FINAL REPORT OF THE VIRGINIA DEPARTMENTS OF EDUCATION, HEALTH PROFESSIONS, MENTAL HEALTH, MENTAL RETARDATION AND SUBSTANCE ABUSE SERVICES ON

The Effects of the Use of Methylphenidate

TO THE GOVERNOR AND THE GENERAL ASSEMBLY OF VIRGINIA



HOUSE DOCUMENT NO. 28

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COMMONWEALTH of VIRGINIA

December 19 , 1990

TO: The Honorable Lawrence Douglas Wilder Governor of the Commonwealth of Virginia

The Members of the General Assembly of Virginia

It is our privilege to present this report which constitutes the response of the Departments of Health Professions; Mental Health, Mental Retardation and Substance Abuse Services; and Education to the request contained in the House Joint Resolution No. 146 of the 1990 Session of the General Assembly of Virginia.

This report provides the findings of a special task force regarding the use of methylphenidate (Ritalin) in Virginia to treat children diagnosed as having Attention Deficit Hyperactivity Disorder. We appreciate the efforts of this group of volunteers and endorse the findings and recommendations of their report.

The task force report and appended literature review were prepared with the support of the Department of Health Professions staff and with funding provided by the Department.

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Enclosure

VIRGINIA DEPARTMENTS OF

EDUCATION,

HEALTH PROFESSIONS,

AND

MENTAL HEALTH MENTAL RETARDATION AND

SUBSTANCE ABUSE SERVICES

REPORT OF THE TASK FORCE ON THE USE OF METHYLPHENIDATE IN THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER DIAGNOSED CHILDREN

In Response To

House Joint Resolution Number 146

of the

1990 Session of the General Assembly of Virginia

TABLE OF CONTENTS

PAGE

HOUSE	JOINT RESOLUTION NUMBER 146	i		
LIST	OF TASK FORCE MEMBERS	ii		
EXECUTIVE SUMMARY				
I.	INTRODUCTION	1		
II.	PURPOSE OF THE STUDY	1		
III.	STUDY METHOD	2		
IV.	THE DIAGNOSIS AND PREVALENCE OF THE DISORDER	3		
v.	THE EXTENT OF METHYLPHENIDATE PRESCRIPTION AND TREATMENT	6		
VI.	EFFECTS AND SIDE-EFFECTS OF METHYLPHENIDATE TREATMENT	8		
VII.	ABUSE, DIVERSION AND REGULATORY ISSUES	10		
VIII.	OTHER APPROACHES AND BEST PRACTICES RELATED TO ADHD	14		
APPENDIX A - LITERATURE REVIEW & REFERENCES				
Appeni	DIX B - CHILD DEVELOPMENT CLINIC SURVEY AND LEARNING RESOURCE CENTER'S SURVEY OF ADVOCACY GROUP PARENTS			

APPENDIX C - PUBLIC COMMENTS

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HOUSE JOINT RESOLUTION NO. 146

Requesting the Department of Health Professions, the Department of Mental Health. Mental Retardation and Substance Abuse Services. and the Department of Education to study jointly the effects of the use of methylphenidate.

Agreed to by the House of Delegates, March 1, 1990

Agreed to by the Senate, February 27, 1990

WHEREAS, it is estimated that, nationally, twenty percent of the school age population exhibit developmentally inappropriate degrees of inattention, impulsivity and sometimes hyperactivity for their mental and chronological age and can be diagnosed as having "Attention Deficit Disorder" (ADD); and

WHEREAS, children between the ages of eight and ten years are most likely to be diagnosed as having ADD, and such condition generally limits concentration, impedes learning and goes undetected during the early years of childhood; and

WHEREAS, such children, often very bright and talented, manifest frustration, intolerance, temper outbursts, low self-esteem, variable moods, and academic underachievement which mask their innate abilities and their attention problems; and

WHEREAS, because there is neither conclusive evidence concerning the cause of ADD, nor a single treatment modality for the disorder, chemical therapy is the most common course of treatment when ADD is diagnosed as with hyperactivity, and methylphenidate is the drug most often prescribed; and

WHEREAS, although methylphenidate is a central nervous system stimulant classified as a Schedule II drug by the federal government, it has been prescribed for decades, and its use has substantially increased, having been prescribed for nearly one million children in the nation; and

WHEREAS, the use of methylphenidate has generated considerable controversy concerning its benefits, safety, side effects, and alleged misuse due to its implication in a growing number of tragic and fatal incidents among children for whom it has been prescribed; and

WHEREAS, there is a need to ensure that children with ADD receive a quality education appropriate for their learning styles and developmental levels without complicating their difficulties through medication that may be unnecessary or contraindicated for some such children; and

WHEREAS, a study of the needs of children with ADD, the extent to which methylphenidate is prescribed for such condition, its effectiveness, and the growing concern about its misuse is necessary in order to determine whether appropriate alternative treatments for ADD are possible, warranted, and feasible to protect the health and well-being of such young children in this Commonwealth; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Department of Health Professions, the Department of Mental Health, Mental Retardation and Substance Abuse Services, and the Department of Education are requested to study jointly the effects of the use of methylphenidate.

The Departments shall review the relevant findings and recommendations of the Joint Subcommittee Studying School Dropouts and Ways to Promote the Development of Self-Esteem Among Youth and Adults concerning the educational and social needs of children with ADD. The Departments shall determine (i) the number of school-age children diagnosed as having ADD, (ii) the type of methylphenidate treatment employed in such cases, (iii) the extent to which methylphenidate and related drugs are prescribed for such children, (iv) the adverse effects, if any, from the use of methylphenidate, (v) with the assistance of appropriate law-enforcement agencies, the number of violent and fatal incidents in Virginia in which the use of methylphenidate is implicated, (vi) appropriate alternative treatment and instructional approaches, counseling of parents, training of educators and the medical profession concerning the needs of such children, (vii) the need for early identification and research, and (viii) whether there is sufficient evidence to warrant requesting the U.S. Food and Drug Administration to reclassify methylphenidate, limit its use, or both, to protect the health and well-being of such young children.

The Departments shall complete their work in time to submit their findings and recommendations to the Governor and the 1991 Session of the General Assembly pursuant to the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

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EXECUTIVE SUMMARY

Attention deficit disorder (now more commonly conceptualized as Attention Deficit Hyperactivity Disorder, or ADHD) is a serious condition affecting many children, adolescents, and adults. The disorder is generally characterized to include age-inappropriate levels of motor activity, and inattention. The etiology of the condition is not well established.

Concepts of exactly which clusters of behaviors and deficits comprise the disorder have evolved -- and continue to evolve -over time. There is considerable inexactitude in how these behaviors and deficits are measured. The probability of an ADHD diagnosis differs depending upon whether a single clinician or an interdisciplinary team conducts the evaluation and makes the diagnosis.

Due largely to this lack of diagnostic clarity, estimates of the extent of the disorder in school-aged and the general population vary. Reported estimates of prevalence range from one to twenty percent. A more defensible estimate of prevalence for school-aged children appears to fall within a range of three to five percent.

Psychostimulant medications, especially methylphenidate (Ritalin), are effective in controlling behavioral and other symptomatic manifestations of the disorder but do not constitute a cure. The behavioral and other effects last only as long as the effects of the medication.

Ritalin is a Schedule II drug. A Schedule II drug is one which is a most restrictively regulated substance for approved medical treatment. Moreover, Ritalin is classified as a Schedule II drug because of its potential for abuse and/or dependency. Manufacturers of methylphenidate caution against its prescription to children under six (due to a lack of research in younger age groups), recommend careful titration of dosage, medical monitoring for side-effects, drug holidays, and discontinuation when negative side-effects occur. Further, it is recommended by professionals that the drug should not be used as the only intervention for ADHD.

Side-effects of Ritalin therapy are generally mild and controllable, but some serious and persisting effects have been reported to occur in rare cases.

There is no evidence of widespread abuse or diversion of methylphenidate in the Commonwealth, but dramatic increases in distribution of the drug to retail outlets over the last decade, and isolated incidents of abuse or diversion create cause for some concern. The major abuses of the drug, however, appear to lie in its use without appropriate adjunctive measures, and in its prescription without benefit of an adequate, interdisciplinary, differential diagnosis of ADHD or careful monitoring of children using the medicine over time.

A task force appointed by the Departments of Education, Health Professions, and Mental Health Mental Retardation and Substance Abuse Services has studied the use of methylphenidate in the treatment of ADHD in response to House Joint Resolution 146 of the 1990 Session of the Virginia General Assembly.

The task force found no evidence that the public was in eminent danger from prevailing diagnostic practice or the effects of methylphenidate, but there is evidence of the need to improve the monitoring and use of methylphenidate.

The development of defensible public policy will require better documentation of the extent of ADHD and therapeutic intervention. A number of "best practice" recommendations seem prudent, but no policy interventions should be undertaken that prevent ADHD children who require appropriate medication from receiving it.

The task force has presented its recommendations in the form of "best practice" suggestions with additional suggestions on how the recommendations might be implemented. A summary of these recommendations and suggestions follow.

TASK FORCE RECOMMENDATIONS

To improve the accuracy and coordination of the diagnosis and treatment planning for Attention Deficit Hyperactivity Disorder:

 Diagnosis, treatment, and planning for children diagnosed as ADHD should involve a multidisciplinary process including medical, psychological, and educational professionals. Diagnosis and prescription of treatment for children with ADHD should include involvement of parents or their surrogates.

To improve educational services for children diagnosed as having ADHD:

- The Department of Education should conduct a survey to determine the prevalence of ADHD among school children and the use of methylphenidate.
- Communication between physicians and educators regarding the use of methylphenidate for school-aged children should be improved.
- Appropriate treatment and instructional approaches (behavioral and cognitive therapy and other accommodations and adjustments) should be developed to provide alternatives or to complement drug therapy.

- Medical personnel should be available in every school to administer medications and record information on observable signs and other appropriate information associated with medication used to treat ADHD.
- School nurses should provide leadership in coordinating health and related services for ADHD students, including the administration of medications.

To facilitate the most appropriate use of methylphenidate as the preferred psychostimulant medication for ADHD:

- o Medication should not be used as an isolated treatment. Proper classroom placement, behavior modification, and counseling, should be used <u>before</u> a trial of pharmacotherapy is attempted.
- o The effects of the drug therapy must be evaluated on a regular basis.
- The use of medication should be consistent with manufacturers' recommendations or current research regarding use, initial titration of dosage, monitoring, maintenance dosage, length of use, and drug holidays.
- The effects of methylphenidate treatment should be carefully evaluated by the prescribing physician at least every six months. Accurate records should be maintained as required for Schedule II substances.
- o The child's medication records may be shared with school officials for proper coordination of treatment.
- Adjunctive treatment should always accompany drug therapy to include appropriate school accommodation or adaptation and parent education. Other interventions should be used as needed, including psychotherapy (for parents and/or child), behavior therapy, specialized education programs, and family support.

To assess the current levels of use and misuse of methylphenidate:

o The pharmaceutical drug diversion study conducted by the Department of Health Professions and the Department of State Police under the direction of the Virginia Crime

1

One task force member does not agree that other interventions should be attempted before beginning pharmacotherapy, rather they should be used in combination.

Commission should include information on the use of methylphenidate.

 The Department of Medical Assistance Services should reinstate methylphenidate in its quarterly analysis of prescription, dispensing and consumption patterns related to Medicaid providers and recipients and provide these analyses to appropriate enforcement and regulatory agencies including the Department of Health Professions and the Department of State Police.

To ensure that parents and families are appropriately included in the identification and management of ADHD:

- o Parents and families of ADHD children should participate actively in the professional management of children.
- Membership in organizations of ADHD parents and families is encouraged as a means for understanding the disorder, its treatment, and the vital role played by family and in the homes of ADHD children.

To facilitate the widest understanding and acceptance of these recommendations:

- Intensive in-service educational programs should be instituted on the needs and appropriate interventions for children with ADHD for physicians, other health care professionals, mental health professionals, school personnel, and parents.
- o The members of the General Assembly of Virginia are requested to consider a resolution requesting the distribution of these recommended best practices by the appropriate public and private agencies, including regulatory boards, State agencies, professional associations, parents' organizations, civic and community organizations, and others.

REPORT OF THE TASK FORCE ON THE USE OF METHYLPHENIDATE IN THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER IN CHILDREN

INTRODUCTION

House Joint Resolution 146 (HJR 146) of the 1990 Session of the Virginia General Assembly requested the Virginia Departments of Education, Health Professions, and Mental Health Mental Retardation and Substance Abuse Services to study the effects of methylphenidate (Ritalin) in the treatment of children diagnosed with attention deficit disorder. A task force to study the issues delineated in HJR 146 and to prepare a report and recommendations for consideration by the Governor and the General Assembly was appointed to represent constituencies of these three departments. Individuals appointed to the task force and staff were selected to represent a number of relevant perspectives:

- Education (public and private) including superintendents, principals, teachers, and educational diagnosticians;
- Medicine (pediatrics and psychiatry), psychology (clinical, school, and experimental), pharmacy and pharmacology, and sociology;
- Nursing (public health, school, and pediatric), nurse practitioner, and nursing administration;
- Professional regulation and the regulation of controlled substances; and
- o Parents of children diagnosed and treated for attention deficit disorder.

This Report is a result of the study conducted by the task force. The Report comprises an Executive Summary, this narrative, and appended materials including a literature review with references (Appendix A), the results of two surveys conducted by task force members and staff (Appendix B), and public comments received from survey respondents and as a result of an invitation for public comment (Appendix C).

PURPOSE OF THE STUDY

House Joint Resolution 146 requested that the following issues be considered:

- 1. The number of school-age children diagnosed as having attention deficit disorder;
- 2. The type of methylphenidate treatment employed in such cases;

- 3. The extent to which methylphenidate and related drugs are prescribed for such children;
- 4. The adverse effects, if any, from the use of methylphenidate;
- 5. With the assistance of appropriate law enforcement agencies, the number of violent and fatal incidents in which the use of methylphenidate is implicated;
- 6. Appropriate alternative treatment and instructional approaches, counseling of parents, training of educators and the medical profession concerning the needs of such children;
- 7. The need for early identification and research; and
- 8. Whether there is sufficient evidence to warrant requesting the U. S. Food and Drug Administration to reclassify methylphenidate, limit its use, or both, to protect the health and well-being of such children.

The task force has integrated these issues into five general topics which provide the structure and organization of this Report.

- The diagnosis and prevalence of the disorder;
- o The extent to which methylphenidate is prescribed;
- o The effects and side-effects of methylphenidate treatment;
- o Abuse, diversion and regulatory issues related to methylphenidate; and
- o Other approaches and "best practices" related to the treatment of the disorder.

STUDY METHODS

The task force met three times during the course of the study and presided at a public hearing held in Richmond on September 12, 1990. Subcommittees met between meetings of the full task force to address three specific aspects of the study:

- 1. Preparation of the literature review;
- 2. Research, including the design and interpretation of survey instruments; and
- 3. Evidence of abuse, diversion and regulatory problems related to methylphenidate.

To ensure a common baseline of understanding among task force members and staff, earlier studies which focused on children diagnosed as having ADHD and alternative interventions were discussed. An overview of the Legislative Subcommittee Studying School Dropouts and Ways to Promote the Development of Self-Esteem Among Youth and Adults as related to the educational and social needs of students was provided to task force members. Issues concerning proper treatment of the disorder and the relationship to school performance, particularly, dropout prevention were discussed.

The report <u>Attention Deficit Hyperactivity Disorder (ADHD)</u> and the Schools (Virginia Department of Education, 1989), which is regarded to be a state-of-the-art review of issues related to ADHD and interventions from the perspective of educators and the public school system, was discussed. Further, the findings of this report established a framework/foundation for the components of HJR 146.

THE DIAGNOSIS AND PREVALENCE OF THE DISORDER

While HJR 146 refers to methylphenidate as the focus for study, it is clear that (ADHD) is also of concern since one of the primary uses of Ritalin is in the pharmacotherapy of ADHD.

The etiology of ADHD is not definitely known, although contributions have been made in attempts to discern specific genetic and metabolic factors as well as general social, physiological and functional bases.

Because definitions and concepts are emerging, the range of estimates of the extent of ADHD is varied. The range of estimates of the extent of the disorder in school-aged and other populations and the confusion that confounds discussions of incidence and prevalence of ADHD are evident in the following quotation from a current review:

Attention deficit hyperactivity disorder (ADHD) is a serious condition which affects from 3-5 percent of the school population. Defining characteristics of the disorder include age-appropriate levels of motor activity, impulsivity, and inattention with the attentional problems typically being the most debilitating.

Further,

. . . Estimates of the <u>incidence</u> rates of ADHD vary widely, from fewer than 1% to more than 20% of the population. This variation occurs because of the imprecision of terms such as 'overactivity' and 'impulsivity.' As criteria for the disorder have become more objective, a clearer picture of the <u>prevalence</u> has emerged. The best current estimates are that between 3% and 5% of school age children have this problem. (emphasis added) The confusion which limits the credibility of these estimates include:

- Lack of consensus on precisely which characteristics are to be included as symptoms of the disorder;
- o Imprecision in the conceptualization and measurement of these symptoms;
- Failure to identify exactly the population or subpopulation for which estimates are attempted;
- Inappropriate comparisons between and among populations (e.g., total population vs. school-aged children); and
- o Extent of "new cases" representing the incidence only, or the total morbidity (prevalence) for any given time.

Comparisons of incidence or prevalence vary. Earlier studies may estimate only "attention deficit" disorder (with or without hyperactivity); more recent estimates tend to include hyperactivity as a defining characteristic.

The question of who provides the diagnosis is also relevant to the discussion of the extent of the disorder. Although medical diagnoses are legally performed only by physicians, it is clear that ADHD diagnoses may be made using a multidisciplinary approach to include teachers, parents, psychologists, counselors, and other qualified professionals. One study indicated that a much higher rate of diagnosis occurs when a single clinician performs the evaluation than when parents and teachers as well as clinicians were involved.

Indirect support for an estimate of the prevalence of a segment of the school-aged population is provided from information obtained from the Department of Medical Assistance Services. Of all children receiving Medicaid-reimbursed services during the first quarter of this year, 1.3 percent were prescribed methylphenidate. The proportion varies by subcategory of Medicaid recipient; one percent of Aid to Dependent Children recipients and four percent of "disabled" and "special" recipient children received methylphenidate treatment in that quarter. It is not prudent to extrapolate this estimate to the general population of children, however, for several reasons.

The professional expert advice of task force clinicians and the current research literature suggest that socioeconomic correlates to ADHD diagnosis and psychostimulant medication exist. Specifically, although verification with existing data is not possible, it is suggested that disadvantaged children and economically privileged children are diagnosed with the disorder more frequently than children of working-class families. This may be because children eligible for public assistance and children from families with relatively high income levels are more likely to receive medical and/or psychological or other counseling than other children. The incidence and/or prevalence of ADHD in Virginia may differ from national estimates or norms because of the dramatic increases in distribution of methylphenidate to the retail level (pharmacies and physicians) over the past decade. The reasons for this increase appear quite complex and warrant more indepth examination beyond the scope of this study.

Public policy related to ADHD and its treatment should be informed by better estimates of prevalence than are currently available, and correct estimates of prevalence hinge on better diagnostic procedures.

There is professional consensus that diagnosis and treatment planning for ADHD children should be multidisciplinary, involving medical, psychological, and educational professionals and parents. Nevertheless, available data suggest that multi-faceted diagnostic evaluations are not typically conducted. An audit of records in a pediatric clinic and a family practice clinic in two military hospitals found that only about one-half of the children treated with psychostimulants for ADHD met a review team's criteria for the disorder. In Virginia, a survey of parents conducted by a task force member at The Learning Resource Center found that fewer than one child in five diagnosed as ADHD received the recommended interdisciplinary evaluation (involving medical, psychological, and educational diagnosticians).

There is also evidence in public comments that parents are inadequately counseled and involved in the diagnosis and treatment planning.

The task force recommends that the diagnosis of ADHD and the treatment planning be an interdisciplinary process involving medical, psychological, and educational professions that includes, at a minimum, assessment of the child's physical, cognitive, social, behavioral, and educational functioning. The diagnosis and prescription of treatment should include significant and meaningful involvement of parents or their surrogates.

The need for coordination of medical, educational, and family support services requires that educational planners have more valid and reliable information on the extent of ADHD in the community. Research directed at documenting the extent of ADHD in school-aged children should also relate the prevalence of ADHD to demographic, social, and economic characteristics of the communities served by each school.

The task force recommends that the Department of Education conduct a survey to determine the numbers and characteristics of ADHD children served in each public school, including an analysis of the relationship of the prevalence of ADHD and community characteristics.

As requested by HJR 146, the task force also considered mechanisms for early identification of ADHD children. At some future time it may be feasible to implement ADHD evaluations

along with the medical and sensory screening already in place for pre-schoolers. Given the state of the art and science of ADHD diagnosis, and the fact that methylphenidate should not be prescribed before age six, the task force position on this issue is equivocal.

THE EXTENT OF METHYLPHENIDATE PRESCRIPTION AND TREATMENT

Methylphenidate (Ritalin) is an amphetamine-like central nervous system stimulant used in the treatment of narcolepsy (a relatively rare condition) and ADHD. It is the medication of choice for most children accurately diagnosed as ADHD. When used in combination with appropriate support and monitoring services, the drug has proven to be effective in treating the symptoms of ADHD, and it is relatively safe when used appropriately.

It is essential to note, however, that Ritalin is defined by federal law and Virginia statute as a Schedule II drug. Schedule II drugs meet the following criteria:

- 1. The substance has high potential for abuse;
- 2. The substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restriction; and
- 3. The abuse of the substance may lead to severe psychic or physical dependence. (Code of Virginia Sec. 54.1-3447)

Schedule II drugs are the most restrictively regulated substances that have accepted medical uses; only drugs without accepted medical uses are more rigidly controlled. Other Schedule II drugs include morphine, Demerol, and short-acting barbiturates such as Seconal. (See Table 1, page 11).

The most commonly prescribed brand of methylphenidate, Ritalin, is manufactured by Ciba-Geigy in 5, 10, and 20 milligram (mg.) tablets. The 20 mg. dosage unit is available in sustained release preparations.

Because of a lack of research in children younger than the age of six, Ciba-Geigy recommends that no child under six be prescribed the drug. For children six and over, dosage levels should be adjusted for the individual, starting with 5 mg. twice daily, and increasing gradually as necessary in increments of 5 to 10 mg. weekly. The maximum dosage recommended is 60 mg. per day.

If improvement is not observed over a one-month period, the manufacturer suggests that the drug be discontinued. If side effects appear and persist, it is recommended that dosages be reduced, "drug holidays" be implemented, or the drug be completely discontinued. Survey findings indicate that 75 percent of ADHD children seen in Child Development Centers and 95 percent of all ADHD-diagnosed children whose parents responded to a survey of members of ADHD parent support groups are or had been prescribed Ritalin. Information provided by Department of Medical Assistance Services on children receiving Medicaid reimbursed services indicate that <u>average</u> dosages fall well within the manufacturers recommended limits. Average dosage ranged from 7 to 38 mg. daily, however, these averages may obscure important extremes and differences.

While Ritalin is an effective treatment when appropriately prescribed, professional consensus is that medication alone is not an acceptable treatment for ADHD. The task force concurs with the Council on Child and Adolescent Health of the American Academy of Pediatrics in recommending that:

. . . Medication should never be used as an isolated treatment. Proper classroom placement, physical education programs, behavior modification, counseling, and provision of structure should be used before a trial of pharmacotherapy is attempted. Once administered, the effects of the drug therapy must be evaluated on a regular basis. (See Footnote 1, page vi in the Executive Summary)

The task force members also assert that the hallmarks of "best practice" for Ritalin or other psychostimulant medication extend beyond these recommendations:

- o The use of medication should be consistent with manufacturers' recommendations regarding use, initial titration of dosage, monitoring, maintenance dosage, length of use, and drug holidays.
- Although prescriptions for methylphenidate are not refillable, and some minimal physical monitoring is built into the system, the task force believes that the effects of methylphenidate treatment should be <u>carefully</u> evaluated by the prescribing physician at least every six months. Accurate records should be maintained as required for Schedule II substances. These records should be shared with school officials for proper coordination of treatment.
- o Adjunctive treatment should always accompany methylphenidate or other drug therapy including appropriate school accommodation or adaptation and parent education. Other interventions should be used as needed, including psychotherapy (for parents and/or child), behavior therapy, specialized education programs, and family support.

-7-

School systems and parents should also be aware of legal and regulatory provisions governing **administration** of methylphenidate as well as its prescription. Public comments, the professional advice of task force members, and responses to task force surveys indicate that administration of methylphenidate and other controlled substances often does not have standardized procedures in school settings. (It should be noted that school nurses are not available in all schools.)

- o The task force recommends that trained personnel be available in every school to administer medications, and record information on observable signs and other appropriate information associated with medication.
- o School nurses (where available) should provide leadership in coordinating health and related services provided in schools, including the administration of methylphenidate and other controlled substances.

The task force emphasizes that Ritalin, properly prescribed, administered, monitored, and coordinated with adjunctive services in the home and school is an effective medication. The chief problems associated with methylphenidate are those attributable to the prescription of the drug as the only treatment and to inadequate diagnosis and/or follow-up and monitoring over time.

EFFECTS AND SIDE-EFFECTS OF METHYLPHENIDATE TREATMENT

Methylphenidate minimizes certain symptoms of ADHD but is not a "cure" for the disorder. Largely because of its effectiveness in altering certain central nervous system functions and in controlling **behaviors** associated with ADHD, methylphenidate has been the medication of choice for both attention deficit and hyperactivity symptoms for several decades.

As the literature review (Appendix A) indicates, scientific and professional studies and findings related to methylphenidate are difficult to interpret due largely to methodological problems. Nonetheless, certain consistent findings are notable.

- o Both ADHD and "normal" children respond to methylphenidate treatment with heightened attention level and decreased non-directed motor behavior. Compliance behavior increases and off-task, hostile, and deviant behaviors decrease.
- o Vigilance and reaction time measures show improvement with Ritalin treatment, as do short-term memory measures.

- o Although behavior is judged to be calmer with Ritalin, and academic performance (school grades) and memory measures improve, the impact of the drug is limited. There is no real improvement in academic achievement or reading comprehension as measured by standardized tests.
- o Methylphenidate breaks down quickly in the body and is removed through the bloodstream, and its effectiveness is restricted to only a few hours per dosage.

These findings are supported generally by public comments received during the study and by clinical experiences of task What is not apparent in the professional force members. literature is the value to children, their parents, teachers, and peers in the substantial benefits obtained from methylphenidate treatment. To the concerned parent, the teacher beleaguered by disruptive classroom behaviors, and to ADHD children themselves, chemically modulated behavior may have significant value.

As with any drug, methylphenidate carries a potential for undesirable side-effects. Ritalin's side-effects are generally mild and subside with time and/or dose reduction, with the possible exceptions related to hypertension, tics, Tourette's syndrome, and psychotic reactions. The following side-effects have been reported:

Frequently Occurring Short-Term Side Effects

- insomnia
- loss of appetite -
- weight loss
- irritability
- abdominal pain

Occasionally Occurring Short-Term Side-Effects

dizziness nausea ----

lethargy - anxiety

- euphoria
- nightmares

- increased hearing acuity

- fearfulness

- dry mouth
- constipation
- headaches
- Long-Term Side Effects tics (rare)
- Gilles de la Tourette's Syndrome (rare)
- psychotic reactions (extremely rare, usually in connection with other controlled drugs or with excessive dose levels of methylphenidate)

This listing may cause undue concern. It is emphasized that side-effects are generally amenable to control. Nevertheless, the possibility of these effects argues for careful diagnosis -including screening for any contraindications to stimulant treatment (e.g., hypertension, family history of Tourette's Syndrome) -- and for frequent monitoring by the prescribing physician.

ABUSE, DIVERSION AND REGULATORY ISSUES

As a Schedule II drug, methylphenidate is carefully controlled. The task force members indicated that this control is warranted and that any attempt to reschedule the drug to a lower level of restriction should be resisted.

To assess any evidence of abuse and/or diversion of the drug, a subcommittee of the task force met with representatives of the enforcement divisions of the Department of Health Professions (DHP), the Department of State Police (VSP), and the Department of Medical Assistance Services (DMAS). These agencies and the U. S. Drug Enforcement Administration (DEA) participate in an interagency Pharmaceutical Drug Diversion Investigation Unit charged with detecting and investigating allegations and evidence of illegal uses of pharmaceutical drugs.

Although there is no documentation of widespread diversion or abuse of or child addiction to methylphenidate, several reported incidences and other anecdotal evidence -- coupled with dramatic changes in the distribution of methylphenidate to retail outlets in the Commonwealth over the past decade -- create cause for concern.

- o The quantity of methylphenidate distributed to retail sources in Virginia (standardized as grams per 100,000 population) tripled over the past decade, and Virginia rose in rank from 38th to 8th among 54 states and territorial jurisdictions. (See Figure 1, page 12).
- "Doctor shopping" by a mother of an ADC Medicaid eligible child who feigned symptoms of ADHD was of sufficient interest to DMAS that a computer routine was established to detect "outliers" among providers and recipients who prescribe, dispense, or receive unusual quantities of all controlled substances. Similar incidents have been reported in other states.
- o VSP reports indicate a number of thefts of methylphenidate from retail outlets, although it seems clear that the stolen drugs were part of a larger sweep.
- Anecdotal evidence suggests that Ritalin is the drug of choice at truck stops and among students seeking stimulants to stay awake.
- Recent reports in the controlled substance literature confirm that primary care physicians, including pediatricians, underestimate the abuse potential of methylphenidate. The drug is often used in combination with other licit and illicit substances (especially cocaine). Intravenous injection of Ritalin is associated with greater system toxicity than other similar drugs. Twenty milligram tablets, referred to as "poor man's cocaine" are the preferred form.

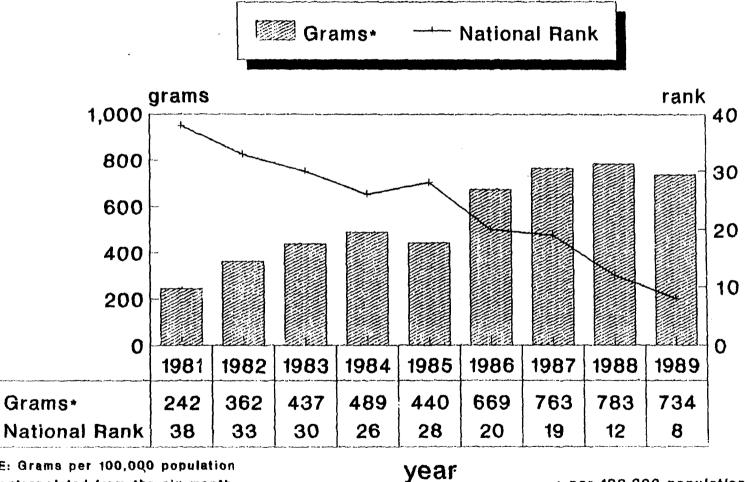
TABLE 1: CONTROLLED DRUG SCHEDULES

- <u>Schedule I</u> Non-medicinal substances with high abuse potential dependence liability. These drugs are used for research only. Examples include: LSD and heroin. It is not legally available for medicinal use by prescription.
- Schedule II Medicinal drugs that have the highest potential abuse and dependence liability. Examples include: opium derivatives (morphine, codeine), merperidine (Demerol), methylphenidate (Ritalin), amphetamines (Dexedrine), short-acting barbiturates (Amytal, Nembutal, Seconal). A written prescription is required. However, under emergency circumstances, telephone prescribing is allowed. No refills are allowed.
- <u>Schedule III</u> Medicinal drugs with abuse potential and dependence liability less than Schedule II drugs but greater than Schedule IV, V, or VI drugs. Examples include: codeine, hydrocodone, and opium in combination with non-narcotic drugs, some hypnotics (Doriden, Noludar), some appetite suppressors (Didex, Tenuate, Sanorex). A telephoned prescription is permitted, to be converted to written form by the dispensing pharmacist. Prescriptions must be renewed every 6 months. Refills are limited to 5.
- <u>Schedule IV</u> Medicinal drugs with less abuse potential and dependence liability than Schedule III drugs. Examples include: pentazocine (Talwin), propoxyphene (Darvon), all benzodiazepines (Librium, Valium), certain hypnotics (Placidyl, Notec). Prescriptions requirements are the same as for Schedule III.
- <u>Schedule V</u> Medicinal drugs with the lowest abuse potential and dependence liability. Examples include: diphenoxylate (Lomotil) and codeine/hydrocodone in combination with other active, non-narcotic drugs. Drugs in this category are for cough and diarrhea and may be sold without a prescription in specified quantities by a pharmacist who is required to maintain a record of sales.
- <u>Schedule VI</u> Drugs in this Schedule consist of all of the prescription drugs on the market except those in Schedules II-V. These drugs are considered dangerous drugs and are restricted to prescriptions under the supervision of a practitioner. Virginia is the only state that has a Schedule VI designation for these drugs.

FIGURE 1

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METHLYPHENIDATE DISTRIBUTION TO RETAIL OUTLETS IN VIRGINIA



NOTE: Grams per 100,000 population are extrapolated from the six month experience, January 1 ~ June 30, 1989.

per 100,000 population



Although the literature reports small numbers of cases in which long-term polydrug abusers experience serious or fatal consequences, the task force could find no evidence of tragic or fatal consequences attributable to methylphenidate in Virginia.

A number of Virginia hospitals participate in a voluntary reporting system, the Drug Abuse Warning System (DAWN), sponsored by the National Institute of Drug Abuse. Participating hospitals report emergency room admissions for overdoses and suicides related to controlled substances. No reports implicating methylphenidate have been made during the years the program has operated. In addition, regional forensic laboratory analyses of confiscated drugs have identified methylphenidate only once in the memory of long-term staff members.

Evidence of abuse or diversion is insufficient to support any recommendation that would intrude into medical practice. Nonetheless, the task force believes there is a need for a systematic study of methylphenidate <u>use</u> including any documented or suspected misuse. The study should be conducted in such fashion as to prevent any perception that methylphenidate should not be prescribed when an interdisciplinary diagnosis of ADHD has been made and a systematic treatment, monitoring, and follow-up plan that includes adjunctive services as well as medication has been devised.

The opportunity for such a review exists in a study now underway. The Department of Health Professions and Department of State Police, at the request of the Virginia State Crime Commission, are studying the extent of pharmaceutical drug diversion and the costs and effects of initiatives to control diversion undertaken in other states.

The study will correlate use and misuse of controlled substance with demographic, social, health status indicators, and health services indicators in a social epidemiological model. Inclusion of methylphenidate as a focal substance is feasible and agreeable to the participating agencies. The study is to be reported to the 1992 session of the General Assembly.

The task force recommends that the pharmaceutical drug diversion study conducted by the Department of Health Professions and the Department of State Police under the direction of the Virginia State Crime Commission include information on the use of methylphenidate.

An additional opportunity for extending the knowledge base exists in the extensive information collected by DMAS regarding prescription and dispensing of controlled substances by Medicaid providers, and the consumption of these substances by Medicaid recipients. Since more than 400,000 Virginians now participate in Medicaid it is possible to construct a comprehensive profile of methylphenidate use in a large population and to identify unusual prescribing, dispensing, and consumption patterns. Identification of unusual patterns does not alone suggest abuse or diversion, but may indicate a need for investigation. Methylphenidate was originally included in quarterly analyses prepared by DMAS, but has been excluded in the recent past. The agency is agreeable to reinstating methylphenidate in its analyses.

The task force recommends that the Department of Medical Assistance Services reinstate methylphenidate in its quarterly analysis of prescription, dispensing, and consumption patterns related to Medicaid providers and recipients and provide these analyses to appropriate enforcement and regulatory agencies including the Department of Health Professions and the Department of State Police.

It is emphasized that the needs of patients for appropriate medication constitute the foremost consideration in designing and implementing any drug monitoring system. Although restraint is recommended in prescribing any controlled substance, this restraint should not inhibit treatment with methylphenidate when psychostimulant medication is clearly indicated.

OTHER APPROACHES AND BEST PRACTICES RELATED TO ADHD

The task force believes that the recommendations presented throughout this Report, taken together, constitute the beginning of a "guide to best practices" related to the treatment of ADHD with methylphenidate. The guide is incomplete in its failure to provide direct guidance for the parents and families of ADHD-diagnosed children.

Some notion of the anguish and frustration faced by ADHD parents and families is evident in the written comments presented in Appendix C. As consumers of health care and educational, psychological, and related services, ADHD parents and families have a right to expect that clinicians, teachers, counselors, and others conform to the best practices presented in this Report.

Much information and some controversy surround ADHD and its treatment. It is alleged that Ritalin makes children "zombie-like," it provides a "chemical straight jacket," and the side-effects of Ritalin are described as "devastating." The drug is claimed to be "highly addictive," and to turn normal children into drug addicts. Murder, suicide attempts, and long-lasting emotional disabilities have also been attributed to medication, or to withdrawal from medication. The conclusions of the current review are unequivocal: none of these allegations is validated either in the scientific literature or by the clinical experience of task force members.

Parents and families of ADHD children are encouraged to join support groups dedicated to understanding the characteristics of ADHD, the terminology of diagnosis and treatment, the appropriate involvement of parents and family along with professionals, and advocacy for ADHD children. An important basic handbook, <u>How to</u> <u>Own and Operate and ADHD Kid</u> (Maxey, 1989) is referenced in Appendix A. The task force recommends that parents and families of ADHD children participate actively in the professional management of these children. Membership in the organizations of ADHD parents and families is encouraged as a means for understanding the disorder, its treatment, and the vital role played by the family and in the homes of ADHD children.

With the addition of this recommendation, the task force believes that the intent of the House Joint Resolution 146 has been appropriately addressed. The Legislature has reason for some concern regarding ADHD and its treatment, but the task force cautions against any overreaction that would unduly constrain the treatment of this serious disorder.

Our recommendations are in the nature of delineating the best practices related to ADHD and Ritalin. A summary of the recommendations along with suggestions for their implementation follows.

The task force appreciates this opportunity to be of service to the government and people of the Commonwealth.

SUMMARY OF TASK FORCE RECOMMENDATIONS

To improve the accuracy and coordination of the diagnosis and treatment planning for Attention Deficit Hyperactivity Disorder:

The task force recommends that diagnosis and treatment planning of ADHD be an interdisciplinary process involving medical, psychological, and educational professions that includes, at a minimum, assessment of the child's physical, cognitive, social, behavioral, and educational functioning. The diagnosis and prescription of treatment should include significant and meaningful involvement of parents or their surrogates.

To improve the capability and competence of public schools in meeting the needs of ADHD children, their parents, and the community:

The task force recommends that the Department of Education conduct a survey to determine the number of characteristics of ADHD children served in each school, including an analysis of the relationship of the prevalence of ADHD and community characteristics.

Communication between physician and educators regarding the use of methylphenidate with school-aged children should be improved.

Appropriate treatment and instructional approaches (behavioral and cognitive therapy and other accommodations and adjustments) should be developed to provide alternatives or to complement drug therapy.

Trained personnel should be available in every school to administer medications, and record information on observable signs and other appropriate information associated with medication used to treat ADHD.

School nurses (where available) should provide leadership in coordinating health and related services provided for ADHD students, including the administration of methylphenidate and other controlled substances.

To facilitate the most appropriate use of methylphenidate as the preferred psychostimulant medication for ADHD:

The task force recommends medication not be used as an isolated treatment. Proper classroom placement, physical education programs, behavior modification, counseling, and provision of structure should be used <u>before</u> a trial of pharmacotherapy is attempted (see Footnote 1 in the Executive Summary). Once administered, the effects of drug therapy must be evaluated on a regular basis.

The use of medication should be consistent with manufacturers' recommendations regarding use, initial titration of dosage, monitoring, maintenance dosage, length of use, and drug holidays.

The effects of methylphenidate treatment should be carefully evaluated by the prescribing physician at least every six months. Accurate records should be maintained as required for Schedule II substances. These records should be shared with school officials for proper coordination of treatment.

Adjunctive treatment should always accompany drug therapy to include appropriate school accommodation or adaptation and parent education. Other interventions should be used as needed, including psychotherapy (for parents and/or child), behavior therapy, specialized education programs, and family support.

To assess the current levels of use and misuse of methylphenidate.

The task force recommends that the pharmaceutical drug diversion study conducted by the Department of Health Professions and the Department of State Police under the direction of the Virginia State Crime Commission include a focus on methylphenidate.

The task force recommends that the Department of Medical Assistance Services reinstate methylphenidate in its quarterly analysis of prescription, dispensing, and consumption patterns related to Medicaid providers and recipients and provide these analyses to appropriate enforcement and regulatory agencies including the Department of Health Professions and the Department of State Police.

To ensure that parents and families are appropriately included in the identification and management of ADHD:

The task force recommends that parents and families of ADHD children participate actively in the professional management of these children. Membership in organizations of ADHD parents and families is encouraged as a means for understanding the disorder, its treatment, and the vital role played by the family in the homes of ADHD children.

To facilitate the widest understanding and acceptance of these recommendations:

The task force recommends intensive in-service educational programs be instituted on the needs and appropriate interventions for children with ADHD for physicians, mental health professionals, and school personnel.

The task force respectfully requests that the Virginia General Assembly consider a resolution requesting the distribution of these recommended best practices by the appropriate public and private agencies, including regulatory boards, State agencies, professional associations, parents, organizations, civic and community organizations, and others.

APPENDIX A

LITERATURE REVIEW AND REFERENCES

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LITERATURE REVIEW

INTRODUCTION

Attention Deficit Hyperactivity Disorder (ADHD) is a medical diagnosis used to encircle a collection of educationally and socially undesirable behaviors exhibited by some children. ADHD is described in the current <u>Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R)</u> (American Psychiatric Association, 1987) as a condition primarily characterized by inappropriately high levels of inattentiveness, impulsivity, and restlessness. The particular behaviors which have been used to classify individuals as having ADHD are defined and measured by a variety of methods.

More than fifty years ago, clinicians began using available stimulant medications to treat a variety of child psychiatric problems which had not responded to traditional psychotherapy (Bradley, 1937). Treatment first with dextroamphetamine (Dexidrine) and then with methylphenidate hydrochloride (Ritalin) became increasingly popular for use with hyperactive children who exhibited symptoms of anxiety, minimal brain dysfunction, aggression, psychoses, hysteria, depression and school phobia. For a number of reasons, the use of dextroamphetamine in treating ADHD has diminished significantly. Today, Ritalin is the most frequently prescribed stimulant medication for ADHD. In the vast majority of reported cases, it is either the primary or only means of treatment.

This review examines the issues which surround ADHD diagnosis and treatment by presenting a topical summary of the scientific and professional literature. The following examples are alternative reviews of ADHD and the use of psychostimulant medications which should be read by those with a serious interest in ADHD/Ritalin issues.

- Brown, R. T., Borden, K. A., & Clingerman, S. R. (1985).
 Pharmacotherapy in ADD adolescents with special attention to multimodality treatments.
 Psychopharamcology Bulletin, 21, 192-210.
- Dulcan, M. K. (1990). Using psychostimulants to treat behavioral disorders of children and adolescents. Journal of Child and Adolescent Psychopharmacology, <u>1</u>, 7-20.
- o Dulcan, M. K. (1985). Attention deficit disorder: Evaluation and treatment. <u>Pediatric Annals</u>, <u>14</u>, 383-400.

Policy makers in the Commonwealth, as well as teachers, health professionals, and parents should also study <u>Attention</u> <u>Deficit Hyperactivity Disorder in the Classroom</u> (Virginia Department of Education, 1989), a general review of ADHD prepared from the perspective of teachers and the school system. A publication of particular interest to parents is <u>How to Own and</u> Operate and Attention Deficit Disordered Kid (Maxey, 1989). These publications address general issues related to ADHD, including reference to methylphenidate and other medications. The present review focuses more specifically on issues related to the diagnosis of ADHD and its management with methylyphenidate.

The diagnosis of children with behavior disorders as "ADHD" is a process that varies among professionals. There is no single determinative process or test for arriving at the diagnosis. Rather, ADHD is diagnosed largely by rating the severity of behaviors that except for their frequency or severity are common to childhood. The magnitude of an individual's deviation from "normal" behavior patterns is commonly assessed with a combination of psychometric and educational testing, physician evaluation, and observation and evaluative questionnaires filled out by teachers, parents, and health professionals.

Because ADHD does not have distinctive or unique symptoms (such as those characteristic of measles, chicken pox, mumps, or other such maladies that tend to affect children), the process of diagnosing ADHD is not similar to diagnosing medical conditions. Diagnosis of ADHD requires an almost exclusive reliance on the judgment of the teacher, parent, and/or healthcare professional; unequivocal measurements of distinctive phenomena characteristic of ADHD are not available as indicators.

This review addresses four major topic areas:

- o conceptualization of ADHD, including its general description, definition history, etiology, current definition, and prevalence estimation;
- o diagnostic routine and level of adherence to best practice.
- general educational, behavioral, and cognitive responses and side-effects to Ritalin; and
- o alternative approaches to Ritalin therapy.

WHAT IS ADHD?

General Description of Symptoms and Characteristic Behaviors

The primary symptoms of ADHD are high levels of impulsivity, restlessness and inattentiveness. Children diagnosed as having ADHD typically appear to have difficulty modulating their behavior in accordance with situational demands. They are characterized as tending to display careless, disorganized, or nonreflective behavioral styles, and they employ inefficient search strategies and problem-solving skills. They are not necessarily more active than other children; however, they have been seen as exhibiting more non-goal-directed, impulsive motor behavior (Gordon, 1979), resulting in poor school performance (Abikoff & Gittelman, 1985a). The social interactions of ADHD children also tend to be filled with conflict: with their parents, especially their mothers (Barkley, 1988, 1985; Campbell, 1975; Cunningham & Barkley, 1979); with teachers (Whalen, Henker & Dotemoto, 1980); and with peers (Cunningham & Siegel, 1987).

History of the Definition of ADHD

Several terms have been used to denote ADHD, including hyperkinetic brain disorder, hyperkinetic child syndrome, minimal brain dysfunction, minimal brain damage, hyperkinetic-impulsive disorder, Straus-Lehtinen Syndrome, and attention deficit disorder--with or without hyperactivity.

Ideas about attentional deficits have been shaped by reports dating to the turn of the century which describe characteristic behavioral patterns in adults and children following brain injury. In 1902, Still commented that even though many cases of inability to sustain attention or concentrate seemed to result from central nervous system insults, these disorders also often occurred in children with no history of illness or accident that could be related logically to brain injury.

In the 1930's and 1940's prevailing theory held that minimal degrees of anoxia or birth injury resulted in minimal brain damage. As discussed later, however, it has yet to be established that children exhibiting this "brain damage syndrome" have, in fact, experienced central nervous system damage (Shaywitz & Shaywitz, 1984a).

Since 1937 when Bradley first reported the benefits of amphetamine sulfate (Benzedrine) on the school performance and conduct of children with a wide variety of behavior problems, stimulant medications have been the psychotropic agents of choice used in the management of children's behavior.

It was not until Laufer and Denhoff (1957) that hyperactivity became a specific focus in stimulant medication research. Laufer and Denhoff reported that stimulants were most effective when used in children who exhibited signs not only of hyperactivity but also of short attention span, impulsivity, poor handwriting, poor school work, low frustration tolerance, impulsivity, visual motor problems, and writing and reading reversals. The Laufer and Denhoff report and the development of methylphenidate in 1954 provided impetus for what was to become an extensive but relatively unsystematic research effort related to the clinical use of psychotropic medication in children.

A significant concern among researchers and clinicians has been with the manner in which hyperactivity is conceptualized. Before Laufer and Denhhoff, Strauss and Lehtinen (1947) identified a syndrome of hyperactivity, distractibility, short attention span, and disinhibition, usually with concurrent learning and perceptual deficits and "soft" neurological signs. The ascription of these behaviors to **neurological** anomalies was confusing and vague because no specific neurological abnormalities were consistently identified within this population. Thus, in 1980 the American Psychiatric Association recharacterized the syndrome as "attention deficit disorder--with or without hyperactivity." The focus was diverted from neurologic dysfunction to emphasize instead a behavioral base for diagnostic purposes. This reconceptualization also changed the focus from hyperactivity to attention deficits and posed the possibility of attentional problems in children without the presence of hyperactive behavior. In 1987, the Association reintroduced hyperactivity as an essential component of this disorder. With this modification came the current name, "attention deficit hyperactivity disorder" (ADHD).

Etiology

Discussions of the etiology of ADHD are essentially theoretical. No generally accepted cause or collection of causal factors for ADHD has been established. Current explanations include **genetic sources** (evidenced by children having parents with various types of sociopathy or mental disorders), familial dysfunction (evidenced by children developing behaviors in response to dysfunctional parents), and **physical sources** (including neurological disorders, and nutritional-chemical imbalance); also included are other environmental stressors, and the **presence of other childhood psychopathologies** which may express with ADHD-type symptoms.

Evidence for genetic and/or environmental causes of ADHD include the following. Cantwell (1972) compared the levels of psychiatric illness found among parents of children with "hyperactive child syndrome" to parents of normal children and found that a significant number of the parents of hyperactive children were themselves psychiatrically ill, with significantly higher rates of alcoholism, sociopathy, and hysteria. The author suggests that the "hyperactive child syndrome" is a familial disorder that passes through generations, and that the mechanism of this transmission could be either genetic or environmental.

Early research into the physical causes of "hyperactivity" (as it was then known) included a search for associated brain David, Clark, and Voeller (1972) examined the damage. association between hyperactivity and raised levels of body-lead since lead ingestion at toxic levels has been demonstrated to result in severe brain damage. The authors hypothesized that levels below toxicity could result in minimal brain damage of the thought to be associated with "hyperactivity." The type researchers administered a heavy metal chelating agent to both normal control and (penicillamine) hyperactivity-diagnosed children to unbind lead that would be

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¹APA still recognizes the viability of ADD without the hyperactivity component. <u>DSM-III-R</u> provides for two classifications 314.01 - ADHD, and 314.00 - undifferentiated ADD.

accumulated in the bony tissues of the children. The researchers found an association in the excreted levels of lead and hyperactivity.

Neurologic explanations of the disorder focus on dysfunctional brain activity. Evans, Gualtieri, and Hicks (1986) offered the theory that hyperkinetic syndrome results from a genetically (rather than injury) caused dysmaturation of the frontal (lobe)-striatal dopamine transmission systems. A noted similarity in symptomology between patients with damaged frontal lobes and hyperkinetic children was the source for this theory.

Support for the neurological explanations of ADHD from laboratory analyses is sparse. Moreover, there has been no support for the hypothesis that ADHD children's brains are abnormal at the level of analysis available from computerized axial tomographic (CAT) scans of the brain (Kinney, Shaywitz, Shaywitz, Sarwar, and Holahan, 1990). (See also Synek, Reuben, & Duboulay, 1979; Pedersen, Glydensted, & Glydensted, 1979; and Shaywitz, Shaywitz, Byrne, Cohen, & Rothman, 1983 for a discussion of normal child neuroanatomy as displayed through CAT scan methodology.)

Although often cited in the ADHD research literature, the meaning of different electroencephalograph (EEG) patterns is a topic of considerable controversy and cannot be considered an adequate measurement for signs of brain abnormality. Depending upon the criteria used, between 10 to 55 percent of "normal" subjects who have no known history of organic damage have abnormal EEGs (Ross & Ross, 1976).

The search for Evans' hypothesized relationship of hyperactivity and brain abnormalities continues. A highly publicized article in the November 15, 1990 <u>New England Journal</u> of <u>Medicine</u> reported a significant difference between the cerebral glucose metabolism of childhood onset hyperactive adults' brains and those of non-hyperactive controls. The authors used positron emission tomography (i.e., PET scan) to trace low-dosage radioactive glucose in 60 brain sites. Global metabolism was 8.1 percent lower for hyperactive subjects than for controls. Also, 30 of the 60 sites showed group differences in metabolism (Zametin, Nordahl, Gross, King, Rumsey, Hamburger, and Cohen, 1990).

² Caution must be used when interpreting these results. The authors used a statistic which was inappropriate to test whether the two subject groups' metabolism rates were significantly different. By choosing the Student's t test to make multiple group comparisons, they increased the likelihood that they attributed the differences between the groups to differences in metabolic rate when they could be due to chance alone (i.e., a Type II Error).

(Footnote Continued)

In summary, the current understanding of the brain's functioning is at a seminal level and the methods used to examine its physiological functioning are far from precise. Current "direct observations" through PET or CAT scan or EEG technology provide little support for the contention that ADHD is "caused" by brain abnormality in structure or neuroelectrical function. The current focus is on the possible role of neurochemical abnormalities.

Current Definitions

The absence of a determinate cause or etiology for ADHD may reflect the lack of agreement on the clinical manifestation of ADHD or a distinct, diagnostic disorder.

The distinctiveness of the ADHD disorder, that is the extent to which it can be or is uniquely definable as a child and adolescent psychiatric illness, is a matter of controversy. Hinshaw (1987) points out that two classes of behavior problems define most of the children who receive professional intervention. The first are behaviors characterized as hyperactive-inattentive-impulsive, and the second as excessively aggressive and exhibiting marked anti-social conduct (i.e., conduct disorder).

If the standards used to differentiate **medical** diagnoses are applied to the criteria used to evaluate these two types of behavior problems, however, few distinctions between the clusters can be drawn. For example, the two types of behavior problems do not have known distinctions in etiology, and there is little evidence that individuals with the two types of behavior problems respond differently to similar treatment. The difficulty in establishing the clear independence (and thereby, the validity) of the ADHD diagnosis from others stems from this inherent vagueness of characteristics used to define the disorder.

The American Psychiatric Association's <u>Diagnostic and</u> <u>Statistical Manual of Mental Disorders</u> is the most frequently cited source for the terminology and symptom concepts that define ADHD. The following are the behavioral criteria cited for ADHD:

- A. A disturbance of at least six months during which at least eight of the following are present:
 - often fidgets with hands or feet or squirms in seat (in adolescents, may be limited to subjective feelings of restlessness);

(Footnote Continued)

Before any credence can be given to the results of this study, it must be scrutinized through peer review. Reanalysis with a more appropriate statistic may result in significant group differences. Given the analysis reported, however, the conclusions are suspect.

- 2. has difficulty remaining seated when required to do so;
- 3. is easily distracted by extraneous stimuli;
- 4. has difficulty awaiting turn in games or group activity;
- 5. often blurts out answers to questions before they have been completed;
- has difficulty following through on instructions from others (not due to oppositional behavior or failure of comprehension) (e.g., fails to finish chores);
- 7. has difficulty sustaining attention in tasks or play activity;
- 8. often shifts from one uncompleted activity to another;
- 9. has difficulty playing quietly;
- 10. often talks excessively;
- 11. often interrupts or intrudes on others (e.g., butts into other children's games);
- 12. often does not seem to listen to what is being said to him or her;
- 13. often loses things necessary for tasks or activities at school or at home (e.g., toys, pencils, books, assignments);
- 14. often engages in physically dangerous activities without considering possible consequences (not for the purpose of thrill seeking) (e.g., runs into street without looking);
- B. Onset before the age of seven;
- C. Does not meet the criteria for a Pervasive Developmental Disorder.

The DSM-III-R "criteria," which are essentially subjective ratings of an individual's behavior, are relied upon extensively to establish and/or corroborate the diagnosis of ADHD (Edelbrok, 1986). These ratings are usually accomplished through administering scales and tests designed either for the purpose of diagnosing ADHD or for assessing a more general range of The scales and tests are completed by teachers, behaviors. parents, and clinical personnel. The general idea is that each test can establish a standard which measures the behaviors of "normal" children. Deviations from these normalized scores are then used as a gauge for establishing thresholds for "abnormal" behaviors. In short, normal childhood behavior is used as the for a medically diagnosed, essentially social referrent phenomenon.

Even though ADHD is **primarily** associated with children, several researchers have challenged the notion that the symptoms of the disorder attenuate with the arrival of adolescence. Gittelman and Mannuzza (1985) have tested this supposition and discovered that ADHD children retain many of the impulsive, hyperactive, and attention problems that were ascribed to them by their parents during childhood. Hechtman (1985) also provides a review of the adolescent outcomes in ADDH (ADHD) children previously treated with chemical stimulants. Despite stimulant medication in childhood, these young adults had significant emotional and academic problems along with continuing ADHD symptomology. Stimulant medication treatment, alone, would not appear to result in improved prospects for adolescents, since the problems in social and emotional functioning persist.

That ADHD is seldom used to describe or diagnose adult behavior may be due primarily to the absence of a consistent social milieu in which the behaviors are noted as dysfunctional. However, many clinicians believe that dysfunctional behaviors continue into adulthood.

WHAT IS THE PREVALENCE OF ADHD IN THE UNITED STATES?

Several researchers have attempted to answer this question, but no consistent estimate has been forthcoming. Published estimates of prevalence have varied from less than one percent to 20 percent of the population of school-aged children (Rutter, Tizard & Whitemore, 1970; Huessy, Marshall, and Gendron, 1973; Huessy and Gendron, 1970; Huessy, 1967, 1974).

In separate reviews of the literature, nearly a decade apart Bosco and Robbin (1980) and Szatmari, Offord, and Boyle (1989) noted similar inconsistencies in research design which help explain fluctuations in reported estimates.

First, researchers varied in how they defined their study population. While most agreed that hyperactivity and short attention span are necessary, others have also employed symptoms such as low frustration tolerance, irritability, poor peer relationships, and temper tantrums. Further, some require that the child pervasively exhibit hyperactive symptoms while others require it only in a school setting (Landman & McCrindle, 1986).

Second, sampling methods differed from study to study. For example, Lambert, Sandoval, and Sassone (1978) used a two-county area while most of the other researchers used single counties or individual schools as samples, or relied either upon convenience or ad hoc samples. These differences are relevant since the incidence of ADHD could be associated with demographic differences in social ecology.

Third, sources of information differed. Some studies used parents as information sources (Werner, Bierman, French, Simonian, Connor, Smith & Campbell, 1968; Shekim, Kashani, Beck, D. Cantwell, Martin, Rosenberg, & Costello, 1985), others used teachers (Miller, Palkes, & Stewart, 1973; Glow, 1981; Holborrow, Berry, & Elkins, 1984), still others used physicians (Lambert et al., 1978); and some used interviews with children, alone or in some combination (Shekim et al, 1985). These differences are important. For example, Lambert et al.(1978) reported rates which varied eight percent when comparing parent versus teacher reports.

WHAT IS THE DIAGNOSTIC ROUTINE?

Level of "best practice" diagnostic routine

The Council on Child and Adolescent Health of the American Academy of Pediatrics has endorsed the following recommendations for diagnosing ADHD and for prescribing drug therapy.

To establish an accurate diagnosis, information must be obtained on factors such as: (1) the child's birth, developmental, family, medical, psychosocial, and scholastic history; (2) sensory screening; and (3) a physical, neurologic, and neuromaturational examination. Medication should never be used as an isolated treatment. Proper classroom placement, physical education programs, behavior modification, counseling, and provision of structure should be used before a trial of pharmacotherapy is attempted. Once administered, the effects of the drug therapy must be evaluated on a regular basis (Committee on Children with Disabilities - Committee on Drugs, 1987, p. 758).

There is, unfortunately, no verifiable indication of adherence to this "best diagnostic routine" or to any other. Anecdotal evidence indicates that current diagnostic practices are judged by peers to be poor both in diagnostic accuracy and in quality of follow-up.

Jensen, Xenakis, Shervette, Bain, and Davis (1989) report the results of a utilization review process in which the charts of children with a presumptive diagnosis of attention deficit disorder with hyperactivity (ADDH) were examined. The study was conducted at a pediatric clinic and a family practice clinic in two military general hospitals.

Four criteria were deemed as essential to a correct diagnosis for ADDH:

- behavioral evidence of inattention, impulsivity, and hyperactivity;
- o documentation of mental status examination;
- o entry of height and weight; and
- o inclusion of a school or teacher's report.

Eight criteria were used to assess the quality of follow-up care:

- o documentation of an update of the history,
- o update of the mental status examination,

- o ongoing monitoring of height and weight,
- o follow-up of any school intervention,
- o follow-up of any psychotherapeutic intervention,
- o documentation of exact dosages,
- o evidence of appropriate drug holidays, and
- o follow-up visits every four months or less.

The audit revealed that only about one-half of the children treated with stimulant medication met these criteria. A school intervention plan was documented in only 16 percent of the cases (with documented follow-up in only 13 percent of these cases). Psychotherapy was noted for fewer than one in five of the children (with documented follow-up in only seven percent of these cases). A mental status examination update was recorded for only twelve percent of the cases. Height and weight were routinely monitored in only one-third of all the cases. Exact dosages were documented in three-fifths of the cases; follow-up visits within four months were scheduled for only three-quarters of the children.

The small number and special nature of the study sites make it difficult to generalize the findings to other settings. The results were nonetheless germane to the need for improvement in these settings. The authors reported that the two clinics now require double-blind placebo testing before a child is placed on a regimen of stimulant treatment. Further, they have established an ADDH clinic where multidisciplinary evaluations and treatment are provided.

It is usual that parents, teachers, physicians and other clinicians are involved in the diagnosis of ADHD. This being the case, it is significant to public policy that Levine et al. (1982) report that 30 percent of school children in their study were diagnosed as hyperactive when only one source (teacher, parent, or clinician) of information was used. When all three sources were required, only nine percent were diagnosed as hyperactive. Results of this kind are of concern to researchers and clinicians alike. Landman and McCrindle (1986) express fear that reports from one source (e.g., the school) that a child's behavior is not acceptable may cause the child to be placed on methylphenidate or other medication without supporting data from other important sources.

WHAT ARE THE RESPONSES TO RITALIN TREATMENT?

The results of methylphenidate treatment for ADHD were explored by reviewing research dealing with educational, behavioral, and cognitive responses to treatment as well as reviewing methylphenidate's reported side-effects. The topics are addressed as follows.

What is the Educational Development Response to Ritalin Use?

General academic performance (as measured by school grades) during Ritalin treatment was assessed by Famularo and Fenton (1987). Ten children who were diagnosed as ADD-without hyperactivity were treated with Ritalin and their pre-treatment, treatment period, and post-treatment school grades were compared. The authors found a statistically significant improvement in the mean grade point average of the children using Ritalin during the treatment period, followed by a statistically significant decline after Ritalin treatment was discontinued.

ADDH (ADHD) diagnosed children's reading responses have been investigated comparing Ritalin (two levels) and no Ritalin conditions (Ballinger, Varley, & Nolen, 1984). The study involved a double-blind experiment with nine ADDH children, all of whom had reading deficits. The children were divided into groups receiving high dose, low dose, and placebo. Outcome measures for reading ability were assessed using tests of reading comprehension and language processing ability. Ritalin was found to have no discernable effect on the speed or accuracy of oral reading or reading comprehension, while a positive dose-related effect on language processing ability was found.

What is the Behavioral Response to Ritalin?

Behavioral responses to Ritalin in children have been investigated in a variety of studies which examined levels of activity, academic performance, attention, and compliance, among others. (See Dulcan (1985) for a good review of this literature.)

Methodological problems in the literature pointed out nearly fifteen years ago (Barkley, 1976) continue and make it difficult to identify clear or unambiguous predictors of behavioral responses to the drug. Among these problems are the following:

- Definitions of hyperkinesis varied across studies and across time;
- Drug dosage levels and length of treatment were not consistent;
- There were substantial differences in experimental design and levels of control;
- Very different measures have been used for similar constructs; and
- o Definitions of improvement varied widely.

Also notable was the fact that the treatment effect of stimulants for the disorder was initially viewed as "paradoxical" in children with brain anomalies. But, Rapoport, Bushsbaum, Mikkelson (1980)Zahn, Ludlow, Bartko, and Weingartner, that the normal response stimulants in demonstrated to school-aged children includes heightened attention level and decreased non-directed motor behavior (Garfinkel, 1986). In theory, these effects relate to chemical stimulation of processes that mediate behaviors characteristic of ADHD (inattentiveness, aggression, hyperactivity, etc.).

Despite these methodological and conceptual concerns, the following findings are consistent in the literature reviewed:

- o Abikoff and Gittelman (1985a) studied the "normalizing" effect of Ritalin on the classroom behavior of ADDH children. The level and type of motor activity, compliance, and interference behaviors exhibited by ADDH children treated with Ritalin were largely indistinguishable from the behaviors of non-ADDH children. However, ADDH children were different from non-ADDH children relative to measures of attention.
- Gittelman-Klein and Feingold (1983) reported reduced gross motor movements, vocalization, and disruption in a group of hyperactive boys to a level indistinguishable from "normals."
- o Barkley (1988) reported dose-related reductions in off-task behavior and improvement in compliance to requests from adults (especially mothers).
- Barkley, McMurray, Edelbrock, & Robbins (1989) reported dose-related reductions in "hostile and deviant" aggression; Brown, Borden, and Clingerman (1985) indicated that disruptive and anti-socal behaviors responded best to Ritalin in ADDH adolescents.
- Whalen, Henker, Collins, McAulifee, and Vaux (1979) reported that Ritalin did not normalize peer communication.
- Whalen, Collins, Henker, Alkus, Adams, and Stapp (1978) and Leter, Artner and Leter (1979) report improvements in handwriting.

Follow-up studies on adolescents and adults provide no evidence that administration of Ritalin in childhood has long-term effects (Brown et al, 1985; Hechtman, Weiss, & Perlman, 1984; Klee, Garfinkel, & Beauchesne, 1986). Also, during childhood the effectiveness of Ritalin both academically and socially is restricted to the time in which the child is medicated (Brown et al., 1985; Famularo & Fenton, 1987). Ritalin is rapidly converted in the bloodstream to an inactive agent, ritalinc acid (Dulcan, 1985). Thus, even with long-term dosage, it is not reasonable to expect a drug to have continuing effects beyond its presence in the organism.

What is the Cognitive Response to Ritalin?

Current investigations into "normal" cognitive functioning differ widely in terms of theoretical base and methodology and often report inconsistent and inconclusive findings. This literature is sparse with regard to ADHD. Unfortunately, reports of stimulant drug effects on purely cognitive tasks (i.e., those involving reasoning) have been inconsistent and seem to vary both with the drug dosage administered and the nature of the task (Solanto & Wender, 1989).

Improvements in performance on laboratory tasks involving less complex mental functions, however, have been well-documented. Both Ritalin and Dexadrine are reported to enhance performance on highly structured tests of vigilance and reaction time (Rapoport et al., 1980; Sykes, Douglas, & Morgenstern, 1972, 1973; Solanto & Connors, 1982). One study reports a direct linear relationship between Ritalin dosage level and performance on a vigilance task (Charles, Schain & Zelniker, 1981). Evans, Gualitieri, and Amara (1986) report dose-related improvements in storage and retrieval measures on a verbal recall task. Kupietz, Winsberg, Richardson, Maitinsky and Mendell (1987) found similar improvement in short-term memory measures and associative learning tasks in reading-disabled children diagnosed as ADHD following Ritalin administration.

Following these reported findings, Solanto and Wender (1989) explored the effects of Ritalin dosage on a more complex type of cognitive processing, namely divergent thinking.

Tests of divergent thinking are believed to tap the ability to generate multiple "correct" responses within a specified situation. This is opposed to assessments of convergent thinking--such as traditional intelligence tests--which focus on the ability of the respondent to provide a single correct answer.

In the Solanto and Wender study, administration of Ritalin was double-blind with placebo and three dosage levels. ADDH subjects were extensively evaluated prior to the study and matched with controls on age and vocabulary level. Results indicate no difference in overall performance between controls and ADDH children. However, ADDH children's performance did decline on the days they received placebos.

Studies conducted in the classroom setting report another consistent finding--improvements in academic **performance** following Ritalin administration. However, this association does not appear to hold for improvement in academic **achievement**. (Ballinger, Varley, & Nolen, 1984; Barkley & Cunningham (1978); Klee, Garfinkel, & Beauchesne, 1986; Riddle & Rapoport, 1976).

For example, Balinger et al., 1984 reported a significant dose-related impact of Ritalin in the performance of nine ADHD-diagnosed boys on simple language processing tests (letter matching, sentence verification) but no improvement on standardized measures of oral reading or reading comprehension. Although this study was cross-sectional in nature and the subject size was very small, other authors report similar findings using different designs with larger samples. For example, Riddle and Rappoport (1976) reported improved performance with stimulant therapy but no improvement in academic achievement tests in initial measurements and in a 2-year follow-up study of 72 hyperactive boys.

What Are the Side-Effects to Ritalin?

The short-term side effects of Ritalin therapy are those typically associated with stimulant medication and generally subside as tolerance is developed, dosage level is reduced, or the medication is discontinued.

Symptoms **frequently** reported as side effects include: insomnia, loss of appetite, weight loss, irritability, and abdominal pain.

Short-term side effects **occasionally** reported include: dizziness, nausea, euphoria, nightmares, dry mouth, constipation, lethargy, anxiety, increased hearing acuity, fearfulness, and headaches (Dulcan, 1985, 1990; Long, 1985).

Side-effects with more long-term consequences include cardiovascular changes, tics, Tourette's Syndrome, and, in excessive doses or combination with other drugs, psychotic symptoms.

Much is written in the literature on a possible connection between Ritalin and height-growth. However, no firm support for a significant effect has been established.

Cardiovascular Effects

Laboratory studies report inconsistent and inconclusive results regarding cardiovascular effects. For example, Goodman and Gilman (1985) indicated that neither respiration nor blood pressure was significantly affected by the use of Ritalin, while Martin, Sloan and Sapira (1975) found increases in resting heart rate for the first few months. But the rate returned to normal within 5 months of therapy. Ballard, Boileu, Sleator, Massey, and Sprague (1976), however, reported that increased heart rate did not subside over time.

Dulcan (1990) notes that although the magnitude and direction of change in cardiovascular functioning vary among children, the findings of these studies are not clinically significant. Brown and Sexton (1989) reported an unexpected rapid increase in diastolic blood pressure in black adolescents in a study examining only black subjects. They postulate that this group may be at a greater risk for rapid diastolic pressure increase, but the study has yet to be replicated.

Tics

A <u>rare</u> side effect is a condition known as "tics" in which the child experiences involuntary movements or spasmodic repetitive movements. The occurrence of these tics may be brought about or exacerbated by drug therapy. The incidence level is estimated by Denckla, Bemporad, and MacKay (1976) at 1.3 percent of all minimal brain dysfunction diagnosed cases (based upon 20 out of 1,520 of their patients diagnosed with minimal brain dysfunction). The authors report that in most cases tics subside following reduction of dosage or cessation of treatment. In only one case the tics persisted beyond adjustment of the treatment.

Tourette's Syndrome

Also rare but more severe as a possible side-effect is Gilles de la Tourette's Syndrome (Tourette's Syndrome or TS). Tourette's Syndrome is characterized by vocal barking, squalling, echolalia, coprolalia, facial grimacing, head, shoulder, and torso jerks, and tics (Bremnas & Sverd, 1979). Although a number of authors have reported a link between Ritalin and TS, the link is not clearly established.

- Pollack, Cohen and Friedhoff (1977) described a child whose TS symptoms worsened to include vocalizations along with multifocal tics when Ritalin was administered. This child had a family history of TS.
- o Golden (1974; 1977) reported development of TS in children with no such history, and two children continued to have TS symptoms after Ritalin was discontinued.
- o Bremnas et al. (1979) also report a case of persistence of TS after Ritalin was discontinued.
- Recent evidence suggests that stimulant drugs cannot be presumed to cause TS and their effects on tic symptoms are varied, with some patients showing tic amelioration (Sverd, Gadow, & Paolicelli, 1989; Shapiro & Shapiro, 1981; Rapoport, Nee, Mitchell, Polinsky, & Ebert, 1982; Erenberg, Cruse, & Rother, 1985; Comings & Comings, 1987). Comings and Comings (1984; 1987) conjecture that stimulants might even delay the onset of TS, and Price, Leckman, Pauls, Cohen, and Kidd (1986) and Wasserman, Lal, and Gauthier (1983) propose that stimulants might reduce the long-term severity of TS symptoms.

Given these conflicting results, a causal relationship cannot be claimed. Dulcan (1990) suggests, however, that prior to treatment with Ritalin, any suspect movements in the child should be evaluated as well as the child's family history with regard to TS.

The TS literature consists almost exclusively of case studies, and it is likely that more parsimonious explanations for the development of TS may be found in time.

Psychotic symptoms

Reactions such as hallucinations, delusions, mania, stereotyped or compulsive behaviors, and self-biting are extremely rare and usually occur when stimulants are taken concurrently with sympathomimetic drugs such as ephedrine and pseudoephedrine or are taken in excessive doses.

Height Growth

The literature on the effects of stimulants on growth is difficult to interpret because of a lack of uniform methodology and a diversity in findings. The studies share no standardization of dosages, measurement techniques, or controlled study time periods. Some have inadequate baseline measures against which to evaluate growth, and some track subjects receiving multiple psychoactive drugs (Greenhill, 1981).

A number of studies reported a slowing of height growth during the time of treatment and that it is related to dosage size and duration of therapy (Gittelman-Klein, Landa, Mattes, & Klein, 1988; Mattes & Gittelman, 1983; Safer & Allen, 1975). However, the slowing is believed rarely to reach levels which significantly impact on final adult size. Also, a "growth rebound" effect (i.e., a compensatory increase in growth rate) has been evidenced in prepubescent children (Satterfield, Cantwell, Schell, & Blaschke, 1979; Safer et al., 1975). Further, Gittelman-Klein and Mannuzza (1988) and Hechtman, Weiss, and Perleman (1984) report no significant difference in height distributions between controls and adults who had received Ritalin therapy as children.

Given the current state of the literature, even with a relatively large body of literature devoted to the topic, it has not been substantiated that Ritalin significantly affects height-growth.

OTHER THERAPIES

Other treatments for ADHD include behavioral and cognitive therapies, but these options are rarely discussed in the clinical literature unless they are used in tandem with psychostimulant medication. That is, behavioral and/or cognitive therapy as an exclusive treatment for ADHD is unusual. There are a number of reasons why this is so.

Behavior therapies are more expensive and time-consuming (for the clinician, parent, and patient), have high attrition rates, and are more difficult to manage as long-term treatments (Hansen & Cohen, 1984).

There is also disagreement as to the efficacy of non-pharmacological alternatives. The efficacy of cognitive training--a behavior modification technique designed to improve self-regulatory skills--as an adjunct to medication was examined in a double-blind experimental study (Abikoff & Gittelman, 1985b). While these researchers discovered that combining cognitive training with stimulant medication resulted in no discernable improvement in the academic performance or behavior of the children studied, other observers (Hansen & Cohen, 1984) have noted that behavior modification techniques have resulted in improved academic performance, and reduced hyperactivity.

SUMMARY

The principal finding of this review is the lack of uniformity in the conceptualization of ADHD. This lack of conceptual consistency importantly affects subject selection and the consequent generalizability of results.

Throughout the body of literature reviewed, researchers were found to rely on subjective assessments to categorize subjects as "normal" versus ADHD (or ADD, or ADDH). Even the type of rater (i.e., teachers, parents, and/or healthcare workers) varied from study to study, and sometimes within the same study. As a result, it is unsure that the same "type" of child is included in any two of the studies reviewed.

Despite this constraint, several findings are consistent, and these findings center on the use of Ritalin.

- o "Normal" children and ADHD children respond in the same manner to Ritalin, that is, with a reduction in non-directed motor behavior and increased attention level (Rapoport et al., 1980).
- Ritalin helps to reduce interference, off-task, and hostile and deviant behaviors; to increase compliance; and to help improve handwriting (Abikoff & Gittelman, 1985a; Barkley, 1988; Barkley et al., 1989; Gittelman-Klein and Feingold, 1983; Whalen et al., 1978; Leter et al., 1979).
- o Vigilance and reaction time measures improve with Ritalin treatment (Rapoport et al., 1980; Solanto et al., 1982; Sykes et al., 1972, 1973), as do short-term memory measures (Evans et al., 1986; Kupietz et al., 1987).
- With Ritalin therapy academic performance improves but not achievement (see Ballinger et al., 1984; Klee et al., 1986).
- Follow-up studies of those no longer on Ritalin as well as placebo studies indicate that Ritalin is effective only so long as it is in the central nervous system (Dulcan, 1985, 1990).
- Ritalin's side-effects are generally mild and subside with time and/or dosage reduction. The possible exceptions are related to hypertension, tics, Tourette's syndrome, and psychotic reactions when taken with other drugs or in excessively high doses.
- Other treatments--such as behavioral modification and counseling techniques--have been studied primarily as an adjunct to stimulant medication rather than as a replacement; the results with regard to the efficacy of these adjunct therapies are mixed.

 Little or nothing is known concerning follow-up by physicians, teachers or others to evaluate treatment efficacy and/or side-effects. Anecdotal evidence suggests that children are being prescribed Ritalin based on ad hoc judgment and are receiving only brief follow-up services.

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APPENDIX B

CHILD DEVELOPMENT CLINIC SURVEY

AND

LEARNING RESOURCE CENTER'S

SURVEY OF ADVOCACY GROUP PARENTS

CHILD DEVELOPMENT CLINIC SURVEY

Dear Parent:

The General Assembly of Virginia has asked several state agencies to study the issue of methylphenidate (Ritalin) use in Virginia by ADD and ADHD children. We would very much appreciate your participation in this brief survey. Your responses to this survey will be kept completely anonymous and confidential. Please do not write your name on this survey. When you are finished, please send your survey in the included stamped envelope. Thank you for your participation.

- 01. Who first suggested to you that your child may have Attention Deficit Hyperactivity Disorder (or Attention Deficit Disorder or Hyperactivity)? (Please circle your answer)
 - 1. Friend 5. Physician
 - 2. Family Member6. Other health professional3. Teacher(not a physician)4. Other school personnel7. Other (Please specify)
 - 4. Other school personnel 7. Other (Please specify) (not a teacher)

02. Which of the following statements is true for your child?

- 1. My child is currently taking Ritalin
- 2. My child has taken Ritalin before, but is not taking it now
- 3. My child has never taken Ritalin

IF YOUR CHILD HAS NEVER TAKEN RITALIN, PLEASE SKIP THE FOLLOWING QUESTIONS

03. How long has (did) your child taken Ritalin?

1.	less than 1 year	4. 3 to 4 years
2.	1 to 2 years	5. 4 to 5 years
3.	2 to 3 years	6. more than 5 years

04. Has (did) your child's behavior improved while taking Ritalin?

1. Yes 2. No

05. Has (did) your child's school work improved while taking Ritalin?

1. Yes 2. No

A report including the results of this survey will be submitted to the General Assembly. If you have any comments or other remarks concerning your experiences that you would like to have included (anonymously) in the report, please write them below, or attach a separate sheet to this survey.

If you would like to submit any additional remarks that include your name, or would like to request information about the study, please send your remarks or requests in a seperate envelope to the address below.

Department of Health Professions ADHD Task Force 1601 Rolling Hills Drive, Suite 200 Richmond, VA 23229-5005

B-1

RESULTS FROM THE SURVEY OF CHILD DEVELOPMENT CLINIC PARENTS

The following pages provide a view of the survey results. In total, 139 responses were received out of approximately 400 surveys which were sent.

- o The results indicate that teachers, physicians, and other healthcare professionals are the individuals who first suggest to parents that their children have the disorder.
- Approximately two-thirds of the children diagnosed as ADHD are currently taking Ritalin, and eleven percent have taken it previously.
- o Fewer than one-fourth of the children have never taken Ritalin.
- Parents indicated overwhelmingly that Ritalin has been effective in improving the behavior and school work of their children.

The specific results for the survey data collected are listed below and on the following page.

1. Who first suggested to you that your child may have Attention Deficit Hyperactivity Disorder (or Attention Deficit Disorder or Hyperactivity)?

		Frequency	Percent
1.	Friend	5	3.6
2.	Family Member	18	12.9
3.	Teacher	41	29.5
4.	Other School Personnel	10	7.2
5.	Physician	23	16.5
6.	Other Health Professional	27	19.4
7.	Some combination of		
	the above	13	9.4
8.	Other	2	1.4
		139	100.0
		± 0 0	

2.	Which of the following statements is child?	true	for your
	<u> </u>	requenc	y Percent
	 My child is currently taking Ritalin. My child has taken Ritalin 	92	66.2
	before, but is not taking it now. 3. My child has never taken Ritalin.	15 32	10.8 23.0
		139	100.0
3.	How long has (did) you child taken Rita	lin?	
	Fr	equency	Percent
	 less than 1 year 1 to 2 years 	45 31	42.5 29.2
	3. 2 to 3 years	12	11.3
	4. 3 to 4 years 5. 4 to 5 years	10	9.4 5.7
	6. more than 5 years	6 2	1.9
	-	106	100.0
4.	Has (did) your child's behavior improv	ved whi	le taking
	Ritalin?		
		remeno	y Percent
	-		88.5
	Yes No	92 12	11.5
		104	100.0
5.	Has (did) your child's school work	improv	ved while
	taking Ritalin?		
	F	requenc	y Percent
	Yes	97	91.5
	No	9	8.5
		106	100.0
	Comments about Ritalin and other comme	nte re	ceived in

Comments about Ritalin and other comments received in open-ended responses in this survey appear in Appendix C.

LEARNING RESOURCE CENTER'S SURVEY OF ADVOCACY GROUP PARENTS

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THE LEARNING RESOURCE CENTER--PRELIMINARY DATA FROM ADHD SURVEY

1. What type of professional diagnosed your child?

General Practitioner
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 38
 31
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 11< Pediatrician Developmental Pediatrician Neurologist Psychologist Multi-disciplinary Team (includes Educational Diagnostician) Psychiatrist **GP** + **Pediatrician** GP + Psychologist GP + Teacher + Principal Pediatrician + Psychologist Pediatrician + Psychiatrist Pediatrician + Neurologist + Psychologists Pediatrician + Neurologist + Parent Pediatrician + Mother Pediatrician + Clinical Social Worker Pediatrician + Psychologist + Psychiatrist Pediatrician + Psychologist + Dev. Ped. Pediatrician + Neurologist + Psychiatrist, Social Worker Dev. Ped. Teacher Dev. Ped + Dev. Psy. Psychologist + Teacher Psychologist + Neuorlogist + School Board Psychologist + School Eval. Psychologist + Neurologist Psychologist + Neurologist + Teacher + Parent Psychiatrist Psychiatrist + School Report Teacher

Though a multi-disciplinary approach was recommended to Congress in 1987, only 18% of the evaluations included the medical, psychologicial and educational disciplines.

2. How long did the evaluation take?

0-30 minutes	20
30-60 minutes	33
1 - 3 hours	37
3 - 6 hours	70

The evaluations ranged from 0-30 minutes to 2 years.

3. How long was the explanation of the results?

0-15 minutes	28
15-30 minutes	37
30-60 minutes	75
1 - 2 hours	38

4. Is your child on medication? Yes <u>163</u> No <u>11</u> Not now <u>15</u> What type of medication is your child taking

Ritalin Desoxyn Gradument Dexidrine Cylert Desoxyn Litho tabs Lidiomil Tofranil Imipramine Melloral

How is your child's medication dispensed at school? (Who gives the medication to your child at school?)

Clerical Worker	-	27				
Nurse	-	76				
Teacher	-	9				
Many children didn't receive	medic	ine d	during	the	school	day.

Where is the medication kept at school?

Clinic	-	78
Office	-	13

At what age did your child begin medication?

5	yrs	or below	-	16	- most	were 5
6	yrs	- 10 yrs	-	118		
11	yrs	- 12 yrs	-	9		
13	yrs	- 18 yrs	-	6		

5. Did the professional who evaluated your child give you a written report you could take to school or other situations to help explain your child's problems or obtain services?

Yes 99 No 84

Written reports were not provided by 46% of the professionals conducting ADHD evaluations.

6. Would the professional who did the evaluation go to school to help you obtain services or accommodations for your child?

Yes 74 No 69

Parents reported that 47% of the professionals conducting ADHD evaluations would not go to the school to help obtain services.

Did you give the report to the school? Yes 95 No

When reports were obtained, 97% of the parents gave the report to the school.

7. Did your assessment provide sufficient information so the school would have information about the child's learning and behavior so intervention planning would have clear guidelines? Yes 107 No 27

Eighty percent of the parents felt that their assessments provided adequate information.

APPENDIX C

PUBLIC COMMENTS

The comments which follow are drawn from write-in responses in a survey of Child Development Clinic parents of ADHD diagnosed children and include written statements filed in response to an invitation for public comment. The latter statements are reprinted intact.

The comments are included to provide evidence of the range of opinions and concerns surrounding ADHD and its treatment.

(The responses, by their nature, cannot be considered to represent public or professional opinions.) I have heard people complain about giving Ritalin to kids, but my son couldn't be controlled in school without the Ritalin. His schoolwork has improved a great deal since, starting the Ritalin several years ago.

I would rather that schools teach kids without medication, but I find that schools are only willing to teach children that are "well behaved." There seems to be no tolerance for active children.

We tried psychiatrists, Feingold diet modification--nothing worked. The Arlington system tested our son and found the ADDH possibility. After all else failed, we tried Ritalin. It has been great. He's on a low dosage--school work and social development improved dramatically.

Ritalin is too readily dispensed. It did more harm than good for my child. It may work for some, but it didn't work for mine.

I was ambivalent about giving Ritalin to my son. I took him off the medication for a week to see if the teacher could discern a difference in his behavior. His attention in class was much shorter. Helping with homework was also a chore.

I must state that I was somewhat surprised and disappointed by the evaluation that he received from the developmental pediatrician. He wrote a few things on paper for this pediatrician and answered a few questions. However, a neurological examination looking for soft signs was not done. Medical therapy with Ritalin was immediately recommended.

One final note:

I had to be aggressive with teacher and principal to have my son evaluated. My son's teacher kept emphasizing that he was making B's and C's and was therefore okay. She stated that I wanted him to be a "little scholar" like my two other sons. I reminded her that I was not looking at grades but at my son's difficulty in remembering concepts previously taught and at his inability to stay on task. Once starting on Ritalin he was able to complete assignments; his attention was longer. An average student made the "Honor Roll" after taking medication for 3 months.

I believe too many doctors prescribe this drug too freely. I had my child checked by eight different doctors before I would give this to him. It helps, but it does cause my child to have mood swings coming off of the drug. With so many children being diagnosed with this I would like to see a study done about a long term outcome of use of the drug and also a study of the cause of the problem.

Ritalin is a good drug for ADHD children, but its dose takes a long time to work, and children who take it should know its dose takes time and patience, too.

It makes him sick to his stomach. If given before breakfast or at lunch, he will not eat his meals.

He has learned to control himself in school. I think it really has helped him.

His behavior hasn't improved. He gets into trouble alot. Sometimes he can be real good. His schoolwork has improved alot.

My son's schoolwork & attention span has improved greatly with Ritalin. He now makes the honor role. Before the Ritalin he had failing grades.

After using Ritalin for one year, we used a generic methylphenidate for one month with nearly disastrous results - the generic was very ineffective. We use Ritalin only on school days, not in off days or summer days out of school with no problems.

My son failed second grade. He then began taking Ritalin. He is now in the second six weeks of 3rd grade. He is now an A-B student. 86 was his lowest grade.

I have a Ph.D. in pharmacology and am employed in the field of neuropsychopharmacology; therefore, I believe that I am more gualified than most parents to speak on the use of methylphenidate. I remain unconvinced that methylphenidate is truly effective in the therapy of ADD, due to the paucity of good, well-controlled clinical studies. Even if methylphenidate proves to be an effective drug for the therapy of ADD or ADHD, one must remember that it is also a dangerous drug which is capable of producing deleterious mental and physiological side effects. It may be damaging to a child's self esteem to do poorly in school. However, it is possible to educate a child with ADD without the use of medication--it is just more labor intensive. I believe that many children are being needlessly medicated with methylphenidate, quite possibly on the advice of unqualified teachers and physicians, simply because it is an inexpensive, convenient approach to the problem, with no concern being given to the child's welfare. My son has mild ADHD and does not require special treatment. However, if we were forced to medicate him, I would choose to educate him at home, rather than be forced to administer a drug which I believe to have more disadvantages than advantages.

It is clear that Ritalin is a control medication and has been a great benefit to our son. he has just begun Ritalin 3 months ago and we are slowly finding appropriate Ritalin doses. He only takes in the morning and in the evening his impulses and lack of control are very pronounced.

I say control medication, as unfortunately Ritalin is not a cure. For our son to be helped to control his impulses allows him greater concentration so that he may accomplish tasks at school and feel better about himself. At first he resented taking the Ritalin but now is glad to take it and feels it is truly helping his ADD. We are all grateful.

My son's teacher worked hard to convince me to try Ritalin. I did. Ritalin guickly induced Tourette's syndrome in my son. I would never recommend Ritalin for anyone. My son will never stop having TS, thanks to Ritalin.

Without this medication my son is uncontrollable. He was also making D's and F's in most subjects. He is now making A's & B's. This has been a great help for my son. I believe some children really need Ritalin.

I have two children who are ADHD, one male (oldest)(7), female (5) (never taken Ritalin). Both have high I.Q.'s over 115 and the schools don't offer classes for these children. Help!

I was very pleased that the doctor didn't encourage drug use with my son immediately. We watched him and especially since he is doing well with his teacher this year, he will not be using Ritalin for now.

From experiences with our son there is a definite need to include special educational programs for these children. My son is in a classroom with over 25 other children. His teacher has even told me he would benefit from a smaller class and more one-on-one instructional work. I believe this is true. I also have a son with a learning disability but he had the advantage of LD services. Unfortunately, ADD and ADHD children do not. These kids could be just as good in doing their work as their peers. Why are there programs for gifted children and the children who are LD, when these kids with ADD and ADHD are left in the cracks as I say? Thanks for your interest in these children. I hope to see more done for them before its too late.

He has some problems when the Ritalin wears off. He gets very emotional.

My son started out taking 20 mg. the first year. The second year increased to 30 mg. But this year 1990 he seems to do better dropping back to 5 mg a day.

When he was on Ritalin through school days he lost weight, when summer came he was taken off of it he gained back alot.

We are combining the use of Ritalin with efforts to organize more efficiently and efforts to improve study habits.

The Health Department where I took my child did not help me. They were more concerned with the importance of not giving my son Ritalin. He's very hyper and his attention span is very short. I did not appreciate them saying that I needed to see a therapist before they could help my child. A therapist for me is not helping my child.

For several years I received complaints of my child's behavior. Finally we received the blessing of Ritalin. It helps tremendously.

Our son has benefited by taking Ritalin. He is not physically hyperactive--he is unable to attend. For him, Ritalin has made his life almost normal.

Under appropriate supervision and doctors care I believe Ritalin is an important alternative for ADD and ADHD children.

If my children needed penicillin they would receive it till they showed an allergic reaction. Thus they need Ritalin. Our son has benefited by taking Ritalin. He is not physically hyperactive--he is unable to attend. For him, Ritalin has made his life almost normal.

That 30 day supply rule is totally stupid and very expensive for struggling young families.

My child took Ritalin only during a one month double-blind trial. The results of which were mixed. We may decide to try the drug again this year.

My daughter was bringing home school work with 20's, 30's. and 60's. My husband and I became worried. We talked with the pediatrician and he put her back on Ritalin 5 mg. twice a day. Now she makes almost straight 100's. Sometimes 98. The teacher brags on her all the time - now! We didn't like having to put her on Ritalin but we couldn't afford to let her fail either.

My husband and I feel that Ritalin has helped our son tremendously. He is much better at handling the pressures at school with this medication. He was tested thoroughly at MCV and was found to have moderate to severe ADHD.

I have 2 boys, age 10 and 12 1/2 who are on Ritalin. We could not be more pleased with the results. The boys were totally different in their study/learning habits: one was easily distracted and on the move; the other was "daydreaming" and quiet (the polite, well behaved student). With medications their attention spans and focusing abilities have greatly improved. The results have been improved grades, interest in school and self esteem.

I was exposed to a co-worker who referred negatively to "Ritalin" as being given in their school to unruly children as a "think" medicine, before children were diagnosed. I tried to read as much literature and ask questions on the pros and cons (i.e., weight loss, lack of appetite) as I could. My children have shown positive results.

I hope the General Assembly can be made aware of the benefits, to each child and society as a whole, that Ritalin can help produce-along with correct diagnosis, medication, school, and parental involvement. Otherwise these bright children will continue to become very frustrated as they continue to fail because their attention span will not allow them to focus and concentrate on the task before them. Each child's success or failure in school can help create the best or worst in society throughout their lifetime. I know he had a learning disorder. The doctor just said he did.

Any help you can get to the school system to get them to recognize this (ADD) as a handicap and a learning disability and provide help for these children would be appreciated.

Ritalin has really been a life saver for my child. They were going to kick him out of school before he started taking it. He went from D and F to A and B level in school.

I think there is a great need to educate teachers about ADD.

His behavior hasn't improved. He gets into trouble alot. Sometimes he can be real good. His schoolwork has improved alot.

Because my child was in first grade at the time it was very hard for the school to believe she had a problem. It was only after months of testing at MCV with a very competent doctor that the school would believe she had serious problems. The doctor she saw at MCV said if she had not been tested when she was it might have been too late. He said schools don't believe in testing for problems until earliest 3rd and 4th grade. Unfortunately this is true, they convinced themselves my child only wanted attention by being disruptive or confused. I'm glad I pursued this and precious time was not lost. It's amazing the difference in just a few months. Parents should fight their school system and follow their heart, we each know our child best.

In my case the school principle insisted my son was a disciplinary problem and would not ok the testing being done in the county where we live. His teacher and family physician arranged testing 60 miles away.

My son is a happy, bright little boy now that he takes Ritalin. Before, times were very difficult to deal with him and he was not happy with himself.

I would just like to say that Ritalin has helped my son enormously in school. He is able to sit still and focus his attention now where in the past he has not been able to. I think the school system should have better educational services for these children. My son needs extra help because of his ADHD, but is too smart for Special Ed. so there is nothing available to him and teachers don't understand.

We can see a marked difference behavior and attitude-wise when our son is taking Ritalin. He has gained some weight which we don't think is related to the medication.

I wish the school system had not waited so long to provide services. My child was evaluated at a private facility. I pay the cost because we don't want to wait. Research and my personal experience indicates the longer you wait the student will lose self confidence, increase low confidence, etc.

Impulsiveness & attention span are more of a problem than hyperactivity with our child. He only took it for 2 months. However, he has made many of his own modifications, is in private school & doing nicely without medication.

Taking Ritalin has done wonders for our child. His school work, attitude and behavior improve when he takes it. This does so much for his improved self-concept.

Teachers should have classes about this disorder. Many teachers think children that have this disorder are just being mean or bad. Therefore, they make the child sit in the hall for long periods at a time. They don't understand!

My child is highly intelligent yet was marked as behavioral problem in grades K - 2. Since diagnosed as ADD, she loves school, has friends and made honor roll this quarter. I only wish those first 3 very important school years were not lost to her. It took some time for her to put that behind her and to begin striving forward.

I have two children who are ADHD, one male (oldest)(7), female (5) (never taken Ritalin). Both have high I.Q.'s over 115 and the schools don't offer classes for these children. <u>Help</u>!

The dramatic difference in my child's ability to sit in class, refrain from disrupting other children, and his

enhanced self-esteem have been very positive benefits from treatment with Ritalin.

Any help you can get to the school system to get them to recognize this (ADD) as a handicap and a learning disability and provide help for these children would be appreciated.

My child is <u>hypoactive</u> ADD. Ritalin improves his concentration and results in a noticeable improvement in schoolwork.

I feel that there needs to be information re: ADD passed on to educators (teachers) so they understand these children and their needs.

My child has ADD but is not hyperactive. There is a very noticeable improvement in the child's ability to concentrate while on Ritalin.

I was very apprehensive about putting my child on Ritalin. But, it turns out it was very successful for my son.

This child had been on Cylert for over 4 yrs. Ritalin has done more for him than the Cylert. He has been on Ritalin for for 9 months.

To the General Assembly of Virginia,

Two of our three children are on Ritalin. The youngest may have to be tested for A.D.H.D. by the time he starts school.

I read or watch anything concerning Ritalin. Right now it's 50-50 to our family.

Yes, it does help our children with their behavior, school, etc. For now it's fine. But what the future brings God knows. Fifty percent of what I hear after long term use of this drug scares the hell out of me!! But what can I do? I'm stuck between a rock and a hard

But what can I do? I'm stuck between a rock and a hard place. Without this drug my children couldn't cope because one is so hyper, the other is so aggressive. Neither can sit still, or concentrate, maintain what they learn, etc.

Plain and simple, I'm stuck with trying to do what's best for their welfare, but I may be destroying them also.

Our daughter is presently being tested for ADD/LD problems. Also she has been found to have cafe au lait spots, indicative of possible neurofibromas that can affect learning.

The effects of Ritalin made my child worse than before taking it. He was nervous, talking to objects, making weird faces and also very hyperactive.

I feel Ritalin has done wonders for my child. Without the medicine, he is very unruly and very hard to deal with. With the medicine, he acts normal, which is pleasant to be around.

I took my son off the medicine. My reason was the withdrawl that they go through when getting off Ritalin, and I feel like he's just a child, so I say let him enjoy. I can stand the pressure.

It has been suggested that my daughter take Ritalin during the school year. Although we decided to wait and see how her new teacher this school term could handle her. We are now currently waiting for an appointment to get this medication.

My child responded well to Ritalin, but was allergic to it.

Henrico School Board currently has no vehicle in place to help parents of ADHD kids unless the child qualifies as physically or emotionally handicapped or has a demonstrated learning disability. Claim is made by the Board that the learning of social skills is an important part of the "school experience," yet unless a child with ADHD, who has great difficulty with social skills, demonstrates an academic handicap, there is no help for him.

Each child has to be treated on an individual basis. Two of my children have been on Ritalin. One with very good results, the other not much help at all. She is in Special Education now without Ritalin. So far she is doing fine.

My child is using Ritalin now as a result of a thorough health, mental, and educational evaluation. We have had no problems with its use.

DIRECTORS SEP 1 2 1990



DEPARTMENT OF NEUROLOGY

F.E. DREIFUSS, M.B., F.R.C.P., F.R.A.C.P. PROFESSOR NEUROLOGIST - CHILD NEUROLOGIST September 11, 1990

George J. Stukenborg, Research Associate Department of Health Professions 1601 Rolling Hills Drive Richmond, VA 23229

Re: Methylphenidate (Ritalin) in the treatment of Attention Deficit Disorder

Dear Mr. Stukenborg:

Over the past decade it has become common or standard practice to administer stimulant medications to children with attention deficit disorders. The most commonly used drug is Methylphenidate.

I would like to provide a word of caution. It is easy to over treat with stimulant medications and it has become almost a reflex act to prescribe stimulant medications to children with this condition on the part of many physicians. This is not only ill advised and in many cases unnecessary but it has taken the place of more time consuming but less potentially hazardous treatments such as behavior modification therapy. There is some evidence that Methylphenidate among other things may precipitate the appearance of Tourette's Syndrome.

While I do believe that there is a place in selected cases for the use of Methylphenidate, this drug is considerably overused. It is frequently requested by school teachers who find children with ADD difficult to handle in the classroom as a "quick fix" solution and these requests are too often complied with in the vein of "anything for a quiet life".

With kind regards,

Sincere vours F.E. Dreifuss, M.D.

FED: dmp

SCHOOL OF MEDICINE BOX 394 CHARLOTTESVILLE, VIRGINIA 22908 804-924-5669 To: Members of the Task Force on ADHD/Methylphenidate

My name is Loretta Clement and I am a parent of a child who has been diagnosed as having an attention-deficit, hyperactivity disorder (ADHD). My daughter's disorder became more apparent when she started first grade last year.

She experienced difficulty remaining in her seat in the classroom; difficulty sustaining attention to tasks, no matter how short and simple they were; and she was easily distracted by classmates. My daughter's emotions were very intense whether she was happy or sad and she often moved to the extremes of her emotions. She became overexcited and drew attention to herself in a sometimes negative way.

My daughter's symptoms are problematic as a result of the frequency and intensity of the behaviors displayed. Behaviors such as, running rather than walking, talking excessively, climbing on sometimes dangerous things without consideration of the consequences, and inability to wait for her turn, usually caused problems and frustrations for my child in almost every situation.

By the middle of the school year, and after many meetings with my daughter's teacher, I decided something must be done. At one of the many parent-teacher conferences, my daughter's teacher recommended that I have her tested and evaluated for an attention-deficit disorder. I was apprehensive at first, however, I was more concerned with the ongoing problems and frustrations experienced daily by my daughter.

After extensive consultation with my daughter's physician, a referral was provided for testing and evaluation. When the testing and evaluation were completed, the report was forwarded to my daughter's physician. My daughter's physician and I discussed medication and we agreed to try Ritalin on a trial basis. While taking Ritalin, my daughter was monitored at home and in the school to determine the effects of the drug. In addition to drug therapy, positive behavior modification techniques were also utilized to improve my daughter's self-esteem, social skills and the development of self-monitoring of negative behaviors.

I am pleased and delighted to announce tonight that my daughter has passed into the second grade; appreciates a high success rate on tasks assigned in the classroom; and has become more organized as a result of the drug therapy.

The positive effects of this stimulant drug, including reduction of activity levels, improvement of fine motor skills and attention outweighed the disadvantages associated with no drug therapy at all.

The only adverse side-effect my daughter experienced as a result of taking Ritalin was difficulty in getting to sleep at night. In my daughter's case, close monitoring of the drug dosage minimized the side-effects associated with the use of Ritalin.

The use of Ritalin is only one treatment modality of ADHD. Other treatment modalities are available to assist in dealing with the problems and frustrations experienced daily by children of ADHD. As a parent of an ADHD child, I was inspired to learn as much as possible about ADHD and to share that information with teachers, scout leaders, family members, other parents and interested individuals.

Because my daughter was fortunate to have had a teacher who really cared and took an interest, I was able to overcome some of the obstacles and frustrations related to ADHD. My child and other children are at risk, as there is no identifying label for an ADHD child as there is for a mentally retarded child or a child who is autistic. The lack of recognition for these at risk children make it difficult to identify their needs.

I am confident that the Task Force will make recommendations in these areas:

o thorough assessments of the child be conducted;

- o close monitoring of the drug dosage;
- close and consistent communication among the parent,
 physician and school personnel;
- treatment to include the combination of drug therapy and behavior modification techniques.

I would like other parents to have the positive experience that I had in helping my child cope with the disorder.

I challenge Virginia's educational system to take the lead in preparing teachers for the ability to understand this disorder. I appreciate this opportunity to express my views and personal experience as a parent of a child with ADHD. THANK YOU.

mo Loretta H. Clemen

Ms. Loretta H. Clement 1908 Beaver Road Highland Springs, VA 23075 (w) 786-3988

Public Hearing Dupt. of Education Dr. Pat White Duar Sin En 2000 May husband and I would like - him. The to upperd an concern about the use of "Ritalin medication" leing used in our schools in Viliginia. I would also like to tell your the stars abant our son who in now light years old-"Two years ago, when he started school pept on chindering us about the indication. She kept isaying that du you wanten't isit still, to his work " even lister to the teacher. W.2 ad meeting with her. She might have give un knowledge aback the medication leut, we didn't ipoit. I went to my pediatricion and los was against giving the medication. ut he said, we could try it for auhile und if it wacks the would stay on it

2) husband and I were against the medication. Well, I grade lame along, and he started complaining of childred and stanad ades. The only effects it the time the Pldiatrician said, was loss of appetite, I finally, took chim to the pediatrician for a thorough examiiation. and he couldn't find out anythin. We were really getting warried. It was almost every day he would complain af a hladade. Someon told one about a neurologies. So we decided to take this for a complete that - up. To our suprise, the neurologist found something. He said, if we that waited any longer than we did. He would loose lys sight in bath eyer for good or have a leain tumod. He immediately put him in the hospital for complete tests given such as a lerain wave, lerain sean, and a spinal tale was also given. An al il and ain and a she at the

3) time. after the spinal tab the neudint, said, that our son was one out up a 1, Dod that had the effect. He relieve the pressure by the spinal tap. The pressure was coming from his left lyee goin ung its his head. We were iso stand, not knowing what was going to happen to him. We immediately, manodton our child with no medication given whatsone. The school didn't like it. after we told the school attration In it duant anymore imore implication. we had to take him to a psychologist. e gave a serier of tests and a IQ test. He said, has I quo about average and he ad some leaving disablitien. So man he is un a illaming disabilities clou at schoolo at this iteme & called The bood and Dung Edministration to try to get them to Bar the medication, they wouldn't Roit. They iscid, it would have to be "non than one core and usid, they were - ony unhat had chappaned to ing son. I was wally upset and iwanted something done about it then.

I am wenting to you in you response of your newsletter "HAAD Sept. To answer some of your question, 'we feel they should do away the Ritalin medication . Some parents doesn't know how it can harm you child. 2 It shouldn't be give in schooles, Because, some teaching and pringado would want them to have at just to relieve some of the teacher pressure from day to day. (3) There is effect from Pitalin " 4) Then should be any lady identif ication and research befor any type of medication is give. and and be dalla. (5) If you want to protect the health and well-bein of such young Children in our schools. Then it should be against the law for a stacked or principal to have such medication in the ischald. Please, please, please, do isomethin about it. Before it leans to me - TT-

? Child. Dew son is now 8 yrs. old. He is doing dietter. This happened the year 1987 - 1988. I istill blance our school for what. they did. I cknow its grobably too late to do somethis about it in one - But, maybe this would are help another Child but There somewhen. Thank- you for listening to car. We just had to write to you about our roncen about the Pitaline indication.

Sinchely your, Mus. Tures a Timberry

P.S. We are unable to attend the meeting. So this is why I am uniter, to you.

I am Celia McNay, co-founder and West End Director of HADDA, a parent support and education group for parents of ADHD children. We are local to Richmond City, Hanover County, Henrico County, and Goochland County. We have approximately 325 individuals and organizations on our mailing list from Virginia and neighboring states. I am also a parent of six children. two of whom are diagnosed with ADHD. They both have been or are presently are using Ritalin.

As a public group we support the use of medications. including Ritalin as an important part of a multi-faceted approach of treatment: including behavior management. counseling and support, and educational accommoations. We strongly urge that Ritalin not be used as a sole or primary diagnostic tool. Diagnosis must come from a multi-disciplinary evaluation. The use of medication should be only one of several factors in establishing an accurate diagnosis of ADHD. Every effort should be made to eliminate the negative stigma Ritalin carries so parents and other professionals will use this medication as an intrinsic part of the total treatment plan.

We as a group, and I personally have witnessed the effectiveness of Ritalin for treatment of ADHD. Me son. now 12 years old. was failing second grade. School testing determined he had a "bad attitude" and implied that I had better fix him. Through private evaluation, he was accurately labeled as ADHD and treatment was started in all areas previously mentioned. He began taking a minimal dosage of Ritalin. With his dramatic improvement in attention skills, self-control, fine motor skills, and hyperactivity, he was on the Honor Roll during the very next six week grading period. Now as a seventh grader, he is in the Gifted and Talented program, the Learning Disabled program, maintains an A-B average and is a Boy Scout. You can see that with medication. proper placement in schools. support, counseling, and training at home, young people with this disorder can achieve their unique potential. Withdraw medication and an important part of the foundation of success is missing. Thank you.

Dear Mr. Stukenborg,

This letter is in reference to the public hearing scheduled for September 12, on ADHD. I was not able to attend but would like to respond to the issue.

I will express my views as both an educator and more importantly as a parent of a child with ADHD. I am certified as a school psychologist, regular elementary teacher and teacher of the Mentally Handicapped grades 1 - 12. I have 5 years of teaching experience and this is my fourth year as the Administrator of Special Education. Despite my skills and certainly training and/or qualifications to be a " parent " I still had difficulty patenting my special child. Having my child diagnosed as ADHD and properly medicated with Ritalin is the very best thing that I could have done for my child. The schools may have a wealth of methods, modifications, and concessions useful with these children but for any child with moderate to severe symptoms none of these can begin to alter the emotional state of these children whose mood swings can make or break any attempts schools can make. As our elementary guidance said, without proper medical treatment these children will "die" without medication just like the child with diabetes or heart disease but the death is slower and can be more painful because it consists of knowing teachers do not like them and were always correcting them for the unacceptable things they do, in turn peers start to not like them because the teachers do not. The child's family tries to tolerate them but they disrupt the parents' marriage and constantly harass their siblings, doing all these things without wanting to and yet not being able to stop misbehaving or understand why they did them.

The problem many parents and the children face is the lack of trained school personnel. They have these children often more than the parents. There also are a number of untrained medical professionals who do not know how to identify or treat these children medically. The medication gets a wealth of bad press but not enough good press to help parents make a valid judgement of its many positive benefits. There is also no recourse for schools when children do extremely well when properly medicated and the parents out of fear or ignorance stop buying it. Without drugs such as Ritalin these children have no hope regardless of what any school can do because there is much more to life than just getting an education. Think of what happens to these children when they are not in school, since ADHD is a medical condition that lasts 24 hours a day.

Thank you for this opportunity to respond. My fear is that Ritalin could be taken off the market and I do not know what would happen to my child. I thank God that it is available.

Sincerely,

Cathy E. Davis Buena Vista City Schools

HADDA 9321 Coleson Road Glen Allen. VA 23060 Sept. 26,1990

George J. Stukenborg Department of Health Professions 1601 Rolling Hills Dr.. Suite 200 Richmond, VA 23229-5005

Dear Mr. Stukenborg,

Enclosed is the text of my testimony given at the public hearing on Ritalin, Sept. 12. 1990. I am grateful to have the opportunity to express my views and represent our parents support group, HADDA.

Flease forward to me a copy of the final draft and recommendations prepared for the General Assembly by the Task Force Study. Send it to the address above. Thank you very much.

Sincerely,

Celia Money

Celia McNay West End Director, HADDA

DIRECTORS DCT 0 1 1990

13109 Morning Hill Lane Midlothian, Virginia 23112 September 28, 1990

Mr. George J. Stukenborg Research Associate Virginia Department of Health Professions 1601 Rolling Hills Drive Richmond, Virginia 23229-5005

Re: <u>Treatment of Children with Attention Deficit Hyperactivity Disorder (ADD or</u> <u>ADHD) with Methylphenidate (Ritalin)</u>

Dear Mr. Stukenborg:

In response to a public hearing announcement, dated September 12, 1990 regarding the treatment of children with ADD or ADHD, I wish to submit this as my personal comments.

Personal Testimony

I am a mother of an 8-year-old child diagnosed as having ADD by the school psychologist. The request for psychological testing was initiated by me and supported by my child's second grade teacher. While testing was requested during the third month (November) of the school year, final analysis by the school psychologist did not occurred until the fifth month (January). Parents-teacher-psychologist conferences began soon after that.

The school psychologist's description of my child was that he was extremely bright (bordering on being "gifted"), very articulate, high-level reading skills, high analytical skills, and had marginal ADD with little or no hyperactivity. A behavior modification program was put in place by the school with full cooperation of the parents. The result of this program was only moderate. With special, added attention by the teacher in the classroom, my child was able to achieve E's and S's (grades that were equivalent to A's and B's). In prior years when his ailment had not been diagnosed, his academic performance was noted with only average grades (equivalent to C's).

Towards the end of that school year, it was strongly recommended by my child's school teacher and the school psychologist to have the child medicated with Ritalin. It was felt that Ritalin might be needed in order for my child to perform successfully in an "upper level" math class (called "CSMP") the following year.

As I also have a 9-year-old child who had previously qualified for this "upper level" math class and as I have a B.S. in mathematics myself, I am fully in tune with the mathematical and analytical skills that are to be developed in that class. I could not then and cannot now understand why my child needs to be placed on Ritalin in order to attend that class. Having expressed this to the second grade teacher, I discovered that she ultimately recommended my child for the CSMP class the following year (third grade).

Again, upon consulting my child's pediatrician this last summer, I was advised that Ritalin was not recommended for him as the first alternative. As a matter of fact, the pediatrician told me that the best thing I could do for my child was to "get him a tutor".

Now that the current school year is in full swing, I find myself in a position where the third grade teacher is having problems with my child "staying on task". I have already had two conferences with her, and I must say that I am thoroughly pleased to find that she recognized a potential problem so early in the school year. She also informs me that hyperactivity is not presently a problem but that short attention span is. She, herself, can see my child's intellectual and academic potential but finds herself repeatedly instructing him on what and when to do classroom activities. Meanwhile, my child, with the exception of one D grade, is bringing home A's on his papers. Although I have specifically asked whether my child is in the CSMP program or not, I have only been told that all third grade classes are presently self-contained and that he will be given CSMP instruction later during the year.

At this point in time, I am extremely confused as to what to do. On the one hand, the teacher is telling me of her classroom problems with my child and inferring Ritalin as a solution, while the pediatrician is saying Ritalin is not currently a good alternative. My main concern at this time is that if this teacher does not continue to repeat instructions to my child, he may not academically perform well, due to his short memory retention problem. However, if the teacher does continue to repeat instructions to him, she feels that it is "unfair" to the other class members. I cannot say that this is an unfair view on her part.

In all fairness to the school, however, I cannot at this time do anything but praise both of my child's teachers. They have performed in an outstanding manner in being concerned with not only my child's academic growth but with his overall growth.

My main concern is that there appears to be little information/education/ training/guidelines available to teachers and parents concerning ADD without hyperactivity. Please be aware that this is different from ADHD and is even different from ADD with hyperactivity. My child is neither hyperactive nor a discipline problem. He is extremely bright but, with such a high IQ, falls into a 2 percentile of all children having ADD. Is he going to fall through the cracks of the existing educational system?

The Honorable Robert Tata wonders if the "schools are using Ritalin as a means of controlling classroom behavior". In my case, I must say that I am feeling somewhat

Mr. George J. Stukenborg September 28, 1990 Page 3

"blackmailed" into using Ritalin in order for my child to be given the educational opportunities to excel. With or without Ritalin, however, I do recognize that my child cannot achieve ultimate academic success without the full support of the principal, teachers, and school support staff. With my existing perception of the school regarding the use of Ritalin with my child, what chance do I have of getting support if I don't put my child on Ritalin?

One of panel members attending the public hearing on September 12 asked Dr. Lillian C. Lindemann, a renown pediatrician and psychiatrist in her own right, whether or not children on Ritalin qualified for LD classes. She did not make a definitive statement one way or another but said that it should be evaluated on an individual basis. If my child was to be "automatically" placed into an LD program because of his ADD ailment, he would almost immediately become a discipline problem - not because of physically being placed in such a program but because of a lack of progressive mental stimulation.

I want my child to be educated in such a manner as he will be able to attain his highest academic potential. I do not want him taken out of the mainstream of students and labeled by his peers as being "one of those students". I feel that in this instance, we should be able to educate without medicating.

Please forward any information/findings/recommendations that this task force may have concerning children with ADD without hyperactivity.

Announcement of Public Hearing

My second primary concern with regards to this task force is the manner in which this public hearing was announced. The chair began this hearing by saying he apologized for not formally publicizing the hearing, but that due to budget cuts, funds are not available to publish this hearing in the newspapers. Please be aware that most newspapers in the Commonwealth of Virginia, as well as most television and radio stations will announce public hearing without cost. Most of these medias consider it their public obligation to do so. I personally learned of this hearing through an acquaintance who works for one of the State agencies represented on the task force. If you will recall, all but one of the speakers offering testimonies during this hearing were employed by one of the State agencies represented on this task force. Not only that, but all but one speaker offered testimony for the use of Ritalin. Delegate Tata even jokingly asked one speaker if she worked for the manufacturer of Ritalin.

I really don't think that this task force will be able to get random, unbiased testimony from parents unless parents know that this task force exists and that its mission is to comment on HJR 146. If this is a true State legislative study, then why are funds not available to publicize these hearings? Why have such a study if funds are not available to obtain true opinions from the good people of the Commonwealth?

Mr. George J. Stukenborg September 28, 1990 Page 4

I will state that I was pleased to find that this public hearing was held at 6:00 p.m., thus affording working parents the opportunity to attend. I wonder if the "public hearing" held at 11:00 a.m. the following day at Innsbrook was well attended, whether it was publicized any differently from the one that met on September 12, and what the turnout was. Are you also holding "public hearings" outside of Richmond? After all, the proposal, if passed, will be applicable throughout the State.

Other Questions/Comments

Why is the educational system getting involved in the medication of school-aged children? Shouldn't they just be addressing the issue of how to educate children with ADD or ADHD versus whether or not they are on any medication?

In what way is the Commonwealth of Virginia considering recommending the reclassification of methylphenidate? Shouldn't the testing of this drug be performed nationally and conducted by the U.S. Food and Drug Administration?

What are the long-term effects of methylphenidate? Dr. Lindemann stated during the hearing that it was initially prescribed in the early 1930's. How has that drug affected the brains of those now adults? I dare say that no formal study has yet been publicized.

In summary, I thank you for allowing me to state my feelings on this issue and for your consideration. I look forward to hearing from you.

Sincerely,

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/mwm

 cc: Joseph A. Spagnolo, Superintendent of Public Instruction, Department of Education Bernard L. Henderson, Jr., Director, Department of Health Professions King E. Davis, Commissioner, Department of Mental Health, Mental Retardation and Substance Abuse Services Patricia A. White, Department of Education Gary F. MacBeth, Department of Mental Health, Mental Retardation and Substance Abuse Services Richard D. Morrison, Department of Health Professions The Honorable Robert Tata, House of Delegates November 26, 1990

Richard Morrison Executive Director Department of Health Professions 1601 Rolling Hills Drive Richmond, Virginia 23229

Dear Mr. Morrison,

Through the years since my child was diagnosed as ADD I have learned a lot about the system, what it can, will, or will not do. Since 1979 I have fought to receive an appropriate education for this child only to have the school system fail in its effort to do this. Not only has the school system failed, but so has all the other areas of health and social services that could have assisted the school system if only the school system would ask, and all the different groups would get together to preform what is needed for the child and not look at where the money is coming from, who is responsible for paying, and are we setting a precedence that will cost us more in the future.

Methylphenidate (RITALIN) was the medication of choice for my child who after a number of years became emotionally maladjusted, was hospitalized and taken off of ritalin and placed on an anti-depressant. I am not sure if that is even working. Now, I learn of a new diagnoses of being BY-POLER and ADD for some children. Some of the symptoms are the same as ADD. I understand that LITHIUM is the choice of medication.

We now have three drugs that could be used for the same diagnosis of ADD, however with some slight differences in characteristics of ADD.

It seems to me that if people are saying that we are over prescribing ritalin, then perhaps we should look for a better method of diagnosis of the problems before we say that a particular drug can be used for the problem.

It would be great if the child study team, mental health, social service, medical, schools, parents, private physicians, etc could work together. I suggest that we have in place the beginnings of a team approach that could monitor the child from first thru twelfth grades. This monitoring must be on a regular bases and must include the entire team. People and organizations must give of themselves and not ask for or look for returns. I am convinced that if a proper team is put together that proper medication will be prescribed and administered to the children.

I want to thank you for allowing me to serve on the task force studying the use of METHYLPHENIDATE and are of service to you at any time. As a parent I can tell you that unless you are extremely rich that the management of an ADD/ADHD child is devastating to all in the family and most of all to the child because he may end up in the jail or he may be one of the lucky ones and be a productive citizen.

Incidently, the good effects of ritalin far out ways the adverse effects. It is a matter of proper monitoring of the medication. I believe that this type of medication has to be monitored at least every 4 months and the child must be seen by a physician.

I look forward to reading the final report.

Sincerely yours,

Jeffrey E. Brown, Vice-President Attention Deficit Disorder Association of Virginia

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COMMONWEALTH of VIRGINIA



CHESTERFIELD COUNTY HEALTH DEPARTMENT

P. O. Box 100 Chesterfield, Virginia 23832

October 2, 1990



TO WHOM IT MAY CONCERN:

I am writing to express my perception of the problems associated with the diagnosis and treatment of children with possible attention deficit disorder with or without hyperactivity. I am a physician and have worked as a public health clinician in Chesterfield Health District for about 4 years. We currently do see about 25 children a month for physical exams in two special education placement clinics at Chesterfield. A child may be thought to have ADD by the parent of teachers. In fact, sometimes the child may have been observed in the classroom by the school psychologist or both parents and teachers may have filled out Connor's questionaires suggestive of ADD prior to the physical exam, but usually the clinician is not aware of this. Thus questions in diagnosis arise as the school psychologists seem reluctant to diagnose ADD and most clinicians would be reluctant to diagnosis on the basis of a twenty-thirty minute exam and a history using only DSM III-R guidelines. When ADD is suspected, referral is then discussed with the parent, quardian or, in some cases, another relative or friend.

If the child has a private doctor, usually there is no problem in referring a child for further evaluation. However, if the child does not have a private doctor, then referrals to MCV's Child Development Clinic or the Chesterfield Montal Health Center may take as long as six months. Transportation and finances from Chesterfield may also play a role in whether a child's parents actually goes to MCV or not. Sometimes parental separation is a factor. I have followed a few children over the past several years who have taken methylphenidate or perhaps pemoline. The school nurses, psychologists and teachers have provided followup when requested. Children who did not respond were referred usually to the Child Development Clinic, and usually have significant behavioral problems as well. The school psychologist or mental health were requested to provide the following behavioral counselling.

Moar children were seen every one - three months and were monitored for side effects, growth, BP, pulse, etc. A CBC was obtained yearly. Some patients were noncompliant. Often parents called by phone to let me know of the child's progress/response to medication. Some type of tickler system needed to be developed too, so that the children would not run out of medicine as the methylphenidate has to be ordered through the state's central pharmacy. Only the shorter-acting mathylphanidate seemed to be available on state contract so that the child received at least the second dose at school. I know of one parent with an older teanager who could not safely keep the medicine at home and requested that the school administer both doses.

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As studies seem to show that methylphenidate has different effects on learning and behavior at different doses, it would seem important to develop some type of monitoring/testing which would aid in adjusting doses apart from clinical impressions or periodic Connor's questionaries.

Furthermore since there are significant numbers of children with possible ADD it would be helpful if somehow the evaluation process could be streamlined so that criteria for diagnosis could be agreed upon by mental health professionals, educators, primary care providers, and pediatric subspecialist in order to decide which children need to be seen and followed by pediatric neurologiests, child development specialists, psychologist or psychiatrists and which may be routinely followed by a pediatrician or family physician along with e.g., the school psychologist. For example, since the Medical letter recently reported the death of a child on an antidepressant, I doubt that any primary care physician would prescribe them for ADD. From my prespective, methylphenidate seems appropriately prescribed by primary care doctors, when working with a health professional.

Sincerely,

(. R. Hinson, M.D.