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LSD 1902

THE USE OF PSYCHEDELIC AGENTS WITH AUTISTIC SCHIZOPHRENIC CHILDREN

Robert E. Mogar & Robert W. Aldrich

Evidence from seven independent studies indicates LSD may help free the most severely imprisoned minds.

In recent years, a number of exploratory investigations have been reported involving the administration of psychedelic agents to young children suffering from severe forms of psychological disturbance (Abramson, 1960; Bender, et al., 1962; Bender, et al., 1963; Fisher & Castile, 1963; Freedman, et al., 1962; Rolo, et al., 1965; Simmons, et al., 1966). As either therapeutic or experimental undertakings, these studies are extremely fragmentary and suffer gross shortcomings. As a case in point, wide diversity along major dimensions known to influence drug response and treatment effectiveness characterize this work. These include the agent employed, dosage level, number and frequency of administrations, therapist expectations and previous experience with psychedelic drugs, and finally the setting and circumstances surrounding the drug-induced state. With regard to patient characteristics. the children treated were demographically varied and covered a broad age range. More importantly, the samples were markedly heterogeneous with respect to the nature, severity, and duration of modal symptoms. The major experimental shortcomings included small samples, subjective and vague criteria of drug effects and improvement, and grossly inadequate follow-up.

Despite their diversity and severe limitations, these seminal explorations in an extremely complex area of research seem worthy of wider reportage and more serious attention than they have hitherto received. Almost without exception, these reports have appeared in obscure publications or remain unpublished. A more significant reason for their relative neglect has been the polarized controversy surrounding psychedelic agents which has all but completely curtailed publicly-sanctioned research.

In this critique of the use of psychedelic agents with severely disturbed children, the various studies conducted thus far will be comprehensively reviewed and integrated. Particular attention will be given to their similarities and differences along known relevant dimensions in order to detect communalities and possible reasons for inconsistent findings. While some attempt will be made to resolve seemingly contradictory results, the heuristic value of this work will be emphasized rather than its conclusiveness. Hopefully, the tentative conclusions derived from these initial efforts will point the way for more definitive studies into the therapeutic efficacy of psychedelic agents with childhood disorders.

PATIENT CHARACTERISTICS

A fairly exhaustive search of clinical and research reports revealed a total of 91 severely disturbed children who have been administered one or more psychedelic agents for experimental and/or therapeutic purposes. As detailed in Table 1, this collective group of patients ranged from five to fifteen years of age, with the large majority between six and ten years of age. Careful examination of the seven independent studies disclosed little basis for assuming a significant relationship between age and drug response. However, tentative relationships were suggested by both Bender (1963) and Fisher and Castile (1963). Bender noted that in contrast to pre-adolescents, younger children manifest consistently different reactions to a variety of medical and pharmacological treatments. For this reason, she hypothesized that her older patient group (12-15, N = 8) would not show the dramatic positive changes obtained with the younger children. Contrary to expectations, comparable favorable effects were found irrespective of age

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differences. Fisher and Castile, on the other hand, concluded that older children were better candidates for psychedelic therapy because verbal communication was possible and also because they tended to be less withdrawn, more schizophrenic than autistic, and displayed more blatant symptomology. While these patient features were obvious advantages for the particular therapy technique employed by Fisher and Castile, it is unlikely that this symptom picture consistently distinguishes older from younger psychotic children. Thus, on the basis of the available evidence concerning the immediate and subsequent effects of psycholic drugs on children, age per se appears to be an inconsequential variable.

All of the patients treated in these studies were described as severely and chronically disturbed with a primary diagnosis of autism or childhood schizophrenia. With regard to duration of illness, most had been hospitalized for periods ranging from two to four years. Many were afflicted since birth. An apparent exception was the single patient studied by Rolo and his co-workers (1965). This twelve year old boy had been hospitalized for four months. No estimate of the duration of his illness was reported. At the opposite extreme, the twelve children treated by Fisher and Castile were probably the most severely disturbed with an average illness duration of 7.6 years.

The modal symptoms characterizing the majority of children given psychedelic treatment were well summarized by Simmons and his coworkers (1966): (1) preoccupation with and stereotyped manipulation of objects (toys, etc.); (2) isolation of the self from contact with animate objects (including minimal eye contact); (3) failure to acquire general social behaviors (including speech); and (4) bizarre rhythmic repetitive motor patterns. This syndrome conforms closely to the classical picture of infantile autism (see e.g., Rimland, 1964). As suggested earlier, the symptoms picture of the older children treated by Bender and by Fisher and Castile resembled adult schizophrenia more than infantile autism. This was also true of Rolo's single patient. Although autism was invariably present, the "schizophrenic" children were less withdrawn and manifested a

greater variety of symptoms including overt aggression, hallucinations, paranoid delusions, and psychosomatic disturbances. Almost without exception, long-standing mutism was characteristic of all 91 patients prior to psychedelic treatment.

Despite these significant communalities among the seven groups of children studied, individual differences in patient characteristics extended over a fairly broad range. Without discounting the possible importance of individual differences, there is little indication in the work reviewed here of differential response or benefit as a function of age, diagnosis, duration or severity of illness. As will become apparent in subsequent sections of this paper, the failure to detect such relationships seems partly due to fragmentary patient data and the crude estimates available of drug response and subsequent changes in behavior. Consistent with this hypothesis, the differential findings reported by Fisher and Castile appear to reflect their more detailed assessment of personal history information and individual differences in both pre- and post-treatment symptomology. They also applied more stringent criteria of improvement than the other investigators.

RATIONALE AND HYPOTHESES

Explicit hypotheses or theoretical bases for administering psychedelic drugs to disturbed children are almost completely absent in these exploratory studies. The lack of a definite rationale is hardly surprising when one considers the enigma surrounding both schizophrenic behavior in children and response to psychedelic drugs. Despite great diversity in expectations and technique, there was one point of departure shared by all investigators, namely, that all known forms of treatment had been attempted without success. Thus, the use of a potent experimental drug with the particular chronic patients selected seemed justified.

With regard to the purpose of these studies, all were to some extent exploring the therapeutic potential of psychedelic drugs rather than their psychotomimetic properties. This was least true of Freedman and his coworkers (1962) who viewed LSD primarily as a means of studying the schizophrenic

process by "intensifying pre-existing symptomology." This orientation contrasted sharply with Bender's view. Noting that withdrawn children became more emotionally responsive while aggressive children became less so, she hypothesized that psychedelic drugs "tend to 'normalize' behavior rather than subdue or stimulate it." This basic difference in expectations seems at least partially responsible for Bender's extremely favorable outcomes and Freedman's rather poor results. Regarding all forms of psychotherapy, it has become a truism that "where there is no therapeutic intent, there is no therapeutic result" (Charles Savage in Abramson, 1960, p. 193).

Consistent with their explicit therapeutic intent, Bender, Fisher, and Simmons each offer essentially the same hypothesis based on a psychological interpretation of childhood schizophrenia: "The working hypothesis of this study is that the psychosis is a massive defensive structure in the service of protecting and defending the patient against his feelings and affectual states" (Fisher & Castile, 1963). Psychedelic drugs were viewed as a powerful means of undermining an intractable defense system and thereby making the patient more receptive to contact and communication with others. In attempting to explain the predominantly positive results in this area of research (see Table 1), it is worth emphasizing that the collective work of Bender, Fisher, and Simmons accounts for over 75 per cent of the 91 children treated with psychedelic drugs. Although their techniques differed considerably, these investigators shared a psychological conception of autistic symptoms and a psycho-therapeutic orientation to drug treatment.

Although Freedman was prompted to use LSD primarily as an experimental device to study psychosis, he did mention that he was influenced to some extent by the dramatic improvement in autistic children reported by Peck and Murphy (in Abramson, 1960) and by the apparent success of Cholden, Kurland, and Savage (1955) in their work with adult mute catatonic patients. As will become apparent in the discussion of results, a partial and often transient alleviation of mutism by LSD treatment has been one of the most consistent effects reported in the children studies.

A final secondary objective worth mentioning is that the more recent studies (Rolo, et al., 1965; Simmons, et al., 1966) were influenced by Bender's earlier reports of successful LSD treatment. These studies were attempts to replicate Bender's findings using various control measures and other methodological refinements.

DRUG REGIME

As indicated in Table 1, LSD-25 has been by far the most frequently employed psychedelic agent in work with psychotic children. An exception was Bender's second study (1963) in which she gave one-half of her patients LSD-25 and the other half UML-491. The experimental drug UML-491 was described as a more potent serotonin inhibitor without the psychedelic properties associated with LSD-25. Based on a variety of biochemical indices and observations of differential behavior changes, Bender reported no apparent differences between the action or effectiveness of the two drugs.

Fisher and Castile employed LSD-25 and psilocybin at times singly and at times simultaneously. These investigators were unique in using a variety of dosage leveldrug combinations both with the same patient on different occasions and with different patients on the same occasion. The specific drug regime adopted for a given session was determined by clinical criteria of the patient's particular defense structure and his expected resistance to psychedelic drugs. Stated differently, Fisher and Castile were the only investigators who attempted to optimize the psychedelic experience for a given patient rather than mechanically administering a constant dosage of the same agent to all patients. This feature of their method was consistent with the greater attention paid to individual patient differences and their general orientation to psychedelic therapy as a psychopharmacological process.

Concerning dosage level, most investigators settled on 100 micrograms as optimal. Although this was the average dosage used by Bender, she differed from the others

by starting treatment at a relatively low level (50 mcgs.) and gradually increasing the amount to as high as 150 mcgs. As suggested earlier, Fisher and Castile usually administered multiple agents and employed a wide range of dosage levels (with LSD, 50 to 400 mcgs.). As their work progressed, they developed a definite preference for the prolonged high dose psychedelic experience, especially with older schizophrenic children. Their most effective results were obtained with pre-treatment medication of 10 mg. Librium, 10 to 15 mg. of Psilocybin given approximately one-half hour later, followed by 250 to 300 mcg. of LSD administered twenty minutes later. In addition, Fisher and Castile often gave "boosters" during the session itself ranging from 25 to 100 mcg. of LSD. Boosting was considered beneficial "(a) when the patient seemed to be caught up in a problem area which he could not break through; (b) when the patient kept defending himself from new experiences; (c) when the patient increased his defensive, stereotyped behavior and the psychotic controls became intensified."

With regard to frequency and total number of treatments, the seven studies varied widely -from Freedman's single session per patient to Bender's daily sessions over periods as long as one year. Although more frequent and prolonged treatment was often impossible for non-clinical reasons, Fisher's group averaged five sessions per patient given preferably at two week intervals. With both Rolo's single patient and Simmons' pair of identical twins, experimental requirements precluded an optimal therapeutic regime. Both investigators attempted double-blind procedures and more objective observational methods. Rolo administered 100 mcg. LSD on 28 consecutive days while Simmons gave a total of nine 50 mcg. LSD treatments, approximately two per week, interspersed with inert placebo sessions and control (no-drug) trials.

After citing extensive evidence indicating rapid tolerance of LSD-25, Freedman concluded that repeated administrations would be ineffective with psychotic children. Bender, on the other hand, found little indication of either rapid or sustained tolerance to LSD using her method of continued daily admini-

strations over extended periods. With her relatively large group of patients, Bender did observe a leveling off of reactivity after several weeks or months of uninterrupted treatment. She considered it unlikely, however, that this effect was due to physiological drug tolerance. The impressive improvement rates obtained by Bender in contrast to Freedman's results offer support for a high frequency regime of moderately large doses. It is worth noting that Fisher and Castile arrived at a similar conclusion without knowledge of Bender's work. Parenthetically, the significance of a possible drug tolerance effect is further lessened by the findings of more recent experiments indicating that tolerance to LSD diminishes almost as rapidly as it develops (Hoffer, 1965).

PHYSICAL AND PSYCHOLOGICAL MILIEU

It should be emphasized that the findings obtained in these studies are the result of an interrelated set of determinants, only one of which is the ingestion of a particular chemical agent. The significance of seemingly contradictory results has often been obscured by the persistent search for static, "drug-specific" reactions to LSD. Inconsistent findings become more understandable if the psychedelic experience is viewed as a dynamic configuration of intimate patienttherapist-milieu transactions. In short, the administration of LSD is inextricably embedded in a larger psychosocial process which should be optimized in accordance with particular treatment goals.

Even a cursory examination of the work with autistic children clearly reveals that at least some important aspects of the physical and psychological milieu were considerably less than optimal. In the seven studies reviewed here, only Fisher and Castile attempted to create a specifically non-medical atmosphere that was minimally threatening to the patient. Modeled after the technique Saskatchewan widely-adopted (Blewett & Chwelos, 1959; Hoffer, 1965), the procedure developed by Fisher and Castile included the following key features: (1) a high dose, 7 to 10 hour session; (2) the use of a variety of therapeutically-meaningful or aesthetically-pleasing stimuli (music, flowers, pictures, food, etc.); (3) a positive



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Detail of painting by Allen Atwell

patient-therapist relationship formed prior to the session itself; (4) the presence of both a male and female therapist who "had thorough acquaintance with the phenomena of the drug through personal experience"; and (5) active therapist involvement with the patient including role-playing (e.g., father, mother). Importantly, these conditions have repeatedly been found to significantly enhance the personal value of psychedelic experiences.

In each study, the circumstances under which the session was conducted were consistent with the purpose and expectations of the investigator. Consistent with his psychotomimetic orientation, Freedman's patients were supervised by a familiar psychiatrist primarily for the purpose of careful observation and note-taking. No attempts to relate to the children or personal experience with the drug were reported. The same applies to Bender's group although the intent in this case was clearly therapeutic. She apparently administered LSD as a conventional daily medication that did not require any special conditions of preparation, therapist involvement, or setting. However, her reports are replete with descriptions of spontaneous interactions between staff and children. Supervision of Bender's patients was performed mainly by ward attendants. The adults present in the sessions conducted by both Rolo and Simmons were also ward attendants.

The primary purpose of the studies reported by Rolo and Simmons was explicitly methodological. Both research projects employed the double-blind method and attempted to follow a predetermined, uniform procedure during each experimental and control session. As means of standardizing the sequence of events and increasing objectivity, both investigators systematically presented various playing objects, games, and tasks to the child. Rolo's single patient was encouraged to engage in quite simple, familiar activities such as throwing a baseball or playing cards. Simmons, on the other hand, created a far more elaborate series of game-like situations that were novel and intrinsically interesting, requiring sustained patient-adult interactions, and importantly were specifically designed to simulate or elicit normal social behavior and emotional responsiveness.

A number of probable effects of the physical and psychological milieu are suggested in these studies that bear a significant relationship to the investigator's orientation, on the one hand, and differences in benefit or outcome, on the other. As indicated earlier, the expectations of a particular research team seem highly related to various aspects of both drug regime and setting. With regard to differential improvement rates, a major determinant seems to be the

degree of active therapist-patient interactions permitted during the drug-induced state. Secondly, greater therapeutic benefit seems to occur in congenial settings offering some opportunity to experience meaningful objects and interpersonal activities. Finally, psychedelic therapy with psychotic children seems most effective in natural, flexible settings that are reasonably free of artificiality, experimental restrictions on spontaneous behavior. and mechanically administered procedures. Converselv. barren medical or laboratory environments seem clearly anti-therapeutic.

RESULTS

As emphasized previously, each of these exploratory studies suffered major shortcomings either as therapeutic or experimental undertakings. Almost without excertion, the findings reported consist mainly of observational data obtained during the acute phase of drug reactivity. The use of pre-treatment baselines against which to measure change either during or after psychedelic therapy were generally absent. In most cases, follow-up data was not obtained. Although caution in interpreting results is certainly indicated, it should be pointed out that these limitations are shared by the bulk of research on drug- and psycho-therapies. Furthermore, objective evaluation of improvement in severely disturbed children presents unique problems due to the nature of autistic symptoms, especially the ubiquity of mutism. Even the few cases not suffering from a complete absence of speech were untestable by standard psychological assessment methods.

In their initial study, Bender and her coworkers (1962) administered the Vineland Maturity Scale at the beginning of treatment and again three months later. At the followup testing, ratings were qualitatively higher for all children. In the second study (Bender, et al., 1963), the Rorschach, Draw-A-Person, and Bender-Gestalt tests were given to the ten verbally responsive children on at least two occasions; before treatment and again after a three to eight month interval. In these aggressive, overtly psychotic patients, Bender reports that "there were two major changes observed: (1) There was a decrease in personalized ideation and a corresponding gain in accuracy of response; and (2) An inhibition of strongly emotional or 'feeling' reactions to the cards." Other favorable changes reported included decreases in hallucinations, negativism, and regressive defenses with a corresponding increase in reality-contact. Similar types of improvement were found in the older children treated by Fisher and Castile.

With regard to her major group of young autistic children, Bender reported significant improvement in speech and verbal communication:

"...the 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" (1963, p. 91).

Since mutism is a cardinal symptom of autistic children and probably the major impediment to successful therapy, it is worth emphasizing that at least temporary speech improvement has been one of the most frequently reported effects of LSD in the work conducted thus far. Other communalities include an elevated mood. less compulsive ritualistic behavior, and increased interaction with others. All investigators reported some favorable change in these major areas with the exception of Rolo's single patient. Rolo's group abandoned the attempt to estimate improvement since their judges could not distinguish between LSD and non-LSD trials. Bender, on the other hand, made the following observations:

"They appeared flushed, bright eyed, and unusually interested in the environment... They participated with increasing eagerness in motility play with adults and other children... They seek positive contacts with adults, approaching them

	No. of Patients	Age Range In Years	Agent Used	Dosage Level (in mcgs)	No. of Treatments Per Patient	Treatment Schedule	Effects of Treatment ^a		
Reference							Excel.	Good	Poor
Abramson (ed.), 1960	6	5-14	LSD	40	3-6	Weekly	5		1
1960			:		av. 4				
Freedman, et al., 1962	12	6-12	LSD	100	1			5	7
Bender, et al., 1962	14	6-10	LSD	100	₄₅ b	Daily	7	7	
Bender, et al., 1963	44	6-15	LSD UML	50-150 4-12 mg.	60 ^c	Daily	20	21	3
Fisher and Castile, 1963	12	5-13	LSD Psilo.	50-400 10-20 mg.	1-11 ^d av. 5	Biweekly/ Monthly	4	4	4
Rolo, et al., 1965	1	12	LSD	100	28	Daily			1
Simmons, et al., 1966	2	5	LSD	50	9	Twice Weekly	2		
Total	91					Totals	38	37	16

Table 1. Summary of Patient Samples, Drug Regime, and Improvement Estimates

(a) Due to the paucity of follow-up data available, these extremely tentative ratings are based primarily on response during treatment.

(b) In a later report, Bender reports continued daily treatments with this group over a 12 month period, i.e., each patient received a total of approximately 365 LSD and/or UML treatments.

(c) With this second sample, one-half were given LSD and one-half were given UML.

(d) Based upon estimates of patient resistence, a wide variety of dosage level-drug combinations were used both within- and between-subjects. Psilocybin and LSD were employed at times singly and at times simultaneously.

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SUMMARY AND CONCLUSIONS

1. Seven independent studies are reviewed involving a total of 91 austistic schizophrenic children who had been given psychedelic drugs for therapeutic and/or experimental purposes.

2. The large majority of children treated in these studies were between six and ten years of age and were completely refractory to all other forms of treatment.

3. There was only slight indication of any differential response or benefit as a function of age, diagnosis, duration or severity or illness.

4. A variety of psychedelic agents, dosage levels, frequency of administrations, and treatment schedules were employed. The most effective results were obtained with at least 100 microgram doses of LSD-25 given daily or weekly over relatively extended periods of time.

5. Concerning the physical and psychological milieu, greater therapeutic benefit was related to: (a) the degree of active therapist involvement with the patient; (b) an opportunity to experience meaningful objects and interpersonal activities; and (c) congenial settings that were reasonably free of artificiality, experimental or medical restructions, and mechanically administered procedures.

6. The most consistent effects of psychedelic therapy reported in these studies included: (a) improved speech behavior in otherwise mute children; (b) increased emotional responsiveness to other children and adults; (c) an elevation in positive mood including frequent laughter; and (d) decreases in compulsive ritualistic behavior.

7. Differences in patient attributes, treatment technique, research design, and other non-drug factors seemed to effect the frequency and stability of favorable outcomes. The types of improvement found were essentially the same in each study.

8. Although each of these studies contained serious therapeutic and experimental flaws, it was concluded that the collective findings

argue strongly for more extensive applications of psychedelic drugs in the treatment of austistic children.

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with face uplifted and bright eyes, and responding to fondling, affection, etc." (1962, pp. 172-3). "There is less stereotyped whirling and rhythmic behavior... They became gay, happy, laughing frequently... Some showed changes in facial expression in appropriate reactions to situations for the first time" (1963, pp. 90-91).

As indicated earlier, Simmons' patients were subjected to a uniform sequence of game-like situations that evoked a variety of measurable responses. During each LSD session and non-LSD session, a total of 20 specific behavioral measurements were taken by a recorder observing the patient through a one-way screen. The behaviors recorded included physical contact with the adult present, vocalizations, destructive acts, laughter, stereotyped movements, and eveto-eye contact. In contrast to non-LSD trials, the most pronounced and consistent changes observed during LSD sessions were: "(1) An increase in social behaviors manifested by increased eye to face contact and increased responsiveness to adults, (2) An increase in smiling and laughing behavior generally considered an indication of a pleasurable affective state, and (3) a decrease in one form of non-adaptive behavior demonstrated by a reduction of self-stimulation."

Considering the wide diversity in these studies, the major findings of Bender, Fisher and Castile, Freedman, and Simmons are remarkably similar. Differences in orientation, patient attributes, drug regime, setting, treatment technique, research design, etc. seem to affect the frequency and stability of favorable outcomes (see Table 1). The types of improvement, when and if they occur, appear to be essentially the same in each study. In short, when LSD is effective with autistic children, it is effective in characteristic ways.

The influence of non-drug factors is well illustrated in the work of Fisher and Castile. Although they optimized the physical and psychological milieu, their patients were the most severely disturbed and displayed the greatest variety of symptoms. Furthermore they made conservative estimates of improvedment based on the extent and stability of favorable changes after treatment was terminated. In contrast, most of the findings reported by the other investigators concerned the immediate effects of treatment. These differences account in part for the relatively modest improvement rates reported by Fisher and Castile.

The lack of even short-term follow-up data on the majority of children treated with psychedelic drugs has been a major limitation of the work reviewed bere. Follow-up information is particularly crucial because the available evidence strongly suggests that when used alone, LSD produces only transient alleviation of symptoms. In order to bring about enduring improvement, the druginduced state requires active therapistpatient interaction and/or subsequent psychotherapy. In this connection, Simmons noted that:

"Therapeutic intervention in severely retarded or regressed children utilizes to a great extent close physical interaction to which the child must respond. In the usual state it is often difficult to intrude upon the child because of a general lack of responsiveness... The results of our experiments clearly demonstrate changes in exactly these areas with increased attendance to physical and face contact with an attending adult and concomitant reduction of competing self-stimulatory behavior... Thus, two possible criteria for the successful intervention into autistic children are met... A third piece of data which must be considered is the increase in smiling and laughing behavior..." (1966, p. 1207).

The collective work reviewed here supports the main conclusion reached by Simmons and his co-workers and argues strongly for more extensive and systematic applications of psychedelic drugs in the treatment of autistic schizophrenic children: "LSD-25 appears to offer a useful adjunct to psychotherapy because of its positive effect in the areas described which are closely related to the process of psychotherapy."

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2. The large majority of children treated in these studies were between six and ten years of age and were completely refractory to all other forms of treatment.

3. There was only slight indication of any differential response or benefit as a function of age, diagnosis, duration or severity or illness.

4. A variety of psychedelic agents, dosage levels, frequency of administrations, and treatment schedules were employed. The most effective results were obtained with at least 100 microgram doses of LSD-25 given daily or weekly over relatively extended periods of time.

5. Concerning the physical and psychological milieu, greater therapeutic benefit was related to: (a) the degree of active therapist involvement with the patient; (b) an opportunity to experience meaningful objects and interpersonal activities; and (c) congenial settings that were reasonably free of artificiality, experimental or medical restructions, and mechanically administered procedures.

6. The most consistent effects of psychedelic therapy reported in these studies included: (a) improved speech behavior in otherwise mute children; (b) increased emotional responsiveness to other children and adults; (c) an elevation in positive mood including frequent laughter; and (d) decreases in compulsive ritualistic behavior.

7. Differences in patient attributes, treatment technique, research design, and other non-drug factors seemed to effect the frequency and stability of favorable outcomes. The types of improvement found were essentially the same in each study.

8. Although each of these studies contained serious therapeutic and experimental flaws, it was concluded that the collective findings

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