acting pursuant to powers conferred on him by the 1965 amendments.[8] Prior to this law many researchers investigated a variety of beneficial medical uses of LSD, some of which are described below.

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14 INDIAN PRAC. 195 (1961). For a more detailed account of Dr. Hofmann's experience, *see* Smith, *Lysergic Acid Diethylamide: An Historical Perspective*, 1 J. PSYCHEDELIC DRUGS 1 (1967).

[3]Smart *et al.*, Lysergic Acid Diethylamide (LSD) in THE TREATMENT OF ALCOHOLISM 3, 6 (1967).

[4]Hoffer, *D-Lysergic acid diethylamide (LSD): A Review of its Present Status*, 6 CLIN. PHARMACOL. THER. 183 (1965).

[5]Szara, *The Hallucinogenic Drugs — Cure or Blessing*, in DRUG ABUSE: MEDICAL AND CRIMINAL ASPECTS 215 (MSS Information Corp. ed. 1972).

[6]*Supra*, note 1.

[7]Ford, *LSD and the Law: A Framework for Policy Making*, 54 MINN. L. REV. 775 (1970). For a detailed analysis of what scientists have ascertained about LSD in this area *see* Hoffer, *D-Lyservic acid diethylamide (LSD): A Review of its Present Status*, 6 CLIN. PHARMACOL. THER. 183 (1965); Pahnke *et al.*, *The Experimental Use of Psychedelic (LSD) Psychotherapy*, in HALLUCINOGENIC DRUG RESEARCH: IMPACT ON SCIENCE AND SOCIETY 48 (J. Gamage and E. Zerkin eds. 1970); and HOFFER AND OSMOND, THE CHEMICAL BASIS OF CLINICAL PSYCHIATRY (1960).

[8]31 FED. REG. 4679 (1966).

A. TERMINAL ILLNESS

There have been numerous successful projects using LSD with terminally ill patients. Dr. Eric Kast researched the use of LSD with terminally ill patients for a number of years. One of his projects involved eighty patients suffering from terminal malignant disease with an estimated life expectancy of only weeks or months. Only patients who had been informed of their diagnosis were included in the study. Dr. Kast summarized his result as follows:

> The results of this study seem to indicate that LSD is capable not only of improving the lot of pre-terminal patients by making them more responsive to their environment and family, but it also enhances their ability to appreciate the subtle and aesthetic nuances of experience. This increased delicate sensitivity is as marked as that usually encountered in normal volunteers subjected to LSD. Here, however, this imagery not only gives aesthetic satisfaction, but creates a new will to live and a zest for experience which, against a background of dismal darkness and pre-occupying fear, produces an exciting and promising outlook. Patients who had been listless and depressed were touched to tears by the discovery of a depth of feeling they had not thought themselves capable. Although short-lived and transient this state of affairs was a welcome change in their monotonous and isolated lives, and recollection of this experience days later often created similar elation. Of course, these subleties cannot be appraised in numerated terms. In human terms, however, the short but profound impact of LSD on the dying patient was impressive.[9]

Dr. Walter Pahnke reported the results of a study involving twenty-two terminal cancer patients who suffered a depressive reaction to their physical condition. After LSD treatment, fourteen of the twenty-two patients showed improvement, including a decrease in depression, anxiety and fear of death, and improvement in ability to relax, acceptance of medical management, and interpersonal family relationships. Eight patients remained essentially unchanged. Dr. Pahnke concluded that "skilled use of the psychedelic procedure can be a relatively safe and promising approach in an area which has been most discouraging up to the present."[10]

A third study involved seven terminally ill patients. The report described one patient who had been heavily addicted to drugs because of pain. For the last six months of the patient's life he was essentially free from the need for narcotics, apparently as a result of three LSD sessions at two month intervals. The patient reported that

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[9]Kast, *LSD and the Dying Patient*, 26 CHICAGO MEDICAL SCHOOL Q. 80, 87 (Summer, 1967).
[10]Pahnke *et al.*, *LSD-Assisted Psychotherapy with Terminal Cancer Patients*, in PSYCHEDELIC DRUGS 33, 42 (R. Hicks and P. Fink eds. 1969).

the pain had not diminished, but that he had learned to live with it.[11]

In a recent publication, the Bureau of Narcotics and Dangerous Drugs affirmed the potential value of LSD to the terminally ill:

> One of the most promising uses of LSD consists in making more bearable the agony suffered by patients dying of cancer or other diseases — pain that cannot always be relieved by analgesic drugs.[12]

It would be unfortunate to curtail research and clinical use of LSD in this area when such beneficial medical uses have been shown.

B. ALCOHOLISM

Research groups in Canada and the United States have used LSD as a method to cure alcoholics. This "psychedelic therapy" allows the alcoholic to recognize the underlying problems which cause him to drink, thus facilitating the solution of the problems by conventional methods.

Dr. Ross MacLean observed the therapeutic effects of LSD in one-hundred patients — sixty-one alcoholics and thirty-nine non-alcoholics with other psychiatric disabilities. The study used professional therapists and a single LSD experience. After treatment thirty of the alcoholics and twenty-two of the other psychiatric patients were much improved:

> The results were best in the alcoholics without complications, in alcoholism with personality trait disturbance or anxiety reaction neurosis . . . The conclusion is reached that LSD-25, used with the described treatment method, is effective in the treatment of alcoholism and the psychiatric disabilities categorized as anxiety reaction, neurosis and personality trait disturbances.[13]

Seven years later, Dr. Maclean published a cumulative report on seven years of research and clinical use of LSD. The over-all study involved 338 patients who were treated between 1958 and 1964. After a 38 month mean follow-up period, 31% of the 217 alcoholics were "much improved," 22% were "improved" and 47% exhibited no change. Of the 121 non-alcoholics, which included psychopaths, narcotic addicts and psychotics, 46% were "much improved," 37% "improved" and 17% showed no change. Dr. Maclean concluded that

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[11] Savage *et al.*, *Therapeutic Applications of LSD*, in DRUGS AND THE BRAIN 309 (P. Black ed. 1969).

[12] L. RICHARDS *et al.*, LSD-25: A FACTUAL ACCOUNT. LAYMAN'S GUIDE TO THE PHARMACOLOGY, PHYSIOLOGY, PSYCHOLOGY AND SOCIOLOGY OF LSD 19 (1969). For other accounts of the use of LSD by a terminally ill person under medical supervision *see* Cohen, *LSD and the Anguish of Dying*, 231 HARPER'S 69 (1965); and Avorn, *Beyond Dying*, 246 HARPER'S 56 (1973). Both articles include a statement from the patients themselves.

[13] MacLean *et al.*, *The Use of LSD-25 in the Treatment of Alcoholism and Other Psychiatric Problems*, 22 Q.J. STUD. ALCOHOL 34, 44 (1961).

psychedelic therapy "has both intrinsic merit and potential, in the treatment of many psychiatric and psycho-social disorders."[14]

Other researchers have documented equally favorable results. [15] Dr. Pahnke treated 135 alcoholic patients with psychedelic psychotherapy, half of whom received only one treatment. Of the latter group, 44% were rehabilitated after a high dosage of LSD and 25% were rehabilitated after a relatively low dosage. Dr. Pahnke commented that "the group of patients with the most profound psychedelic-peak experiences had the highest percentage of patients who showed evidence of rehabilitation."[16]

In a study at the Spring Grove State Hospital in Baltimore, Maryland, 69 male in-patients received three weeks of intensive psychotherapy with one highly structured LSD session. The extent of the benefit was considerable in some cases, and, according to both clinical evaluations and psychological test data, no patient was harmed.[17]

While some reports have concluded LSD is not beneficial,[18] or not more beneficial than regular therapy,[19] the fact that many alcoholics

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[14]MacLean *et al.*, *LSD 25 and Mescaline as Therapeutic Adjuvants*, in THE USE OF LSD IN PSYCHOTHERAPY AND ALCOHOLISM 407, 418 (H. Abramson ed. 1967).

[15]Savage *et al.*, *Therapeutic Applications of LSD*, in DRUGS AND THE BRAIN 309 (P. Black ed. 1969) which discusses in depth the mechanics of LSD when administered to an alcoholic. Soskin, *Personality and Attitude Change After Two Alcoholism Programs*, 31 Q.J. STUD. ALCOHOL 920 (1970) was a study involving a comparison of two different therapies on very similar patients, one utilizing LSD and the other a Human Relations Training Laboratory. *See also* Fox, *Is LSD of Value in Treating Alcoholics?*, in THE USE OF LSD IN PSYCHOTHERAPY AND ALCOHOLISM 477 (H. Abramson ed. 1967); Van Dusen *et al.*, *Treatment of Alcoholism with Lygerside*, 28 Q.J. STUD. ALCOHOL 295 (1967); and Godfrey, *Psychedelic Drugs as Therapeutic Agents*, in PSYCHEDELIC DRUGS 226 (R. Hicks and P. Fink eds. 1969).

[16]Pahnke *et al.*, *The Expermental Use of Psychedelic (LSD) Psychotherapy*, in HALLUCINOGENIC DRUG RESEARCH: IMPACT ON SCIENCE AND SOCIETY 48 58, (J. Gamage and E. Zerkin eds. 1970).

[17]Kurland *et al.*, *Psychedelic Therapy Utilizing LSD in the Alcoholic Patient: A Preliminary Report*, 123 AM. J. PSYCHIATRY 1202 (1967).

[18]Smart *et al.*, Lysergic Acid Diethylamide (LSD) in THE TREATMENT OF ALCOHOLISM (1967).

[19]Johnson, *LSD in the Treatment of Alcoholism*, 126 AM. J. PSYCHIATRY 481 (1969). This experiment involved 95 alcoholic patients in 4 treatment groups, two without LSD. All groups showed significant improvement in the areas of drinking and employment, but there was no significant different between the groups on any improvement criterion measure. *See also* Ludwig, *LSD Treatment in Alcoholism*, in HALLUCINOGENIC DRUG RESEARCH: IMPACT ON SCIENCE AND SOCIETY 40 (J. Gamage and E. Zerkin eds. 1970) which involved 176 patients who were committed to Mendota State Hospital in Madison, Wisconsin. The patients who were treated with LSD improved the same amount as patients who were undergoing other treatments. Other studies include Bowen *et al.*, *Lysergic Acid Diethylamide as a Variable in the Hospital Treatment of Alcoholism*, 150 J. NERV. MENT. DIS. 111 (1970); and Denson and Sydiaha, *A Controlled Study of LSD Treatment in Alcoholism and Neurosis*, in 116 BR. J. PSYCHIATRY 443 (1970) (a study conducted in Great Britain).

have been rehabilitated through the use of LSD is support for wider use of LSD therapy in this field. This conclusion is buttressed by the belief of many researchers that even if improvement cannot be demonstrated harm will not be incurred if the LSD is administered under proper medical supervision.

C. AUTISTIC AND SCHIZOPHRENIC CHILDREN

LSD has been used with more limited success in the treatment of autistic and schizophrenic children. One of the first reported research projects, in 1959, involved 12 autistic children between the ages of 5 and 12. Although some beneficial effects were observed, the children did not begin speaking.[20]

The failure did not discourage Dr. Lauretta Bender from conducting a similar study several years later. She studied approximately 50 children from 6 to 12 years old, with autistic or psychotic schizophrenia. All the autistic children, regressed and non-verbal prior to the use of LSD, showed some type of response, although it varied in degree and characteristics:

> There were definite changes in response to the environment, which was most remarkable in these autistic children. They became gay, happy, laughing frequently, especially early in the treatment program. Nearly all of them were more alert, aware and interested in watching other persons. Some showed changes in facial expression for the first time; many were able to understand and follow directions more readily. This increase in awareness was noted by all observers, including families, and was one of the most encouraging signs in these very withdrawn, regressed children.[21]

Dr. Bender also observed changes in communication patterns:

> . . . [T]he vocabularies of several of the children increased after LSD or UML; several seemed to be attempting to form words or watched adults carefully as they spoke, many seemed to comprehend speech for the first time or were able to communicate their needs. . . . Very few of these changes in communication had been noted previously in such a large number of children, and at such a relatively rapid rate.[22]

Dr. R. Mogar and Dr. R. Aldrich support Dr. Bender's findings in a review of the literature on the use of psychedelic drugs with schizophrenic. children. The most consistent effects of psychedelic therapy included improved speech behavior in otherwise mute children, an elevation in positive mood including frequent langhter, an increase in emotional responsiveness to other persons and a decrease in compulsive ritualis-

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[20] Freedman *et al.*, *Autistic Schizophrenic Children*, 6 ARCH. GEN. PSYCHIATRY 203 (1962).
[21] Bender *et al.*, *LSD and UML Treatment of Hospitalized Disturbed Children*, 5 RECENT ADVANCES IN BIOLOGICAL PSYCHIATRY 84, 87 (J. Wortis ed. 1963).
[22] *Id.* p. 88

tic behavior. The reviewers concluded that the collective findings argue quite strongly for more extensive applications of hallucinogenic drugs in the treatment of autistic and schizophrenic children.[23]

D. MENTAL ILLNESS

LSD has been used in the treatment of a variety of mental illnesses, including neuroses, schizophrenia and other psychoses and personality disorders. LSD aids psychotherapy by exposing formerly unconscious material to the patient's full view, enabling the patient to understand the underlying nature and implications of the problem.[24] Psychotherapy relies on "psycholytic" treatment, administering LSD once or twice a week for several weeks or months, while alcoholic therapy relies on "psychedelic" treatment, which involves only one intensive LSD session.[25]

Dr. Arthur Chandler attempted to evaluate the use of LSD-25 as an aid in psychotherapy and to develop procedures for its most effective use. He studied 110 patients whose diagnoses included psychoneurosis, personality disorders (including paranoia and schizoid patients) and sociopathic disorders (including sexual deviants and drug addicts). The patients were not amenable to traditional analysis or other type of comprehensive psychotherapy. After a combined total of 690 sessions with LSD, 66.4% of the patients showed improvement. In addition. 69% improved their rate of therapeutic progress subsequent to the treatment.[26]

According to a study which involved over 350 out-patients over a seven year period such favorable results are not unusual. The LSD treatment apparently forces the patient to experience a feeling of disintegration with a favorable result:

> To relive such a feeling in an atmosphere of support and understanding may have lasting benefit for the patient; he may be able for the first time to be convinced of some inner strength, some willingness and capacity to live on, and to face and to resolve lesser conflicts without escaping into symptom formation.[27]

Mr. Leo Hollister, an outspoken critic of the medical use of LSD, did find LSD useful in the treatment of psychopathic patients. His research indicated LSD mobilized anxiety in such patients, a useful

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[23] Fisher, *The Psycholytic Treatment of a Childhood Schizophrenic Girl*, 16 INT. J. SOC. PSYCHIATRY 112 (1970). *See also* Simmons *et al.*, *Modification of Autistic Behavior with LSD-25*, 122 AM. J. PSYCHIATRY 1201 (1966).

[24] Savage *et al.*, *Therapeutic Applications of LSD*, in DRUGS AND THE BRAIN 309 (P. Black ed. 1969).

[25] RICHARDS, *supra* note 12.

[26] Chandler and Hartmann, *Lysergic Acid Diethylamide (LSD-25) as a Facilitating Agent in Psychotherapy*, 2 ARCH. GEN. PSYCHIATRY 286 (1960).

[27] Buckman, *Theoretical Aspects of LSD Therapy*, in THE USE OF LSD IN PSYCHOTHERAPY AND ALCOHOLISM 83, 86 (H. Abramson ed. 1967).

therapeutic measure.[28] This encouraging result is supported by a Dutch researcher, who successfully treated 21 severe criminal psychopaths with LSD.[29] Other studies involving the successful treatment of neurotics[30] and doubtful schizophrenics[31] have been conducted.

IV. THE PRESENT LAWS

A. 1965 ACT

The Drug Abuse Control Amendments Act of 1965[32] was the first major statute providing for federal control of hallucinogenic drugs. Prior federal law had attempted only to keep hallucinogenic drugs within prescription and research channels.[33] The pre-1965 regulatory scheme allowed for the wide ranging research efforts described above. However, passage of the 1965 Act signalled an end to most of the creative research with LSD.

The 1965 Act was designed to control the abuse of barbituates and amphetamines, both legitimate prescription drugs, by preventing the diversion of supplies into illicit channels.[34] Originally this Act did not specifically include hallucinogens. However, widespread unfavorable publicity[35] persuaded the Secretary of Health, Education and Welfare (actually the Food and Drug Administration), using the discretionary powers granted by Congress,[36] to include hallucinogenic drugs in the classification of "depressant or stimulant drugs."[37] When the Commissioner of the Food and Drug Administration announced his intent to include in this category drugs with an

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[28] L. HOLLISTER, CHEMICAL PSYCHOSIS: LSD AND RELATED DRUGS 135 (1968).
[29] Arendsen-Hein, *LSD in the Treatment of Criminal Psychopaths*, in HALLUCINOGENIC DRUGS AND THEIR PSYCHOTHERAPEUTIC USE 101 (R. Crockett *et al.* eds. 1963).
[30] Ling, *The Use of LSD and Ritalin in the Treatment of Neurosis*, in THE USE OF LSD IN PSYCHOTHERAPY AND ALCOHOLISM 129 (H. Abramson ed. 1967).
[31] Sedman and Kenna, *The Use of LSD-25 as a Dignoastic Aid in Doubtful Cases of Schizophrenia*, 111 BR. J. PSYCHIATRY 96 (1965).
[32] Act of July 15, 1965, Pub. L. No. 89-74, 79 STAT. 226.
[33] Notes, *Hallucinogens*, 68 COLUM. L. REV. 521, 544 (1968).
[34] The 1965 Amendments apply to "depressant or stimulant drugs." Public Law 89-74, 79 STAT. 226, 89th Cong., 1st Sess. (July 15, 1965). This term is designed specifically to include barbituates (Food, Drug and Cosmetic Act, § (v)(1), 79 STAT. 227) and amphetamines (Food, Drug and Cosmetic Act, § 2(v)(2), 79 STAT. 227).
[35] The following list gives only a few examples of articles published regarding LSD: 87 TIME 52 (April 22, 1966); 61 PTA MAGAZINE 31 (Sept. 1966); 67 NEWSWEEK 100 (April 18, 1966); 87 TIME 44 (March 11, 1966); 83 LADIES HOME JOURNAL 52 (August, 1966); 61 U.S. NEWS 82 (July 18, 1966); 61 LIFE 24 (Nov. 11, 1966); 60 LIFE 28 (March 25, 1966); and 89 READER'S DIGEST 56 (Sept. 1966).
[36] Act of July 15, 1965, Pub. L. No. 89-74, § 3, 76 STAT. 226.
[37] *Id.*

hallucinogenic effect, including LSD,[38] many scientists who had been using LSD in research spoke out against the legislation.[39] However, after considering the comments and suggestions filed in response to the proposal, the Commissioner concluded that the drugs should be included.[40]

Strict controls were placed on the use of hallucinogenic drugs, LSD in particular, in addition to the standard requirements governing actual research with all other "depressant and stimulant drugs."[41] After the 1965 Act, The National Institute of Mental Health, which controlled the entire legitimate supply of LSD,[42] did not distribute LSD for use in psychotherapy[43] and encouraged research only designed to uncover the dangers of the drug.[44] The National Institute of Mental Health's normal policy was to send research drugs to the researcher upon request, and the researcher simply reported the transaction to the Food and Drug Administration.[45]

There were other problems peculiar to research with LSD. The National Institute of Mental Health provided a great deal of the financial support for mental health research. The Institute became extremely slow to approve LSD research projects on animal subjects.[46] It was unusual for research projects involving humans to be approved at all.[47] Also, since LSD was not approved by the FDA for general research, the prospective researcher had to file an Investigational

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[38] 31 FED. REG. 565 (1966).

[39] Osmond, *Alcoholism: A Personal View of Psychedelic Treatment*, in PSYCHEDELIC DRUGS 225 (R. Hicks and P. Fink eds. 1969) stated:

> Have we any right to keep such treatments from very ill people on the basis of legislation? Medicine is frequently in conflict with the law. I don't mean it is necessarily engaged in actively illegal behavior. I mean that our position is quite different from that of lawyers, jurists and politicians. It is our duty to tell medical and scientific colleagues, the sick, their relatives and the public at large what the score seems to be. These are potentially useful substances; they are not panaceas, but one day I believe they will be widely and usefully employed in a variety of ways for the benefit of many of our patients.

See also Szara, *The Hallucinogenic Drugs — Curse or Blessing*, in DRUG ABUSE: MEDICAL AND CRIMINAL ASPECTS 215, 219 (MSS Information Corp. ed. 1972); and Fort, *Social Aspects of Research with Psychoactive Drugs*, in HALLUCINOGENIC DRUG RESEARCH: IMPACT ON SCIENCE AND SOCIETY 115 (J. Gamage and E. Zerkin, eds 1970).

[40] 31 FED. REG. 4679 (1966).

[41] 21 U.S.C. § § 321, 511 (1970).

[42] 24 CONG. Q. 1149 (1966).

[43] Laughlin, *LSD-25 and the Other Hallucinogens: A Pre-Reform Proposal*, 36 GEO. WASH. L. REV. 23, 55 n. 150 (1967).

[44] *Id.* at 26 n. 20.

[45] *Id.* at 55 n. 149.

[46] Chayet, *Legal Aspects of Drug Abuse*, in PSYCHEDELIC DRUGS 119, 123 (R. Hicks and P. Fink eds. 1969).

[47] R. MASTERS AND J. HOUSTON, THE VARIETIES OF THE PSYCHEDELIC EXPERIENCE 66 (1966).

New Drug Application with the Food and Drug Administration, which was a rigorous procedure.[48]

Consequently, as will be demonstrated later in this article, very little research occurred from 1966 to 1970. What research did take place was designed primarily to demonstrate the dangers of LSD. The only major change in the federal laws during this period was the transfer of jurisdiction over dangerous drugs from the Food and Drug Administration to the Justice Department.[49] These amendments were the final piece of legislation which preceded the Comprehensive Drug Abuse Prevention and Control Act of 1970.

B. 1970 ACT

The Comprehensive Drug Abuse Prevention and Control Act of 1970 (containing the Controlled Substances Act)[50] repealed almost all prior federal drug legislation, and continued restrictions on LSD research through a new comprehensive scheme for federal drug control. Under this Act, narcotics and dangerous drugs are divided into five categories of controlled substances.[51] To be included in the first category, or Schedule I, a substance must have a high potential for abuse, must have no currently accepted medical use, and cannot be used safely even under medical supervision.[52] LSD, as well as DMT, mescaline, marijuana and psilocybin, were found to qualify for Schedule I, and are thus subject to the most rigid controls.[53] Due to this categorization, obtaining LSD for research or clinical use is a lengthy process with much potential for abuse.

To request an initial supply of a Schedule I controlled substance for preclinical research, an investigator must apply for registration with the Drug Enforcement Administration (DEA), formerly known as the Bureau of Narcotics and Dangerous Drugs.[54] The application must be accompanied by three copies of a research protocol detailing the investigator's qualifications, the purpose of the project and the approval of a Human Research Committee for Human Studies.[55] For clinical research in humans a special certification in lieu of the protocol is required, and in addition an Investigational New Drug Application must be submitted to the FDA.[56]

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[48] *Id.*
[49] Reorganization Plan No. 1 of 1968, 28 U.S.C. § 509 (1970).
[50] Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 812 *et. seq.* (1970).
[51] 21 U.S.C. § 812 (1970).
[52] 21 U.S.C. § 812 (c)(c)(1970).
[53] *Id.*
[54] National Institute on Drug Abuse, PROCUREMENT OF SCHEDULE I CONTROLLED SUNSTANCES 1 (August 27, 1973).
[55] 37 FED. REG. 28712 (1972).
[56] National Institute on Drug Abuse, PROCUREMENT OF SCHEDULE I CON-

Preclinical or clinical research without human subjects must be approved only by the DEA. If the DEA determines the protocol is not meritorious or the applicant is not qualified, the applicant may request a hearing,[57] or may file a statement of his position on the matters of fact and law in lieu of a hearing.[58] The DEA carries the burden of proof at a hearing.[59] This hearing must be held within 70 days of the receipt of the application.[60]

The application and approval process necessary to conduct clinical research in humans is much more rigorous. The Commissioner of the Food and Drug Administration may refuse to approve the application if he determines that the described research may be unsafe or will not have the results anticipated by the researcher.[61] Before issuing such an order he must offer the applicant an opportunity for a hearing within 180 days from receipt of the application.[62] If the applicant desires a hearing he must file a written appearance stating reasons why the application should not be refused, supported by factual data.[63] If the Commissioner finds there is a substantial issue of fact a hearing will be held.[64] Otherwise, he will enter his order without holding a hearing.[65]

The procedures briefly described here are very time consuming and involve a great deal of paperwork.[66] A substantial amount of discretion is vested in both the Secretary of the DEA and the Commissioner of the Food and Drug Administration. Such stringent procedures have been in effect since hallucinogenic drugs were included in the Drug Abuse Control Amendments in 1966. The decrease in research after this date is attributable to those rigorous procedures and, in general, the unfavorable attitude of the federal government toward LSD research.

V. RESEARCH AND CLINICAL USE SINCE 1965

After the Drug Abuse Control Amendments became effective in 1966 almost all medical use of LSD and research into its effects ceased. An indication of this is the small number of grants approved and funded after 1966. Also, the type of research approved indicates that the federal agencies are less concerned with the medical benefits

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TROLLED SUBSTANCES 2 (August 27, 1972) and 37 FED. REG. 28712 (December 29, 1972).

[57] 21 C.F.R. § 301.54 (a) (1973).
[58] 21 C.F.R. § 301.54 (c) (1973).
[59] 21 C.F.R. § 301.55 (b) (1973).
[60] 21 C.F.R. § 301.42 (a) and (d), § 301.48 (c) (1973).
[61] 21 C.F.R. § 130.12 (a) (1973).
[62] 21 C.F.R. § 130.12 (b) (1973).
[63] 21 C.F.R. § 130.14 (b) (1973).
[64] *Id.*
[65] *Id.*
[66] 21 C.F.R. 130 (1973).

of LSD than with the possible damage the drug can cause.

The National Institute of Mental Health dispersed only 11 grants for research with LSD between 1967 and the present. Five projects are still active, but only three are involved in clinical research. One is designed to determine the clinical value of new drugs for treatment of psychiatric disorders and alcoholism.[67] Another uses psychotropic drugs, especially LSD, at a special research ward of Bellevue's psychiatric division.[68] The third is a study of changes in humans using a variety of drugs, including LSD.[69]

Out of 54 research grants and contracts relevant to LSD funded by the Alcohol, Drug Abuse and Mental Health Administration, only 9 were in the four areas of clinical research described in this article. More of the studies were designed to discover the genetic hazards of hallucinogens than to discover the beneficial medical uses.[70] Neither the National Institute on Alcohol Abuse and Alcoholism nor the National Institute on Drug Abuse is presently funding research involving the use of LSD.[71]

The federal government in the past had provided significant financial support for LSD research, and these cutbacks have discouraged wide-ranging and diverse medical use of LSD. The diminished level of research activity is attributable to the stricter regulations controlling use of LSD.

VI. WHY THE FEDERALS LAWS AND REGULATIONS SHOULD BE CHANGED

The rationale asserted for the current law is that LSD has a high potential for abuse, has no currently accepted medical use and cannot be used safely even under medical supervision.[72] These were the reasons asserted in Congressional hearings[73] and debates.[74] They were apparently the reasons Congress passed the 1970 amendments.

These justifications are not adequate support for the restrictions

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[67] NIMH RESEARCH GRANTS RELEVANT TO ALCOHOLISM AND LSD ADMINISTERED BY BRANCHES OTHER THAN THE INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM, computer printout, Program Analysis and Evaluation Section, Division of Special Mental Health Programs, NIMH. (April 18, 1972).

[68] *Id.*

[69] *Id.*

[70] ADAMHA RESEARCH GRANTS, RESEARCH CAREER PROGRAM AWARDS AND CONTRACTS RELEVANT TO LSD, computer printout, Program Information Systems Branch, OPPE, Alcohol, Drug Abuse and Mental Health Administration (February 4, 1974).

[71] Letter from Marc Hertzman, M.D., Executive Assistant to the Director, Alcohol, Drug Abuse and Mental Health Administration, Department of Health, Education and Welfare (February 1, 1974).

[72] 21 U.S.C. § 812 (c)(c) (1970).

[73] HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE REPORT, 91-1444, Part 1, p. 23 (1970).

[74] 116 CONG. REC. 33300 (1970) (remarks of Representative Springer).

on LSD research. That LSD has a high potential for abuse places it in the same category as thousands of other drugs, such as codeine and phenobarbitol. As with these uncontrolled drugs presently available by prescription, the possible harm of LSD may be outweighed by the potential benefit to the patient through research and clinical use. The present laws discount the benefits demonstrated by the pre-1966 research.

LSD does have a currently accepted medical use in the United States. Hundreds of papers published since the late 1940's have chronicled the beneficial medical uses of LSD.[75] Section III of this article presented only a small number of the successful research and clinical projects. In European countries the use of LSD is accepted,[76] unhampered by the type of laws present in the United States.

LSD has been used safely and extensively under medical supervision. Doctors who have administered the drug under supervised conditions almost unanimously defend its safety. Dr. Pahnke, who has used LSD with alcoholics as well as in other areas, states:

> When psychedelic drugs are administered under controlled medical conditions (as has been the case in several large scale research projects in recent years), permanent adverse affects have been rare. Since 1963 at the Spring Grove State Hospital, and now at the Maryland Psychiatric Research Center, over 300 patients have been treated with LSD without a single case of long-term psychological or physical harm directly attributable to the treatment, although there have been two post-LSD disturbances which have subsequently responded to conventional treatment.[77]

Some researchers find LSD is a "safe" drug, even when not under medical supervision:

> In our opinion the fears connected with these drugs which have arisen and have been reported, stressing dangers of cultism and fanaticism, or thrill seeking, are overrated. While LSD-25 can amaze and even overwhelm the individual through changes in perception, it has a built in control. Attempts to misuse it are self-limiting because it can produce extreme physical and psychological discomfort without any special danger.[78]

In addition, the legality of LSD research and clinical use in European countries is also evidence of its safety.

The validity of two of the three justifications for subjecting LSD to strict control, the risk involved and the lack of accepted medical

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[75] Hoffer, *D-Lysergic acid diethylamide (LSD): A Review of its Present Status*, 6 CLIN. PHARMACOL. THER. 183 (1965).
[76] W. CALDWELL, LSD PSYCHOTHERAPY 17 (1968).
[77] Pahnke *et al.*, *The Experimental Use of Psychedelic (LSD) Psychotherapy*, in HALLUCINOGENIC DRUG RESEARCH: IMPACT ON SCIENCE AND SOCIETY 48, 62 (J. Gamage and E. Zerkin eds. 1970).
[78] MacLean *et al.*, *The Use of LSD-25 in the Treatment of Alcoholism and Other Psychiatric Problems*, in 22 Q.J. STUD. ALCOHOL. 34, 44 (1961).

use, is subject to grave doubt. The third justification, that LSD has a high potential for abuse, loses its force when LSD is compared to non-controlled drugs. Thus the reasonableness and validity of the governing laws may be questioned, and suggestions for legislative and administrative reform are appropriate.

VII. PROPOSED ADMINISTRATIVE AND LEGISLATIVE CHANGES

The present laws should be amended. The most logical change would be to move LSD from Schedule I[79] to Schedule III,[80] which bears fewer restrictions. In order to do so, it would be necessary to establish that LSD has a potential for abuse less than the drugs in Schedule I and II, that LSD has a currently accepted medical use and that LSD leads only to moderate or low physical dependence or high physiological dependence.[81] LSD would join codeine,[82] opium,[83] and morphine[84] in this category. This change could be made by Congress in the form of an amendment to the Drug Abuse Prevention and Control Act of 1970 or by requesting the United States Attorney General to transfer LSD between schedules.[85]

This transfer would diminish the burden of compliance with federal regulations. For instance, applications by practitioners who wish to conduct clinical research with LSD would not have to be referred to the Secretary of the Department of Health, Education and Welfare for determining the applicant's qualifications and competency. Nor would the Attorney General have the opportunity to deny the application.[86]

Another possible avenue for legislative change to allow for wider and more diverse uses of LSD would be for Congress to pass a resolution asking the Attorney General to waive, by regulation, the requirement for registration of dispensers of LSD in medical research and clinical use.[87] This change would eliminate one time-consuming registration process, while maintaining the safeguards of the Investigational New Drug process.[88]

Another step that would make research less difficult, yet still subject to some control, would be to change the Food and Drug Administration rule requiring FDA approval prior to the inauguration of

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[79] 21 U.S.C. § 812 (b)(1) (1970).
[80] 21 U.S.C. § 812 (b)(3) (1970).
[81] 21 U.S.C. § 812 (b)(3) (A)-(C) (1970).
[82] 21 U.S.C. § 812 (C) Schedule III (d)(2) (1970).
[83] 21 U.S.C. § 812 (C) Schedule III (d)(7) (1970).
[84] 21 U.S.C. § 812 (C) Schedule III (d)(8) (1970).
[85] 21 U.S.C. § 811 (a)(1) (1970).
[86] 21 U.S.C. § 823 (f) (1970).
[87] 21 U.S.C. § 822 (d) (1970).
[88] 21 U.S.C. § 355 (1970); 21 C.F.R. § 130 (1973).

clinical investigations with LSD.[89] The only other instances in which such preclearances are necessary are investigations of certain listed drugs so toxic that their use may be justified only under special conditions and projects involving the reactivation of a study terminated by the FDA.[90] By eliminating LSD from this preclearance category and treating it like other new drugs, a clinical investigation would be able to proceed once the Investigational New Drug application had been submitted, unless the Food and Drug Administration presented an objection.[91]

Federal officials have fairly unlimited discretion to allow or disallow research and clinical use of LSD. If the application process can be streamlined through legislative and administrative action, thereby allowing more research and clinical use, then the beneficial uses can be brought to their attention, hopefully changing their restrictive attitudes and policies.[92]

VIII. CONCLUSION

This article outlined the areas of beneficial research and clinical use of LSD that occurred in the past, the laws and regulations that discouraged this research, and the projects and studies presently allowed by these restrictive laws. Several proposals for legislative and administrative action have been suggested that would solve the problems caused by the present laws, allowing wider and more creative research efforts.

This article speaks only to the lack of meaningful medical research and clinical use of LSD, and tries to weigh the documented benefits of the drug against the reasons for restricting its use. At a time when the drug is shown to be able to help, and sometimes cure, gravely ill people, restrictions should be lifted unless benefits are outweighed by the risks. As the risks under these conditions have not been substantiated, LSD should be available to alcoholics, psychotics, psychopaths, schizophrenic children, the terminally ill and other people who in many instances have no other hope.

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[89] U.S. DEPT. OF HEALTH, EDUCATION AND WELFARE, THE IND PROCEDURE: ASSURING SAFE AND EFFECTIVE DRUGS 2 (1971).
[90] *Id.* at 3.
[91] *Id.* at 2.
[92] *See also* Ford, *LSD and the Law: A Framework for Policy Making*, 54 MINN. L. REV. 775 (1970); Laughlin, *LSD-25 and the Other Hallucinogens: A Pre-Reform Proposal*, 36 GEO. WASH. L. REV. 23 (1967); Fort, *Social and Legal Response to Pleasure Giving Drugs*, in UTOPIATES, THE USE AND USERS OF LSD-25, 205, 220 (R. Blum and Associates eds. 1964).