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A Clinical Trials Evaluation of a Double-Blinded Protocol to Assess the Therapeutic Effectiveness of Stimulant Medication Prescribed for Children Diagnosed ADHD

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A CLINICAL TRIALS EVALUATION OF A DOUBLE-BLINDED PROTOCOL TO ASSESS THE THERAPEUTIC EFFECTIVENESS OF STIMULANT MEDICATION PRESCRIBED FOR CHILDREN DIAGNOSED ADHD

by

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This clinical trials investigation developed and evaluated a protocol for determining the therapeutic effectiveness of medication prescribed for children diagnosed ADHD. The protocol included two separate baseline periods of two week durations, each of which were followed by four randomly assigned probes of one week duration, consisting either of Methylphenidate or placebo capsules. Baseline probes were unblinded, but medication and placebo probe trials were double-blinded. Therapeutic effect, expectancies, and integrity of the double-blind control were assessed through a battery of rating scales and forms completed by the parent, teacher and child at the end of each protocol week, including baseline weeks. Multiple samples of systematic classroom observations also were collected for the child and a yoked peer to compare with data derived from the rating forms.

Symptomatic rating forms and in-class observation data were not always in agreement regarding Ritalin's therapeutic effectiveness for a particular child. There were low and even negative correlations between parent and teacher ratings as well as between two teachers of the same child. Behavioral observation data were more consistent and reliable and suggested children were on-task 6.2% more during blinded Ritalin probes than during placebo probes. Whether these small observed differences would be clinically significant in the classroom or at home is hard to determine.

Parents and teachers did not "break the code" for the double-blind control: most often they indicated they did not know which condition was in effect during any given

week. In addition, neither parents nor teachers varied their weekly ratings in a way consistent with their expectations about which probe condition (medication or placebo) was in effect. Expectations appeared to influence symptomatic ratings because for parents there was a 36% and for teachers a 21% differerence in favor of unblinded over blinded Ritalin conditions on the Conners Rating Scales.

Children did not rate themselves more externally after the protocol and instead rated themselves in a more internal direction. Parent and Teacher ratings on symptomatic rating scales did not appear to be contaminated by mood or marital/job happiness.

Basing medication decisions on more systematically collected and analyzed data from drug evaluation protocols using multiple sources, and double-blind placebo controlled probes, may reduce the unnecessary use of medications with ADHD children.

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A clinical trials evaluation of a double-blinded protocol to assess the therapeutic effectiveness of stimulant medication prescribed for children ADHD

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Ann V. Thompson

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CHAPTER I

INTRODUCTION

ADHD A Syndrome or Disease/Disorder?

Although the pairs of terms symptom vs. sign as well as syndrome vs. disease are commonly used by clinicians interchangeably and without regard to their precise meanings, these terms have very distinct meanings that may help clarify issues in diagnosing and treating Attention Deficit Hyperactivity Disorder (ADHD). Symptom technically refers to a subjective verbal report by the client, whereas sign refers to an objective indicator confirmed by a therapist or other examiner (cf., Stedman's Medical Dictionary, 1982, p. 1285). A symptom may become a sign once confirmed by an examiner. Some symptoms by nature cannot become signs (e.g., headache or toothache pains).

Syndromes and diseases both are defined by delineated collections of symptoms and signs, which develop with a specific history and which run a predictable course. Syndrome, however, technically refers to a collection of symptoms and signs for which there is no known cause or etiology. Disease or disorder, by comparison, refers to a collection of symptoms and signs for which the disease process or causal mechanism of action is known (Stedman's Medical Dictionary, 1982, pp. 1382 & 403).

Syndromes often will be found through later research to have been comprised of more than one disease process. Typically, the various causal mechanisms for the different disease processes in a syndrome are identified one process (or disease) at a time. For example, at the beginning of this Century anyone presenting with the signs

and symptoms of congestive respiratory distress might have been diagnosed as having the "consumptive syndrome." The causes of the symptoms and signs in this syndrome were not known. The consumptive syndrome eventually was found to contain a number of specific disease processes, each with distinct causal mechanisms. Among those to be uncovered eventually included tuberculosis, fungus of the lung, arthritis of the lung, cystic fibrosis of the lung, and pneumonia.

A sign that marks a specific causal pathway is called a pathognomonic sign. Thus, a lung X-ray may provide pathognomonic signs allowing one to differentially diagnose pneumonia from tuberculosis disease processes. Finding pathognomonic signs often allows development and application of treatments that target the causal mechanism rather than only the symptoms. Today one no longer diagnoses the syndrome of "consumption," because the ability to diagnose the diverse and specific disease processes that cause the collective signs and symptoms of consumption has made the syndrome label less useful.

Identifying the causal mechanism for a disease can lead to specific and strategic treatment if a way can be found to break the causal chain or process (e.g., streptomycin works by blocking an enzyme needed by streptococcus bacterium to build cell walls). Often we do not know the cause of a syndrome (e.g., Adult Respiratory Distress Syndrome). For diseases, sometimes we know the cause, but do not have an effective treatment (e.g., measles, AIDS). For some diseases, we know the cause but can only prevent rather than treat the disease process (e.g., polio, measles, smallpox). In cases where the cause is unknown (syndrome) or where the cause is known but effective treatments are unavailable (common colds), we often can treat the symptoms and signs. The signs of fever can be treated with aspirin and alcohol baths without identifying the cause. Symptoms and signs are treated, where possible, to give temporary relief to the

patient while other naturally occurring healing processes (e.g., immune system) are given time to eventually eliminate the causal mechanism.

All syndromes (as well as all diseases for which there are no available treatments) are thus treated "symptomatically." For example, people with colds take medications to alleviate the symptoms of their colds (e.g., antihistamine for "runny" nose; aspirin for aches and fever reduction). Their immune systems do the work of fighting the causes of their distress: viral infections.

Attention-deficit hyperactivity disorder (ADHD), as most recently described within the DSM III-R (American Psychiatric Association, 1987), consists of a core collection of symptoms and signs (e.g., inattention, impulsivity, and hyperactivity) for which there is no known etiology or pathogonomic sign. ADHD thus qualifies as a syndrome, and more accurately at this time a behavioral syndrome. With the causal process unknown, only the symptoms and signs (i.e., behaviors) can be treated at this time. Psychostimulant medications provide one method of treating the symptoms and signs of ADHD behavior syndrome while time allows (hopefully) other normal processes to work to correct whatever is causing the expression of these behaviors. If these normal processes are ineffective, exacerbation of the behaviors (i.e., relapse) would be expected once medications are withdrawn. High relapse rates indeed occur after withdrawing stimulant medication from children diagnosed as ADHD syndrome, even after a year on medication.

Behavioral treatments have been developed which treat the symptoms and signs of ADHD behavior syndrome as effectively as do stimulant medications, although behavioral programs require considerably more training, skill, effort and time to implement effectively. Most behavioral programs also treat ADHD behavior syndrome symptomatically, because the causes of these behaviors remain unknown. However, if functional contingencies were identified that controlled these symptoms and signs (e.g.,

escape- avoidance or reward contingencies), these would qualify as pathognomonic contingencies because they mark the causal mechanism maintaining the behavior patterns. This logically would move this syndrome into the "disease" category, even though the causal mechanisms identified lie not inside the body (i.e., biochemical) but outside the skin (environmental-behavioral). Nothing in the medical model requires that all causal mechanisms be restricted to factors and processes within the skin. This would place the outdated limitations of reductionism in science on the medical model. If pathognomonic behavioral contingencies were clearly identified and targeted successfully, this would qualify not as symptomatic of a syndrome but as causal treatment of a specific behavioral (contingency) disorder.

Parent and teacher verbal reports (e.g., interview and checklists) are most often solicited in helping the physician/psychiatrist determine a diagnosis of ADHD behavior syndrome and in making dosage adjustment decisions (Gadow, 1993). These reports comprise symptom rather than sign data. These reports are then, at best, not the most reliable for diagnoses because different parents and teachers may report different behaviors as well as levels of behaviors for the same child.

Different physicians and psychologists may disagree on the diagnosis because, "a consensus definition of ADHD has never been developed" (Murphy & Pelham, 1989, p. 235). Although the DSM III-R definition is the most widely used (Murphy & Pelham), the behaviors of ADHD syndrome are only generically outlined. Thus, a parent or teacher must only report that the child behaves in ways that evidence inattention, impulsivity, and hyperactivity to a degree that is developmentally inappropriate. Diagnoses are based on verbal reports about the child's behavior by others (symptomatic data) rather than on direct observations of the child's behavior by an examiner (sign data). Fourteen criteria are listed in DSM III-R to help define each of the three core areas but no objective, normative, cut-off scores exist for these criteria

and each examiner is left to his/her own discretion in deciding whether the child's inappropriate behaviors are "...considerably more frequent than most people of the same mental age" (DSM III-R, p. 52).

Thus, it appears that the Attention Deficit Hyperactivity *Disorder* label may be misleading because its name implies a known disease process. Disorder is defined by Stedman's Medical Dictionary (24th ed. p. 414) as "a disturbance of function, structure, or both resulting from a genetic or embryological failure in development, or from exogenous factors such as poison, injury, or disease". Although the DSM III-R criteria specify onset before the age of seven, implying a developmental problem, no direct genetic link has been found. Furthermore, there are no other direct sign data to diagnose this collection of symptoms with 100% reliability and accuracy.

Because of the tendency to blur the distinctions between syndrome vs. disease/disorder, as well as symptom vs. sign data types, research and general knowledge about ADHD behavior syndrome includes many misconceptions, which contributes to so much confusion surrounding ADHD. This will be a topic for discussion in the next section.

Prevalence & Efficacy

Recent controversy is growing within pediatric medicine about the possible over-use of stimulant medication with children. Tillman (in Angell, 1990; see Appendix) reported that "Michigan has consistently ranked one or two in the country [for Ritalin use]" and indicated that there is "...an over-prescribing of this medication without adequate testing and diagnosis and looking at alternatives" (Angell, 1990). Further, according to the U.S. Drug Enforcement Administration (in Angell, 1990), "Michigan consumption of Ritalin was 14 percent higher than in Maryland, the second-ranking state for Ritalin use, in the first half of 1989." Grand Rapids and the

Kalamazoo areas have been targeted for special State hearings (Angell, 1990). In fact, the consumption of Ritalin in the Kalamazoo area has not changed much from the high rates which were previously reported in 1986. The Kalamazoo Gazette at that time reported that this area "consumed Ritalin at about 3.5 times the national rate" (Channing, 1990; see Appendix). Because of this, DeLisle (1991) reports that "...the risks for Michigan's children are exceptionally high."

Throughout the United States, point-prevalence figures for Attention-Deficit Hyperactivity Disorder (ADHD) have ranged from as low as 1% to as high as 20% (Kohn, 1989; Szaatmari, Offord, & Boyle, 1989). A more conservative estimate suggests ADHD behavior syndrome is present in 3% of the population in the United States (American Psychiatric Association, 1987; Barkley, 1982). A major problem for researchers is that under ideal diagnostic conditions, employing two trained examiners, using standard protocols for interviewing and scoring, and interviewing the same child/parent in two successive interviews, the inter-examiner (Kappa coefficient) agreement index (DSM-III) for ADHD syndrome diagnoses was found to be from .50 to .58 (APA, 1980). It is not surprising that the prevalence data vary so widely given such a low consistency in diagnosing ADHD syndrome behavior with children.

Another factor complicating interpretation of research results is the finding that stimulant medication works about equally as well with non-ADHD behavior children as with ADHD syndrome behavior children, and as well with non-ADHD behavior adults, on objectively measured tasks (Peloquin & Klorman, 1986; Rapoport Buchsbaum, Weingarter, Zahn, Ludlow, & Mikkelsen, 1980; Zahn, Rapoport, & Thompson, 1980). Despite these research findings, three-fourths of pediatricians use responsiveness to stimulant medication as a major criteria for accuracy of the diagnosis (Kohn, 1989). Such diagnostic decision making invokes the logical fallacy of "affirming the consequent."

Researchers estimate that between 80% to 86% of children diagnosed as ADHD behavior syndrome are placed on stimulant medication at some point (Kohn, 1989; Ottenbacher & Cooper, 1983). Safer and Krager (1988) estimated that between 750,000 and one million children will have been treated with stimulants by 1990. It is therefore ethically and clinically crucial to demonstrate that each child prescribed medication responds markedly better with the drug than without it. This is especially important when one considers that over-prescribing may occur as a function of the immediate and dramatic effects large doses of stimulant medication have upon behavior (DeLisle, 1991; Kohn, 1989).

Although stimulant medication has been reported to be successful in decreasing some symptoms of this syndrome (Barkley, 1976; Conners, 1971; O'Leary, 1980; Ottenbacher & Cooper, 1983), many children show little therapeutic response, if any, to medication. Across all children diagnosed ADHD behavior syndrome and treated with medication, 35% to 45% improve, 30% to 40% moderately improve, and the remaining 15% to 45% do not respond or become worse (Conners in Davison & Neale, 1982; Elkind & Weiner, 1978; Hall, Lamb, & Perlmutter, 1986; Kohn, 1989; Ross & Ross, 1982). And even responders show only temporary suppression of problem behavior (Kohn, 1989). Long-term efficacy was found in about 60% of hyperactive children prescribed stimulant medication (Department of Health, Education, and Welfare in Lambert, Windmiller, Sandoval, & Moore, 1976). Further, a large proportion of responders also respond to placebo. Treegoob and Walker (in Ottenbacher & Cooper, 1983) indicated that the placebo effect is an important variable which is not sufficiently controlled or even addressed in most studies of stimulant treatment of ADHD behavior syndrome, a fact which has made it difficult to interpret many individual studies. Placebo effects are best controlled by use of double-blind procedures with active placebos and post-checks to ensure the integrity of the double-

blinds. Executing double-blind controls with integrity is difficult in any drug study, and in the case of stimulant medications is considered impossible by some respected researchers (Muñoz, Hollon, McGrath, Rehm & VandenBoss, 1994).

Wolraich (1977) examined 62 studies that reported using double-blind, placebo-controlled procedures. Included in these studies were a total of 1,970 subjects prescribed dextroamphetamine sulfate, methylphenidate, or pemoline. He noted that placebo-controlled and double-blind designs are "two of the most important criteria for valid psychotropic drug research" (p. 512). He noted that because up to 70% of therapeutic effects seen in research protocols can be ascribed to suggestion or placebo effects, "all studies not employing a placebo-control and double-blind condition must be looked at with suspicion" (p. 512).

Wolraich listed several additional criteria needed to increase confidence in findings in drug research. One of the most difficult to standardize across studies is diagnosis. Most studies Wolraich examined assessed and diagnosed ADHD in a variety of ways. He concluded that the lack of a consistent diagnosis was likely due to different factors influencing ADHD behavior in children (e.g., school environment, normal personality variation, central nervous system defect/trauma, emotional factors, home environment). Further, he found that the source of referral was often overlooked as an important criteria (i.e., subjects were referred from varying psychiatric clinics or institutions, direct school referrals, and neurology clinics). This could confound results and make comparisons across studies difficult because referrals from different centers probably include a broad range of ADHD behavior types and severity levels.

Another important criteria for evaluating psychostimulant medications is the use of standardized evaluations for dependent measures. Wolraich indicated, "no one group of standardized tests definitely indicates the effectiveness of stimulant therapy" (p. 513). He explained that the variability in results obtained across different studies

relates partly to this factor. Performance measures (e.g., reaction time, continuous performance, Proteus-Maze, motor activity) were somewhat successful in detecting effects but also tended to support Wolraich's conclusion, "that even in the area of simple motor activity different devices do not always measure the same phenomena" (p. 514). Intelligence and achievement tests did not show a consistent positive result. Instead, medication seemed to allow the children to react more quickly, concentrate, and remain alert without any affect on intelligence.

Because ADHD currently qualifies as a syndrome (i.e., with unknown etiology) rather than a disease, the causal mechanism or pathway is not known and thus cannot be targeted for treatment. Symptoms (behaviors) of ADHD can be targeted for relief by treatment, and all treatments for the syndrome of ADHD thus would be considered "symptomatic treatments." Wolraich concluded that psychotropic medications treat "the symptoms of short attention span, distractibility, and increased motor activity rather than a specific disease entity" (p. 515). He compared psychostimulant treatment to antihistamine treatment of nasal congestion which can be caused by any number of factors. "Antihistamines ameliorate the symptoms but are not curative and are frequently limited in their effectiveness...and it may be helpful to look at [stimulant medication] usage in [this] perspective" (p. 515). Wolraich's review of the literature also uncovered some consistency among findings: (a) positive short-term effects of stimulant treatment are seen in the schools and may be seen at home; (b) methylphenidate and dextroamphetamine are relatively equally effective; (c) a single morning dose is often adequate (versus a morning and afternoon dose) and; (d) there may be tolerance to psychostimulants in some cases.

Of the six longitudinal or follow-up studies Wolraich examined, none showed positive results. Further, one five-year study using a control group showed no difference between the ADHD behavior syndrome children taking stimulant medication

and those ADHD behavior children who were not. This suggests "therapies so far have not found the answer to remediation....[and] that long-term outcomes may not be substantially affected by stimulant medication" (p. 516).

O'Leary (1980) found similar results in a more recent evaluation of the literature on psychostimulants and behavior therapy. He found that studies evaluating the short term effectiveness of psychostimulants have demonstrated their efficacy in the classroom and in laboratory settings. However, none of the long-term studies evaluating psychostimulants that he examined met the criteria required of true experimental designs. O'Leary concluded that there have been no long-term studies demonstrating that children diagnosed as ADHD behavior syndrome and taking stimulant medication fare better than those who do not.

Factors Undermining Confidence in Previous ADHD Research

A significant factor undermining confidence in previous research is that much of it is based on parent and teacher verbal report rather than direct observations of the child under medication and placebo conditions. Methodological research in this area suggests that often there is little agreement between what adults say a child does, and what the child is observed to do in the natural environment. Data on validity of verbal report (e.g., behavior rating checklists) as it corresponds to observed behavior is weak across many areas of clinical child psychology and especially in the area of child behavior problems (Patterson, 1982).

Wolraich (1977) found that teacher scales were most consistent in detecting differences between drug and no-drug conditions. However, no interobserver reliability or agreement data on behavior rating scales were reported in any of the 64 double-blind, placebo-controlled studies he investigated. Because these questionnaires

involved verbal report, responses checked may have been easily influenced by factors other than the child's actual behavior. For example, Wolraich (1977) indicated that the teacher or parent may not be a good reporter, or one reporter may find a behavior unacceptable, while another is undisturbed by the same behavior, and so different reports, and thus, scores, can be obtained. Additionally, rating scales are susceptible to rater bias, halo effects, and other subjective factors, (Barkley, 1987). Further, all rating forms require a certain level of literacy, which usually is not assessed. Specific behavioral criteria for judging anchor points such as "Not at all" or "Pretty much" often are not given, which can lead to wide discrepancies in the way informants interpret and fill out the forms (Barkley, 1987).

Additionally, the behavior of the child may be interpreted differently depending on the mood or general marital satisfaction of the parent (or teacher) filling out the questionnaire (Dangel & Pollster, 1984; Porter & O'Leary, 1980). Thus, the level of distress of parents completing forms as well as their general level of satisfaction in marriage should be evaluated to provide a context for interpretation. As an example, Porter and O'Leary (1980) obtained measures of overt marital hostility, general marital adjustment, and children's behavior problems from 64 children. They found that, "overt marital hostility correlated significantly with many behavior problems of boys." Kohn (1989) also indicated that families of ADHD behavior children have more mental health and marital difficulties and are more punitive and authoritative. Barkley (in Kohn, 1989) suggested that these demands and punishments appear to decrease once their child is placed on medication. Barkley (1987) recommended that other methods of assessment be used in conjunction with such evaluations (e.g., direct observation, self-report scales, laboratory measures, structured interviews) in order to counteract these and other potential biases in rating scales.

In evaluating agreement between teacher report and direct observation of classroom outbursts and aggressiveness, Shapiro, Lentz, and Sofman (1985) reported that indirect and direct observation measures ultimately end up assessing different behaviors. In a study reported by Schnell (1974), the author concluded: "...the results are clear in illustrating the potential for the total invalidity of questionnaires as representative of behavioral change, even when the questionnaire is very specific and does not ask for subjective statements from the client" (p. 343).

In a review of difficulties with these types of data, Gerald Patterson (1982) concluded: "The bias is a relatively consistent tendency on the part of the parents of disturbed children to report improvement in the behavior of the child when in fact no real changes have occurred....roughly two-thirds of such parents will report improvements when asked for global judgments. This means that even if the therapy isn't working, the therapist will receive supportive comments from the majority of families with which he works..." (p. 43). The rates of improvement reported when no detectable behavior change occurred are similar to those generally found for placebo effects (Frank, Hoehn-Saric, Imber, Liberman, & Stone, 1978; Frank and Frank, 1991; Kirsch, 1990; Ottenbacher & Cooper, 1983). These findings have direct implications for assessing the therapeutic impact of treatments with ADHD children. The child for whom others report behavior change after medication, when no behavior change can be detected, may need a different treatment (e.g., placebo) from the child whose behavior does improve on medication.

Another factor undermining confidence in previous research reports is statistical regression. Milich, Roberts, Loney, & Caputo (1980) found that statistical "regression toward the mean" (i.e., scores above the mean will be lower on re-testing and scores below the mean will be higher) could explain improvements in the performance of children as assessed by the Conners questionnaires. They recommended that the

Conners be given at least once to account for practice and regression effects before study baseline administration. Most studies examined administered the Conners questionnaire only once at the start of intervention and did not include a second administration until post-test.

Variable compliance with treatment protocols also undermines confidence in research results reported in the literature. Firestone (1982) found that the longer the elapsed time since the prescription was first written, the more likely parents were to stop giving their child the medication. Firestone (1982) also reported that out of 76 children (68 boys, 8 girls aged 5-9 years) studied, 26% of the total group refused treatment, 20% stopped using medications by the end of the fourth month and only 55% were still taking their medication by the end of the tenth month. Furthermore, less than 10% of those families who terminated treatment sought medical consultation before terminating. Only during routine calls by investigators did these families report a change in their medical regimen.

Anastopoulos and Barkley (1988) discussed several possible etiologies of ADHD behavior syndrome but also indicated that much of the previous research (not just etiology-based research but general research with ADHD behavior) has been seriously flawed and future research should pay closer attention to several methodological considerations. Methodological problems they noted included: (a) an inadequate diagnosis of ADHD behavior patterns (i.e., the use of "obsolete diagnostic terminology and criteria" such as Minimal Brain Damage); (b) lack of attention to the level of severity of ADHD symptomatology; (c) the inclusion of subjects with syndromes other than ADHD (e.g., conduct disorder and depression); (d) faulty assumptions about causal mechanisms derived from correlational research (e.g., past correlational research suggesting that ADHD syndrome behavior is caused by high sugar intake when actually expectations were more significant than the sugar ingested);

and (e) "affirming the consequent" (e.g., inferring that ADHD behavior is caused by disorders or diseases which sometimes lead to ADHD-like symptoms). Early researchers found damage to neurological functions coincident to ADHD-like behaviors. They then assumed that the ADHD behaviors were "caused" by the neurological damage when in fact there was, and still is, little research (or even theory) to support or explicate a causal pathway connecting basic neurochemical activities directly to gross motor activities engaged in by children in educational settings. This is an example of a misplaced application of a linear, mechanistic, reactive reductionist model that has largely been abandoned in the life sciences in the later part of the 20th Century in favor of a reciprocal, interactional field model. The implications of adopting an interactional field model for understanding behavior are addressed in the next sections, especially when discussing emanative, placebo and expectancy effects of treatments.

Physiological Side Effects & "Emanative Effects" of Stimulant Medication

As with any medication, there is danger of misuse and overuse of psychostimulants (Grinspoon & Singer, 1973) as well as the danger of adverse side effects (e.g., increased blood pressure, increased heart rate, decreased appetite, sleeplessness, decreased seizure threshold, and in a few cases, increased susceptibility to Tourette's Syndrome) (DeLisle, 1991; Kohn, 1989; O'Leary, 1980). More recently, a mild dysphoria or flattening of affect has been noted in children taking stimulant treatment (Whalen, Henker, & Granger cited in Whalen & Henker, 1991). These side effects are usually controllable and risks are minimal with careful evaluation and monitoring (Whalen & Henker, 1991).

However, there are less apparent side effects of taking medication. Children known by classmates to be taking psychostimulants may be teased more often. Some children may develop psychological dependency on the drug, and view medication as a panacea (Whalen & Henker, 1976, 1980). Whalen & Henker (1976) cautioned that medication treatment carries a profound message, "...it communicates to the child and others that a definable problem exists, most likely a physiological one, and that it can be alleviated through chemical means" (p. 1122). Such information conveyed during treatment can yield "emanative effects" (i.e., effects flowing from the treatment: see Whalen & Henker, 1976 & 1991) that may prove either therapeutic or iatrogenic.

Henker and Whalen (1980) conducted an exploratory and purely descriptive study to determine the impact of medication on self-perceived competencies, expectancies, and coping styles. They used a semi-structured interview procedure which included open-ended, forced-choice, and "pretend" questions. Twenty-four boys and three girls diagnosed as hyperactive and receiving stimulant medication were interviewed. Results indicated that the children did not necessarily like taking the medication but knew why they had to take it and accepted the need for it. The investigators concluded that the children tended to attribute their problems to physiological causes rather than to personal or social factors. One adverse consequence of this attribution pattern was that the children ascribing "...their problems to physiological factors tended to view medication as the primary solution and were less likely to focus on the role of personal or social factors as either causal or ameliorative agents" (p. 150).

Whalen and Henker (1976) emphasized the importance of medication as only one component to treatment. They found that in practice, however, medication is the major, and often the only, component in the treatment protocol for ADHD behavior children. This is important because clinical practice and current research both

recommend that stimulant medication be used as part of a total treatment plan including behavioral and educational interventions (Bower, 1989; Henker & Whalen, 1989; PDR, 1989). The Physician's Desk Reference (1989) specifies that,

> Ritalin is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following...[ADHD] symptoms (p. 856).

Therefore, not only should other interventions be used concurrent with psychostimulant treatment but attention should be paid to all factors potentially influencing the child's behavior under medication treatment.

Placebo & Expectancy Research

As suggested from the above, further research on the effectiveness of stimulant medication is warranted. This is highlighted by Ottenbacher and Cooper's (1983) review of 61 double-blind studies (i.e., drug versus placebo, placebo versus control, drug versus control). They concluded that although results clearly indicated that stimulant trials yielded major improvements on behavioral/social measures and minimal improvements on IQ and academic achievement measures, an analysis of effect-sizes suggested that 30% of the relative improvement found in the drug versus control conditions could be attributed to placebo phenomenon. Ottenbacher and Cooper indicated, however, that placebo effects were likely underestimated because placebo and drug effects were calculated as being independent and additive rather than allowing for the potential enhancement of active drug effects by non-specific factors such as suggestion. With placebo trials, any improvement is attributed to placebo. With active medication, all improvement is usually credited to medication, even though some of the effect arguably should be attributed to placebo effects. Further, these reviewers noted that placebo effects might have been estimated as even more pronounced had they not

assigned a zero value to all non-significant effects and had the studies examined been of longer duration.

Although double-blind controls are touted as the ideal solution to minimizing some of these emanative placebo effects, in practice there is growing skepticism about the feasibility of executing true double-blind controls with psychoactive medications. Often both patient and examiner are able to "crack the code" by detecting side-effects of the medication. Research in the areas of Depression and ADHD suggests that much of the therapeutic effects attributed to medications by examining physicians may be based on detection of side-effects rather than therapeutic effects of the drugs. When side-effects are reported but therapeutic effects are not, some medical examiners conclude improved therapeutic effects in the research protocols. When active placebos are used that produce the same side-effects but not the therapeutic effects, medical examiners often conclude that therapeutic effects have occurred (Greenberg, Borstein, Greenberg, & Fisher, 1992).

Other lines of research into placebo effects have demonstrated significant changes, both on verbal reports (symptom data) as well as on physiological and observed behavior (sign data). Mavissakalian (in Kirsch, 1990) reported that agoraphobic clients given a placebo pill in addition to in-vivo behavioral treatment improved more than those who were given only in-vivo behavioral treatment. These patients also improved as well as did 94% of subjects in the control group, after eight weeks of treatment. Davison and Valins (in Farina & Fisher, 1982, p. 60-61) reported that subjects who had been told that during prior shock trials they had received a drug effective for counteracting the effects of shock coped less effectively with subsequent shock trials without the drug than those who were told that they had received only a placebo during previous shock trials. Davison, Tsujimoto, and Glaros (1973) found that insomniacs who received relaxation training and also were told that they had

received an active dose of chloral hydrate throughout their relaxation training complained more about sleepless nights during follow-up. Those subjects who were trained with relaxation techniques and told that they had not received an active dose of chloral hydrate throughout the duration of treatment slept better during follow-up.

These three studies support Morris and Kanouse (1979) who suggested that people respond more favorably when they view their improved condition as due to their own skills rather than to medication. For example, Borden & Brown (1989) in their investigation of the effects of Ritalin, placebo, and no-pill on ADHD behavior children and their parents concluded that overall, parents and children who relied on medication as a solution to their problem tended to report more negative scores on behavior and cognitive impulsivity of their children. Morris and Kanouse (1979) suggested that when clients believe they have exerted control over their environment they are also more likely to believe that they have acquired the skills necessary to cope with their problem, and in many cases this appears to be true. They indicated that this kind of thinking mobilizes clients to cope with future difficulties rather than simply passively accepting their situation.

This relationship is not always clear, however. Morris and Kanouse (1979) noted that after taking a drug it becomes difficult to determine which behavior changes are due to one's own recuperative power and which to medication. "The way in which expectancies influence outcomes...is difficult to specify. Expectations about a drug's effects probably trigger a number of psychological processes that influence drug response; it is difficult, for example, to separate the effects of suggestion, the mobilization of hope, classical conditioning, and the production of internal standards" (p. 13).

Frank, Hoehn-Saric, Imber, Liberman, & Stone (1978) suggested that positive responses to placebo medication or suggestion "...depends primarily on the interaction

of the patient's state at a particular time with certain properties of the situation" (p. 13). They found that dependency, emotional reactivity, and conventionality (i.e., enduring personality characteristics) seemed to correlate with responsiveness to placebos. Isolation and mistrustfullness seemed to lead to failure to respond to placebos, in studies of patients experiencing surgical pain. An illustration of this relationship can be found in a study conducted by Park and Covi (in Frank et al., 1978). Park and Covi fully described to their "psychoneurotic" adult outpatients what a placebo pill was but added that it led to improvement in some people. Subjects were then told to take the placebo three times a day for one week and to report changes on three different assessment forms. Almost all subjects reported improvements on all measures. Those subjects who had no doubts (either that the placebo worked or did not work) reported significantly more relief of distress than those who had doubts. "Those who were certain either way linked their certainty to their conviction that the doctor was [prescribing the placebo] to help them" (p. 6).

Expectations also can affect patients' continued compliance with medication regimes. Morris and Kanouse (1979) listed three factors influencing how people decide when or if they should modify or discontinue their current drug regimen: (1) level or degree of change expected (e.g., the person must know that they have ingested a drug and know what its expected effects are); (2) degree of confidence they hold in their convictions about the drug (which is mainly dependent upon prior exposure to the drug rather than verbal behavior from others about the drug's effects); and (3) the actual physiological effect of the drug in their body. These factors may influence the differential response rates obtained by different doctors prescribing the same medication. Clients likely use indirect and subtle communications from their therapist to form expectations about their condition and therapy (Uhlenhuth et al., in Morris & Kanouse, 1979). Therapists also can use these factors to enhance compliance.

Kanouse (1971) suggested the need for more research in the area of attribution because of people's tendency to maintain personal causal attributions and to not give other potentially satisfactory alternatives serious consideration. Additionally, Farina and Fisher (1982) indicated that a vicious cycle can begin whereby patients receive drugs, begin to believe they are suffering from an illness, and "...thereafter cope with their problems in a less satisfactory way than before. Their worsened problems and increased dependence on the mental health expert make them continue as patients, in consequence of which they receive more drugs, and so on" (p. 60). Thus, clients and therapists alike tend increasingly to think that they have no control over their problems and then do little to improve or cope with their condition. Farina and Fisher suggested that this type of iatrogenic "disease belief" may teach individuals to view themselves as helpless, "...leading people to expect no contingency between their efforts to alleviate their problems and the outcomes" (p. 67).

Thus, covert verbal behavior can play a clinically significant role in any medication regimen, leading to either negative results, no observable differences in behavior, or to enhanced results beyond those normally expected. This view is supported by Kirsch (1990) who indicated that there was an additive relationship between expectation and medication treatment such that, "...positive expectancies can enhance the effects of medication, whereas negative expectancies can inhibit those effects" (p. 34-35). He suggested that it "...does not matter whether the initial change is due to the treatment itself, to expectancies generated by the treatment, or simply to random fluctuations. The important thing is that it be noticed by the client and interpreted as a sign of improvement. Feedback, especially experiential feedback, strengthens the effects of positive expectations" (p. 35). He thus recommended attending to and shaping the client's expectations before administering treatment. "At the very least, the purpose of the intervention and the way in which it will produce

change should be carefully explained. The more certain subjects are that a treatment will be effective, the more effective treatment is likely to be" (p. 35). He suggested offering positive, but not overly generous, descriptions of the benefits of the medication (see also Morris & Kanouse, 1979).

Kirsch's position is further supported by evidence obtained by Weisz (1986). Weisz assessed whether outcome contingency, personal competence, and control could be used as predictors of psychotherapy results in 78 adolescents. He found that 29% of the variance in problem resolution during therapy could be attributed to the child's perceived contingency and perceived control. Weisz concluded children who do not believe they can control their problems (i.e., if they report they do not believe they can solve the problems if they try) and that problem resolution is not contingent on their behavior, are likely to show fewer gains in therapy than those who believe their problem can be controlled and that problem resolution is contingent on their behavior (i.e., they believe the solutions to their problems are contingent on "kids and what they do").

Weisz suggested that children usually attend therapy unwillingly and thus are less likely to believe in therapy's effectiveness in controlling or resolving problems than adults who enter therapy voluntarily. Therapy with a child should be conducted only after assessing the child's belief in the controllability of the problem and the contingency between problem resolution and the child's behavior. If the child does not believe in self-efficacy, this area might be targeted as the first goal in a successful treatment plan.

More evidence for this phenomena comes from Reid and Borkowski (1987) who designed an attribution training program to enhance ADHD syndrome children's belief in their own efforts for their achieved successes. They defined antecedent attributions as "...pervasive self-perceptions about the causes of learning operative in a

child at the time a new instructional program is initiated....These long-standing attributions about one's learning ability accumulate through self-evaluation based on past performance attributions (i.e., success and failure experiences) as well as through feedback from parents, teachers, and peers...." (p. 296). They defined another attributional style as program-generated which "...emanate[s] from the immediate treatment intervention" (p. 296). For example, a child may attribute success to an external agent such as a medication rather than to personal efforts (Whalen et al., 1991; Whalen & Henker, 1976, 1991). The authors found that severely hyperactive children receiving attribution training demonstrated less hyperactivity in the classroom and more self-control than severe ADHD behavior children who did not receive attribution training. Further, ADHD behavior children receiving attribution training, "...used more complex strategies, demonstrated higher personal causality scores endorsing effort, and displayed reduced impulsivity" (p. 296) and that these results were maintained during a ten month follow-up.

Reid and Borkowski attributed success of their attributional training program to several factors. First, the authors dealt with dysfunctional antecedent and program-generated attributions with "failure-coping dialogues as well as by giving the specific reasons why some items were correct and others incorrect" (p. 305). Second, they focused on personal effort and strategies for success. Finally, rather than eliminating failure opportunities, teachers helped children learn from mistakes by giving elaborate corrective feedback. The authors concluded that a child's belief in the importance of effort can help to motivate that child to use already available strategies and persist in these strategies even in the face of failure.

Not only the client's, but also the expectations and attributions of the client's significant others, can influence outcomes of medical regimens (Borden & Brown, 1989; Knights & Hinton, 1969; Parsons, Adler, & Kaczala, 1982; Whalen & Henker,

1976). As Knobel (reviewed in Whalen & Henker, 1976) observed nearly three decades ago, the whole family can influence how well an individual member functions on medication. In fact, he suggested two types of families: those which rejected medication as a viable treatment and those which were more accepting of medication. Studies assessing the expectancies and attitudes affecting ADHD behavior children and their families while the children were treated with medication are limited in number and scope (Whalen et al., 1991). However, pioneering research in this area has offered some support for the importance of cognitions (i.e., covert intraverbal behavior) of children treated with medication.

Borden & Brown (1989) assessed attributions of ADHD behavior syndrome children and their parents when children were treated with cognitive behavioral training and also randomly assigned to groups taking either Methylphenidate, placebo, or no pill. The investigators found that parents of children in the no-pill group believed most strongly that their child could solve his/her own problems. Children in the placebo group most strongly believed that solutions were the direct result of external, uncontrollable factors. The fact that children in the placebo group formed beliefs that solutions depended on factors beyond their control suggests that when medical treatment fails, the client's belief in the seriousness and hopelessness of his/her problem may be strengthened (Whalen & Henker, 1991) and that such potential attributions need to be carefully considered under these conditions. Borden and Brown further observed that the attributions of both parents and children were consistent (effects were correlational only) which emphasizes the importance of monitoring attributional sequelae of both parents and their children (Whalen & Henker, 1991).

Milich, Licht, Murphy, & Pelham (1989) found that subjects diagnosed as ADHD syndrome who received Methylphenidate were more likely to attribute their success on specific tasks to ability than those subjects receiving placebo tablets. This

would seem contrary to other findings in attribution theory and research. However, Whalen and Henker (1991) suggested that these results might have occurred because the boys were under the impression that they were continually being medicated. "Because they ingested the pill regularly, they had no basis for attributing changes--whether positive or negative--to either medication or its absence" (Whalen & Henker, 1991, p. 19). Whalen and Henker (1991) proposed that "Attributions are neither mutually exclusive nor internally consistent" (p. 20). They would not be surprised if a child claimed that "...the pills do not help him but then requests an extra one before an exam, nor would it be unreasonable to find him believing that his improved performance resulted from both effort and medication" (p. 19 & 20).

Whalen et al. (1991) found similar results. All hyperactive boys in their study judged their own effort to be high regardless of the difficulty of the task presented. These authors indicated, however, that the children were simply reflecting societal norms (i.e., that medication ranks lower than effort when given a choice between the two explanations for behavior). Moreover, they add that a child may invoke effort as an explanation yet still believe that these efforts did not influence the results. Whalen et al. (1991) concluded: "...the meaningful finding is that medication has entered the child's list of causal options, not that medication fails to ascend over effort" (p. 11). They added that medication more often serves as an explanation when children are asked open-ended questions because structured questions may prompt the categories of effort or ability, yielding these as the number one choice for explaining their behavior.

A meta-analysis of children's causal attributions for success and failure conducted by Whitley & Frieze (1985) may help explain how seemingly contradictory results can occur within attribution research. The authors examined 25 studies and grouped them according to question wording style (i.e., informational attribution in which experimenters questioned whether luck, ability, effort, or task difficulty were

present in a situation and causal attribution in which experimenters questioned whether these factors caused, influenced, or determined a particular outcome) and research context (i.e., natural or experimental settings). A distinction was made between the presence of a factor and the cause of an outcome because Whitley & Frieze indicate,

> ...it is possible for persons to believe, for example, that they have high ability on a task, but that the task was so easy that ability was irrelevant to the outcome. Under such conditions, a high informational rating of ability would not reflect the perceived causal influences in the situation (p. 609).

In general, Whitley and Frieze found that ability and effort (internal attributes) were more likely to be invoked when situations involved success rather than failure and occurred in natural rather than experimental contexts. They also found that task difficulty (external attribution) was more likely to be invoked under failure situations. Further, the authors concluded that the way in which questions were structured markedly affected how children responded. The best way to avoid contradictory results would be to include both types of question wording and to exercise caution when generalizing attribution results across research contexts and task domains (i.e., comparatively little research has been conducted with academic tasks but most studies attempt to generalize results to academic settings). Finally, Whitley and Frieze concluded that more naturalistic tasks conducted in educational settings are needed.

In Whalen and Henker's (1991) investigations of children in academic settings, medication was often viewed by children as a "magic pill" which, rather than personal effort, was credited with behavior change. This effect is exemplified by a study conducted by Rosen, O'Leary, & Conway (1985) in which a 9-year-old hyperactive boy was gradually taken off of psychostimulant medication. Although the child's dosage of Ritalin was quite low (.1 mg/kg) and was possibly not even at therapeutic blood levels, his behavior deteriorated quickly when he "ran out" of medication.

Further, comments made by the subject at these times suggested that he was not accepting responsibility for his behavior (e.g., he stated, "my pills make me get done with the work" as a reason for not completing his assignment and indicated that he became angry with his peers because, "I get angry without my pill").

When this subject began taking placebo tablets after the no-pill condition, his academic and on-task behavior immediately improved. His comments during this time were: "You see, the pill helps me" and "I need [the pill] to do my work." Rosen et al. (1985) emphasized that attributions that help to facilitate improved performance while on psychostimulant treatment may "...present significant problems when the plan is to terminate drug therapy or when parents forget to refill the prescription..." (p. 543). Whalen and Henker (1991) recommended that regardless of whether the child, the pill, or both are given credit for the changes observed in the child, researchers and clinicians should not overlook the importance of the "emanative effects" of medication (i.e., the information conveyed during the medication regimen, see Whalen & Henker, 1976 & 1991). They noted that "...the message of the medication is usually left to chance, unrecognized, or ignored when treatments are designed and evaluated" (p. 17).

Finally, using a double-blind cross-over design, Whalen et al. (1991) gave fifteen ADHD behavior boys either placebo tablets first followed by medication, or medication first followed by placebo, over a two-day period. Pills were given twice each day. Subjects and parents were fully informed about placebos and told that the experimenters might try to fool them by administering fake pills. The experimenters assessed the boys' ability to predict their own performance before and after they were told which pill they had taken. Objective measures were obtained through performance with a computer game which was pre-set so that boys first failed and then succeed on the game. After the game, the boys evaluated their performance based on the importance of three causes: effort, ability, and difficulty. Finally, all boys were asked

to rate the effectiveness of medication and how their performance would differ if they had taken medication (or placebo).

All boys predicted they would perform better on medication than on placebo. Boys taking placebo rated their behavior more positively, especially following success (i.e., said that they tried harder and performed better) than when they believed they had taken medication. After failure, boys in the placebo condition were more likely to attribute failure to lack of effort than boys taking medication (possibly related to attenuated effort, greater candor, or a combination of the two). Most boys had a relatively positive attitude towards medication and predicted poorer performance under placebo conditions compared to medication conditions.

Although the results by Whalen et al. (1991) are limited by the small sample size, lack of validated measures, limited range of situations and functions assessed, and the inability to cross-over informed and actual medication status, their results suggest the importance of assessing self-perceptions of children taking stimulant treatment. Whalen et al. concluded that there is a need to monitor covert as well as overt changes in children taking medication.

Purpose of the Current Study

The scientist-practitioner model of clinical psychology proposes that science and practice can be melded seemlessly to provide the best treatments. Science provides the data base on which better practices can be built, and practice poses problems best explored through further scientific research. Many, however, consider that science and practice mix as well as oil and water: resulting in a murky colloidal suspension at best. This study developed a drug evaluation protocol that provided a method for clinicians to make more rigorous, data-based treatment decisions about the therapeutic effectiveness of stimulant medication prescribed for children diagnosed as ADHD. The protocol was

developed based on the best scientific findings available, and can be used by clinicians in normal practice settings to make treatment decisions based on more scientifically sound methods. It is an attempt to meld science and practice to provide clinical trial evaluations of therapeutic decision making.

This drug evaluation protocol assessed the efficacy of psychostimulant medication prescribed for six out-patient children diagnosed as ADHD by their own pediatrician/psychiatrist by way of natural referral processes. It was hoped that the protocol would give helpful and more detailed information with which the child's pediatrician/psychiatrist could make more effective medication decisions. The protocol employed a double-blind placebo controlled series of weekly medication probes and weekly assessment by teacher, parent and child on the effects of these probes.

The major question addressed was whether or not the current protocol under evaluation would lead to improved clinical decision-making regarding the therapeutic effectiveness of Ritalin prescription for children diagnosed with ADHD. Secondary questions related to whether or not parents and teachers would break the double-blind code used in the protocol, whether or not the currently used symptomatic rating scales (i.e., Conners and ADD Evaluation parent and teacher Scales) were accurrate and sufficient to evaluate the clinical significance of Ritalin for a particular child, as well as an attempt to determine if stimulant medication was effective with each child for whom it had been prescribed within normal clinical practice. Furthermore, an attempt was made to determine if, and how much, expectations and beliefs about psychostimulant medication influenced parent and teacher ratings on symptomatic rating forms typically used to evaluate the therapeutic effectiveness of Ritalin. That is, would parents and teacher ratings be biased toward a particular treatment modality if their beliefs/expections about which probe was in effect for their child/student during a given

week, were influenced in a pre-set direction (i.e., by informing them that the child received Ritalin under accurate and inaccurate conditions).

This study added to previous research by addressing the larger issue of the messages or information conveyed during the medication regimen (i.e., emanative effects). It was an attempt to clarify the relationship between expectancy and the effects of medication versus placebo which may be heavily influenced by expectancies (Kirsch, 1990). This study extended Whalen & Henker's work by obtaining general information about attitudes regarding medication regimens prior to, and after, treatment with Ritalin medication. This was done in order to assess whether there was a relationship between taking medication and a perceived effect because of a bias towards (or against) medication and/or because of the current state of the individual versus a real effect of the medication which could be directly and objectively observed. Additionally, this protocol ran longer, included a no-pill and placebo condition, and used a double-blind, cross-over design. Finally, attempts were made to determine how locus-of-control and medication attitudes affected response to the medication regimen.

It was hypothesized that parents' ratings of their child's behavior as either appropriate or inappropriate would vary according to the parents' current level of depression, his/her marital satisfaction, and his/her belief that his/her child was receiving actual medication or a placebo pill. It was also hypothesized that parents and teachers with a positive view of a medical regimen (as assessed by the Medication Attitude Survey) would rate the child's behavior as improved when they were told the child was receiving active medication versus when told the child was taking a placebo. Further, it was hypothesized that children with an external locus-of-control would express more positive attitudes (or acceptance) towards a medication regimen.

CHAPTER II

PROCEDURE

Characteristics of Protocol Subjects

Background

Six subjects between the ages of 4.7 to 13 years of age (kindergarten to fifth grade) were recruited to participate in this study. There were three boys and three girls. All were Caucasian except Ss#4 who was African American. Ss#3 was a 13 year old male in the second grade; Ss#4 was a 9 year old male in the third grade; Ss#7 and Ss#10 were 5 and 4.7 years old respectively and were both in kindergarten; Ss#8 was a 7 year old male in the second grade; and Ss#9 was a 10 year old girl in the fifth grade. Ss#3 and 4 were in special classes for learning disability.

All subjects were diagnosed ADHD syndrome and prescribed Ritalin medication at a local Midwestern child counseling agency according to customary clinical practice by the psychiatrist who worked at the agency. All were recommended by the physician for the drug evaluation protocol for hyperactive behavior. All children received individualized doses of medication. The psychiatrist made all medication decisions according to standard clinical practice and also monitored each child's medical progress while in the study. Children were given their capsules every morning (including Saturday and Sunday so parents could observe their children under the effects of the capsule) and in the afternoon after lunch by the school nurse. Children were not taking any other medication, either prescribed, or "over the counter." All parents and teachers as well as the school principals agreed to participate in this protocol prior to its implementation.

All of the children received individual psychotherapy in combination with Ritalin treatment. None of the subjects had a history or diagnosis of neurological disorder, or severe emotional disorder and with a few exceptions, the children did not have severe behavioral, emotional, or sleep problems. All children were assesed with an average-level I.Q. without severe academic problems except for Ss#3 and 4 who were diagnosed as Learning Disabled and attended special classes. Further, it was the clinical impression of the subjects' therapists that the children referred for this study were not neglected, or physically, emotionally, or sexually abused on a chronic or ongoing basis (i.e., the children may have been in the past but the abuse or neglect was no longer occurring at the time of the referral).

Ss#3 was diagnosed by the referring clinic as having severe behavior problems which may have resulted from the reported physical abuse he suffered from his step-father (who was no longer in the subject's home at the time of the referral). However, these two issues were reportedly being dealt with during individual psychotherapy sessions on a weekly basis. Ss#7's mother indicated her child had a severe behavioral problem, sleep disorder and had been previously neglected/abused. However, these problems/issues were not confirmed by the child's psychologist or psychiatrist. Ss#8's mother indicated her "grandson" was neglected/abused by his parents who lost custody of their son to the grandmother.

Children had to have been diagnosed ADHD syndrome and prescribed medication by the referring agency as a prior condition for being considered for this protocol. Diagnoses were made by the psychiatrist in combination with the referring clinic's psychologist. Only Ss#9 was assessed with symptoms of ADD without hyperactivity. Parent and teacher symptomatic complaints mainly concerned Ss#9's symptoms of inattention and impulsivity. Subjects #3 and 4 had been diagnosed at least one-and-a-half years before they were referred into the protocol. The rest of the

subjects were diagnosed just prior to the start of the protocol. All children were at, or above, the cut-off score for the parent and teacher Conners Rating Scale, or less than one point away.

After a diagnosis of ADHD syndrome was made (or the parent of a previously diagnosed child was seen during a regularly scheduled office visit), the psychiatrist informed the parent of the current evaluation protocol. If they agreed to participate, they signed the "Consent To Release Information" (Appendix A). Roughly 90% of clients seen by the referring psychiatrist who were diagnosed with ADHD syndrome agreed to be seen by the experimenter. The 10% who declined to give their names to the experimenter did so because they wanted to start psychstimulant treatment "right away." Ultimately, twelve subjects were recruited but six dropped out because the child's school principal and/or teacher were unwilling to participate in the protocol (i.e., their reasons were that the effort was too great, the questions asked were believed to be too personal, lengthy, or irrelevant and/or they did not want observers in the classroom). The parents of these children did, however, want their children to be included in this evaluation. They worked hard to try to convince their respective school teachers and principals to be involved, all to no avail.

When the experimenter met with the parent and child, they were fully informed of the study, the parent signed the "Informed Consent" (Appendix B), and the child signed the "Informed Assent" (Appendix C). To save time, parents and children were given the pre-protocol forms to complete before the school/teacher was contacted. If the teacher agreed to participate in the protocol, he/she signed the "School Release Form" (Appendix D) and was given the pre-protocol forms to complete. Once all parties agreed to participate in the study, teachers and parents were given a packet of assessment forms which they were asked to complete on a weekly and timely basis. In addition, before filling out the packet of forms, parents and teachers were asked to refer

to their child/student's calendar indicating weekly probe conditions on a monthly basis (Appendix E). This was done to attempt to influence their expectations about actual probe conditions.

Data were collected for only seven weeks from teacher 3b and for only eight weeks from teacher 3c and Ss#3's parent. Teachers for Ss#3 wished to stop participation because they believed Ss#3 was becoming worse by not being on his previous (unblinded) medication regime. The remainder of the subjects completed all 12 weeks of the protocol and all teachers turned in at least 12 weeks of data. Some parents turned in less than 12 weeks of data. Teachers for Ss#9 and 10 turned in 15 and 14 weeks of data respectively. The parent for Ss#7 (i.e., 7a) turned in 12 weeks, 8a turned in 15 weeks of data and 9a turned in 15 weeks of data. However, 10a turned in only 10 weeks of data.

Four subjects (i.e., Ss# 4, 7, 8, and 9) had never taken Ritalin or psychostimulants before this protocol and two subjects (Ss# 3 and #10) were taking Ritalin prior to the protocol. At the time of the referral, Ss#3's mother and psychiatrist questioned whether Ss#3 still needed Ritalin and asked for the drug evaluation to help make this determination. Ss#10 was referred because the psychiatrist questioned the administration of Ritalin in a child so young.

Independent (Probe) Variables

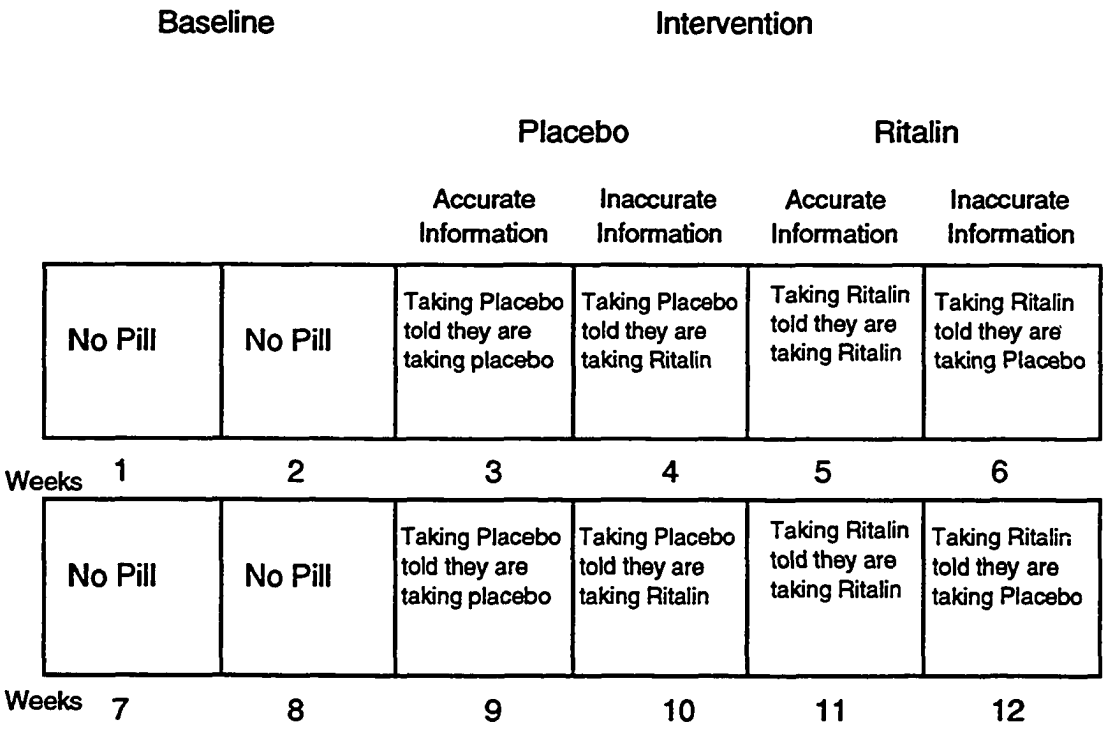
Methylphenidate is a fast acting, quickly metabolized medication, yielding no active metabolites, and requiring no build up over doses to therapeutic blood levels (i.e., unlike Cylert). A medical doctor working at CIBA-GEIGY (the manufacturer of Ritalin tablets) indicated by correspondence, that: "Peak plasma concentrations of methylphenidate are attained, on the average, 1.9 hours after administration.

Methylphenidate is eliminated from the plasma with a mean half-life of two hours. The wash-out period for drugs is about five times the half-life and for methylphenidate it will be about ten hours" (Seshamani, personal communication). Therefore, alternating medication and placebo on a weekly (or even a daily) basis is not contraindicated.

This drug evaluation protocol assessed two levels of the independent variable. First, a twice daily dose of placebo capsules (i.e., lactose powder with no active ingredients) or active medication (Methylphenidate Hydrochloride or Ritalin). Ingredients were crushed by the pharmacist and placed in identical white capsules. The pharmacist followed the procedures outlined by McBride (1988, p. 138) for making the placebo and active medication capsules. Both capsules were identical in color, size, and shape.

Second, on a weekly basis, an attempt was made to influence expectations about the actual probe (treatment) condition in effect (i.e., either Ritalin or placebo) by giving the parents and teachers a copy of an individualized calendar (Appendix E). The calendar indicated day-by-day what the child was taking (i.e., either no pill, placebo, or Ritalin). Parents and teachers were asked to look at the calender each week and keep track of which condition the child was in before they completed the weekly data forms.

Baseline and medication or placebo weekly probe conditions were alternated but divided equally among the twelve weeks of the protocol. For baseline weeks (i.e., one, two, seven and eight) children received no pills but parents and teachers were asked to complete all data forms as for the other protocol conditions. During the four weeks following each two week baseline period, Ritalin capsule probes were alternated weekly with placebo (i.e., sugar pills) capsule probes. Ritalin and placebo weekly probe conditions were alternated randomly by the pharmacist (see Figure 1 below), who kept the code for which subject had received which probe condition for which protocol week (other than baseline).



This diagram illustrates only one possible sequence. Protocol conditions were alternated but equally divided in the 12 week evaluation study. Subjects took no pills for four weeks, placebo for four weeks, and Ritalin for four weeks The two protocol conditions were randomized and neither teachers, parents, children, nor experimenters knew when the child was receiving medication and when s/he was receiving a placebo. The no pill conditions were not double-blinded.

Figure 1. Diagram of Protocol Conditions.

As a clinical trials drug evaluation, many unpredictable naturally occurring complications were expected and modifications in the protocol were allowed and made as needed during the evaluation. For example, baseline data collection was accelerated for several subjects (who started the study late in the school year) to accommodate the approaching close of school. Thus, for subjects 4, 7, & 10, data were collected twice during one week rather than twice over two weeks as called for in the original protocol and as done with the other two subjects. Furthermore, although weekly probe

conditions were randomized by the pharmacist and included no more than four weekly probes for each condition, at times an additional weekly probe was added to "make-up" for weeks during which no, or incomplete, data had been obtained from parents and/or teachers.

All children had at least one week in the no pill condition and several children who had been taking Ritalin prior to the study were evaluated under their usual medication regime (i.e., unblinded Ritalin trials were conducted for Ss#3, 4, and 10).

The pharmacist randomized the order of the protocol probe conditions on a weekly basis but related this information only to the prescribing psychiatrist in charge of primary care for the patient. The physician was not involved in collection of dependent data, and did not interact with evaluation staff, who were located at another site. The psychiatrist needed to be informed not only for ethical reasons as the primary care physician but also for legal reasons in order to write prescriptions as required by law (i.e., because Methylphenidate is classified as a Schedule II drug, prescriptions must be filled within three days of writing, and because placebo capsules were alternated with active medication, capsules could not be sent out in advance). To maintain a triple-blind procedure, the pharmacist did not tell the experimenters which weeks were active medication probes and which weeks were placebo probes.

An important condition was the accuracy of information given to the parents and teachers. This was handled by asking the pharmacist to make up a phony list of weekly probes which could then be related to the parents such that for two out of four weeks in each treatment condition the information given to the parents would be accurate, whereas for two other weeks the information would be inaccurate. The pharmacist also was instructed to alternate weekly probes for each subject so that active drug probes would be presented to each subject at least twice during the four or five week phase following each baseline condition. The experimenter then used the phony list of

weekly probes to construct individualized "calendars" (Appendix E). Thus, each parent and teacher were given calendars with dates of the month and the treatment condition the child was in during a given week.

Children, parents, and teachers were informed that on some days pills would contain Ritalin and on other days pills would contain no active medication (see "Informed Consent" in Appendix B). Expectations were primed by informing parents and teachers that the pharmacist had randomized the capsules and told the experimenter which pills were placebo and which Ritalin. However, in order to obtain approval from the Human Subjects Institutional Review Board in relation to the requirement of "fully informed consent," the experimenter then had to inform the parents that this information was likely to be inaccurate in some cases due to the nature of this drug evaluation protocol.

Although protocol probe conditions were randomized weekly rather than daily, parents and teachers were led to believe that their child might not receive the same probe for the entire week. This was done to deter parents and/or teachers from "cracking the code" based on possible detection of obvious side effects of the active medication (Ritalin). Thus, even though parents and teachers were informed weekly of which medication condition (Ritalin or placebo) their child was taking, they were also informed that the medication on any given day might be different than what they had been told.

Dependent (Therapeutic Effect) Variables

As there is no single and reliable test or means to assess ADHD syndrome in children or to assess therapeutic effects on signs and symptoms. Each dependent variable has its own particular strengths and weaknesses (see Barkley, 1987). This drug evaluation protocol incorporated a variety of assessment tools which Barkley

(1987) recommended as the current standard protocol for research on ADHD. These included parent, teacher, and child interviews, parent and teacher rating scales of ADHD symptoms, child self-report ratings, and systematic classroom behavior observations.

1. Children were asked to fill out a weekly form in which they indicated whether or not they believed they had received the medication (Appendix G). Children were asked on a weekly basis whether or not they benefited from the medication that week, to assess whether or not they knew if they received medication, and also to assess the integrity of the design.

2. Parents and teachers filled out a similar form as the one just described (in #1 above) in which they were asked to indicate whether they thought their child/student received active medication or not (see Appendix G). Parents were asked to complete all forms on Sunday night, after they had an opportunity to observe their child's behavior over the week-end. Teachers were asked to complete their forms on Friday afternoon. To maintain compliance, forms were picked up each Monday, for parents, and Friday, for teachers.

Parents and teachers were also asked to fill out the forms listed below regarding their child's/student's level of hyperactivity, inattention, and impulsivity on a weekly basis. Parents and teachers were asked to fill out each of these forms once prior to baseline to mitigate potential practice effects (Barkley, 1987; Milich, Roberts, Loney, & Caputo, 1980).

3. 48-item Conners Parent Rating Scale-Revised (CPRS-R) (Goyette, Conners, & Ulrich, 1978)

4. 28-item Conners Teacher Rating Scale (CTRS-R) (Conners, 1969; Goyette et al., 1978)

5. Attention Deficit Disorders Evaluation Scale - Home & School Versions (McCarney, Ed.D.)

The Conners scale is "the most commonly used rating scale in research with AD-HD children...." (Barkley, 1987, p. 213). Barkley (1987) reported that the revised form of the parent's scale has "the most satisfactory normative data....yields separate factor scores for Impulsive-Hyperactive and Conduct Problems scales...[and] is briefer and more easily repeated over short time intervals than is the longer, [96-item original form]...making it useful in evaluating response to treatment" (p. 214). The original version of the Conners Parent Scale (93-item form) has a reliability score of .85 but has considerable variability on the factor scores (Barkley, 1990). The 39-item original Conners Teacher Scale has reliability scores of .70 to .90 for one month and .35 to .57 for one year (Barkley, 1990). The revised 28-item Conners Teacher scale has reliability scores of .91 to .98 for one week and .89 for two weeks (Barkley, 1990).

The ADD Evaluation Scale was used because it is easily administered, easily scored, and incorporates normative data on both age and sex of the children and youth. The 46-item home and the 60-item school ADD Evaluation scales measure three dimensions of the child's ADHD behavior, inattention, impulsivity, and hyperactivity (the three characteristics present in the DSM III-R definition of ADHD). The reliability and validity of the Home version was gathered on a normative sample of 1,754 children and youth ages 4 to 20 years from 12 states. For the School Version, normative data were gathered from 4,876 students aged 4 to 20 years, from 78 public schools in 19 states. McCarney (1989) reported test-retest reliability scores of .90 to .92 for the three subscales for the Home Version and .89 to .97 the School Version. Inter-rater reliability coefficients from 172 pairs of parents selected randomly from the standardized sample ranged between .80 to .94 for all age levels with an average correlation of r=.82. For the School Version, 237 pairs of educators assessed 462

randomly selected students and inter-rater coefficients averaged r=.85 (range from .81 to .90 from all age levels). Using a Kuder-Richardson 20 formula, internal consistency reliability for all three subscales exceeded .93 (Home Version) and .90 (School Version), well above the .70 level generally considered to be adequate. Item/total score correlations for each of the three subscales exceeded .66 (Home Version) and .60 (School Version), well above the .30 level which is considered acceptable. The relationship between the ADD Evaluation Scale-Home Version and the ADHD-H Comprehensive Teacher's Rating Scale (ACTeRS) (Ullman, Sleater, Sprague, 1988) for all three subscales yielded criterion-related validity coefficients of .50 to .61 (Home Version) and .57 to .68 (School Version), well above the .30 to .35 levels of acceptability considered necessary.

Because these questionnaires involved verbal report, responses may have been influenced by factors other than the child's actual behavior (Kohn, 1989; Porter and O'Leary, 1980). To detect some of the more probable influences, the level of distress of the parent and teacher filling out the forms also was assessed using the following three checklists.

6. The abbreviated version of the Self-Rating Depression Scale (Zung, 1965)
7. Marital Happiness Scale (Azrin, Naster, & Jones, 1973))
8. Teaching Happiness Scale (Alessi, 1991; Appendix H)

Zung et al. (1965) reported a split-half reliability coefficient of .73 (with $p<.01$) for the Self-Rating Depression Scale. Jegede (1976) reported internal consistency reliability coefficients of .36 to .79 for 206 first year medical students. Brantley and Jones (1989) suggested weekly assessments allowed for measures of trait characteristics while daily assessments measure more unstable and changeable, state characteristics. The Teaching Happiness Scale was devised for the purposes of this study and was included to evaluate the level of satisfaction and pleasure derived from

teaching each week. Because it is a new scale, no information regarding its reliability are available.

A pre- and post-assessment of external and internal locus of control was also included because of research reported in Whalen and Henker (1976) which suggested that long term outcomes of drug treatment can be affected by the construct of "locus of control." For example, an external locus of control is strengthened when the child believes that the problem (ADHD) is due to an external agent (physiological) not under his/her control and can only be treated externally (with Ritalin). Thus, the following measure was included:

9. Children's Norwicki-Strickland Internal-External Locus of Control Scale (Norwicki & Strickland, 1973)

Norwicki and Strickland (1973) examined three grade levels (grades 3, 7, and 10) and found test-retest reliability estimates of .63, .66 and .71 (respectively) for a six week period. Norwicki and Roundtree (1971) reported a test-retest reliability of .76 for twelfth graders during a five-week time period and for the third and fourth grades, Anderson (1976) reported a test-retest reliability coefficient of .67 over a six-week period. The lowest estimate was found by Edwards (1972) who, in a nine-month investigation of third through sixth grade, found a reliability estimate of .63.

10. Also included was an open-ended, pre-/post-protocol questionnaire designed specifically for this study to determine the parents' and child's attitudes and beliefs towards the medication regimen (see Appendix F). An end score was derived to determine whether or not children and their parents view the drug treatment as positive, negative, or neutral prior to the start of the study. This was used mainly for the discussion section of this paper.

11. Medication Attitude Survey (Thompson, 1991)

Finally, to counteract the limitations of subjective assessments such as rater bias, halo effects, and subjectivity (Barkley, 1987), an objective assessment form was also included. Barkley reported that assessments of ADHD behavior in its natural environment offers, "...more ecologically valid measures of the actual behaviors of AD-HD children about which parents and teachers are most concerned" (p. 226-227). The limitation of direct observation methods is that there are no normative available, "...making them less useful for determining the statistical deviance of child behaviors necessary in rendering a diagnosis" (p. 227). Instead of having normative data, this evaluation protocol included observations of the patient and a comparison child. The comparison child was nominated by the classroom teacher as an average student, matching the patient in age and gender but not in ADHD-like behavior. That is, the comparison child's overall behavior was considered to be generally non-problematic by the teacher. Discrepancies between the levels of on-task behavior recorded for the patient and the comparison child would be considered an index of severity of the problem, whereas no discrepancy between the levels recorded for the two children would indicate little problem in that area. The comparison child's data provided a local, micro-norm (Alessi, 1980) as a kind of baseline level of on-task behavior that would be expected to be appropriate for that particular classroom setting, activity and teacher. Thus, even if the patient's observed on-task levels of behavior were not very high (in an absolute sense), if they closely matched the comparison child's levels in that same setting (in a relative sense), on-task behavior then was not considered problematic.

Because standard psychometric constructs generally are not directly applicable to systematic behavior observation data (Alessi, 1980), inter-observer agreement indices were obtained to check the quality of the data. This was done by having two independent observers record data in the same sessions and then calculating the degree to which both agreed or disagreed on the intervals observed. Observations of the target

and comparison children's on- and off-task behaviors were made two to three times a week and inter-observer agreement (or reliability) checks were conducted at least once a week. On- and off-task behaviors were recorded on the sheet listed below (see Appendix J for the actual form used) for both the target and comparison child.

On-task was defined by default when no off-task behavior had been recorded during that interval. Off-task was recorded when the patient engaged in either "passive" behavior (e.g., not responding to a question asked); "small motor" behavior (e.g., playing with a pencil); "large motor" behavior (e.g., getting up out of the chair); "verbal to self" (e.g., talking to oneself); "verbal to others" (e.g., talking to the person next to the subject); or a "termination" response (e.g., disrupting the classroom to such an extent that the teacher had to stop what she was doing to go to the student).

12. On-/Off-Task Behavior Observation Form (Alessi, 1991)

CHAPTER III

INDIVIDUAL PROTOCOL FINDINGS FOR Ss#3

Introduction

Few traditional statistical analyses are appropriate because this series of drug evaluation protocols was not designed as a group experiment to answer a research question and because patients were not randomly assigned across groups. Each protocol was modified as needed to fit the difficulties encountered in each clinical situation. Experimental control would require each protocol to be executed carefully as designed. The purposes of these drug evaluations was, rather, to assess individual treatment responses for each patient. The only broader issue addressed here would be the generality of use of such a protocol for evaluating therapeutic effectiveness of other children beginning a course of stimulant medication for behavior problems.

The analyses presented here are more qualitative than quantitative. The decisions to be made from the data aim more at clinical significance than statistical significance. Each drug evaluation protocol here may be seen in a light similar to that of a standard psychological assessment battery used to assess and plan therapeutic strategies for a patient in therapy. The purpose was to develop such an assessment tool for practice rather than to answer general scientific questions. The following sections, then, separately describe the individual clinical results for each subject in this evaluation protocol. After describing individual results, overall results for the protocol itself will be described.

Each protocol will be described following a format generally applicable for reporting results of a standardized psychological battery: patient identification; reason

for referral to enroll in the evaluation protocol; social history and background information; assessment battery; protocol findings; discussion of protocol findings; and protocol recommendations. Each clinical report herein will be considerably longer than the usual psychological report because of the developmental nature of this protocol and the need to provide sufficient contextual information to evaluate the usefulness of various components. It is assumed that a standard drug evaluation report as used in normal clinical practice would be shortened considerably, including only the details crucial for making specific treatment and dosage decisions.

Although twelve possible subjects were recruited for this protocol, six dropped out for varying reasons. The main reason for drop out was that the principals, teachers, or school boards did not want in-class observations nor did they want the teachers filling out the forms. The parents of all these children did want the evaluation and some worked very hard to try to convince the school to allow their child to participate, all to no avail. The following six case reports present the findings for the patients who remained in the protocol.

Referral Source and Reason for Protocol Enrollment

Ss#3 was referred for this drug evaluation protocol by his psychiatrist to assess Ss#3's continued need for Ritalin. Ss#3's mother agreed to participate in this double-blind drug evaluation because she was concerned about Ritalin's possible side effects and wanted to be certain that it was necessary for Ss#3 to continue taking a psychostimulant.

Social History and Background

Ss#3 was a 13-year-old Caucasian boy who attended the second grade during

this drug evaluation protocol. He had been taking 10mg of Ritalin twice a day for two years prior to his participation in this protocol. His mother completed eleven years of education and did not hold outside employment. She was a single parent and stayed at home to care for Ss#3 and his younger siblings. Of note is that her live-in boyfriend left to work in another state mid-way through the protocol.

Ss#3 had two teachers and a teacher's aide. The teachers taught on alternate days of the week but the teacher's aide was there five days a week. Although the teachers were the only ones who completed evaluation forms for the study, the teacher's aide reported her observations on note paper which she turned in to this examiner at the end of the eight week evaluation period.

The parent for Ss #3 (3a) and one of the teachers (3c) completed 8 weeks of protocol forms while the other teacher (3b) completed only 7 weeks of forms (i.e., she did not complete the last week). Ss#3 was not allowed to complete all 12 weeks of the protocol because his teachers developed a belief during week 6 that Ss#3's increased misbehavior in class was because he was not receiving medication during certain phases of the protocol. The teachers therefore requested that Ss#3 be removed from the protocol and placed back on his regular (i.e., pre-protocol) medication regime. His mother did not want to remove him, but did so reluctantly after the teachers persisted in their requests.

A family development early in the protocol may have contributed to a deterioration in Ss#3's behavior and led to the teacher's request for an early termination of the drug evaluation. On Tuesday night of the fifth week of the drug protocol (i.e., weeks 4 & 5 = placebo), his mother's live-in companion (and Ss#3's father-figure, "Fred") left town. Ss#3's mother became distraught over the loss and abrupt departure of "Fred." This could have negatively affected Ss#3's classroom behavior independent of the protocol. When this examiner spoke with Ss#3 about this, he acknowledged his

concern for his mother as well as his own distress at having the only father-figure he knew leave town without even saying good-bye to him. However, the subject's teachers disagreed with this hypothesis, indicating that Ss#3's poor classroom behavior was not a function of the emotional upheaval taking place at home, but rather was a function of being within the placebo leg of the drug evaluation protocol (which turned out to be true for only two days of the week after "Fred" left, although no one knew for sure at the time which part of the double-blind protocol was actually in effect).

During the following two weeks (i.e., weeks 6 & 7 = Ritalin), Ss#3's behavior deteriorated even further in both teachers' views, and they attributed this worsening to the effects of the (perceived) placebo medication trial. Once the evaluation had been completed and the code "cracked," it turned out that Ss#3 had actually been within the active Ritalin component of the protocol during weeks 6 and 7. Thus, Ss#3 was receiving pills of the same dosage that he had been prescribed for at least a year prior to the drug protocol; a dosage which had been considered effective by his parent and teachers before the protocol began. However, there appeared to be other factors involved. During the middle of week 7 (Ritalin), Ss#3 was sent home for "howling" and tantruming in class. His teacher, certain that Ss#3 was receiving placebo, insisted that he be removed from the evaluation and placed back on his pre-protocol medication regime. The following day, his teachers believed he was back on his pre-study medication schedule and commented on his much-improved disposition. His mother, however, related to the protocol examiner that she did not give her child his new prescription medication until a day after that. Additionally, the mother later reported that Ss#3 did not receive any pill on the day Ss#3 was sent home "howling." It appears as if Ss#3's disruptive behavior that day was the "straw that broke the camel's back" as far as the teachers were concerned and they were eager for a change back to the pre-protocol medication regimen.

In retrospect, it appears that once teachers had mistakenly attributed Ss#3's inappropriate behaviors to the effects of (perceived) placebo pills, they began to interpret all his inappropriate behaviors as due to these placebo effects. Any personal or other factors which might have been interpreted as contributing to Ss#3's behavior apparently were ignored, disregarded, or minimized.

Protocol Assessment Battery

Several pre-/post protocol measures were included in the evaluation: (a) Medication Attitude Survey, and (b) Norwicki-Strickland Locus of Control. In addition, data on the following weekly measures were collected: (a) Conners Parent & Teacher Rating Scales, (b) Attention Deficit Disorders Evaluation Scale (Home & School versions), (c) Accuracy of Teacher & Parent Reported Beliefs, (d) Interobserver Agreement for Classroom Observations, (e) Classroom Behavior Observations, (f) Zung Depression Scale, and (g) Marital Happiness (parent) & Job satisfaction (teacher) forms

Protocol Findings

This section will describe results from several pre- and post-protocol measures. The Medication Attitude Survey was administered to estimate teacher, child, and parent attitudes toward use of Ritalin. The Norwicki-Strickland Locus of Control was administered to estimate the way parents and children view their responsibility for negative and positive events. The rationale for including these tests are included in the introduction and methods section of this dissertation.

In addition, several measures were obtained for each weekly probe throughout the protocol. Four of these, the Conners Parent & Teacher Scales and the ADD Evaluation Form (parent and teacher), are typically used to evaluate behavior

symptomatic of ADHD syndrome in research studies as well as in clinical practice (please refer to the methods section of this report for more details about these measures). To complement these symptomatic parent/teacher report data, direct classroom observations (sign data) were taken of the target and comparison child and compared to ratings on the ADD and Conners forms. In 44% of the total observation sessions for all children combined (70.3 out of 158.61 observation sheets turned in), two observers watched the subject in the classroom and inter-rater reliability scores for these samples were reported. Finally, two weekly parent and teacher measures were included to assess the potential influence of marital happiness (parent) or job satisfaction (teacher) and/or depressed mood on weekly ratings of the ADD and Conners scales.

Pre- & Post-Protocol Findings for Ss#3

Pre-Protocol Medication Attitude Responses

This assessed parents' and/or patients' attitudes about the use of medication (acceptance of Ritalin as a treatment) for improving behavior. This survey was designed by this examiner expressly for the purpose of clarifying beliefs about Ritalin, and medication in general, of those intimately involved in determining the therapeutic effectiveness of Ritalin.

Ss#3 related what he knew about the effects of Ritalin: "It's for me to concentrate so I don't get riled up and banging around...it calms me down....I don't want to take it [Ritalin] but I know it helps so I do want to take it." He believed he would have to take Ritalin until he turned 18 years old. He also indicated he didn't take it during summer and that his behavior was better without it. However, after the examiner's next question he indicated Ritalin improved his behavior by 90% and that it

helped keep him from getting into fights and hitting others. He described others in comparison to himself as "different, older than me, much taller...I don't play with other kids."

Ss#3's mother indicated she was leery and ambivalent about Ritalin because she had seen children who were over-medicated and couldn't talk or move. She indicated she was scared to put him on medication but did so because his teachers were complaining about his work. However, when Ss#3 was started on a low dose of Ritalin, at the request of the psychiatrist, she indicated her whole wall became filled with academic awards from her son's improved performance. She believed that if he didn't take Ritalin his grades and attitude would deteriorate. She believed other children in comparison to Ss#3 were "a lot smarter; their attitudes are different, better, and they seem older."

Teacher 3b indicated she was cautious about Ritalin because she had seen someone look like a "zombie" from over-medication and realized medication wasn't the answer for everybody. She stated she was willing to give it a try with Ss#3 because the whole classroom was getting so bad. She indicated his grades and attitude seemed to improve after taking the medication. She stated he was better able to accept constructive criticism and failure. In comparison to other children, teacher 3b believed Ss#3 was not as satisfied with himself and where he's at, "he doesn't have a best friend but does have a girlfriend...he hangs around his girlfriend and her friends."

Teacher 3c indicated she had concerns about the side effects of Ritalin but didn't worry too much because she stated "the drug doesn't stay in the body too long." She was mainly concerned that it be used consistently. She indicated her daughter was taking Ritalin for a year and a half and that when her daughter was taken off the medication, teacher 3c indicated her daughter's behavior was better than when she was taking Ritalin. Teacher 3c stated she believed Ritalin helped Ss#3's behavior by 75-

80%; helping to control his temper, writing, and frustration tolerance. She stated Ss#3, in comparison to other children, was less able to deal with frustration and conflicts and had lower self-esteem.

Post-Protocol Medication Attitude Responses

Ss#3 indicated Ritalin, "helps me...hang up my clothes, gets me going more quickly. If I don't have Ritalin, I get hyper...I get into a lot of stuff....It helps me be an ordinary kid. It helps me remember to do what I said I'd do." He indicated he didn't want to stop taking Ritalin. He stated that when he wasn't taking Ritalin he felt different, like not doing anything, not playing, he was bored, unhappy and sometimes didn't want to eat; he felt tired and worn out. However, when asked a different question, he negated all of the above. That is, when the examiner asked if he believed Ritalin improved his behavior, Ss#3 replied, "No, I still feel grumpy [and] don't want to do anything. It doesn't help me clean my room, [it] doesn't help me behave...I control myself."

Ss#3 stated he believed the capsules used in the protocol were stronger and that he didn't feel any difference between the two different capsules (Note: when Ss#3 doubted the effectiveness of the protocol capsules, Ss#3 was told during week 6 (Ritalin) that the capsules worked the same way as the tablets he had taken pre-protocol and that they might even work faster since the ingredients were already crushed). However, teacher 3b reported that Ss#3 came up to her (no date was given when this happened in the protocol) indicating that he stated he felt different but couldn't explain how. She reported that he said, "I took that pill and it wasn't the real pill, I could tell and when it burst open, I could feel it." She stated he didn't look real confident about what he was saying, looking down often, and he never said this to her again. He

indicated he liked having the observers come into the classroom. He thought they were doing a test on the class.

Ss#3's mother indicated Ss#3 had an easier time being on the medication than off. She stated she wanted what was best for him but wasn't sure that Ritalin was the best thing for him. However, she stated, "it seems to be working because he calms down and does his work; he's not daydreaming and he buckles down....I just want to make sure he doesn't walk around like a zombie..." However, she also stated that Ss#3's behavior is the same on Ritalin, "he's an obnoxious child with his [good] days." She stated that Ritalin improves his behavior by only 50% (i.e., he's calmer, buckles down and does his work). She stated she would most like to see him become less "mouthy" and learn to get along with others. She stated she was glad that she went through with the protocol, "even though the teacher didn't want to, *I* wanted to...and I'm still not so sure he should be on Ritalin."

Teacher 3b stated that Ritalin had an effect on Ss#3, whether or not it was a "crutch," she stated she wasn't sure. "It makes a difference to him and he does better when he knows he's had it." She believed Ritalin helped improve his behavior by 90% (e.g., she stated "he's not as feisty, he's more calm/laid-back and doesn't argue as much") but that he still seemed mad all the time. She stated there was a difference in how he handled anger when he was on Ritalin, "he sits in a daze and mulls things over, mentally talking it out with others." She indicated his handwriting and his ability to stay in his seat were improved when taking Ritalin. Teacher 3b stated she would like it if Ss#3 acquired better social skills, "he believes the whole world doesn't like him and he has a hard time being friendly and making himself likable...what he thinks is friendly, really isn't."

Teacher 3c stated when she first used the calendar (note: each teacher had a calendar indicating what protocol condition their particular student was in each week, please refer to methods section for more details) she thought it was inaccurate so she didn't use it anymore. Teacher 3c stated she felt confident that Ritalin was necessary for Ss#3 and claimed that it improved his behavior by 80% (e.g., he was less easily upset and was calmer, quieter, happier, and concentrated better). She indicated he still had some inappropriate behaviors but that he didn't have as many conflicts. She claimed that he got more accomplished but he still got frustrated when he couldn't do something. She stated Ss#3 most needed to learn to handle frustrations or conflict situations without losing control; to accept correction without temper tantrums and be able to accomplish his work, accept challenges and be happier. Without medication she indicated Ss#3 had frequent tantrums, couldn't handle conflicts, was frustrated, daydreamed, didn't get his work done, and had a look of "doom and gloom" about him and even came in "growling" one day. (Note: Teacher 3c stated after her daughter was taken off of Ritalin in January, her teachers reported she participated more in school. However, when her daughter complained about feeling "hyper inside" and her grades dropped at school, she was placed back on Ritalin in March, the month when Ss#3 was placed back on his pre-protocol Ritalin regime at the teachers' insistence.)

Summary of Medication Attitude Survey

On this survey, the parent and teachers of Ss#3, as well as Ss#3 himself, endorsed Ritalin as beneficial. Although there was some ambivalence, their attitudes about Ritalin were positive prior to the protocol and these attitudes did not change when they were again questioned after the protocol was discontinued.

Ss#3 believed Ritalin improved his behavior by 90% on the pre-protocol survey and attributed most of his good behavior to the effects of Ritalin. However, on the

post-protocol survey, he was less certain. He first admitted to believing that Ritalin was critical in improving his behavior and then contradicted himself by saying that he controlled himself.

Ss#3's mother was ambivalent. She was afraid of Ritalin's side-effects but saw the positive effects of the medication on her child. However, she was the most cautious about Ritalin's effects, indicating she believed Ritalin improved Ss#3's behavior by only 50%.

Teacher 3b was also afraid of Ritalin's side effects but saw the improvement in Ss#3's behavior after taking the medication. She believed Ritalin helped his behavior by 90%. On the other hand, teacher 3c believed Ritalin improved Ss#3's behavior by 75-80%. She seemed to believe in Ritalin more after her own daughter was taken off the medication, did worse, and was placed back on.

Norwicki-Strickland Locus of Control

This assessed locus of control or tendency to believe that external forces outside his personal control caused his problems. Internality is associated with academic achievement, persistence, higher self-esteem, higher self-concept, higher moral development, greater popularity, more honesty, shorter delay of gratification, lower anxiety, and less interpersonal distance. External scores are associated with emotional, physical, or mental handicaps, psychological maladjustment, vulnerability to sickness and accidents, and hyperkinesis/aggression in boys.

Ss#3 responded "yes" to 60% of the questions (i.e., 24 out of 40 questions), suggesting a tendency towards an external score. This suggests that he may have believed his behavior could only be treated with Ritalin or another external factor. This was consistent with his pre-test answers on the Medication Attitude Survey in which he indicated Ritalin helped him concentrate, calm himself down, and that it improved his

behavior by 90%. However, he did endorse some internal control when he indicated his behavior was better last summer when he did not take Ritalin.

On the Norwicki-Strickland post-test, Ss#3 acknowledged only 10 external responses (i.e., 25% "yes" responses), suggesting he tended to feel more in control of his behavior after the protocol and that Ritalin had less of an impact on his behavior. However, on the Medication Attitude Survey, he seemed to indicate specific ways Ritalin appeared to help him. That is, he believed Ritalin helped him put this things away, kept him from getting into things, helped him to remember, and seemed to make him feel less depressed (i.e., without Ritalin he felt apathetic, listless, bored, unhappy, no appetite). On the other hand, when asked if Ritalin helped improve his behavior, he stated he controlled himself.

Although Ss#3 obtained a lower external score on post-test, he still endorsed Ritalin as effective. However, this endorsement was contradicted by a somewhat more socially acceptable response in which he indicated having control over himself. Thus, it may have been that the subject became "disillusioned" by being off of the medication for some of the weeks in the protocol and came to recognize his own strengths and ways to cope with his behavior that he hadn't experienced before. That, combined with his mother's skepticism, may have contributed to his lowered post-test locus of control score. Furthermore, the subject appeared to be suffering from some symptoms of depression which should be examined more closely.

Weekly Probe Findings for Ss#3

Conners Rating Scale

Applying the cut-off score of 1.52 or more on the Hyperkinetic Index of this

scale for parent ratings and 1.3 and above for teacher ratings (based on normative scores of two standard deviations above the mean), ratings by Ss#3's parent never met clinical criterion to qualify his behavior as hyperactive (see Table 1 below). Ratings by teacher 3b reached criterion for hyperactivity twice (i.e., 2 out of 8 weeks): one week while Ss#3 was taking his pre-protocol (unblinded) Ritalin prescription and one week while he was taking protocol (blinded) Ritalin. Ratings by teacher 3c met clinical criterion for hyperactivity on the last five of the eight weekly probes: twice each under the (unblinded) No Pill and (blinded) Ritalin conditions and once under (blinded) Placebo. The highest ratings on hyperactive behavior (i.e., scores of 19 & 18) were given by the teachers for probe weeks during which Ss#3 had been receiving Ritalin (see Table 1).

Figure 2 graphically depicts the data displayed in Table 1 and is useful in examining the data for trends. This figure shows that parent and teacher ratings initially were very similar. However, by week 3 (NP), ratings started to diverge. Ratings were again similar in the last few probe weeks. Teacher 3b showed a fairly consistent pattern of ratings with peaks during (pre-protocol, unblinded Ritalin) week 2B (Note: teacher 3b did not turn in her data sheet for week 7 so that point is missing in Figure 2.). Teacher 3c's ratings gradually increased, irrespective of the protocol condition in effect. On the other hand, parent ratings were somewhat stable and consistent during the first four weeks but then decreased during week 4 (blinded placebo) and then slightly increased again during week 7 (blinded Ritalin).

Ratings by both the parent and the teachers were highest and clinically significant for hyperactivity when Ss#3 was taking Ritalin. However, these ratings may have been affected by the departure of "Fred," and it is unfortunate that more probes were not run with this patient to try to sort this information out.

Table 1

Parent & Teacher Ratings on the Conners Rating Scale
for Ss#3 by Treatment Conditions

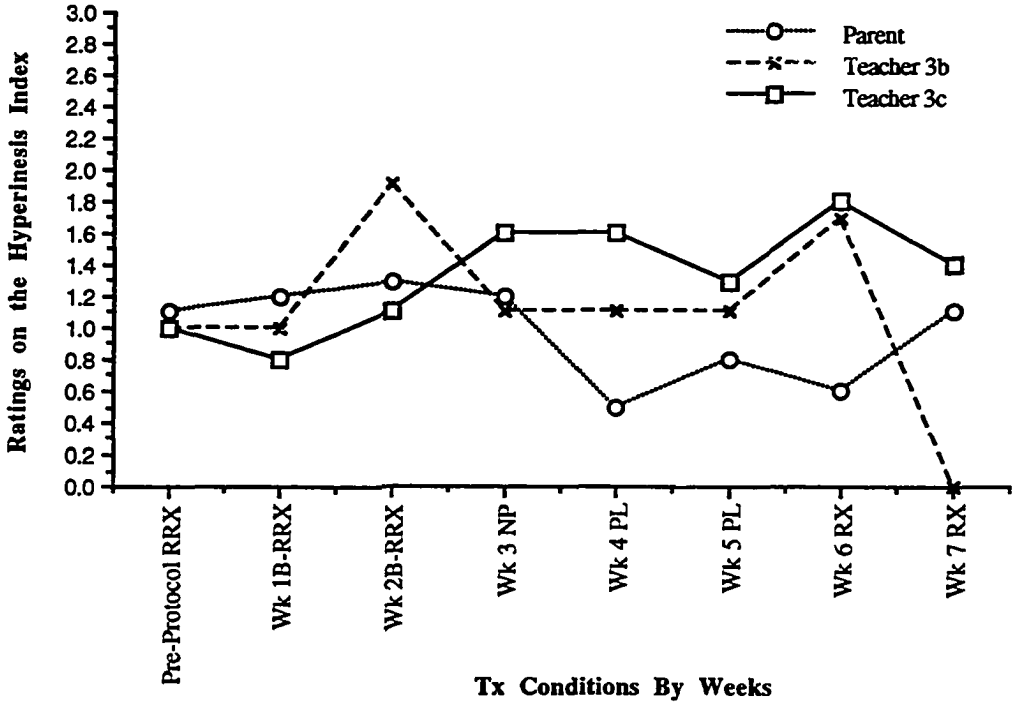
Week Number	Actual Tx Condit	Told re: Tx Condit.	Parent Belief re: Tx Condit.	Teacher Belief 3b/3c	Parent #3a Hyper. Index	Teacher #3b Hyper. Index	Teacher #3c Hyper. Index
Pre-Test	RRX	RRX	RRX	RRX/RRX	1.1	1.0	1.0
B-1	RRX	RRX	RRX	PL/RRX	1.2	1.0	.8
B-2	RRX	RRX	RRX	PL / RX	1.3	<1.9>	1.1
3	NP	NP	NP	DK / PL	1.2	1.1	<1.6>
4	PL	RX	DK	DK / DK	.5	1.1	<1.6>
5	PL	PL	DK	DK / DK	.8	1.1	<1.3>
6	RX	RX	DK	DK / DK	.6	<1.7>	<1.8>
7	RX	PL	DK	DK / RX	1.1	N/A	<1.4>
Parent correct=	0/4 DKs=4/4		3b: correct=	0/4 DKs = 4/4		3c: correct=	1/4 Dks = 3/4

Note: (Scores of 1.52 + for parents and 1.3+ for teachers suggest ADHD behavior). Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Parent and Teacher Rating Scale across three treatment conditions: RRX = pre-protocol (unblinded) Ritalin, NP = no pill (no medication or tablet administered), PL = placebo pill (protocol condition), RX = Ritalin (protocol, double-blinded condition). Scores in brackets indicate significant scores which are indicative of hyperactive behavior. "Actual Tx condition" represents what the child was actually administered; "Told re: Tx condition" indicates what the teachers and parent were told the child was taking; and "Belief re: Tx condition" indicates what the teachers and parent acknowledged to be their belief about what the child was actually taking (DK= Don't know). Teacher 3b did not complete a rating scale for week 7. The parent and teacher 3b answered DK during all four protocol conditions while teacher 3c correctly guessed once and responded DK during the other four protocol conditions.

ADD Evaluation Scale

This scale provides raw scores, subscale standard scores (i.e., obtained by converting raw scores into age-appropriate standard scores which are then used to discriminate between ADD vs. "normal" behaviors), and a percentile score (i.e.,

derived from the sum total of the subscale standard scores and are used to compare the child assessed with those in the standardization sample).



(Note: Scores of 1.52+ for parents s and 1.3+ for teachers suggest ADHD behavior.) Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Parent and Teacher Rating Scale across three treatment conditions: RRX = pre-protocol Ritalin, NP = no pill (no medication or tablet administered), PL = placebo pill (protocol condition), RX = Ritalin (protocol condition). Ss#3 had two teachers (3b & 3c) who completed scales. Teacher 3b did not complete the rating scale for the last week in the protocol so her last data point is missing from this graph.

Figure 2. Parent & Teacher Ratings on the Conners Hyperkinesis Index Subscale by Treatment Conditions & Weeks Before & During Protocol for Ss#3.

The standard scores have a mean of 10 and a standard deviation of 3. Standard scores of 7 through 13 are within one standard deviation above or below the mean and indicate the child behaves no differently than most of the children in the standardization sample. However, standard scores below 7 indicate that the child

behaves more inappropriately than the majority of the students in the normative sample and a specialized intervention program would be recommended to address these behaviors. A standard score of 4 or below is two or more standard deviations below the mean and indicates a serious level of concern. A standard score of 4 or below is considered the point at which a diagnosis of ADHD can be made (along with documentation from other instruments) and a formal treatment plan to address the student's inappropriate behaviors would be recommended.

As seen in Table 2, there were no probe weeks during which either parent or teachers rated Ss#3's behavior in the "extreme" range (4 or below) for inattention, impulsivity, or hyperactivity. For the parent, clinically significant scores were obtained three times, once each during a pre-protocol (unblinded) Ritalin probe, a protocol (blinded) placebo probe, and a no pill (unblinded) probe. The subject, however, was rated as clinically hyperactive only once and this was during the pre-protocol Ritalin probe.

Teacher 3b rated Ss#3's behavior as impulsive on weeks 3 (NP), 4 (PL), and 6 (RX), and as both inattentive and hyperactive on week 6 (RX). Teacher 3c rated Ss#3's behavior as impulsive only on week 5 (PL) and rated inattentive or hyperactive behavior at sub clinical levels throughout the protocol.

Both teachers rated the child as clinically symptomatic on the Conners only on week 6 (RX). Teacher 3c also rated the subject as clinically symptomatic on the ADD scale during week 6. When looking at both the Conners and ADD Scales, neither teacher rated Ss#3's behavior consistently symptomatic and, in fact, his behavior was rated as poor just as often (if not more so) during the Ritalin probes (i.e., week 6 was Ss#3's worst week in terms of combined significant scores).

Percentile Scores for the ADD Evaluation Scale were derived from the Subscale Standard Scores in Table 2. Percentile Scores allow comparison of Ss#3's behavior

ratings with those in the standardization sample for this scale. For example, the parent rated Ss#3's behavior in the 16th percentile during the RRX condition. This means she

Table 2

Parent & Teacher Ratings on the Attention Deficit Disorders Evaluation Form for Ss#3

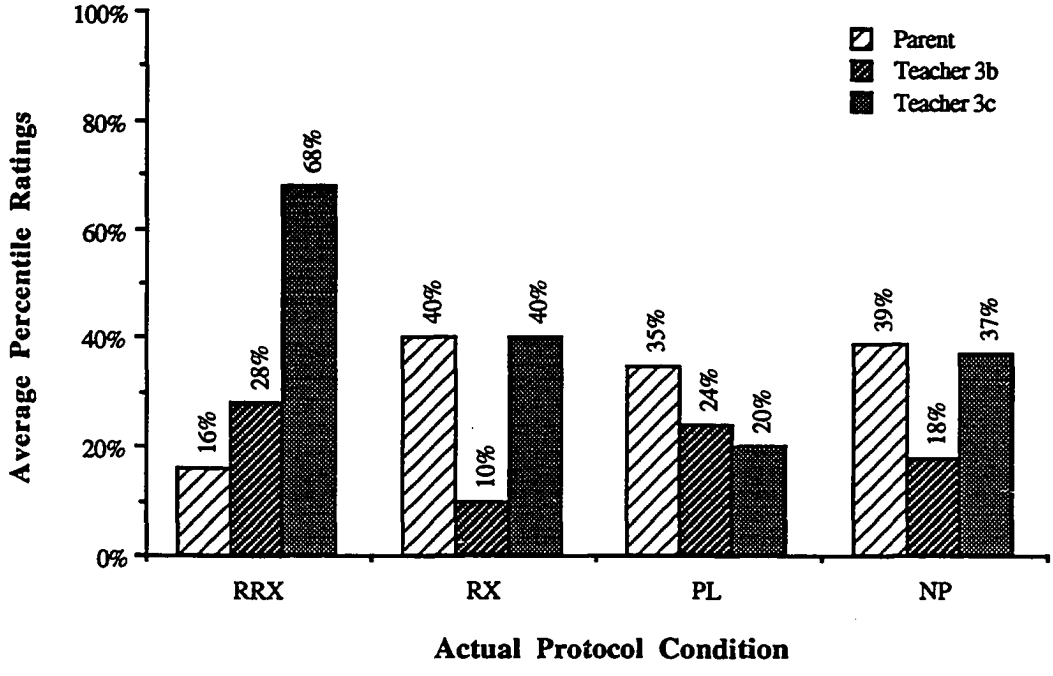
	Parent				Teacher		
Week #	Inatten	Impulsiv	Hyperact	Tx Condit	Inattent	Impulsiv	Hyperact
					3b / 3c	3b / 3c	3b / 3c
B-2	7	7	<6>	RRX	7 / 11	8 / 11	9 / 12
3	10	<6>	11	No Pill	7 / 8	<6>/ 8	7 / 11
4	11	8	10	Placebo	7 / 7	<6>/ 7	8 / 7
5	9	<6>	8	Placebo	8 / 7	7 / <6>	8 / 7
6	10	9	9	Ritalin	<6>/ 8	<5>/ 8	<5>/ 8
7	10	8	8	Ritalin	N/A / 14	N/A /10	N/A / 11

Note: On any of the three subscales (Inattention, Impulsivity, Hyperactivity), a Standard score of below 7 represents significant behavior deviance and scores 4-0 represent extreme behavior. Scores in brackets indicate significant scores. Parent and teacher scores are listed next to the actual medication, placebo or no pill which was being administered to the child for that week in the protocol. This subject had two teachers who completed weekly evaluation forms who are listed as 3b and 3c. Their scores are listed under their respective heading and scores are separated from each other by a slash mark (i.e., 3b/3c). Teacher 3b did not complete data for the last week in the protocol (week 7).

rated his behavior lower than 84% of the students in the ADD Evaluation Scale's standardization sample. Whereas teacher 3b rated Ss#3's behavior lower than 72% of the sample under this pre-protocol condition and teacher 3c rated Ss#3's behavior lower than only 32% of the sample under this same pre-protocol condition.

As seen in Figure 3, parent ratings were more symptomatic under the unblinded RRX (pre-protocol) condition than during any other probe weeks (e.g., she rated his symptomatic behavior at the 16th percentile which falls below 84% of the those in the standardization sample). Ratings under the other protocol conditions were roughly equal (e.g., 40th (RX); 35th (PL); and 39th (NP). Thus, these ratings did not detect

differential effects on Ss#3's symptomatic behavior under any protocol conditions and, in fact, Ss#3's behavior appeared to be worse under his regular (pre-protocol) Ritalin regimen according to the parent ratings. However, there was only one rating for this condition and it was the first probe condition. Both factors may have influenced the parent's rating.



Note: The ratings in this graph were determined by adding the sum of the subscale standard scores (as found in Table 2) and converting them to percentile scores. These Percentile Scores were then summed and averaged for ease of examination. The percentile scores in the above Figure indicates how the subject being rated compares to children in the ADD Evaluation Scale's standardization sample. RRX=pre-protocol (unblinded) Ritalin; RX=protocol (blinded) Ritalin; PL=placebo (no active medication administered); and NP=no pill (no tablet was administered). Note: Teacher 3b turned in only one evaluation sheet for the RX week. The other teacher and parent turned in two for each condition except for the RRX condition, for which everyone turned in only one evaluation sheet.

Figure 3. Average ADD Evaluation Scale Percentile Ratings from Parent & Teachers Across Actual Protocol Conditions for Ss#3.

Teacher 3b's ratings were less clear because she did not turn in her last RX probe data sheet. However, her scores were also roughly consistent except that they were lower during the RX probe conditions (e.g., 28th (RRX); 10th (RX); 24th (PL); and 18th (NP). Teacher 3c's ratings vary across probe weeks but also disagree with ratings from teacher 3b. The greatest discrepancy occurred during the pre-protocol evaluation when she rated Ss#3's behavior as lower than 32% of children in the standardization sample whereas both the parent and teacher 3b rated the child as below 84% and 72% under this same condition. Teacher 3c rated Ss#3's symptomatic behavior as similar under both RX and NP conditions (i.e., 40th and 37th percentile) but worse under placebo conditions (i.e., 20th percentile).

Each teacher appeared to view Ss#3's behavior differently or at least each rated Ss#3's behavior differently under various protocol conditions. Teacher 3b rated Ss#3's symptomatic behavior as best under the pre-protocol RRX condition, followed by the protocol (blinded) placebo and (unblinded) no pill conditions, and rated his behavior worst under the (blinded) protocol Ritalin. Teacher 3c rated Ss#3's symptomatic behavior as best under his regular (pre-protocol) Ritalin regimen. She rated his behavior slightly better under the (blinded) Ritalin condition than the no pill condition but better than under the placebo condition.

Accuracy of Parent and Teacher Reported Beliefs

There were four double-blind probe conditions in this protocol, and teacher 3b responded "don't know" on 100% of the opportunities. Similarly, Table 1 indicates that teacher 3c guessed only once out of the four double-blind probe conditions and responded "don't know" on 75% of the probes (i.e., for 3 of 4 probes).

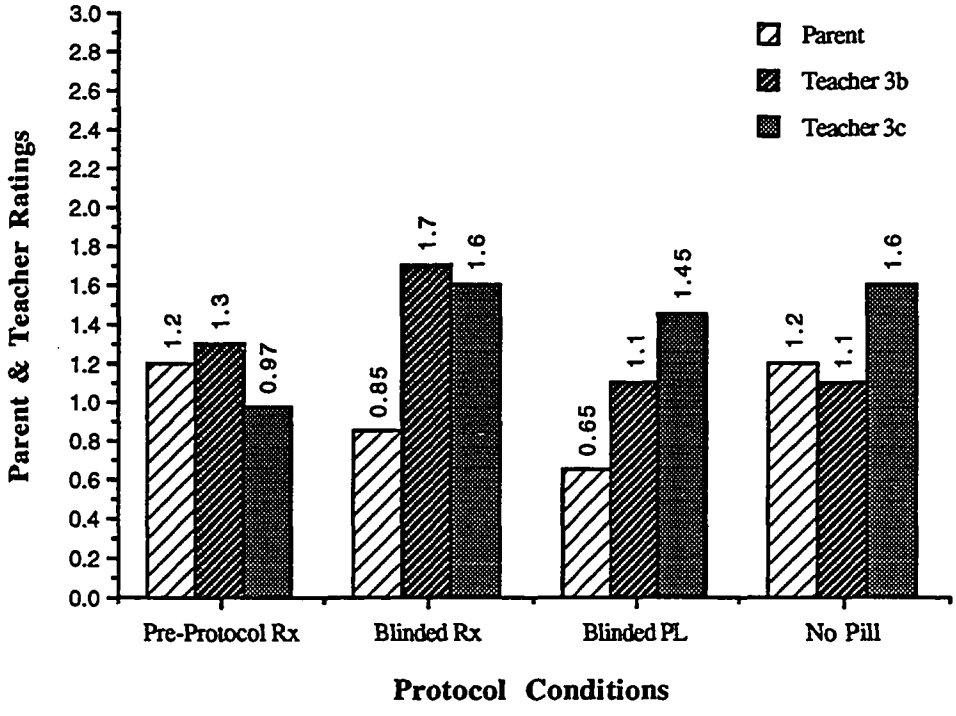
Ss#3's parent offered to guess which protocol condition the subject was in only twice: once while Ss#3 was still taking his pre-protocol baseline medication (unblinded condition) and once when he was not taking any pills (unblinded). Thus, out of the four blinded probe conditions, the parent responded "don't know" all four times (see Table 1 above for a display of the actual probe conditions and the corresponding parent and teacher beliefs).

Although the data are very limited for this subject, on only one occasion did any of the three raters correctly guess that Ss#3 was in a blinded Ritalin probe when they were told something different (i.e., teacher 3c during week 7). Most often it appeared the teachers and parent were unaware of which probe condition was in effect and thus during which weeks Ss#3's behavior might have been affected by medication. Because the teachers and parent offered so few guesses, no real comparison of their beliefs and the actual probe conditions could be made. However, Figures 4, 5, and 6 display parent and teacher ratings according to actual protocol conditions. In Figure 4, teacher 3c rated Ss#3's behavior as hyperactive during all conditions except the pre-protocol Ritalin trial while teacher 3b rated Ss#3's behavior as hyperactive only during the two Ritalin conditions. In Figure 4, the parent rated Ss#3's behavior symptomatic only twice, once during the (unblinded) RRX condition and once during the (unblinded) no pill condition. The average teacher ratings did not meet clinical significance except once during the (blinded) placebo condition.

Ratings of the child's symptomatic behavior on the Conners Parent and Teacher Scales were similar regardless of the probe condition (see Figure 2). In addition, on the ADD Evaluation Scale, neither teachers nor the parent reported clinically significant differences in Ss#3's symptomatic behavior within Ritalin versus placebo or no pill probes.

Interobserver Agreement for Classroom Observations

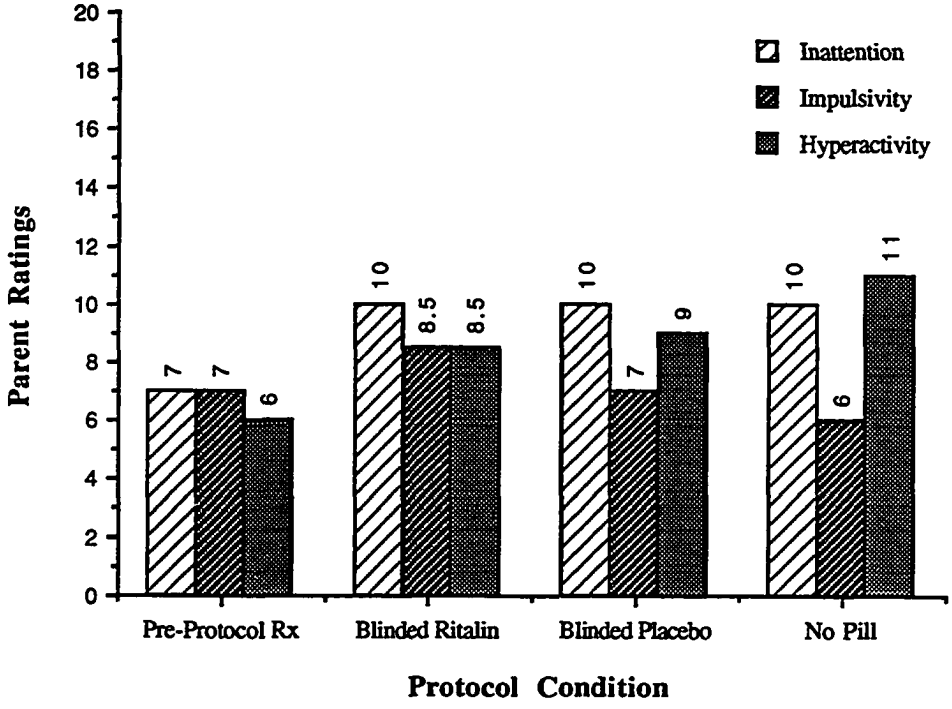
Out of 14.33 observation sheets collected on Ss#3 for on- and off- task classroom behavior, inter-observer agreement checks were available for two (i.e., two observers watched Ss#3 at the same time for only two sessions). Thus, inter-observer reliability was obtained on 12% of the total number of intervals observed for Ss#3 (i.e., 228 out of 1893 intervals).



Average ratings by the parent and teachers are displayed according to the treatment conditions in effect at the time the parent and teachers rated Ss#3's behavior on the Conners Rating Scale. Note: scores of 1.52+ for the parent and 1.3+ for teachers suggest hyperactive behavior.

Figure 4. Parent & Teacher Ratings on the Conners Rating Scales by Actual Protocol Conditions.

For these two checks, the overall (on- and off-task) inter-observer agreement obtained for Ss#3 and the comparison child for the whole protocol evaluation period was 69% (see Table 3, row 4). The agreement indexes obtained for Ss#3 and the

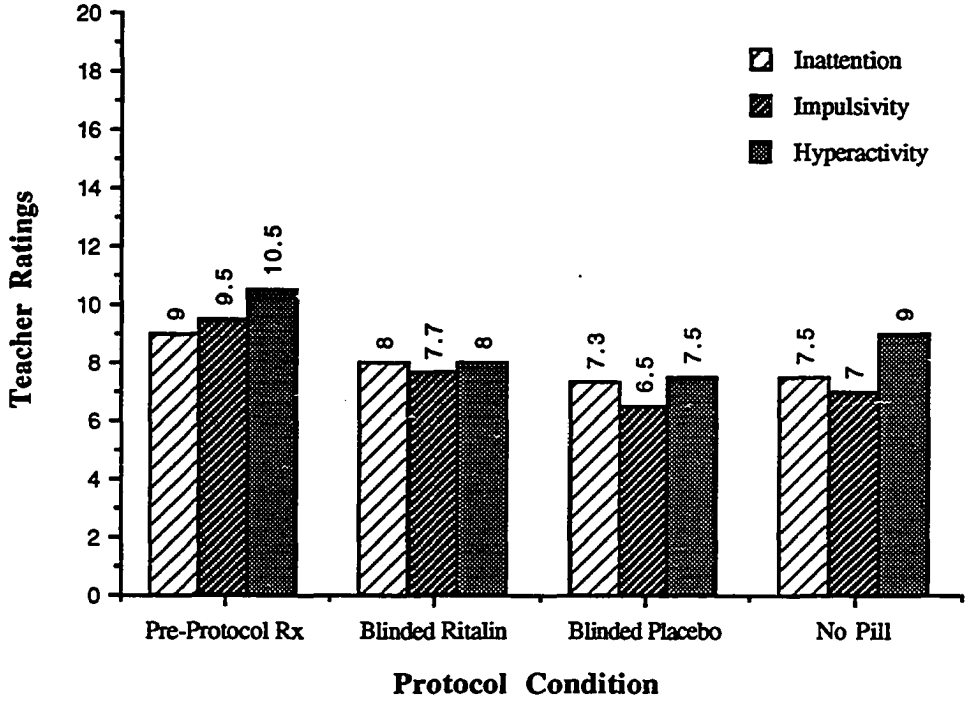


Parent ratings of Ss#3's behavior under four treatment conditions. Scores on the ADD Evaluation Scale were averaged according to the protocol condition in effect at the time of the ratings. Note: ratings of below 7 suggest problems with hyperactivity, impulsivity, or inattention.

Figure 5. Parent Ratings on the ADD Evaluation Rating Scale by Actual Protocol Conditions for Ss#3.

comparison child (combined) for individual weeks was 64% for week 1 and 72% for week 5 (column 4). Broken down further by child per week, the overall (on- and off-task) percentage of agreement for Ss#3 was 49% for week 1 and 73% for week 2 (column 2); and for the comparison child, the percentage agreement was 80% for week 1 and 71% for week 2 (column 3).

Table 3 also displays interval-by-interval agreement indexes for both the target and comparison child for combined on- and off-task behavior. Reliability obtained through this manner is necessarily lower than the overall reliability because the proportion of disagreements to agreements increases when you compare total numbers



Average teacher ratings of Ss#3's behavior under four treatment conditions. Scores on the ADD Evaluation Scale were averaged according to the protocol condition in effect at the time of the ratings. Note: ratings of below 7 suggest problems with hyperactivity, impulsivity, or inattention.

Figure 6. Average Teacher Ratings on the ADD Evaluation Rating Scale by Actual Protocol Conditions for Ss#3.

of disagreements with subcategories of agreements. With this in mind, the total percentage of on-task agreement for week 1 was 60% and for week 5 it was 63% (column 9). For off-task behavior, it was 22% for week 1 and 46% for week 5 (column 10). The agreement indexes for on- and off-task behavior by child and week are also listed in Table 3 (columns 5 through 8).

Table 3

Inter-Observer Reliability of Classroom Observations
For Ss#3 (Target) and a Comparison Child

Percentage of Agreements										
		Overall On- & Off-Task Agreements			*Separated by Child & On-/Off--Task Records (Interval-by-Interval)*					
		Target Child	*Comp Child*	*Ave Daily Agreement*	**Target Child**		**Comp Child**		*Ave Agree ments*	*Ave Agree ments*
	Week Number	*Ave Agree ment*	*Ave Agree ment*	*On+Off T + C*	*% Agree On-Task*	*% Agree Off-Task*	*% Agree On-Task*	*% Agree Off-Task*	*T + C On-Task*	*T +C Off-Task*
	COL 1	COL 2	COL 3	COL 4	COL 5	COL 6	COL 7	COL 8	COL 9	COL 10
ROW 1	Wk 1B	49%	80%	64%	37%	27%	80%	5%	60%	22%
ROW 2	Wk 5	73%	71%	72%	51%	63%	70%	5%	63%	46%
ROW 3	Avg.	62%	75%	69%	43%	47%	75%	5%	62%	36%
ROW 4	Total	Overall	Percent	Reliab	for the	whole	study	=69%		

Ss#3 (T=Target child) and a comparison child (C), a child selected for having an average level of inappropriate behaviors, were observed by undergraduate students and inter-observer reliability data were collected for two of the five observation weeks. Table 3 depicts percent agreements between two observers recording on- and off-task behavior independently of each other. The first three columns represent overall agreement for the whole observation session (not interval by interval) for the target and comparison child (columns 2 & 3); and the overall percentage of agreement (combined scores for on- and off-task as well as for target and comparison) for that observation week (column 4). In the last six columns inter-observer agreements were broken down into percent agreement on an interval-by-interval basis for on-task and off-task behavior for target and comparison child separately (columns 5 through 8) and the average agreement for on-task & off-task behavior for both target and comparison child combined (columns 9 & 10). Row 4 represents the percent agreement for the whole protocol evaluation period and row 3 presents data on the averages for each column.

On-task agreement reliability is substantially higher than off-task agreement. This is expected because on-task is scored by default when either no behavior is observed or a behavior is missed by one or the other observers. On the other hand, inappropriate behavior must be seen in order to score the interval as off-task.

Although the overall per-subject agreement for Ss#3 was low (i.e., 69%, row 4), this consisted of an agreement index for the target child for week 1 that was quite low (i.e., 49%, columns 2 & 3) as well as three higher agreement indexes (e.g., 80%, 73%, 71%). Thus, one should use caution in examining these data, particularly during the first few weeks of the study.

Classroom Observations

Ss#3's on- and off-task behavior was compared with another same-sex child, both of whom where observed in the classroom at various times of the day to evaluate to what extent Ss#3's behavior varied from that of a "normal," non-problematic child in the same classroom, engaged in the same tasks. Interval records used were based on 10-second observations of the child during which an off-task behavior was scored as either a motor, verbal, or termination response (please refer to the methods section of this dissertation for more details). If no off-task behavior was observed, the interval was scored as on-task.

Ss#3 was recorded as on-task for roughly 55% of the intervals observed regardless of the protocol condition (see Table 4 & Figure 7). Observation data were available for five of seven weeks (i.e., a total of 17 observation sheets or 1,893 observation intervals), during which time Ss#3 was recorded as 9%-43% less on-task than the comparison child. Table 4 also depicts records of observations made while Ss#3 was taking Ritalin before the double-blind was in effect (i.e., pre-protocol RRX condition). During week 1B (when Ss#3 was taking his usual pre-protocol medication), there was only a 9% difference between Ss#3's on-task behavior and that of the comparison child. Ss#3 was scored on-task for more intervals than at any other time in the protocol. Thus, this was Ss#3's best relative performance. However, this was also the week in which inter-observer agreement was recorded to be the lowest. In

addition, the teachers indicated that Ss#3's behavior was unusually good during that first week because he knew he was being observed. Therefore, data obtained for week 1B may not accurately represent Ss#3's general classroom behavior.

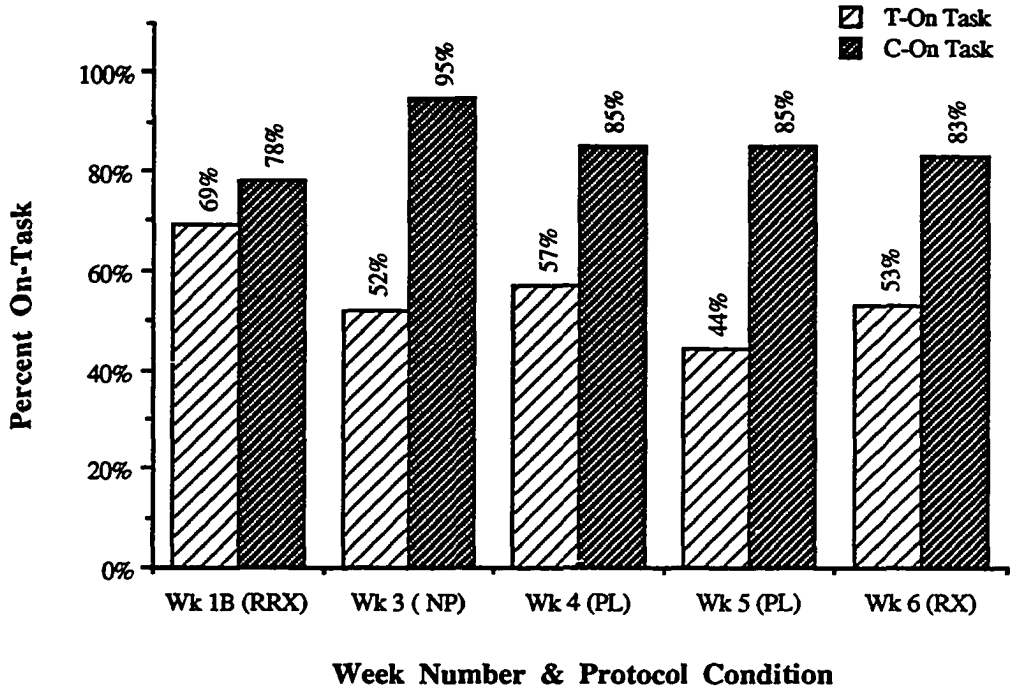
Table 4

Classroom Observation Data for Ss#3 & a Comparison Child

Week Number	Treatment Condition	Target Child Data		Comparison Child Data		% #3 was On Task vs. Compar	Number of observs per week
		On-Task	Off-Task	On-Task	Off-Task		
Week 1B	RRX	69%	31%	78%	22%	9%	2.83
Week 3	NP	52%	48%	95%	5%	43%	3
Week 4	PL	57%	43%	85%	15%	29%	2.5
Week 5	PL	44%	56%	85%	15%	41%	2
Week 6	RX	53%	47%	83%	18%	30%	4
							Observ
Overall Average %		55%	45%	85%	15%	30%	Total= 14.33

Table entries depict weekly averaged percentages of on- and off-task intervals as recorded by undergraduate students during direct classroom observations of the target's and the comparison child's behavior for each week. Data are presented for each week in the protocol according to whether the child was taking medication: pre-protocol Ritalin (RRX), protocol Ritalin (RX), placebo pills (PL), or no pill at all (NP). The number of observations made for that week are recorded to the right as well as the overall average for on- and off-task behavior for both the target and comparison child. A graphic depiction of this table can be seen in figure 7.

Figure 8 graphically depicts Ss#3's observed on-task intervals while under the two double-blinded probe conditions (Ritalin and placebo) as well as the no pill probe. Although these observations were made during different weeks, each protocol week's scores (as seen in Table 4) were summed and averaged for this figure. Data from non-double-blinded Ritalin probes were not included in this graph. In general, under the protocol's blinded conditions, Ss#3 was scored as off-task for as many intervals as he was on-task, whether he was taking placebo, Ritalin, or no pill. Furthermore, his on-



Note: A total of 14.33 observations conducted almost weekly throughout the 7 weeks of the protocol were averaged and the percentage of intervals the children were observed as on-task doing assigned work were recorded in graph format in this figure. Data are presented for weeks during which Ss#3 was taking his pre-protocol prescription of Ritalin (RRX), the protocol trial of Ritalin (RX), the protocol placebo trial (PL), and a no pill trial (NP). Actual numbers of observations made are noted in Table 4 above. Data are displayed by weeks in the medication evaluation protocol.

Figure 7. In-Class Observations of Ss#3 vs. Comparison Child's On-Task Behavior by Weeks in Protocol.

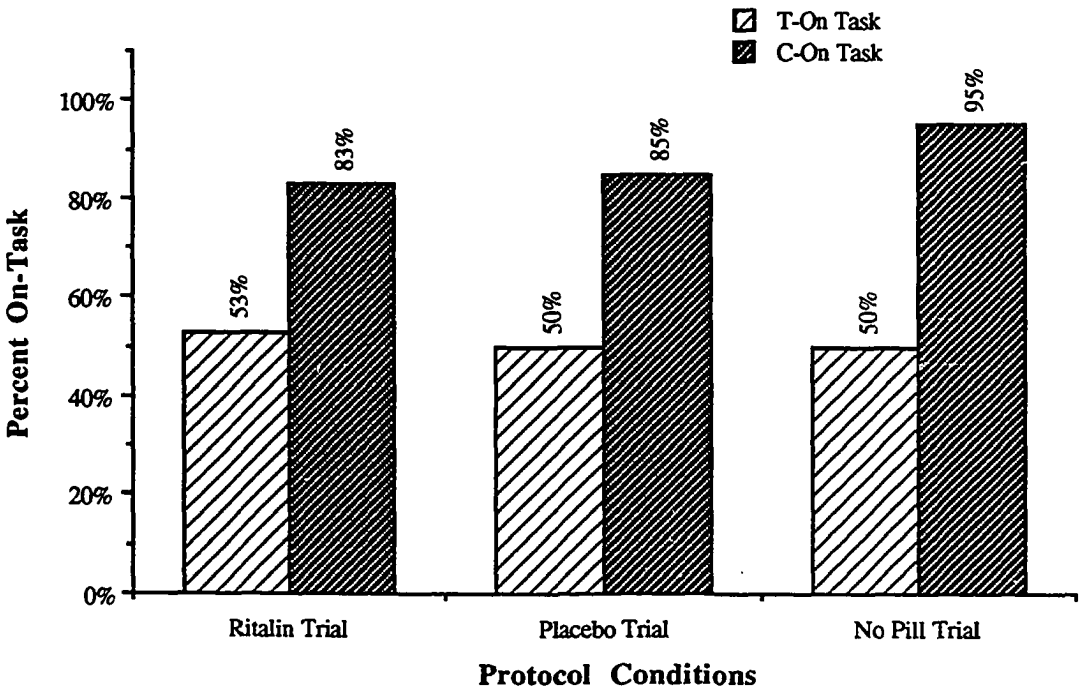
task behavior was only slightly higher when taking Ritalin during blinded conditions.

Zung Depression Scale

The parent acknowledged depressed mood (i.e., minimum to mild mood level) during weeks 1B (RRX), 5 (PL), 6 (RX), and 7 (RX) and rated her mood in the normal range during weeks 2B (RRX), 3 (PL) and 4 (PL). It did not appear that the

parent rated Ss#3's behavior any differently based upon her mood level because she had just as many elevated Conners and ADD Scale ratings when she rated her mood as depressed as she did when she rated her mood "normal."

The teacher ratings on the Zung Depression scale were all within the "normal" range except for teacher 3c who rated her mood in the minimal to mildly depressed range during the pre-protocol assessment. Thus, teacher mood level ratings also did not appear to be correlated with their ratings on the ADD and Conner's Scales.



Direct classroom observations of Ss#3's on- task behaviors as recorded by undergraduate students in which all treatment conditions (pre-protocol Ritalin scores were not included) were added together and averaged by observations made while Ss#3 was on the medication evaluation protocol taking Ritalin, placebo and no pill. The target child's on-task percentages are compared to the comparison child's.

Figure 8. Average On-Task Behavior of Ss#3 & a Comparison Child Across Protocol Conditions.

Marital Happiness & Teacher Satisfaction Scale

The parent rated herself consistently within the moderate range (i.e., 52 to 59 out of a total score of 110) with one score reaching as high as 83 during week 3 (i.e., no pill week). Her ratings on this scale did not seem to correlate with her ratings on the Conners or ADD Evaluation Scales, most notably because her ratings on these scales were so consistent.

The same pattern appears to be true for this scale as it was for the Zung. The teachers rated themselves as consistently highly satisfied with teaching (i.e., scores ranged from 90 to 102) with only teacher 3c rating herself moderately happy during the pre-protocol assessment. (i.e., 53) Thus, little can be said for a correlation between these ratings and ratings on the ADD and Conners Scales.

Discussion of Protocol Findings for Ss#3

It is difficult to estimate how much expectancies affected parent and teacher ratings on the Conners and ADD Evaluation Scales because the parent and teachers did not offer their beliefs about the blinded treatment conditions (except for teacher 3c on one occasion). However, whatever the expectations might have been, their ratings seemed to be roughly the same with little variation regardless of which probe condition was actually in effect (blinded or unblinded).

On the Conners Rating Scale, the parent rated the child's behavior within normal limits every week and also indicated that he was infrequently a problem by her ratings on the ADD Evaluation Scale (i.e., she rated his behavior as hyperactive during a RRX probe and as impulsive during a placebo probe and a no pill probe). One teacher rated the child's behavior as hyperactive twice on the Conners (i.e., during a

RRX week and a RX week) but mainly as impulsive on the ADD Evaluation Scale (i.e., she rated his behavior as impulsive during a NP, PL, and RX probe; inattentive during a RX probe; and hyperactive during a RX probe). On the other hand, teacher 3c rated the child as hyperactive on the Conners (i.e., during the last 5 weeks in the protocol) but not on the ADD Evaluation Scale (i.e., she rated his behavior impulsive once during a PL week but as normal every other week). Thus, it would appear from these data that Ss#3 did not display behavior symptoms and Ritalin might not have been recommended from these data because information was mixed and often conflicting. No consistent symptomatic behavior was found across probe conditions.

However, observer ratings indicated that the target child's behavior was consistently off-task half of the time he was observed. Observer data also showed a clear discrepancy between the subject's and comparison child's behavior. Thus, it appeared the subject displayed symptomatic behavior which was not improved by Ritalin (i.e., observers noted only a 3% improvement in his on-task behavior in comparison to observations made while the subject was taking placebo and no pill).

Although teacher ratings were not clinically symptomatic, they verbally indicated having difficulty managing Ss#3's behavior. Furthermore, they indicated that his behavior was so bad he needed to be taken out of the protocol and placed back on his pre-protocol Ritalin course. During the last week of the protocol, the teachers indicated Ss#3 was "howling" and was severely disruptive in the classroom. They asked the mother to take him back to the psychiatrist and place him back on his regular medication routine. The next day, believing this had occurred, the teachers remarked on his improved behavior. However, the mother noted that she hadn't switched medications yet. In fact, when the triple-blind code was broken, it was found that Ss#3 had been taking Ritalin for that entire week.

Thus, teacher and parent ratings as well as observer data did not detect differences in Ss#3's behavior in placebo versus Ritalin probes. Although Ss#3 had been taking Ritalin for a number of years and his teachers verbally indicated a strong need for Ss#3 to continue medication, neither the parent nor teachers rated Ss#3's behavior severely symptomatic enough on the ADD Evaluation Scale (i.e., a score of 4 or below) to warrant an ADHD diagnosis during any of the pre-protocol or protocol probe periods.

Perhaps the ADD Evaluation Scale was not as sensitive a symptomatic measure as the Conners Scale. Teacher 3b rated Ss#3's behavior as hyperactive twice (i.e., on 2 out of 8 probes), and teacher 3c rated the patient's behavior as hyperactive on five of eight probe weeks on the Conners Scale. However, during the entire eight week protocol, the parent never rated her child as symptomatically hyperactive on the Conners scale. In contrast, direct classroom observation data indicated that Ss#3 was on-task for slightly more than half the intervals observed (55%), but also was on-task for 30% fewer intervals than was the comparison child. Individual observation session (on-task) data ranged from between 9% to 43% fewer on-task intervals than the comparison child. Thus, Ss#3's on-task behavior was low and it was low relative to that of the comparison child regardless of probe condition. Teachers' ADD and Conners symptom ratings may have been affected by Ss#3's off-task behavior in comparison with other pupils, but the items on these instruments may not have been sensitive to precise aspects of Ss#3's behavior that were problematic, leading to a lack of agreement between the teachers (and parent) on these scales.

A combination of factors may have influenced Ss#3's early withdrawl from the protocol: two consecutive placebo probes occurred during weeks four and five of the study, and Ss#3's family life was disturbed during the middle of the fifth week (i.e., Wednesday evening). Ss#3's increased inappropriate classroom behaviors during the

following week may have led to the teachers' stronger conviction of Ss#3's need for medication. Thus, the data gathered during this time may not have been an accurate sample of Ss#3's general classroom behavior, but might still have been a test of the limits of his medication because he was given Ritalin for the week following "Fred's" departure and his symptomatic behavior ratings did not improve. However, his teachers' subjective reports about his behavior did improve once they believed Ss#3 was back on the pre-protocol Ritalin regime.

Additional evidence for the susceptibility of perceptions to influence on patient symptomatic reports/ratings comes from Ss#3 himself. Ss#3 questioned the adults involved about whether he was taking active medication and appeared to be easily influenced by their reports. The first day of what was actually a placebo probe, Ss#3 expressed his doubt that the pill was working. Ss#3 then asked this examiner when the pill would start working and was told "now." He then said he thought so because he had had a lot of concentration in gym that day. The following day was reported to be his best day for that week according to his teachers. After that, he complained that he thought the medication wasn't working. Thus, Ss#3 might have validated the effect of medication on his behavior in either direction, according to his current belief about his present medication status.

Protocol Recommendations for Ss#3

The continuation of Ss#3's pre-protocol treatment was recommended for the remaining 4-5 weeks of school for the following reasons: (a) Teachers were invested in the belief that Ritalin was the only thing that was going to help Ss#3; (b) There weren't enough data points (weeks of evaluation) to determine with confidence that Ss#3 was clinically significantly better under any of the probe conditions; (c) The blinded Ritalin conditions may not have shown clinically significant improvements on

in-class behavior observations over blinded Placebo and No Pill probes because Ss#3 was emotionally distressed by the departure of "Fred"; (d) Symptom rating forms completed by parents and teachers may not have assessed clinically significant intolerable behaviors; (e) It was not clear how many days the parent did not give her child his pill (she only told us she did not give it on one day of week 7); (f) There were relatively few in-class behavior observations and those obtained had fairly low reliability (69% overall reliability); (g) Behavior observations may not have been recording the most distressing behaviors to parent and teachers. Thus, treatment should remain "status quo" because there were no strong symptom or sign data supporting a change.

It was, however, recommended that Ss#3 be instructed so that he could better control his behavior because he appeared to engage in many inappropriate behaviors despite receiving Ritalin. As indicated by Brown, Kaslow, Sansbury, Meacham, & Culler (1991), children with a chronic disorder (the authors originally referred to diabetes but the present author is broadening "chronic" to include children diagnosed with ADHD) should be taught to take personal responsibility for controllable negative events and dissuaded from self-blame for uncontrollable negative events associated with the disorder. For example, ADHD children can be taught about relevant personal behaviors that can be controlled (e.g., diet, exercise, taking medication, working on strategies to increase attention and memory as well as decrease impulsivity) and encouraged to take personal responsibility for independently managing these aspects of their own care. As suggested by Brown et al., "...they need to be supported in the aspects of the illness (e.g., having a chronic illness that is beyond their control as well as accepting the physiological processes associated with the illness, which may occur even during times of good compliance) that are beyond their control....Finally, they

need to be cognizant of the effects of [ADHD] on their lives yet not allow the illness to dominate their daily lives" (Brown et. al, 1991, p. 924).

In summary, the most effective treatment course for Ss#3 would be to continue his current (unblinded) medication regime as well as continue with his current therapist to identify controllable behaviors and to set up contingencies for rewarding increased attention and decreased impulsivity and hyperactivity. A therapist could also focus on encouraging Ss#3 to talk about his thoughts and feelings regarding "Fred" so that he can be guided in ways of dealing with potential adverse effects of these reactions on his daily behavior and social adjustment. In addition, Ss#3 should be evaluated for depression since he acknowledged several symptoms characteristic of depressed mood which might be in reaction to the departure of "Fred" or it may be a long-standing disorder which may be exacerbating his hyperactivity and general inappropriate behavior.

CHAPTER IV

INDIVIDUAL PROTOCOL FINDINGS FOR SS#4

Referral Source and Reason for Protocol Enrollment

Ss#4's mother heard about this drug evaluation protocol and asked if her son could be included to determine if he really needed to be taking medication. She indicated that she hadn't noticed any differences in his behavior since he started taking Ritalin and, in fact, he often complained that the medication upset his stomach and slowed him down when he played soccer. Because of her son's complaints, Ss#4's mother indicated she wanted to make sure the medication was actually helping her son's productivity and/or learning at school.

Social History and Background

Ss #4 was a 9-year-old, African-American boy with an estimated I.Q. score of 78. He attended special education and regular classes in the 3rd grade. Both his parents worked 45-50 hours a week. When Ss#4 was 2 years old, his mother asked the pediatrician if her son was hyperactive but he was not placed on medication until the second grade, at the request of his teachers. Ss#4 was taking 10mg Ritalin twice a day but when he complained of feeling queasy and weak, the dose was lowered to 10mg Ritalin in the morning and 5 mg in the afternoon. He had been taking Ritalin at this lowered dose for about a year before starting the protocol.

Prior permission was obtained for the protocol evaluation by the principals of the schools included in the study, as well as by the teachers, parents, and subjects. However, from March 16th to the 20th, central district administrators requested that the

protocol be suspended until permission to proceed could be obtained from the School Board. Therefore, there is a "break" in this, and all other protocols to follow, starting with Ss#4 (Ss#3 did not experience the break because he had dropped from the study by this time). Some teachers and parents continued to complete the forms even though they were told not to. However, no direct classroom observations were collected during this "break" week. School Board permission was granted within a week and the protocol continued without any further interruptions.

Protocol Findings for Ss#4

Ss#4 completed all twelve weeks of the evaluation protocol with one week officially a "break" but his teacher nevertheless completed her data sheets during the break (i.e., between the first two no pill weeks, B1 and B2). In addition to the pre-test data, Ss#4's mother completed 12 data sheet packets and his teacher completed 13 (an extra being completed by the teacher during the break). Because Ss#4 enrolled in the protocol late in the school year, less than 12 full weeks remained until the close of school. The protocol was compressed by splitting week 7B and 8B (no pill week) so that data were collected twice for that week and are considered to be two weekly probes when inspecting the findings. Between 1-4 classroom observations were obtained per week for 11 out of 12 protocol weeks. During the evaluation, Ss#4 received pre-protocol Ritalin during two probes (during the first week only pre-test data were taken), no pill for four probes (of which one no pill week occurred at the break in the study), Ritalin for four probes and placebo for four probes.

Pre- & Post-Protocol Findings for Ss#4

Pre-Protocol Medication Attitude Responses

On the pre-protocol survey, Ss#4's mother indicated she brought her son in to be evaluated for ADHD after his teachers commented that he might be able to focus his attention better were he taking a psychostimulant. Ss#4's mother was ambivalent about Ritalin use for her child because she had received varying reports from Ss#4's teachers. She estimated that Ritalin improved her son's symptomatic behavior by 20% (e.g., helping him settle down and focusing his attention) but stated that he would probably do as well as he had been doing if he weren't taking Ritalin. Her biggest concerns were that he needed to listen more carefully to directions and follow through without being reminded step by step. Compared to other children, Ss#4's mother saw her son as more social (i.e., "he was awarded best manners and is a generally pleasant child") but as less self-assured and self-confident in an academic environment as he was in his athletic ability. She also saw him as hard-working and persistent even in the face of failure.

Ss#4's reading teacher estimated that Ritalin helped Ss#4's symptomatic behavior a great deal, by 90%, and that it helped control his physical movements and his ability to concentrate. She stated she didn't find his behaviors to be problematic in the classroom but that she did think his attention tended to wander and that he scratched himself and fidgeted more often when he was not on medication (e.g., he bit his nails and tapped on the table). She indicated further that he seemed better able to control his physical movements and concentrate when he took Ritalin. She thought he was more observant and more curious than his peers but that he had lower self-esteem regarding his academic ability than other children. She believed that if he did not take Ritalin his academic abilities would "take a nose-dive" and his self-esteem would become even

lower. This teacher also tutored Ss#4 every morning for 30 minutes to an hour before class.

Initially, Ss#4's math teacher was going to participate in the protocol but after completing the pre-protocol survey she changed her mind. However, on this survey she indicated that Ss#4 did not stand out from the rest of the students in her class since "all the students in the class are bad." She indicated that his parents were at first reluctant to place Ss#4 on medication and stated that it took "gentle and persistent encouragement to get testing and permission to give him extra help and with taking medication. This included meeting with all of Ss#4's teachers who encouraged a medical evaluation and another dose of medication for the afternoon." She stated that her previous experiences with psychostimulants have been positive; that she worked with a number of families and that these were usually obvious and extreme cases. She stated it was "critical" for Ss#4 to be on medication because his parents have such high expectations for him. She believed there was a dramatic difference in Ss#4's behavior on Ritalin, estimating that it improved his behavior by 75% (e.g., he was better able to sit at his desk, not be bothered by the activity of other students around him, and was able to finish independent work, although the quality was not necessarily connected to Ritalin). She also believed that there was a more pronounced effect when he was taking a higher dose.

This teacher noted that she found most distressing Ss#4's "wiggliness," indicating he didn't finish his work because he was too "antsy." He also was sensitive to his performance level and checked out what other students were doing around him which undermined his confidence. In comparison to other students, Ss#4's math teacher indicated that he had the lowest academic performance in his grade level but that "you can't help but like him, he's sensitive, well-mannered, and loves to play with his peers."

Ss#4 indicated that he liked taking Ritalin because it helped him think better and to concentrate. Furthermore, he estimated that it helped improve his behavior by 100% and that it was the only thing that would work for him.

Post-Protocol Medication Attitude Responses

After the protocol was completed, Ss#4, his mother and teacher were again questioned. His mother indicated she still wasn't sure whether Ss#4 needed to be taking Ritalin. She stated that she used to be against children taking psychostimulants until she saw a dramatic improvement in one child's behavior. However, she indicated that she didn't see an improvement in Ss#4's behavior except that maybe it helped by 25% (e.g., slowing him down, allowing him to focus his attention) but she wasn't even sure about this. She has relied on his teachers' feedback in judging improvements in his behavior but stated this feedback hasn't always been consistent and that she was relying on this protocol to give her some more objective, definite answers.

Ss#4's Reading teacher indicated on the post-protocol survey that she didn't find his behavior to be as bad as she remembered the reports to be but then she didn't know when he was on medication and when he wasn't (although she did glance at the calendar noting the weekly treatment probe conditions when she became curious). She saw Ss#4 unable to concentrate occasionally but wasn't sure if it lasted an entire week. However, she then stated that when he knew he was not taking medication he scratched himself more often and engaged in continuous movements. She admitted to feeling very strongly that Ss#4 needed to be on medication at the time of the pre-protocol survey but that now she wasn't so sure. She estimated that if Ritalin did help his behavior, it did so by 50%, giving him better physical control (less constant and continuous fidgeting) and better concentration. Her recommendations were that Ss#4 be placed in situations where he could succeed, which would emphasize structure in

learning. Furthermore, she believed he would do better with a teacher who had a good sense of humor and a lot of patience.

Ss#4 indicated that Ritalin " makes me work better...it helps me from getting wild." However, he contradicted himself when he indicated he thought Ritalin didn't improve his behavior at all (i.e., by 0%). He indicated he didn't like taking it ("I don't like the color...it tastes awful, like plastic...I liked it better when it was a small tablet").

Summary of Medication Attitude Survey

On the pre-protocol survey, the teacher and Ss#4 both endorsed Ritalin as beneficial. Ss#4's teacher estimated that Ritalin improved Ss#4's behavior by 90% and Ss#4 estimated that it improved his behavior by 90%. However, Ss#4's parent appeared to be neutral in regard to Ritalin and stated that she estimated that if it improved Ss#4's behavior, it did so by only 20%.

The parent's attitude about Ritalin remained the same on a post-protocol survey (i.e., she estimated that Ritalin helped improve Ss#4's behavior by 25%). Ss#4's attitude appeared to be ambivalent but more negatively biased against taking Ritalin on a post-protocol survey conducted about 13 weeks later (i.e., he indicated it did not help him at all and estimated 0% improvement in his behavior after taking Ritalin). The teacher's attitude appeared to be more guarded, less enthusiastic, and less firm in her belief of Ritalin's effectiveness for Ss#4. However, she still seemed to favor use of Ritalin, estimating that Ritalin improved Ss#4's behavior by 50%.

Ss#4's math teacher completed only the pre-protocol measures, indicating early in the protocol that she did not want observers in her classroom. However, she appeared to be the most convinced that Ritalin was necessary for Ss#4, suggesting that it was only by her own strong urgings and that of the other teacher that helped get Ss#4

in for an evaluation for Ritalin prescription. Because she declined to participate in the protocol, she was not contacted for a post-protocol survey.

Norwicki-Strickland Locus of Control

This assessed the subject's locus of control or tendency to believe that external forces outside personal control caused his problems. Internality is associated with academic achievement, persistence, higher self-esteem, higher self-concept, higher moral development, greater popularity, more honesty, shorter delay of gratification, lower anxiety, and less interpersonal distance. External scores are associated with emotional, physical, or mental handicaps, psychological maladjustment, vulnerability to sickness and accidents, and hyperkinesis/aggression in boys.

Ss#4 responded "yes" to 76% of the questions (i.e., 31 out of 40 questions), suggesting a tendency towards an external score. In fact, no one in the protocol series had as high an external score. He thus may have believed strongly that his behavior could only be treated with Ritalin . On the pre-test of the Medication Attitude Survey he stated that Ritalin was the only thing that would work for him. Furthermore, he stated that Ritalin helped him think better and concentrate and that it improved his behavior by 100%.

However, on the post-test, Ss#4 acknowledged only 23 external responses (i.e., 58% "yes" responses), suggesting he tended to feel more in control of his behavior and that he believed Ritalin had less impact on his behavior. This was consistent with his answers on the Medication Attitude Survey in which he estimated that Ritalin was 0% effective in improving his behavior but still believed it made him "work better" and helped keep him from "getting wild."

Although Ss#4 had a lower post-test score on the Norwicki-Strickland, he still seemed to believe Ritalin had an effect on his behavior. Why he changed to a more

internal locus of control might be a function of the evaluation protocol. There were times when Ss#4 was not taking medication and those occasions were in close time proximity to occasions when he was taking a pill. Thus, it may be that without medication the subject began to recognize his own strengths and ways to cope with his behavior that he hadn't experienced before. This, combined with his mother's skepticism, may have contributed to his lowered post-test locus of control score.

Weekly Probe Findings for Ss#4

Conners Rating Scale

Applying the cut-off score of 1.54+ for parent symptom ratings and 1.97+ for teacher ratings on the Hyperkinetic Index of this scale, symptom ratings by Ss#4's parent reached clinical criterion to qualify Ss#4's behavior as hyperactive during three out of thirteen possible probes (see Table 5 below): during the pre-protocol Ritalin probe (week B-1) and during two placebo probes (weeks 3 & 12). Teacher symptom ratings never reached clinical criterion for hyperactivity during any of the fourteen probes. Only the teacher completed forms during the break in the protocol. Figure 9 also graphically depicts this information and portrays fairly consistent teacher and parent symptom ratings across all probe conditions.

Parent and teacher symptom ratings on the Conners Rating Scale were similar regardless of the probe condition believed to be in effect or actually in place, except in a few instances (see Figure 9). The teacher never rated the child as symptomatically hyperactive and the parent did so only three times: once during the unblinded pre-protocol Ritalin probe and twice during blinded placebo probes. These were probe weeks for which the teacher rated Ss#4's symptoms of hyperactivity as least severe (see Figure 9 and Table 5).

Table 5

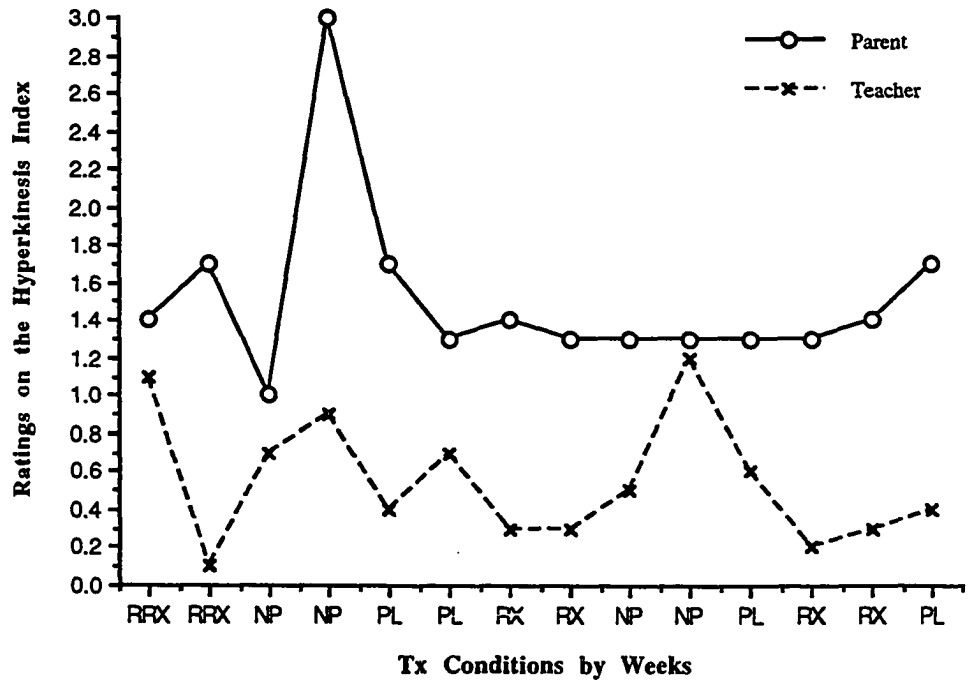
Parent & Teacher Ratings on the Conners Rating Scale
for Ss#4 by Treatment Conditions

Week Number	Actual Tx Condition	Told re: Tx Condit.	Parent 4a Belief re: Tx Condit.	Teacher Belief 4b	Parent 4a Hyper Index	Teacher 4b Hyper Index
Pre-Test	**RRX**	RRX	N/A	N/A	1.4	1.1
B-1	**RRX**	RRX	RRX	RRX	< *1.7* >	.1
Break	**NP**	NP	N/A	NP	N/A	.7
B-2	**NP**	NP	NP	NP	1.0	.9
3	**PL**	RX	PL	RX	< *1.7* >	.4
4	**PL**	PL	DK	DK	1.3	.7
5	**RX**	PL	DK	RX	1.4	.3
6	**RX**	RX	RX	RX	1.3	.3
7	**NP**	NP	NP	DK	1.3	.5
8	**NP**	NP	NP	DK	1.3	1.2
9	**PL**	PL	DK	RX	1.3	.6
10	**RX**	RX	RX	RX	1.3	.2
11	**RX**	PL	DK	RX	1.4	.3
12	**PL**	RX	DK	RX	< *1.7* >	.4
Parent	correct=3/8	DK=5/8		teacher	correct=4/8	DK=1/8

Note: (Scores of 1.9+ for teachers & 1.5+ for parent suggest ADHD behavior.) Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Parent and Teacher Rating Scale across three treatment conditions: RRX = baseline Ritalin (pre-protocol), NP = baseline (no medication or tablet administered), PL = placebo pill (protocol condition), RX = Ritalin (protocol condition). Scores in brackets indicate significant scores which are indicative of hyperactive behavior. "Actual Tx condition" represents what the child was actually administered; "Told re: Tx condition" indicates what teachers and parent were told the child was taking; and "Belief re: Tx condition" indicates what the teachers and parent acknowledged to be their belief about what the child was actually taking (DK= Don't know). The parent correctly guessed the protocol conditions 3 out of 8 times and the teacher correctly guessed 4 out of 8 times. The parent indicated she didn't know which protocol condition was in effect 5 out of 8 times and the teacher indicated "don't know" only 1 out of 8 times (she was incorrect 3 times but guessed RX every time).

Although all teacher symptom ratings of hyperactivity were at sub clinical

levels, peak scores did occur among some probe weeks (see Figure 9 below). Symptoms of hyperactivity were rated as slightly higher during the (unblinded) no pill condition on four out of four such probes. Hyperactivity symptoms were rated as slightly higher during the (blinded) placebo condition on two out of four such probes, and as slightly higher during one of the (unblinded) Ritalin probes among the six Ritalin probes: two of which were unblinded, and four blinded.



(Note: Scores of 1.54+ for parents and 1.97+ for teachers suggest ADHD behavior on this scale.) Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Parent (Revised 48-item) and Teacher (Revised 28-item)Rating Scale across three treatment conditions: RRX = pre-protocol Ritalin, NP = no treatment control (no medication or tablet administered), PL = placebo pill (protocol condition), RX = Ritalin (protocol condition). Ss#4's parent did not complete the rating scale for the second of the no pill conditions therefore a data point is missing from this graph.

Figure 9. Parent & Teacher Ratings on the Conners Hyperkinesis Index Subscale by Treatment Conditions & Weeks Before & During the Protocol for Ss#4.

ADD Evaluation Scale

This scale uses raw scores, subscale standard scores (i.e., obtained by converting raw scores into age-appropriate standard scores which are then used to discriminate between ADD vs. "normal" levels of behaviors), and a percentile score (i.e., derived from the sum total of the subscale standard scores and used to compare the child assessed with those of the standardization sample).

The standard scores have a mean of 10 and a standard deviation of 3. Standard scores of 7 through 13 are within one standard deviation above or below the mean and indicate the child behaves no differently than most of the children in the standardization sample. However, standard scores below 7 indicate that the child behaves more inappropriately than the majority of the students in the normative sample. A specialized intervention program is recommended to address these behaviors. A standard score of 4 or below lies two or more standard deviations below the mean and indicates a serious level of concern. A standard score of 4 or below is considered the point at which a diagnosis of ADHD can be made (along with documentation from other instruments) and a formal treatment plan would be recommended to address the student's symptomatic behaviors.

As can be seen in Table 6, during no weekly probes did the teacher rate Ss#4's behavior in the clinically significant range (6 or below). Ratings by the parent reached clinical criterion for inattention on every probe week (12 out of 12 weeks) and once for impulsivity during a placebo probe week. Overall, scores never reached criterion for all three subscales for either parent or teacher. There was only one extreme score (4 or below) which occurred during week 2 (no pill probe condition).

Percentile scores for the ADD Evaluation Scale were determined for the subscale standard scores in Table 6. Percentile scores allow for comparison between

the subject's ADD symptomatic ratings and those of children in the standardization sample for this scale. For example, the parent rated Ss#4's behavior in the 15th percentile during the RRX condition. This means she rated his behavior lower than 85% of the students in the ADD Evaluation Scale's standardization sample. Whereas the teacher for this same pre-protocol condition rated the subject's behavior lower than only 27% of the children in this standardization sample.

Table 6

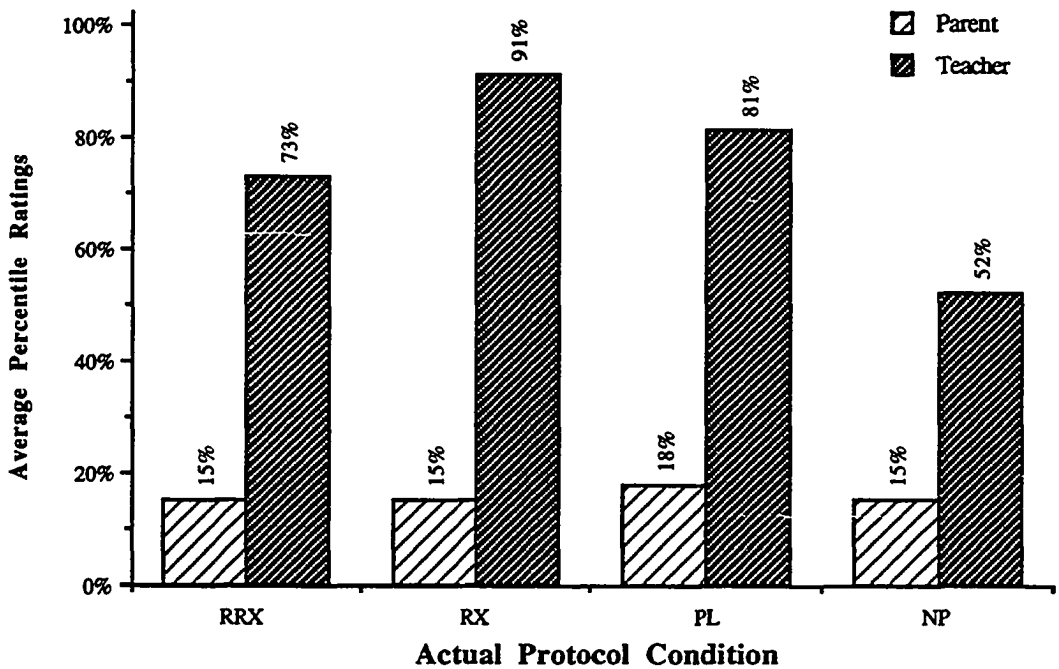
Parent & Teacher Ratings on the Attention Deficit Disorders Evaluation Form for Ss#4

	Parent				Teacher		
Week #	Inattent	Impulsive	Hyperact	Tx Condit	Inattent	Impulsive	Hyperact
1	<5>	7	8	RRX	11	12	12
BREAK				NP	10	11	10
2	<4>	7	8	NP	10	11	10
3	<5>	8	11	PL	13	13	13
4	<5>	7	8	PL	12	12	12
5	<5>	7	8	RX	13	13	13
6	<5>	7	8	RX	13	13	13
7	<5>	7	8	NP	11	13	13
8	<5>	7	8	NP	9	12	10
9	<5>	<6>	8	PL	11	12	12
10	<5>	7	8	RX	13	13	13
11	<5>	7	8	RX	13	13	13
12	<6>	7	8	PL	13	13	13

Note: On any of the three subscales (Inattention, Impulsivity, Hyperactivity), a standard score of below 7 represents significant behavior deviance and scores 4-0 represent extreme behavior, significant for a clinical diagnosis of ADHD (with accompanying data from parents and teachers) according to the ADD Evaluation manual. Scores in brackets indicate significant scores. Parent and teacher scores are listed next to the actual medication, placebo or no pill which was being administered to the child for that week in the protocol. Only the teacher, not the parent, completed data during the break in the protocol.

As shown in Figure 10, the parent consistently rated Ss#4's ADD symptomatic behavior as worse than 85% of the children in the standardization sample. The teacher

rated Ss#4's symptomatic behavior within the normal range under the No Pill, Placebo and Ritalin probe conditions. Ss#4 received the best teacher symptomatic behavior ratings in the (blinded) Ritalin probe conditions, followed in order by the (blinded) Placebo conditions, the (unblinded) Pre-protocol Ritalin condition, and the (unblinded) No pill conditions.



The ratings in this graph were determined by adding the sum of the subscale standard scores (as found in Table 6) and converting them to percentile scores. These percentile scores were then summed and averaged for ease of inspection (there were two data sheets collected for the RRX condition, three for NP; and four each for RX and PL). The percentile scores in the above Figure indicates how the subject being rated compares to children in the ADD Evaluation Scale's standardization sample. Note: RRX=pre-protocol (unblinded) Ritalin; RX=protocol (blinded) Ritalin; PL=placebo (no active medication administered); and NP=no pill (no tablet was administered).

Figure 10. Average ADD Evaluation Scale Percentile Ratings From Parent & Teacher Across Actual Protocol Conditions for Ss#4.

Across all weeks and probe conditions the teacher rated Ss#4's symptomatic behavior as better than did the parent. The teacher rated the subject's symptomatic behavior as better than that of 50% of the children in the standardization sample. Furthermore, only a 10% discrepancy separated the teacher's ratings under RX and PL probe conditions. The parent's symptomatic behavior ratings appeared as clinically significant across all probe conditions.

Accuracy of Parent and Teacher Reported Beliefs

The parent was correct all three times she made a guess regarding which protocol condition Ss#4 was in (see Table 5 above for a display of the treatment conditions and the corresponding parent and teacher beliefs). She responded "don't know" 63% of the time (5 out of 8 times).

Table 5 shows that the teacher guessed Ritalin every time she made a guess. She was correct 50% of the time (4 out of 8 times) and responded "don't know" once. Her tendency to respond "Ritalin" every week may indicate either a lack of effort on her part to detect differences in Ss#4's behavior and write them down or that she did not notice any differences in his behavior from pre-protocol status. The latter appears more likely since her ratings on the Conners and ADD Evaluation Scale were not clinically significant for hyperactive, inattentive, or impulsive behavior. In any event, because the parent made only three guesses and the teacher suggested Ritalin every time she made a guess, no real comparison of beliefs with actual probe conditions can be made. However, some speculations can be offered.

In sum, teacher and parent ratings of symptomatic ADD behavior for Ss#4 did not vary enough between the various probe conditions to suggest that the parent or teacher were able to detect differences in Ss#4's behavior, either on the rating scales or when making guesses regarding actual probe conditions. Their symptom ratings on the

Conners Parent and Teacher Rating Scales were similar regardless of probe conditions, either in effect, or believed to be in effect, with few exceptions (see Figure 9). Of note however, is that teacher ratings of ADD symptomatic behavior never reached levels of clinical significance and that parent ratings did so only on three probes: pre-protocol Ritalin and two placebo probes.

Although teacher symptom ratings did not reach clinical significance, sub clinical peak scores were obtained (see Figure 9). She rated Ss#4 as most hyperactive during the no pill condition and as more symptomatic during two of the four placebo probes. Among the six Ritalin probes, she rated his behavior as symptomatic only on one (unblinded) probe.

Interobserver Agreement for Classroom Observations

Out of 21.9 observation sheets collected on Ss#4 for on- and off-task classroom behavior, inter-observer agreement (i.e., two observers watched the subject at the same time) checks were available for 9.4. There were actually 23 inter-observer observation sheets but not all intervals on all the sheets were completed so only the number of intervals was counted. Thus, inter-observer reliability was obtained on 42% of the total number of intervals observed (1126/2650).

As can be seen in Table 7, the agreement indexes obtained for Ss#4 and the comparison child (combined) for individual weeks (e.g., the percent agreement on the total of the individual daily observation sheets) averaged 79% (column 4, row 11) and ranged between 67% to 97% (column 4). Broken down further by child per week, the overall (on- and off-task) percentage of agreement for Ss#4 (e.g., the percent agreement between one observers' on- and off-task total with the other observer's on- and off-task total scores) ranged between 62% to 98% (column 2) with a mean of 79%

Table 7

Inter-Observer Reliability of Classroom Observations
for Ss#4 (Target) & a Comparison Child

		Percentage of Agreements								
		Overall On- & Off-Task Agreements			***Separated by Child & On-/Off--Task Records (Interval-by-Interval)***					
		Targ Child	*Comp Child*	*Ave Daily Agree*	*Target Child*		*Comp Child*		*T + C On-Tasks*	*T +C Off-Task*
	Week #	*Ave Agree-ment*	*Ave Agree-ment*	*On+Off T + C*	*% Agree On-Task*	*% Agree Off-Task*	*% Agree On-Task*	*% Agree Off-Task*	*Ave rage Agree-msnt*	*Ave rage Agree-ment*
	COL 1	COL 2	COL 3	COL 4	COL 5	COL 6	COL 7	COL 8	COL 9	COL10
ROW 1	Wk #4	82%	100%	91%	80%	28%	100%	100%	90%	30%
ROW 2	Wk #6	62%	87%	74%	51%	36%	86%	33%	70%	35%
ROW 3	Wk #6	86%	78%	82%	83%	55%	76%	30%	79%	43%
ROW 4	Wk #6	93%	94%	93%	90%	79%	94%	30%	92%	69%
ROW 5	Wk 7B	78%	78%	78%	68%	56%	78%	7%	74%	41%
ROW 6	Wk 7B	69%	66%	68%	34%	63%	43%	54%	39%	59%
ROW 7	Wk 7B	77%	70%	73%	75%	20%	65%	31%	70%	26%
ROW 8	Wk 9	76%	57%	67%	74%	30%	55%	9%	64%	18%
ROW 9	Wk 9	64%	78%	71%	57%	32%	78%	0%	69%	22%
ROW10	Wk 10	98%	97%	97%	97%	57%	97%	43%	97%	50%
ROW11	AVG:	79%	81%	79%	71%	46%	77%	34%	74%	39%
ROW12	Total Overall Percent Reliab for the whole study = 80%									

Ss#4 (T= target child) and a comparison child (C), were observed by undergraduate students and inter-observer reliability data were collected for 9.4 of the 21.9 observations. Table 3 depicts percent agreements between two observers recording on- and off-task behavior independently of each other. The first three columns represent overall agreement for the whole observation session (not interval by interval) for the target and comparison child (i.e., columns 2 & 3); and the overall percentage of agreement (i.e., combined scores for on- and off-task as well as for target and comparison; column 4) for that observation week. In the last six columns inter-observer agreements were broken down into percent agreement on an interval-by-interval basis for on-task and off-task behavior for target and comparison child separately (i.e., columns 5 through 8) and the average agreement for on-task & off-task behavior for both target and comparison child combined.(i.e., columns 9 and 10). Row 11 depicts the averages for each column and row 12 represents the percent agreement for the whole study.

(row 11) and for the comparison child, the percentage agreement ranged between 57% to 100% (column 3) with a mean of 81% (row 11).

Table 7 also displays interval-by-interval agreement indexes for both the target and comparison child for combined on- and off-task behavior (e.g., comparing each observer's scores for each interval for which the protocol and comparison child were observed). Reliability (agreement) obtained through this manner is necessarily lower than the overall reliability because the proportion of disagreements to agreements increases when you compare total numbers of disagreements with subcategories of agreements. With this in mind, the total percentage of on-task agreement per week and by condition for both target and comparison child (column 9) ranged between 39% to 97% (mean = 74%) and off-task agreement (column 10) ranged from 18% to 69% (mean = 39%). The agreement indexes for on- and off-task behavior by child and week are also listed in Table 7 (columns 5 through 8).

On-task agreement reliability is substantially higher than off-task agreement. This is expected because on-task is scored by default when either no behavior is observed or a behavior is missed by one or the other observers. On the other hand, inappropriate behavior must be seen in order to score the interval as off-task.

The overall (on- and off-task) inter-observer agreement obtained for Ss #4 and the comparison child (combined) was 80% (row 12). Thus, the overall reliability appears to suggest data of sufficient quality to make guarded clinical decisions about treatment options being considered, especially when treatment continues to monitored and adjusted as needed.

Classroom Behavior Observations

Ss#4 was scored as on-task for roughly 75% of the intervals observed (73% for

the first half of the study and 76% for the second half) regardless of the protocol condition (see Table 8 & Figure 11 below). Although observation data were not available for each week, Ss#4 was scored as on-task only 1% to 17% fewer intervals than the comparison child nearly every week observations were made except for week

Table 8

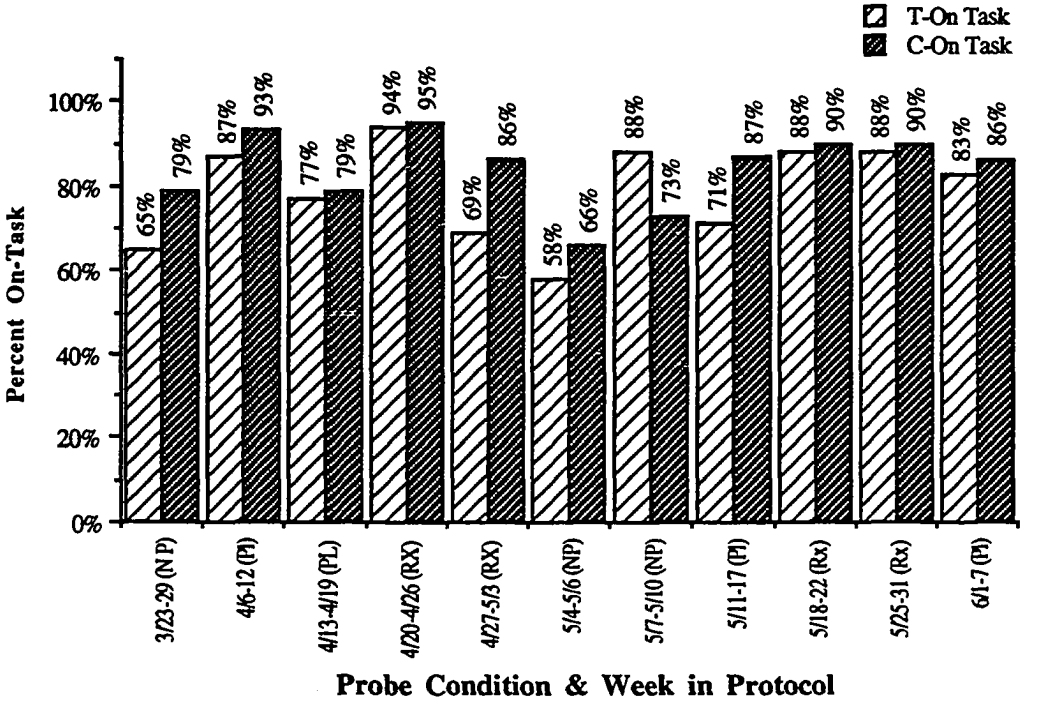
Classroom Observation Data for Ss#4
& a Comparison Child

Week Number	Treatment Condition	Target Child		Comparis Child		% #4 was On Task vs. Compar	Number of observs per week
		On-Task	Off-Task	On-Task	Off-Task		
Week B2	No Pill	65%	35%	79%	21%	14%	4
Week 3	Placebo	87%	13%	93%	7%	6%	1
Week 4	Placebo	77%	23%	79%	21%	2%	2
Week 5	Ritalin	94%	6%	95%	5%	1%	1
Week 6	Ritalin	69%	31%	86%	14%	17%	2.4
Week 7B	No Pill	58%	42%	66%	34%	8%	3
Week 8B	No Pill	88%	13%	73%	27%	*+15%*	1
Week 9	Placebo	71%	29%	87%	13%	16%	2.5
Week 10	Ritalin	88%	12%	90%	10%	2%	2
Week 11	Ritalin	88%	12%	90%	10%	2%	2
Week 12	Placebo	83%	17%	86%	14%	3%	1
Overall Average		75%	25%	82%	18%	7%	21.9
Ave for 1st half of study		73%	27%	87%	13%	14%	10.4
Ave for 2nd half of study		76%	24%	81%	19%	5%	11.5

Table entries depict weekly averaged percentages of on- and off-task behaviors as recorded by undergraduate students during direct classroom observations of the subject's and the comparison child's behavior for each week in the protocol according to whether the child was taking medication (RX=protocol Ritalin), placebo pills (PL), or no pill at all (NP). The number of observations made for that week are recorded to the right as well as the percentage difference between the subject and the comparison child's on-task behavior, overall average for on- and off-task behavior for both the target and comparison child, and the overall average for the first and second half of the protocol. A graphic depiction of averages from this table can be seen in figure 11.

8B (no pill) during which he was scored on-task for 15% *more* intervals than was the comparison child.

Figure 12 graphically depicts Ss#4's scored on-task intervals while under the two blinded probe conditions (Ritalin and placebo) as well as during the (unblinded) no pill condition. Although these observations were made during different weeks, each

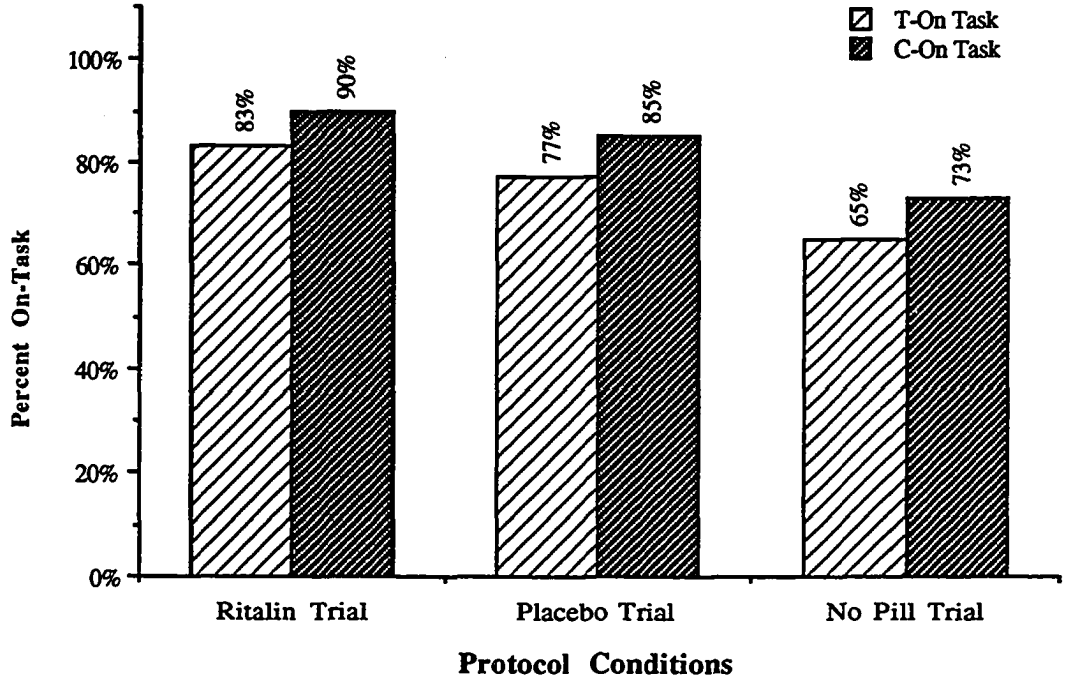


Direct classroom observations of Ss#4's (T=target) and the comparison child's ("C") behavior as recorded by undergraduate students during direct classroom observations by percentage of observation intervals the children were observed to be on-task doing assigned work. A total of 21.9 observations conducted almost weekly throughout the 12 weeks of the protocol are averaged and the percentage of on- and off-task intervals are recorded in graph format in this figure. Data are presented for weeks during which the target child was taking the protocol trial of Ritalin, placebo, and no pill. Actual numbers of observations made are in Table 7.

Figure 11. In-Class Observations of Ss#4 vs. Comparison Child's On-Task Behavior by Weeks in Protocol.

probe condition's weekly scores (as seen in Table 8) were summed and averaged for

this figure. In examining this figure, it appears that any kind of pill might have been therapeutic because Ss#4 was on-task for more intervals when under both (blinded) Ritalin and placebo probes as compared to the (unblinded) no pill trial. Ss#4 was scored on-task for 18% more intervals during the Ritalin probe than during the no pill probe condition but was scored on-task only 6% more intervals during Ritalin probes than placebo probes. Placebo probe performance, in turn, was 12% higher than in the no pill probes.



Direct classroom observations of Ss#4 and the comparison child's on-task behaviors as recorded by undergraduate students in which all treatment conditions were added together and averaged by observations made while the subject was on the protocol taking Ritalin, placebo and no pill.

Figure 12. Average On-Task Behavior of Ss#4 & a Comparison Child Across Protocol Conditions.

As far as comparison child/protocol child behavior discrepancies, there is almost no difference between the two (i.e., there was a 7% difference in favor of the comparison over the protocol child's on-task behavior under the RX condition, 8% in favor under PL, and 8% in favor under NP). Furthermore, Table 8 shows Ss#4's on-task behavior to be 17% lower than the comparison child's on-task behavior during the (blinded) Ritalin probes. This was the greatest difference between the comparison and protocol child at any time throughout the protocol. Finally, in Table 8 it can be seen that Ss#4's on-task behavior was 15% better than the comparison child's on-task behavior when Ss#4 was not taking any pill.

Although when examining individual data it appeared that there were extreme and average "good" days and "bad" days in each of the treatment conditions, Ss#4's on-task behavior appeared to be, on the average, closely matched to that of the comparison child, regardless of the protocol condition in effect even though Ss#4's behavior stood out as unusually good once when he took Ritalin (i.e., during week 5).

Zung Depression Scale

The parent and the teacher both rated their mood in normal ranges throughout the study except during week 4 (placebo week). During this week, the teacher indicated minimally to mildly depressed mood. However, on the next week's form, she also indicated she believed she may have filled out week 4's form incorrectly. The teacher endorsed no symptoms of depression even during week B-2 when her mother died and someone ran into her car, both in the same week. It did not appear that the teacher or parent rated Ss#4 differently based upon changing mood levels.

Marital Happiness & Teacher Satisfaction Scales

Both the teacher and parent rated themselves as highly satisfied/happy with their

role as teacher or parent. The parent's scores ranged between 92 to 103 (out of 110) and the teacher's ranged from 83 to 96. Their ratings on this scale did not seem to covary with their ratings on the Conners or ADD Evaluation Scales.

Discussion of Protocol Findings for Ss#4

Out of three times Ss#4's parent guessed which probe condition her son was in, she was correct all three times. However, she did not rate Ss#4's behavior differently the three times she correctly guessed the condition. Although this is based on a limited sample of three probes, her accurate expectations about probe conditions apparently did not affect her ratings. Only limited conclusions could be made about the parent's expectations because only three definitive guesses were made. She did not venture a guess five times (out of the possible eight protocol conditions).

The teacher's beliefs were limited for a different reason: a tendency for reporting false positives (i.e., she guessed Ritalin for 7/8 protocol conditions, and guessed "don't know" the other time). She expressed a positive attitude toward Ritalin use for this subject at the beginning of the protocol. She indicated that she believed Ss#4 was taking Ritalin almost every week. Although Ss#4's teacher answered "don't know" only three times (twice during the pre-protocol condition), she answered "Ritalin" seven out of eight times during the blinded protocol conditions. Of the eight blinded probes, she was correct four times (50%). Thus, it was difficult to estimate how expectancies may have affected the parent and teacher symptom ratings on the Conners and ADD Evaluation Scales because the parent guesses were infrequent and teacher guesses were skewed consistently in one direction.

On the symptom rating forms, the parent rated Ss#4's behavior inattentive every probe week on the ADD Evaluation Scale and rated his behavior as hyperactive on the Conners on three probe weeks (i.e., once in the pre-protocol Ritalin probe and twice in

the placebo probe condition). She appeared to have a neutral, if not slightly negative, attitude about her child taking Ritalin. Thus, it appeared that she found her son's inattentive behavior consistently symptomatic and his hyperactive behavior only occasionally a problem. Nevertheless, her weekly ratings indicate that these symptoms did not improve with Ritalin.

At no time throughout the protocol did the teacher rate Ss#4's symptoms at clinical levels for hyperactive, inattentive, or impulsive. Thus, she was either influenced by her belief that he was taking Ritalin and thus rated his behavior less severe as a result, or, she did not detect any differences in his behavior regardless of the probe condition in effect. The end result is the same, however. Neither the teacher nor the parent detected enough difference in Ss#4's symptomatic behavior to make a difference on the rating scales.

Direct classroom observation (sign) data indicated that Ss#4 was on-task for 75% of the intervals observed. This was only 7% less intervals on-task than the comparison child (see Table 8). Ss#4's behavior was fairly consistently matched to the comparison child and Ss#4 was on task only 6% less intervals when taking Ritalin versus placebo (see Figure 12). Furthermore, during one no pill week, Ss#4's on-task behavior was actually scored as 15% higher than the comparison child's. Thus, although there appeared to be marked differences in the target child's on-task performance across the probe conditions, there were almost no differences when comparing his data with that of the comparison child's. Observation (sign) data supports the teacher (symptom) data which suggested that Ss#4's behavior was not clinically symptomatic within the classroom. However, these data conflict with parent symptom ratings that Ss#4 was inattentive every week (probe) in the protocol.

Protocol Recommendations for Ss#4

In light of the lack of objective (sign) or subjective (symptom) conclusive evidence for the use of Ritalin for Ss#4 and his own self-report of physical side-effects from the medication (e.g., feeling weak and sick), Ritalin may not be an effective treatment component for this child.

It is, however, recommended that Ss#4 learn to better control his behavior on those times when he may become more hyperactive or inattentive than other days. Because taking a pill to help control his behavior is not the best choice over the long term, he will need other strategies to help him make this adjustment. Ss#4 could be taught to take personal responsibility for controllable negative events and dissuaded from self-blame for uncontrollable negative events. Controllable behaviors and strategies could be identified and contingencies set for increasing attention and decreasing impulsivity and hyperactivity. Furthermore, his teacher emphasized the importance of structure for Ss#4. Thus, increased structure may be as important to Ss#4 as anything else. Increases in structure and task demands may likely have greater therapeutic impact on his on- and off-task behavior whether taking Ritalin or not. The desirability of the rewards as well as the specificity of the contingencies should not be over-looked. The more he wants the reward, the more successful the contingencies will be in affecting his on-task behavior and the more consistent the demands are for participation, the more likely he will be to engage in the tasks.

CHAPTER V

INDIVIDUAL PROTOCOL FINDINGS FOR Ss#7

Referral Source and Reason for Protocol Enrollment

Ss#7's mother took psychostimulant medication as a child and was concerned that Ss#7 might be hyperactive as the mother had been as a child. The mother took Ss#7 for an evaluation and the psychiatrist on staff made the diagnosis of ADHD and referred Ss#7 for this drug evaluation protocol. Ss#7's parents were more than happy to enroll in the protocol because Ss#7's mother believed that taking Ritalin as a youth influenced her to take other drugs as a teenager. She didn't want her child taking Ritalin unless necessary but also was frustrated trying to control her daughter's behavior.

Social History and Background

Ss #7 was a 5-year-old, Caucasian girl who attended kindergarten during the drug evaluation protocol. Her mother was a housewife with some college education and her father was a high school graduate working full-time as a maintenance supervisor. Ss#7 had one younger sibling. Ss#7 had not taken Ritalin prior to this protocol. Her mother complained that Ss#7, "will not listen or obey, screams over everything, and is sassy." She also indicated Ss#7 often got up at 3:00 or 4:00 in the morning to watch television.

Protocol Findings for Ss#7

Ss#7 completed all twelve weeks of the evaluation protocol with the "break"

(please refer to Ss#4's report for clarification see: Background; Note) in the protocol occurring between weeks 4 and 5. Data from Ss#7's mother was missing for weeks 10 (blinded placebo probe) and 11 (blinded Ritalin probe). Thus, there were 11 parent and 13 teacher weekly data sets with the exception of the Conners Rating Scales, for which there were 12 Parent and 14 Teacher forms completed (including the pre-protocol Conners).

The protocol was compressed due to the few weeks remaining in the school year to implement the full 12-week protocol. Weeks 1B and 2B (no pill probe weeks) were split. That is, parents and teachers were asked to fill out two sets of forms, one for the first half of the week, and the other for the second half. This was then considered as two weekly samples of data.

From one to six classroom observations were made per week for 12 out of 13 protocol weeks (or 11/12 actual weeks if the split week is counted as one week). Each probe condition was planned to occur twice. Unfortunately, there was a mix-up in the probe conditions. The probe condition in which the subject was receiving a placebo but parents and teachers were told the subject was taking Ritalin (e.g., PL-RX) was introduced three times, as did the RX-PL probe condition. The PL-PL "true" probe occurred only twice and the RX "true" condition occurred only once. The no pill conditions occurred five times (i.e., one condition occurred during the administration of the pre-protocol forms).

Pre- & Post-Protocol Findings for Ss#7

Pre-Protocol Medication Attitude Responses

On the pre-protocol survey, Ss#7's mother indicated she had read the book

entitled "The Difficult Child" and believed that Ss#7 fit all the characteristics of ADD syndrome and hyperactivity. Ss#7's mother indicated that when she used Ritalin as a child it helped her calm down enough to be hugged by her mother. She thought it probably "saved her" and that it also seemed to help her friend's son. However, she also worried about her daughter becoming "drug-addicted." She estimated that Ritalin would improve her daughter's behavior by 100% (e.g., helping her pay attention, focus, listen more carefully, concentrate, sleep better at night, and go to bed easier). Ss#7's mother indicated she tried just about everything else and believed Ritalin was the only thing she could do right without "wearing herself out." Her major complaints for her daughter were that she screamed all the time, whether happy or sad, and that she lied, often saying "I don't know." Compared to other children, Ss#7's mother believed other children were calmer, more responsible for their own actions, more obedient, and more willing to make their mothers happy.

The teacher stated that he believed Ss#7 was not testing up to her potential and that he didn't endorse or recommend that someone should take a psychostimulant but that he would "go along with it" if it were prescribed. He stated that he wouldn't know if Ritalin would work with Ss#7 unless it was tried but also agreed it should be tried because they had already tried everything else. He had observed positive effects of psychostimulant medication on other children but also indicated he'd seen negative effects. He estimated (hoped) Ritalin would help Ss#7's behavior by 50%.

He believed that following the same routine at home as at school would improve Ss#7's behavior and that Ritalin might allow the mother to "focus on the job she has to do." He stated that the most distressing behaviors Ss#7 exhibited including going from one thing to another, leaving items out of her academic tasks; she had to be watched all the time; and that she constantly fiddled with her shoes and her own person and, as a

result, didn't often participate in class. He indicated other children followed the rules more consistently and didn't need to be reminded as often as Ss#7.

Because Ss#7 was so young and because she hadn't taken Ritalin before, she was unable to answer any questions during the pre-protocol survey.

Post-Protocol Medication Attitude Responses

After the protocol was completed, Ss#7's mother and teacher were again questioned and both expressed positive attitudes toward Ritalin. The parent believed that Ritalin had helped her daughter quite a bit but when she noted that she had also had good days when not taking Ritalin, she thought that she could find another way to manage her daughter (without medication). She said she didn't want her daughter to end up a drug addict adding that it was hard to keep herself (the parent) from taking the stimulant since she knew from experience what it would do for her. Ss#7's mother admitted that if she hadn't taken Ritalin as a child she might have gotten into more trouble than she had. She stated, "I'm hoping to get a handle on her early. I wasn't started early enough on Ritalin because I was hyper and got called a lot of names. I want her to feel good about herself at an earlier age but after I took Ritalin it was hard to stop taking it." She estimated that it helped Ss#7's behavior improve by 50% (e.g., she seemed to become less frustrated and more persistent). The mother stated that within the first week Ss#7 was on medication she sat down and taught herself how to do something (note: for the first two protocol weeks Ss#7 was in blinded placebo probe conditions, but the mother had been informed that the child was receiving Ritalin). The parent indicated that she had noticed an improvement in Ss#7's behavior because better reports were sent home from school and Ss#7 was more willing to try to do her homework.

In comparison to other children, Ss#7's mother saw her daughter as sometimes more aggressive and at other times more shy than her peers but that Ss#7 wanted acceptance badly and would do almost anything to get approval. "Kids tease her a lot because they know what to do to get her screaming, crying, and in trouble. For example if someone asks her to call 'so-and-so' a bad name, she will, and then will say that 'so-and-so' told me to say it." The parent stated that one-on-one Ss#7 is easy to handle but if more than one child is around, Ss#7 tries to attract attention.

The teacher indicated on the post-protocol survey that he would rather Ss#7 not be on medication but that she definitely behaved better during the last six weeks of school than she had all year. The teacher stated, "In January, I couldn't get her to sit still long enough to work on a program but by the end of the year, during the last week, she did great" (note: Ss#7 was in the blinded placebo probe condition during the last school week). On the final test she missed only one sound blending and did better at staying focused. He stated that Ss#7 was still fidgety and still wouldn't come when the whistle was blown but that her academic behavior had improved and he estimated that Ritalin had helped her by 50%. "Ritalin helped improve her academic behavior but I can't say Ritalin caused her to sit still and work in class or if it was due to growing up...it's also possible that having her parents more involved may've helped." Furthermore, the teacher indicated that Ss#7's behavior fulfilled her parents' and grandparents' expectations that she was a behavior problem child. However, he did acknowledge that she might not have progressed as far as she had academically or have been able to work as hard as she had if she had not received Ritalin this year.

Ss#7 thought Ritalin was a vitamin for her coughs and ear aches and that it made her "feel funny" but couldn't offer any more than this on a post-protocol survey.

Summary of Medication Attitude Survey

Because Ss#7 had not received Ritalin before, the parent and teacher were asked to predict how effective it would be for Ss#7. On a pre-protocol survey, the parent endorsed Ritalin as beneficial. Ss#7's parent estimated that Ritalin would improve Ss#7's behavior by 100%. Ss#7's teacher appeared to be neutral in his opinion and stated that he "hoped" it would improve Ss#7's behavior by at least 50%. Ss#7 was too young and inexperienced about Ritalin to question her on this form.

The mother's attitude about Ritalin remained positive on a post-protocol survey but she was less enthusiastic about its effectiveness for her child (i.e., she estimated that Ritalin had helped improve Ss#7's behavior by 50%). Ss#7's father, however, estimated that Ritalin had improved his daughter's behavior by 80%. The teacher's attitude appeared to change toward a more favorable position toward the use of Ritalin for Ss#7 on the post-protocol survey. He was more firm in his belief that Ritalin helped her but was specific in saying that it improved her academic behavior by 50% and added that maturity and her parents' concentrated efforts likely also contributed to her improved on-task behavior. Ss#7 indicated a positive attitude about medication in general during the post-protocol assessment but she again was unable to answer specific questions about Ritalin

Norwicki-Strickland Locus of Control

This assessed locus of control or tendency to believe that external forces outside of one's personal control caused problems. Internality is associated with academic achievement, persistence, higher self-esteem, higher self-concept, higher moral development, greater popularity, more honesty, shorter delay of gratification, lower anxiety, and less interpersonal distance. External scores are associated with emotional,

physical, or mental handicaps, psychological maladjustment, vulnerability to sickness and accidents, and hyperkinesis/aggression in boys.

Ss#7 responded "yes" to 68% of the questions (i.e., 27 out of 40 questions), suggesting a tendency towards external control. She thus may have been susceptible to believing in external causes and resolutions for her problems rather than in her own role to either resolve or cause her problems. Unfortunately, Ss#7 was too young to be interviewed on the Medication Attitude Survey.

On the post-test, Ss#7 acknowledged 26 external responses (i.e., 65%), suggesting very little change in her beliefs. Thus, taking medication did not appear to change her responses on this measure suggesting that taking Ritalin had very little impact on her externally based belief system. This seems reasonable because she also indicated that she understood very little about how Ritalin worked and why she even took it. Therefore, she probably didn't notice the difference in her behavior when she took Ritalin versus when she did not because she wasn't aware that there would be a such a difference. Unfortunately her responses on this questionnaire could not be compared to the Survey because Ss#7 could not answer the questions on the Medication Attitude Survey due to her young age.

Weekly Probe Findings for Ss#7

Conners Rating Scale

Applying the cut-off score of 1.90 or more for parent ratings and 2.08 or more for teacher ratings on the Hyperkinetic Index of this scale, symptom ratings by Ss#7's parent reached clinical significance for hyperactivity for six of the twelve weekly probes for which data sheets were obtained (see Table 9). Parent symptom ratings

Table 9

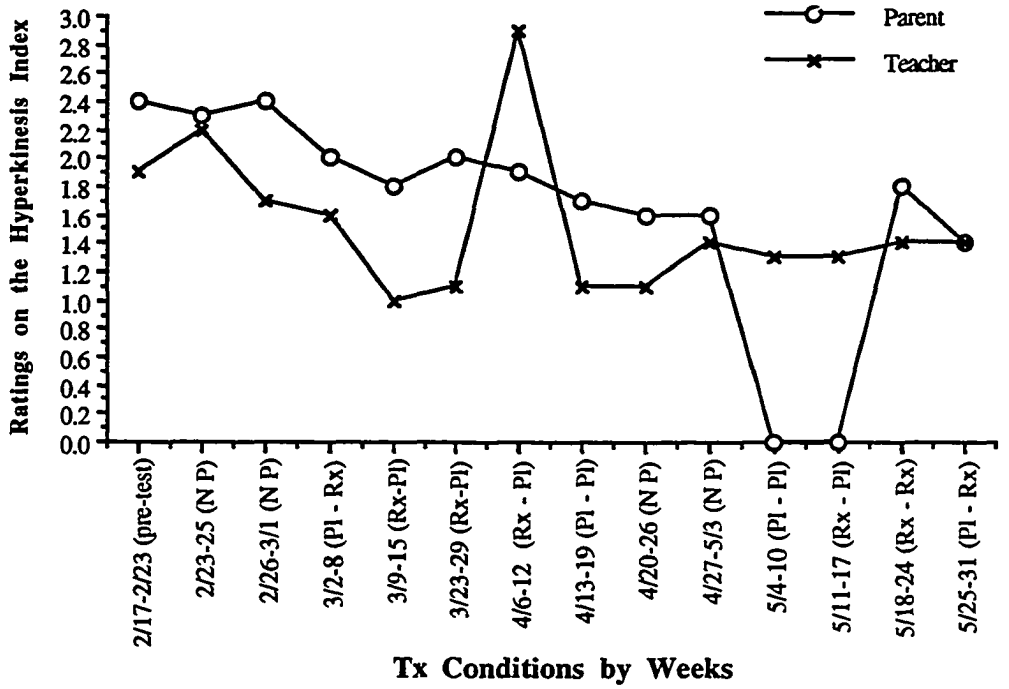
Parent & Teacher Ratings on the Conners Rating Scale
for Ss#7 by Treatment Conditions

Week #	Actual Tx Condition	Told re: Tx Condit.	Parent Belief re: Tx Condit.	Teacher Belief	Parent Hyper. Index	Teacher Hyper. Index
Pre-Test	NP	NP	NP	NP	< *2.4* >	1.9
1-B	NP	NP	NP	PL	< *2.3* >	< *2.2* >
2-B	NP	NP	NP	PL	< *2.4* >	1.7
3	PL	RX	DK	RX	< *2.0* >	1.6
4	PL	RX	DK	RX	1.8	1.0
5	RX	PL	PL	RX	< *2.0* >	1.1
6	RX	PL	DK	RX	< *1.9*>	< *2.9* >
7	PL	PL	DK	RX	1.7	1.1
8-B	NP	NP	NP	RX	1.6	1.1
9-B	NP	NP	NP	NP	1.6	1.4
10	PL	PL	N/A	DK	N/A	1.3
11	RX	PL	PL	DK	N/A	1.3
12	RX	RX	DK	DK	1.8	1.4
13	PL	RX	RX	RX	1.4	1.4
Parent	correct=0/9	DKs= 6/9		Teacher	correct=2/9	DKs= 3/9

(Note: Scores of 1.90+ for the parent and 2.08+ for the teacher suggest ADHD behavior.) Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Parent and Teacher Rating Scale across three treatment conditions: NP = baseline (no medication or tablet administered), PL = placebo pill (protocol condition), RX = Ritalin (protocol condition). Scores in brackets indicate significant scores which are indicative of hyperactive behavior. "Actual Tx condition" represents what the child was actually administered; "Told re: Tx condition" indicates what the teacher and parent were told the child was taking; and "Belief re: Tx condition" indicates what the teachers and parent acknowledged to be their belief about what the child was actually taking (DK= Don't know). Out of 9 protocol conditions, the parent guessed 3 times but was incorrect all three times and answered DK 6 times. The teacher answered DK three out of 9 protocol conditions, guessed RX all 6 times she made a guess during the protocol conditions and was correct only twice.

reached criterion for hyperactivity during 3 of the 5 no pill probes (pre-test week plus

the first two weeks), on 1 of the 5 blinded placebo probes (week 3), and on two of the 4 blinded Ritalin probes (weeks five and six). Parent symptom ratings dropped below criterion levels for the remaining seven consecutive weeks of the evaluation protocol, across both blinded Ritalin and Placebo probes, as well as across two unblinded no pill probe weeks. Teacher symptom ratings met clinical criterion for hyperactivity only on two of the fourteen weekly probes for which data were obtained (i.e., an unblinded no pill week 1-B probe and a blinded Ritalin week 6 probe). Figure 13 graphically depicts this information.



(Note: Ratings given by the parent of 1.90+ and 2.08+ by the teacher suggest ADHD behavior on this scale.) Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Parent (Revised 48-item) and Teacher (Revised 28-item)Rating Scale across three treatment conditions: NP = no treatment control (no medication or tablet administered), PL = placebo pill (protocol condition), RX = Ritalin (protocol condition). Ss#7's parent did not complete the rating scale for weeks 10 and 11. Therefore two data points are missing from this graph.

Figure 13. Parent & Teacher Ratings on the Conners Hyperkinesis Index Subscale by Treatment Conditions & Weeks Before & During Protocol for Ss#7.

Severe symptom ratings were higher in the first half of the study than the second. This is especially striking when inspecting the parent ratings. Parent ratings may have improved for many reasons: having her daughter in the protocol, knowing that Ss#7 would be receiving Ritalin. She may also have become less sensitive to her daughter's inappropriate behaviors once she had the comfort of knowing her daughter's symptomatic behavior was being treated. This may become clearer as further results are examined.

ADD Evaluation Scale

This scale provides raw scores, subscale standard scores (i.e., obtained by converting raw scores into age-appropriate standard scores which are then used to discriminate between ADD vs. "normal" symptomatic levels), and a percentile score (i.e., derived from the sum total of the subscale standard scores and are used to compare the child's scores with those of the standardization sample).

The standard scores have a mean of 10 and a standard deviation of 3. Standard scores of 7 through 13 fall within one standard deviation above or below the mean and suggest the child behaves no differently than most children in the standardization sample. However, standard scores below 7 indicate that the child behaves more symptomatically than the majority of the students in the normative sample and a specialized intervention program would be recommended to address these behaviors. A standard score of 4 or below is two or more standard deviations below the mean and indicates a serious level of concern. A standard score of 4 or below is considered the point at which a diagnosis of ADHD can be made (along with documentation from other instruments) and a formal treatment plan to address the student's symptomatic behaviors may be recommended.

As seen in Table 10 below, the parent rated Ss#7's symptomatic behavior within the clinically significant range (6 or below) every week but rated her behavior in the extreme range score (4 or below) mainly during the first three to four weekly probes of the protocol. Symptomatic ratings by the teacher met clinical criterion for inattention during eight of the 13 weekly probes. Of the five probe weeks during which Ss#7 was rated as more attentive (non-symptomatic), one occurred during an unblinded no pill probe, one during a blinded Ritalin probe, and three times during a blinded placebo probe. Teacher symptom ratings met clinical criteria on every probe week for impulsivity and hyperactivity regardless of the probe challenge in effect.

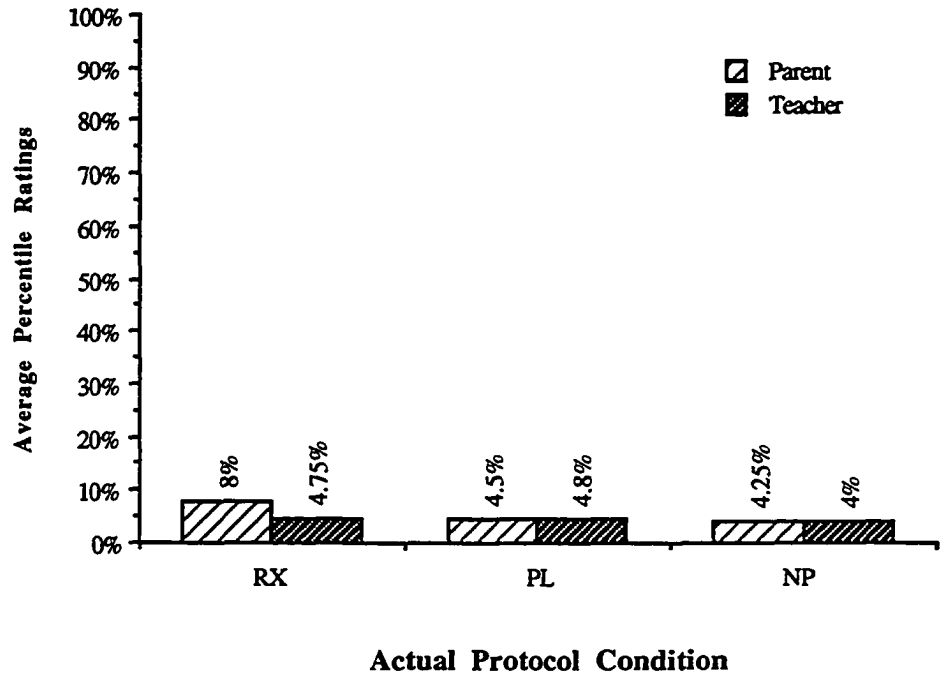
Table 10

Parent & Teacher Ratings on the Attention Deficit Disorders Evaluation Form for Ss#7

	Parent				Teacher		
Week #	Inattent	Impulsive	Hyperact	Tx Condit	Inattent	Impulsive	Hyperact
1-B	<3>	<2>	<3>	NP	7	<2>	<1>
2-B	<4>	<3>	<4>	NP	<6>	<2>	<2>
3	<3>	<3>	<2>	PL	<6>	<3>	<0>
4	<5>	<3>	<3>	PL	<6>	<2>	<1>
5	<5>	<5>	<4>	RX	<6>	<3>	<0>
6	<6>	<5>	<5>	RX	8	<4>	<3>
7	<6>	<4>	<4>	PL	8	<4>	<1>
8-B	<5>	<5>	<5>	NP	<6>	<2>	<2>
9-B	<5>	<5>	<5>	NP	<6>	<3>	<1>
10	NA	NA	NA	PL	7	<3>	<2>
11	NA	NA	NA	RX	<6>	<2>	<2>
12	<6>	<6>	<6>	RX	<6>	<3>	<2>
13	<6>	<6>	<5>	PL	8	<4>	<2>

Note: On any of the three subscales (Inattention, Impulsivity, Hyperactivity), a Standard score of below 7 represents significant behavior deviance and scores 4-0 represent extreme behavior, significant for a clinical diagnosis of ADHD (with accompanying data from parents and teachers) according to the ADD Evaluation manual. Scores in brackets indicate significant scores. Parent and teacher scores are listed next to the actual medication, placebo or no pill conditions which were administered to the child for that week in the protocol. Two weeks of data are missing from the parent.

Percentile scores for the ADD Evaluation Scale were derived from the subscale standard scores found in Table 10. Percentile scores allow for the comparison of the subject's symptomatic behavior ratings with those of the standardization sample for this



The ratings in this graph were determined by adding the sum of the subscale standard scores (as found in Table 2) and converting them to percentile scores. These percentile scores were then summed and averaged for ease of inspection. The percentile scores in this Figure indicate how the subject being rated compares to children in the ADD Evaluation Scale's standardization sample. Note: RX=protocol (blinded) Ritalin; PL=placebo (no active medication administered); and NP=no pill (no tablet was administered).

Figure 14. Average ADD Evaluation Scale Percentile Ratings From Parent & Teacher Across Actual Protocol Conditions for Ss#7.

scale. In Figure 14, weekly probe percentile scores were summed and averaged according to the probe condition in effect at the time the ADD Evaluation Scales were completed. For example, the parent rated Ss#7's behavior in the 8th percentile during the RX condition. This means she rated her child's behavior lower than 92% of the

students in the ADD Evaluation Scale's standardization sample and the teacher rated Ss#7's behavior lower than 95.25% of the children in this standardization sample.

Table 10 can help identify specific symptom areas in need of attention. Figure 14 displays this information to allow detection of overall effects of Ritalin on Ss#7's behavior when compared to the other two probe conditions. As indicated in Figure 14, Ss#7's behavior across all conditions was rated two standard deviations below the normative mean. This suggests extremely inappropriate behaviors in need of a formal treatment plan.

Ss#7's symptomatic behavior did not improve under any probe conditions. Only during the blinded RX probe condition was there even a slight improvement detected in parent symptom ratings. Teacher symptom ratings did not detect improvements in this probe condition.

Accuracy of Parent and Teacher Reported Beliefs

The mother was incorrect all three times she made a guess regarding which protocol condition Ss#7 was in (see Table 9 above for a display of the treatment conditions and the corresponding parent and teacher beliefs). She answered "don't know" 67% of the time (6/9 times).

Table 9 indicates that the teacher thought that Ss#7 was taking Ritalin in six out of the nine blinded probe conditions but was correct only twice (i.e., 22%, less than expected than by chance). He responded "don't know" for 33% of the probes (3/9 weeks). In sum, both teacher and parent noted symptomatic behavior throughout the protocol but did not detect sufficient change in symptomatic behavior across the various probe conditions to allow either parent or teacher to make accurate guesses about the actual conditions in effect. Symptom ratings of the child's behavior on the Conners Parent and Teacher Rating Scale did not appear to covary with any particular probe

condition (see Figure 13). However, the teacher rated the child as clinically significantly hyperactive only twice, once in a no pill probe condition at the start of the protocol and once under a blinded Ritalin condition. The parent rated the child symptomatically as more hyperactive across various probes during the first half of the protocol, and as less hyperactive across various probes during the latter half of the protocol (see Figure 13).

Interobserver Agreement for Classroom Observations

Out of 34.6 observation sheets collected on Ss#7 for on- and off- task classroom behavior, 18.6 included inter-observer agreement checks (i.e., two observers watched the subject at the same time). There were actually 19 observation sheets but not all intervals on all the sheets were completed. Just the number of intervals scored were counted. Inter-observer reliability was obtained on 54% of the total number of intervals observed (2238/4158) for Ss#7.

As seen in Table 11, the agreement indexes obtained for Ss#7 and the comparison child (combined) for individual weeks (e.g., the percent agreement on intervals from all the individual daily observation sheets) averaged 88% (column 4, row 20) and ranged between 75% to 99% (column 4). Broken down further by child per week, the overall (on- and off-task) percentage of agreement for Ss#7 (e.g., the percent agreement between one observers' scored on- and off-task totals with the other observer's scored on- and off-task totals) ranged from 68% to 98% (column 2) with a mean of 88%. For the comparison child, the percentage agreement ranged from 79% to 100% (column 3) with a mean of 89% (row 20).

Table 11 also displays interval-by-interval agreement indexes for both the protocol and comparison child for combined on- and off-task behavior (e.g., comparing each observer's scores on each interval the protocol and comparison child

Table 11

Inter-Observer Reliability of Classroom Observations
for Ss#7 (Target) and a Comparison Child

		Percentage of Agreements								
		Overall On- & Off-Task Agreements			*Separated by Child & On-/Off--Task Records (Interval-by-Interval)*					
		Targ Child	*Comp Child*	*Ave Daily Agreem*	*Target Child*		*Comp Child*		*T + C On-Tasks*	*T +C Off-Task*
	Week #	*Ave Agree-ment*	*Ave Agree-ment*	*On+Off T + C*	*% Agree On-Task*	*% Agree Off-Task*	*% Agree On-Task*	*% Agree Off-Task*	*Ave rage Agree-msnt*	*Ave rage Agree-ment*
	COL 1	COL 2	COL 3	COL 4	COL 5	COL 6	COL 7	COL 8	COL 9	COL10
ROW 1	Wk 1B	78%	94%	86%	72%	50%	94%	0%	84%	44%
ROW 2	Wk 4	68%	83%	75%	59%	41%	83%	0%	72%	31%
ROW 3	Wk 5	78%	84%	81%	51%	72%	83%	37%	72%	63%
ROW 4	Wk 6	92%	99%	95%	90%	67%	99%	0%	95%	65%
ROW 5	Wk 6	91%	94%	93%	89%	61%	94%	53%	92%	58%
ROW 6	Wk 6	88%	84%	86%	88%	33%	82%	46%	85%	41%
ROW 7	Wk 7	94%	91%	93%	92%	81%	88%	69%	90%	75%
ROW 8	Wk 7	94%	92%	93%	93%	73%	90%	67%	92%	70%
ROW 9	Wk 7	96%	96%	96%	96%	38%	96%	62%	96%	52%
ROW10	Wk 8B	85%	98%	91%	71%	76%	97%	75%	88%	76%
ROW11	Wk 8B	98%	100%	99%	93%	96%	100%	100%	98%	96%
ROW12	Wk 9B	88%	82%	85%	52%	87%	79%	41%	73%	75%
ROW13	Wk 9B	93%	92%	93%	69%	92%	90%	66%	86%	86%
ROW14	Wk 9B	94%	82%	88%	46%	94%	73%	63%	69%	83%
ROW15	Wk 9B	89%	84%	87%	68%	86%	83%	33%	79%	74%
ROW16	Wk 10	93%	79%	86%	57%	92%	62%	69%	60%	82%
ROW17	Wk 10	84%	88%	86%	67%	77%	83%	67%	77%	73%
Row18	Wk 11	68%	83%	75%	61%	33%	82%	9%	73%	26%
ROW19	Wk 12	93%	80%	86%	92%	61%	76%	48%	84%	52%
ROW20	Avg.:	88%	89%	88%	79%	77%	87%	53%	82%	64%
ROW21	Total	Overall	Percent	Reliab	for the	whole	study	= 88%		

\Ss#7 (T=target child), and a comparison child (C), were observed by undergraduate students and inter-observer reliability data were collected for 18.6 of the 34.6 observations. Table 11 depicts percent agreements between two observers recording on- and off-task behavior independently of each other. The first three columns represent overall agreement for the whole observation session (not interval by interval) for Ss#7 and comparison child (columns 2 & 3); and the overall percentage of agreement for that observation week (i.e., combined scores for on- and off-task as well as for target and comparison; column 4). In the last six columns inter-observer agreements were broken down into percent agreement on an interval-by-interval basis

Table 11-Continued

for on-task and off-task behavior for target and comparison child separately (i.e., columns 5 through 8) and the average agreement for on-task & off-task behavior for both target and comparison child combined (i.e., columns 9 & 10). Row 22 represents the percent agreement for the whole study and row 21 represents the averages for each column.

were observed). Reliability obtained through this manner is necessarily lower than the overall reliability because the proportion of disagreements to agreements increases when total numbers of disagreements are compared with subcategories of agreements. With this in mind, the total percentage of on-task agreement per week and by condition for both protocol and comparison child ranged from 60% to 98% (column 9) with a mean of 82% (row 20) and off-task agreement ranged from 26% to 96% (column 10) with a mean of 64% (row 20). The agreement indexes for on- and off-task behavior by child and week are also listed in Table 11 (i.e., columns 5 through 8).

On-task agreement reliability is substantially higher than off-task agreement. This is expected because on-task is scored by default when either no behavior is observed or a behavior is missed by one or the other observers. On the other hand, inappropriate behavior must be seen in order to score the interval as off-task.

The overall (on- and off-task) inter-observer interval agreement obtained for Ss #7 and the comparison child (combined) for the whole medication evaluation protocol was 88% (row 21). The overall interval-by-interval reliability appears to be high enough to use these data to make guarded decisions about treatment options for this child, especially when further treatment is monitored and changes made as needed.

Classroom Behavior Observations

Ss#7 was scored as on-task for roughly 54% of the intervals observed (66% for

the first half of the study and 40% for the second half) which averaged 30% less intervals on-task than the comparison child (see Table 12 & Figure 15 below). Although observation data were not available for each week, Ss#7 was scored as on-task for 5% to 56% fewer intervals than the comparison child during each week observations were obtained except for two weeks during which she was scored on task for 2% and 12% *more* intervals than the comparison child (i.e., week 7=blinded placebo; week 12=blinded Ritalin, respectively).

In examining Figure 15 and Table 12, Ss#7's on-task behavior is seen to have been very high during week 2B (unblinded no pill probe). This could have occurred as a result of reactive effects of observers in the classroom because Ss#7's on-task behavior levels then dropped and didn't improve again until the second weekly Ritalin probe (week 6). During the second half of the study, Ss#7's on-task behavior dropped to one of its lowest points during the third trial of placebo (week 7) and the third and fourth no pill trial conditions (weeks 8-B and 9-B). On-task behavior improved under the third and fourth probes of Ritalin (weeks 11 and 12) and maintained during the last week of placebo (week 13).

It might have been useful to have continued either the Ritalin probe for a longer period and/or to continue the placebo probe to determine how well Ss#7's on-task behavior would maintain over time. These data do, however, support the teachers comments that Ritalin was, at the very least, important (and perhaps necessary) in improving Ss#7's behavior.

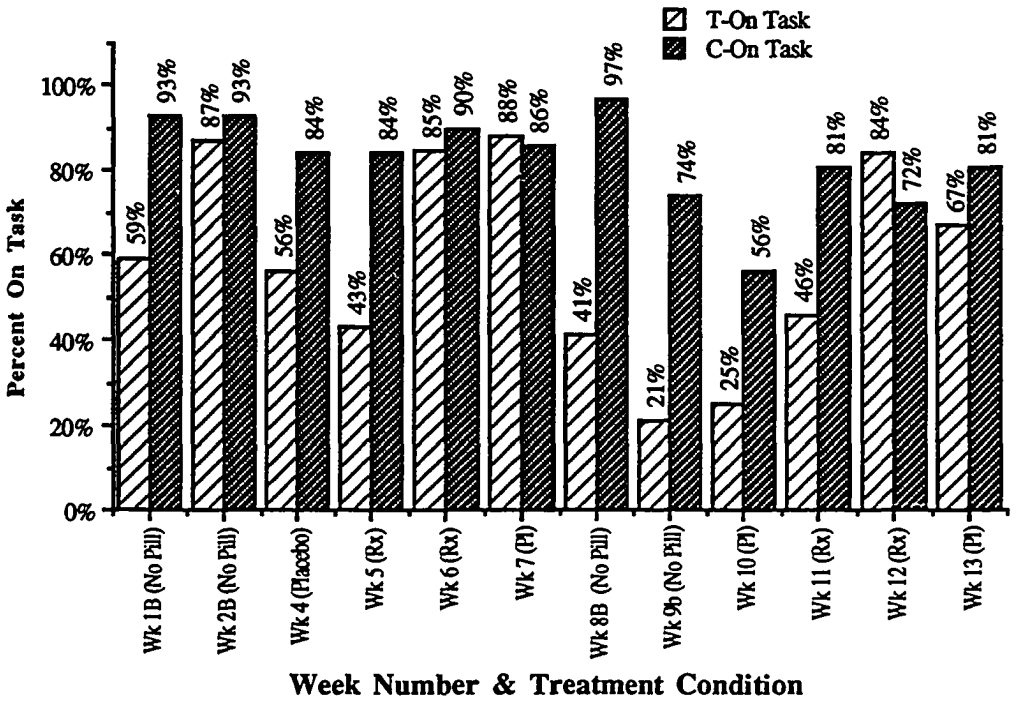
Figure 16 graphically depicts Ss#7's scored on-task intervals while under the two double-blinded probe conditions (blinded Ritalin and placebo) as well as the (unblinded) no pill condition. Although these observations were made during different weeks, each protocol weekly scores (as seen in Table 12) were summed and averaged for this Figure. In examining differences in Ss#7's on-task behavior under the three

Table 12

Classroom Observation Data for Ss#7
& a Comparison Child

Week Number	Treatment Condition	Target Child Data		Comparis Child Data		% #7 was On Task vs. Compar	# of observat per week
		On-Task	Off-Task	On-Task	Off-Task		
Week 1B	No Pill	59%	41%	93%	7%	34%	3.7
Week 2B	No Pill	87%	13%	93%	7%	6%	1
Week 4	Placebo	56%	44%	84%	16%	28%	6
Week 5	Ritalin	43%	57%	84%	16%	41%	2
Week 6	Ritalin	85%	15%	90%	10%	5%	4
Week 7	Placebo	88%	12%	86%	14%	<+2%>	2
Week 8B	No Pill	41%	59%	97%	3%	56%	4
Week 9B	No Pill	21%	79%	74%	26%	53%	4
Week 10	Placebo	25%	75%	56%	44%	31%	2
Week 11	Ritalin	46%	54%	81%	19%	35%	3.9
Week 12	Ritalin	84%	16%	72%	28%	<+12%>	1
Week 13	Placebo	67%	33%	81%	19%	14%	1
Overall Average %		54%	46%	84%	16%	30%	34.6
Ave for 1st half of study		66%	34%	88%	12%	22%	18.7
Ave for 2nd half of study		40%	60%	79%	21%	39%	15.9

Table entries depict weekly averaged percentages of on- and off-task behaviors as recorded by undergraduate students during direct classroom observations of the subject's and the comparison child's behavior for each week in the protocol according to whether the child was taking medication (RX=protocol Ritalin), placebo pills (PL), or no pill at all (NP). The number of observations made for that week are recorded to the right as well as the percentage difference between the subject and the comparison child's on-task behavior, overall average for on- and off-task behavior for both the target and comparison child, and the overall average for the first and second half of the protocol. The two scores in brackets indicate that the target child was 2% and 12% more on-task than the comparison. A graphic depiction of averages from this table can be seen in Figure 15 below.

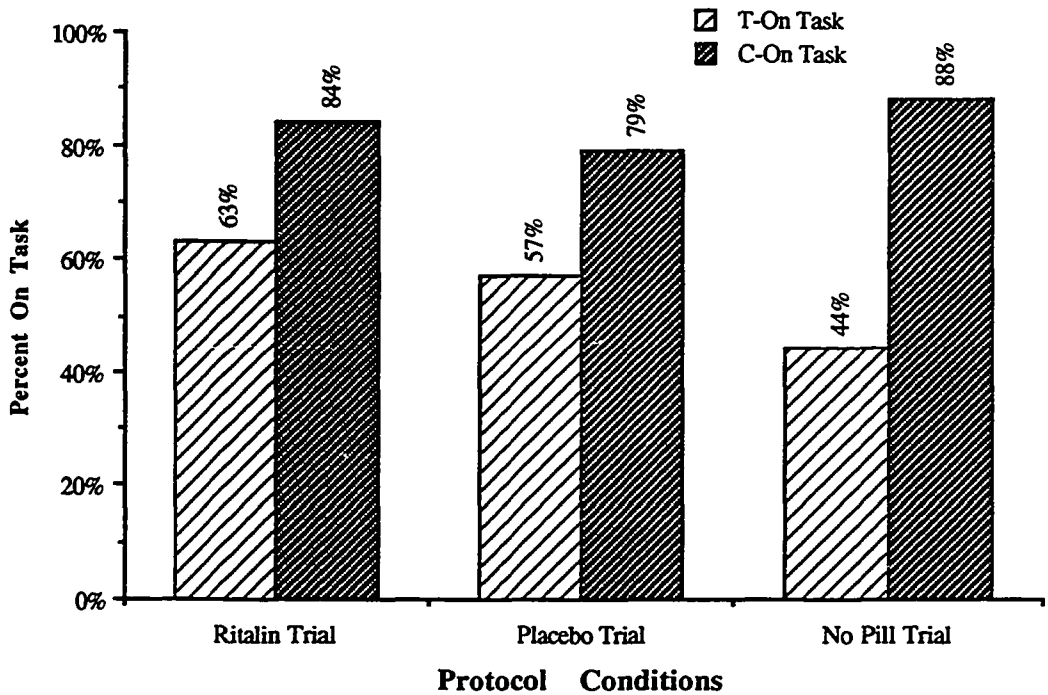


Direct classroom observations of Ss#7's (T=target) and the comparison child's ("C") behavior as recorded by undergraduate students during direct classroom observations by percentage of observation intervals the children were observed to be on-task doing assigned work. A total of 34.6 observations conducted almost weekly throughout the 12 weeks of the protocol are averaged and the percentage of on- task intervals are recorded in graph format in this figure. Data are presented for weeks during which the target child was taking the protocol trial of Ritalin (RX), placebo, and no pill. Actual numbers of observations made are in Table 3 above. Data is displayed by weeks in the medication evaluation protocol. Data for Week 3 is missing because no observations were conducted for that week. Weeks 1B & 2B are actually the first and second half of one week (see Results section, second paragraph above for clarification).

Figure 15. In-Class Observations of Ss#7 vs. Comparison Child's On-Task Behavior by Weeks in Protocol.

conditions, it appears that Ritalin was more effective than the no pill condition in maintaining on-task behavior (e.g., there was a 19% difference in on-task behavior between Ritalin and no pill) but blinded Ritalin was not much more effective than blinded placebo (e.g. there was only a 6% difference between these two blinded conditions).

Furthermore, the comparison child's level of on-task behavior was scored consistently higher than Ss#7's within all protocol probes, but there was a greater discrepancy between the two children during the (unblinded) no pill probe condition. Specifically, the average differences between the comparison and target child were: 21% under Ritalin conditions; 22% under Placebo; and 44% under no pill conditions. This seems to further support the effectiveness of either (blinded) Ritalin or (blinded) placebo over a no pill condition for this child.



Direct classroom observations of the subject's and comparison child's on- task behaviors as recorded by undergraduate students in which all treatment conditions were added together and averaged by observations made while the subject was on the medication evaluation protocol taking Ritalin, placebo and no pill.

Figure 16. Average On-Task Behavior of Ss#7 & a Comparison Child Across Protocol Conditions.

Zung Depression Scale

The parent scored minimally to mildly depressed in mood (i.e., her scores ranged between 45=Normal to 55=Mildly depressed). The teacher reported normal mood ranges throughout the protocol (i.e., his scores ranged between 35 to 38 which is within a normal mood range). Neither teacher nor parent behavior ratings for Ss#7 varied in relation to mood changes because mood ratings remained relatively stable throughout the drug evaluation protocol.

Marital Happiness & Teacher Satisfaction Scales

The teacher rated himself as feeling highly satisfied/happy with his role as a teacher (e.g., out of a possible score of 110, his scores ranged between 101-110) but the parent acknowledged feeling only moderately happy (e.g., scores ranged between 55-69). Their ratings on this scale did not seem to covary with their ratings on the Conners or ADD Evaluation Scales, because their ratings remained fairly consistent throughout the protocol.

Discussion of Protocol Findings for Ss#7

There were nine double-blinded probe conditions. The parent guessed incorrectly all three times she attempted a guess. The teacher guessed Ritalin each time, and was correct on only two of these times. The teacher tended toward false positives (i.e., he reported Ritalin in 6/9 protocol conditions, and responded "don't know" on the other three probes). He expressed a neutral attitude toward Ritalin use for this subject at the beginning of the protocol. By the end of the evaluation protocol he believed Ss#7 had benefited from Ritalin. It is difficult to estimate how much expectancies affected parent and teacher ratings on the Conners and ADD Evaluation Scales because parent

guesses about which probe condition was in effect were so few and teacher guesses were skewed in one direction only.

The parent rated her child's symptomatic behavior as inattentive, hyperactive and impulsive every week on the ADD Evaluation Scale but also rated Ss#7's symptomatic behavior more severe during the entire first half of the protocol. She rated her daughter's symptomatic behavior as hyperactive on the Conners Scale the first six weeks of the protocol (i.e., once during the pre-test and placebo probes and twice during no pill and Ritalin probes). However, the observers scored Ss#7's behavior with more intervals on-task during the first two no pill probes (weeks one and two) and with fewest intervals on-task during the third and fourth no pill probes during weeks 8-B and 9-B (see Figure 15 and Table 12).

The parent expressed positive attitudes about her child taking Ritalin and her symptom ratings and general attitude towards her daughter may have been positively affected by enrollment in the evaluation protocol. Just knowing her daughter was taking Ritalin may have helped her relax about her daughter's behavior which may have contributed to less severe ratings on the ADD and Conners Scales during the second half of the drug protocol. Also, Ritalin could have initiated a positive behavior change which may have contributed to the parent's belief in her child's improved behavior.

The teacher rated Ss#7's symptomatic behavior as hyperactive and impulsive each week and rated her behavior as inattentive nearly every week on the ADD Evaluation Scale. However, he rated her behavior as hyperactive on the Conners Scale only twice (i.e., during an unblinded no pill and a blinded Ritalin probe). Neither parent and teacher ratings of Ss#7's symptomatic behavior detected any differential effect of Ritalin over other probe conditions. However, in-class observations (sign data) did detect differences.

Observations indicated that Ss#7 was on-task for an average of 54% of the intervals observed. Ss#7 averaged 30% fewer intervals on-task than the comparison child evaluation protocol probe conditions, within a range of 21% to 88% fewer intervals on-task (see Table 12). Ss#7 was consistently scored with fewer intervals on-task than the comparison child but this discrepancy was reduced to only 6% when Ss#7 was in the Ritalin versus placebo probe conditions (see Figure 16). There was a 19% discrepancy between the children during the Ritalin and no pill probe conditions.

Direct classroom observation (sign) data suggested that Ritalin was effective for Ss#7, although it appeared to be only slightly more effective than placebo and much more effective than no pill. However, when comparing the differences between the protocol child's on-task behavior with that of the comparison child's, Ritalin appeared even more effective. There was a 21% discrepancy between on-task behavior for the target and comparison child in the Ritalin condition, a 22% discrepancy in the placebo condition, but a 44% discrepancy in the no pill condition).

Some discrepancies existed between data from the parents, teachers, and observers (as well as between the symptom ratings given on the rating scales) on how Ss#7 was behaving during any given week. On the Conners Rating Scale the parent and teacher rated Ss#7's behavior as not hyperactive but on the ADD Evaluation Scale they rated her behavior as hyperactive (as well as inattentive and impulsive) every week, regardless of the protocol condition. However, the in-class observation (sign) data detected subtle changes in Ss#7's weekly performance which could then be used to make recommendations regarding use of Ritalin.

Protocol Recommendations for Ss#7

Ss#7 may benefit from at least a temporary trial of Ritalin but it is important that she be taught alternative ways to control her symptomatic behavior because she seemed capable of maintaining improved behavior under placebo conditions.

To further strengthen her belief in her own ability to control behavior, Ss#7 should be taught to take personal responsibility for controllable negative events and dissuaded from self-blame for uncontrollable negative events. It would likely be important to identify controllable behaviors and to set up contingencies for rewarding increased attention and decreased impulsivity and hyperactivity. Parent participation in this matter would be strongly encouraged.

Furthermore, increases or decreases in structure and task demands may likely have a significant effect on her on- and off-task behavior whether taking Ritalin or not. Ss#7 should be given clear and consistent contingencies for her behavior. The desirability of the rewards as well as the specificity of the contingencies should not be over-looked. The more she wants the reward, the more successful the contingencies will be in affecting her on-task behavior and the more consistent the demands are for participation, the more likely she will be to engage in the tasks.

CHAPTER VI

INDIVIDUAL PROTOCOL FINDINGS FOR SS#8

Referral Source and Reason for Protocol Enrollment

Ss#8 had received psychotherapy at a local clinic and was referred to a psychiatrist on staff for an ADHD evaluation. After the ADHD syndrome diagnosis was determined, the psychiatrist referred Ss#8 for this medication evaluation protocol. This was the first time Ss#8 had been treated with a psychostimulant.

Social History and Background

Ss #8 was a 7-year-old Caucasian boy attending second grade. His grandmother was his legal guardian for the past five years. The courts had found his natural mother guilty of neglecting her son. He lived with his grandmother, grandfather, and his 10-year-old aunt. His grandmother (who will be called his parent in this report) was an unemployed cook with a high school degree. His grandfather quit school after 9th grade and worked 40+ hours a week as a baker. His aunt, Ss#9, was enrolled in another drug evaluation protocol in this series. He and his 10 year old aunt went to the same school and were more like brother and sister. Ss#9 visited with his natural mother and father on some week-ends.

Protocol Findings for Ss#8

Ss#8 completed all twelve weekly probes in the evaluation protocol with one week officially a "break" in the protocol (i.e., between the first two placebo weeks: weeks 3 and 4). His parent also completed her data sheets during the break week.

Thus, including the pre-protocol measures, there were 14 parent and 12 teacher weekly probe data sets except for the Conners Rating Scales, for which there were 15 parent and 13 teacher forms. An extra placebo week was added to make up for a week of missing teacher data.

Between one to three classroom observations (sign data) were made per week for 9 out of 13 protocol weeks. Within the evaluation protocol, Ss#8 received no pill for five weeks (an extra week occurred naturally during the break), Ritalin for four weeks, and placebo for five weeks (the placebo-placebo condition was repeated because teacher data for week three was missing).

Pre- & Post-Protocol Findings for Ss#8

Pre-Protocol Medication Attitude Responses

Ss#8's parent said she had believed her grandson had ADHD for a long time: "the problem was just getting him tested." She indicated she knew her nephew, godson, and Ss#8's father had also been diagnosed as ADHD. She indicated she was leery of Ritalin because Ss#8's father was a "'zombie' on Ritalin for 8 years." She acknowledged trying to hold her opinion until the end of the protocol but also stated that she was running out of patience. She believed Ss#8 had suffered brain damage as a younger child but medical doctors had never found anything physically wrong with him. The parent hoped Ritalin would improve Ss#8's behavior by 90%. She stated she wanted most to see Ss#8 sit in class, do his work, mind, follow the rules, and become a "good kid." She indicated other children sat still and listened to the teacher about 75% of the time and did as they were told. She stated Ss#8 knew when he did something wrong but did it anyway, that he seemed to lack control, got into everything, and had to be the center of attention. She also noted that he was basically a good kid

who didn't think anyone wanted him. She took him to family counseling but stated he did not talk or open up and she wasn't sure what else to do: "spanking doesn't work and he's very defiant."

The teacher stated she did not know what the problem was with Ss#8 but she agreed medication was worth trying to see if it would help him. She had another student in her classroom who was taking Ritalin but indicated it didn't seem to help him and she believed that he needed a higher dose of medication. She believed Ritalin would "probably" work to keep Ss#8 on task and improve his behavior by 90%. The behaviors she wanted to see changed were: increased concentration and increased on task behavior. She acknowledged having five or six students in her classroom who were "just like him." Compared to the other 19 students, however, she stated Ss#8 was less focused, had very low academic performance, and was behaviorally very active. The teacher also noted that Ss#8's inappropriate behavior seemed to increase when with his biological mother but that the grandmother's efforts to keep the mother out of the classroom helped.

Because Ss#8 hadn't taken Ritalin before and was too young to understand the questions on the survey, he was not questioned during the pre-protocol assessment.

Post-Protocol Medication Attitude Responses

After the protocol was completed, Ss#8, his parent and teacher were again questioned. The parent indicated that she didn't see an improvement in his behavior (i.e., she reported 0% improvement) and that his behavior seemed to be getting worse.

> He tries so hard to keep under control and he blows it the last few hours of the day....maybe the dose isn't strong enough....He is violent and destructive, he can hurt himself by throwing himself against the wall or biting himself....When his mood changes we just put in a room by himself.

She believed other children were well mannered and less outspoken. "He kicks, hits, and brags to make himself feel important....we can't seem to give him enough attention, he hates to share his parent's attention." However, in his favor, she indicated he got good grades and that his teacher only noted his negative behaviors and didn't emphasize his positive strengths.

The teacher indicated on the post-protocol survey that Ritalin had not improved Ss#8's behavior (i.e., she reported a 0% improvement) but she still believed it would help him if he were to receive a higher dose. "I expected him to sit at his desk, stay on task, not blurt out his answers, and be more receptive to discipline...He's a likable child but he's just so impatient. I'd like to see him do better, his best." She reported that he couldn't sit still for 15 minutes, he continually interrupted, talked back to the teacher, and constantly played with the toys he brought to class. In comparison to other children, he was reported to be at the bottom 20 generally but in math he was believed to be right in the middle. Reading was his weakest subject: "he can be a good student but he doesn't study. He can pass spelling when his (grandmother) works with him." The teacher recommended that the family receive counseling to help set clear guidelines and not allow him to play his mother off against his grandmother and vice versa.

Ss#8 was also questioned. He knew he was taking medication but didn't know what it was called. He believed he was taking it to help him stay in his seat and not yell. He stated he liked taking Ritalin because "it keeps me from getting out of my seat" but he also didn't like it because it sometimes gave him stomach aches. Before taking Ritalin, he stated, he "acted crazy, sliding down the railing, jumping up and down." He believed it helped his behavior by 100% (e.g., "it keeps me in my seat, helps me talk to you, and helps me get better grades"). He stated that he knew Ritalin helped his behavior because "I've been good, I'm not jumping on furniture anymore." Finally, he

indicated his belief that Ritalin was the only thing that would help him and that he thought he'd have to continue taking Ritalin until he was 18 years old.

Summary of Medication Attitude Survey

On the pre-protocol survey, the parent and teacher both favored trying Ritalin and both had high expectations for the medication. The parent and teacher both hoped Ritalin would help improve Ss#8's behavior by 90%. Ss#8 was too young and inexperienced in taking Ritalin to question during the pre-protocol survey. However, both parent and teacher became more neutral in their attitude about Ritalin on the post-protocol survey. Both wanted to continue but trying a higher dose of Ritalin because both thought there was 0% improvement in his behavior with the current dose. Ss#8 was totally in favor of Ritalin and believed his behavior improved by 100% after taking it. He also attributed most, if not all, of his good behavior to the effects of Ritalin.

Norwicki-Strickland Locus of Control

This assessed locus of control or tendency to believe that external forces outside personal control cause problems. Internality is associated with academic achievement, persistence, higher self-esteem, higher self-concept, higher moral development, greater popularity, more honesty, shorter delay of gratification, lower anxiety, and less interpersonal distance. External scores are associated with emotional, physical, or mental handicaps, psychological maladjustment, vulnerability to sickness and accidents, and hyperkinesis/aggression in boys.

Ss#8 responded "yes" to 55% of the questions (i.e., 22 out of 40 questions), suggesting he partly believed in his own ability and personal effort to manage his own behavior but also partly believed external factors out of his control also influenced his behavior. Because he wasn't questioned during the pre-test his answers couldn't be

compared to the Medication Attitude Survey to explore how he verbally described his "problem" (i.e., ADHD).

On the post-test, Ss#8 acknowledged 21 external responses (i.e., 53% of his responses were "yes"), which was only a slight change from his pre-test score. On the Medication Attitude Survey, he indicated Ritalin improved his behavior by 100% and that it was responsible for his ability to talk to the examiner, stay in his seat, get better grades and not jump on furniture. This would not have been predicted from his moderate scores on the locus of control scale.

Weekly Probe Findings for Ss#8

Conners Rating Scale

Applying the cut-off score of 1.6 or more for parent symptom ratings and 1.8 or more for teacher symptom ratings on the Hyperkinetic Index of this scale, parent ratings met criterion to qualify Ss#8's behavior as clinically hyperactive on 15 out of 15 probe weeks (see Table 13 below). Symptom ratings by his teacher met clinical criterion for hyperactivity on 13 out of 14 weeks. Only once did she rate Ss#8's symptomatic behavior within the normal range (i.e., during week 4 = placebo). Only the parent, not the teacher, completed forms even during the break in the protocol.

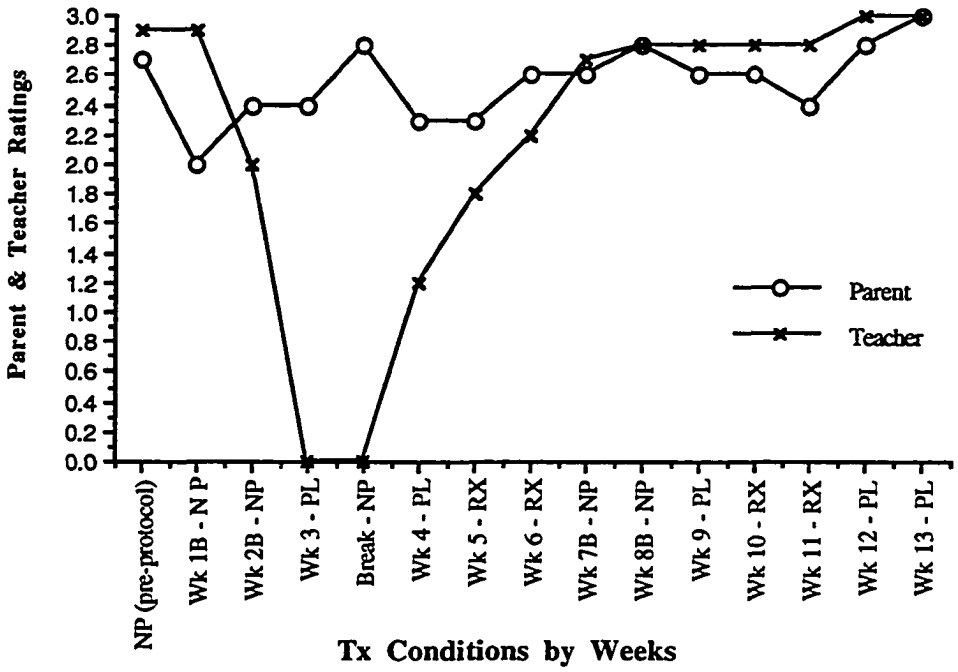
Figure 17 graphically depicts these data and illustrates the consistency among both the teacher and parent symptom ratings across all probe conditions. Ratings of the child's symptomatic behavior on the Conners Parent and Teacher Rating Scale were similar regardless of the probe condition believed to be in effect or actually in effect with only a couple of exceptions.

Table 13

Parent & Teacher Ratings on the Conners Rating Scale
for Ss#8 by Treatment Conditions

Week Number	Actual Tx Condition	Told re: Tx Condit.	Parent Belief re: Tx Condit.	Teacher Belief	Parent Hyperact. Index	Teacher Hyperact. Index
Pre-Test	NP	NP	N/A	N/A	<2.7>	<2.9>
1-B	NP	NP	NP	N/A	<2.0>	<2.9>
2-B	NP	NP	N/A	N/A	<2.4>	<2.0>
3	PL	PL	PL	N/A	<2.4>	N/A
BREAK	NP	NP	PL	N/A	<2.8>	N/A
4	PL	RX	PL	DK	<2.3>	1.2
5	RX	PL	DK	PL	<2.3>	<1.8>
6	RX	RX	PL	DK	<2.6>	<2.2>
7-B	NP	NP	NP	PL	<2.6>	<2.7>
8-B	NP	NP	NP	PL	<2.8>	<2.8>
9	PL	RX	DK	PL	<2.6>	<2.8>
10	RX	RX	DK	PL	<2.6>	<2.8>
11	RX	PL	DK	PL	<2.4>	<2.8>
12	PL	PL	DK	PL	<2.8>	<3.0>
13	PL	PL	DK	DK	<3.0>	<3.0>
Parent:	correct=2/9	DK= 6/9		Teacher:	correct=2/9	DK= 3/9

(Note: Scores of 1.6+ for the parent & 1.8+ for the teacher suggest ADHD behavior.) Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Rating Scale across three medication evaluation protocol conditions: NP = no medication or tablet administered, PL = placebo pill, RX = Ritalin. Scores in brackets indicate significant scores which are indicative of hyperactive behavior. "Actual Tx condition" represents what the child was actually administered; "Told re: Tx condition" indicates what the teacher and parent were told the child was taking; and "Belief re: Tx condition" indicates what the teacher and parent acknowledged to be their belief about what the child was actually taking (DK= Don't know). Out of 9 protocol conditions, the parent guessed 3 times but was correct twice and answered DK 6 times. The teacher guessed 5 times, was correct twice and answered DK 3 times.



(Note: scores of 1.54+ for parents and 1.97+ for teachers suggest ADHD behavior on this scale). Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Rating Scale across three treatment conditions: NP = no treatment control (no medication or tablet administered), PL = placebo pill (protocol condition), RX = Ritalin (protocol condition). No ratings were obtained form the teacher during week 3 and the break following this week.

Figure 17. Parent & Teacher Ratings on the Conners Hyperkinesis Index Subscale by Treatment Conditions & Weeks Before & During Protocol for Ss#8.

ADD Evaluation Scale

This scale provides raw scores, subscale standard scores (i.e., obtained by converting raw scores into age-appropriate standard scores which are then used to discriminate between ADD vs. "normal" levels of symptomatic behavior), and a percentile score (i.e., derived from the sum total of the subscale standard scores and are used to compare the child being assessed with those in the standardization sample).

The standard scores have a mean of 10 and a standard deviation of 3. Standard scores of 7 through 13 are within one standard deviation above or below the mean and indicate the child's symptom profile is no different than that of most of the children in the standardization sample. However, standard scores below 7 indicate that the child behaves more symptomatically of ADD than the majority of the students in the normative sample and a specialized intervention program would be recommended to address these behaviors. A standard score of 4 or below falls two or more standard deviations below the mean and indicates a serious level of concern. A standard score of 4 or below is considered the point at which a diagnosis of ADHD can be made (along with documentation from other instruments) and a formal treatment plan to address the student's inappropriate behaviors would be recommended.

As seen in Table 14, the parent rated Ss#8's symptom behavior as inattentive, hyperactive, and impulsive each week regardless of probe condition. The teacher rated Ss#8's symptom behavior in the clinically significant range (6 or below) on 12 of 12 weekly probes for impulsivity, on 11 of 12 weekly probes for hyperactivity (i.e., week 4=blinded placebo did not reach clinical significance), and on 9 of 12 weekly probes for inattention (i.e., on weeks 4 = blinded placebo; 5= blinded Ritalin; and 6=blinded Ritalin, did not reach clinical significance).

Percentile scores for the ADD Evaluation Scale ratings were derived from the subscale standard scores found in Table 14. Percentile scores allow for comparisons of the subject's symptom behavior ratings with those in the standardization sample for this scale. In Figure 18, weekly probe percentile scores were summed and averaged according to the protocol condition in effect at the time each ADD Evaluation Scale was completed. For example, the parent rated Ss#8's behavior in the "0" percentile during the RX condition. This means she rated his behavior lower than 100% of the students in the ADD Evaluation Scale's standardization sample. Whereas the teacher for this

same pre-protocol condition rated the subject's behavior lower than 92% of the children in this standardization sample.

Table 14

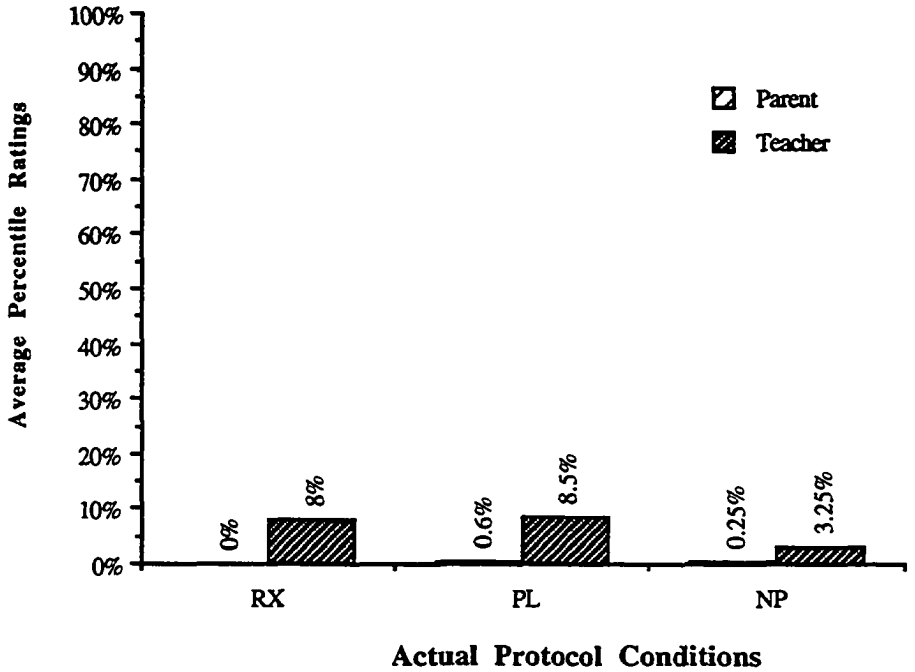
Parent & Teacher Ratings on the Attention Deficit Disorders Evaluation Form for Ss#8

	Parent				Teacher		
Week #	Inattent	Impulsive	Hyperact	Tx Condit	Inattent	Impulsive	Hyperact
1-B	<3>	<3>	<4>	NP	<4>	<2>	<3>
2-B	<1>	<1>	<4>	NP	<6>	<2>	<2>
3	<2>	<2>	<4>	NP	N/A	N/A	N/A
BREAK	<1>	<2>	<2>	NP	N/A	N/A	N/A
4	<3>	<3>	<6>	PL	7	<6>	7
5	<1>	<2>	<3>	RX	7	<4>	<6>
6	<2>	<2>	<4>	RX	7	<4>	<6>
7-B	<0>	<1>	<5>	NP	<6>	<4>	<5>
8-B	<0>	<0>	<1>	NP	<6>	<4>	<5>
9	<0>	<1>	<1>	PL	<6>	<4>	<5>
10	<0>	<1>	<1>	RX	<6>	<4>	<5>
11	<1>	<1>	<4>	RX	<6>	<4>	<5>
12	<0>	<0>	<2>	PL	<6>	<4>	<6>
13	<0>	<0>	<2>	PL	<6>	<4>	<6>

Note: Brackets indicate clinically significant scores in either Inattention, Impulsivity, or Hyperactivity. Parent and teacher scores are listed next to the actual medication, placebo or no pill conditions which were being administered to the child for that week. Only the parent, not the teacher, completed data during the break in the protocol.

Table 14 is useful in pinpointing specific symptom areas in need of attention. Figure 18 averages this information so that one can see if, overall, Ss#8's behavior was improved within the Ritalin as compared with the other two probe conditions. As Figure 18 shows, Ss#8's symptomatic behavior in all probe conditions was rated as two standard deviations below the mean, suggesting clinical levels of symptomatic behavior and a need for a formal treatment plan.

It appeared that Ss#8's symptomatic behavior was unaffected by the protocol conditions in effect at the time of the parent and teacher ratings. Teacher symptom



The ratings in this graph were determined by adding the sum of the subscale standard scores (as found in Figure 14) and converting them to percentile scores. These Percentile Scores were then summed and averaged for ease of inspection. Note: RX=protocol (blinded) Ritalin; PL=placebo (no active medication administered); and NP=no pill (no tablet was administered).

Figure 18. Average ADD Evaluation Scale Percentile Ratings From Parent & Teacher Across Actual Protocol Conditions for Ss#8.

ratings were generally higher than parent's ratings, suggesting a less severe (or perhaps more tolerant) interpretation of Ss#8's behavior. The teacher's symptom ratings were equally high during RX and PL conditions, suggesting that Ritalin did not differentially improve Ss#8's behavior. However, the teacher did notice a difference between Ss#8's behavior under these two (blinded) conditions as compared with the (unblinded) no pill condition, suggesting a slight improvement when some sort of overt treatment was in effect. Whether that improvement is found in the subject's symptomatic behavior or in the teacher's interpretation of the subject's behavior can only be

determined with further contextual data, provided by classroom observations to be discussed in the following sections.

Accuracy of Parent and Teacher Reported Beliefs

There were nine double-blinded medication evaluation probe conditions. The parent guessed on three probes, and was accurate on two of these guesses (i.e., 22% accuracy). She guessed "placebo" each time. She answered "don't know" on six of nine probes (i.e., 67%; see Table 13 above for a display of the probe conditions and the corresponding parent and teacher expressed beliefs).

In sum, it appeared that both teacher and parent noted symptomatic behavior but this did not vary enough across different probe conditions to allow them to detect differences either on the symptom rating scales or when guessing actual probe conditions. Their symptom ratings on the Conners Parent and Teacher Rating Scale did not appear to covary with any particular probe condition (see Figure 17). The parent appeared to rate the child consistently symptomatic (as hyperactive) across all protocol probe conditions (see Figure 17).

Interobserver Agreement for Classroom Observations

Out of 21.68 observation data sheets collected on Ss#8 for on- and off-task classroom behavior, inter-observer agreement checks were available for 10.28 (i.e., two observers watched the subject at the same time). There were actually 11 inter-observer observation sheets but not all intervals on all the sheets were completed so only the number of completed intervals were counted. Inter-observer reliability was thus obtained on 47% of the total number of intervals observed (1228/2596) for Ss#8.

As seen in Table 15, the interval-by-interval agreement indexes (e.g., the percent agreement on the total of the individual daily observation sheets) obtained for

Ss#8 and the comparison child (combined) for individual weeks averaged 82% (column 4, row 13) and ranged between 65% to 96% (column 4). Broken down further by child per week, the overall (on- and off-task) percentage of interval agreement for Ss#8 (e.g., the percent agreement between one observers' on- and off-task total with the other observer's on- and off-task total scores) ranged between 71% to 95% (column 2) with a mean of 82% (row 13) and for the comparison child, the percentage agreement ranged between 53% to 97% (column 3) with a mean of 82% (row 13).

Table 15 also displays interval-by-interval agreement indexes for both the target and comparison child for combined on- and off-task behavior (e.g., comparing each observer's scores on each interval the target and comparison child were observed). Reliability obtained in this manner is necessarily lower than the overall reliability because the proportion of disagreements to agreements increases when you compare total numbers of disagreements with subcategories of agreements. With this in mind, the total percentage of on-task agreement (column #9) ranged between 24% to 94% (mean = 73%) and off-task agreement (column #10) ranged from 19% to 89% (mean = 65%). The agreement indexes for on- and off-task behavior by child and week are also listed in Table 15 (5 through 8).

On-task agreement reliability is substantially higher than off-task agreement. This is expected because on-task is scored by default when either no behavior is observed or a behavior is missed by one or the other observers. On the other hand, inappropriate behavior must be seen in order to score the interval as off-task.

The overall (on- and off-task) inter-observer agreement obtained for Ss #8 and the comparison child (combined) was 82% (row #14). The overall reliability appears to be satisfactory for making guarded decisions about treatment components for this child, especially when further treatment is monitored and changes made as needed.

Table 15

Inter-Observer Reliability of Classroom Observations
For Ss#8 (Target) and a Comparison Child

Percentage of Agreements										
		Overall On- & Off-Task Agreements			*Separated by Child & On-/Off--Task Records (Interval-by-Interval)*					
		Targ Child	*Comp Child*	*Ave Daily Agree*	*Targ Child %*	*Targ Child %*	*Comp Child %*	*Comp Child %*	*T + C On-Task*	*T+ C Off-Task*
	Week#	Ave Agreement	Ave Agreement	On+Of T + C	Agree On-Task	Agree Off-Task	Agree On-Task	Agree Off-Task	Ave Agreements	Ave Agreements
	COL 1	COL 2	COL 3	COL 4	COL 5	COL 6	COL 7	COL8	COL 9	COL10
ROW 1	Wk 1B	73%	NA	73%	56%	60%	NA	NA	56%	60%
ROW 2	Wk 8B	79%	89%	84%	78%	27%	89%	0%	83%	19%
ROW 3	Wk 8B	76%	67%	71%	12%	75%	32%	61%	24%	69%
ROW 4	Wk 8B	71%	87%	79%	62%	44%	86%	30%	75%	40%
ROW 5	Wk 9	85%	85%	85%	67%	79%	76%	72%	72%	76%
ROW 6	Wk 9	76%	53%	65%	41%	71%	32%	40%	35%	56%
ROW 7	Wk 9	90%	93%	92%	82%	81%	92%	67%	88%	77%
ROW 8	Wk 10	94%	97%	96%	92%	84%	96%	91%	94%	87%
ROW 9	Wk 10	95%	87%	91%	95%	40%	80%	70%	89%	66%
ROW 10	Wk 11	93%	97%	95%	88%	88%	96%	91%	92%	89%
ROW 11	Wk 12	74%	77%	75%	70%	34%	45%	71%	62%	58%
ROW 12	Avg.:	82%	82%	82%	72%	66%	75%	62%	73%	65%
ROW 13	Total	Overall	Percent	Reliab	for the	whole	study	=82%		

Ss#8 (T=target child) and a comparison child (C), were observed in the classroom by undergraduate students and inter-observer reliability data were collected for 10.28 of the total 21.68 observations which were collected throughout the protocol. This table depicts percent agreements between two observers recording on- and off-task behavior independently of each other. The first three columns represent overall agreement for the whole observation session (not interval by interval) for the target and comparison child (i.e., columns 2 & 3); and the overall percentage of agreement (combined scores for on- and off-task as well as for target and comparison) for that observation week (column 4). In the last six columns inter-observer agreements were broken down into percent agreement on an interval-by-interval basis for on-task and off-task behavior for target and comparison child separately (columns 5 through 8) and the average agreement for on-task & off-task behavior for both target and comparison child combined (columns 9 & 10). Row 14 represents the percent agreement for the whole study and row 13 represents the averages for each column.

Classroom Behavior Observations

Ss#8 was scored as on-task for roughly 65% of the intervals observed (65% for the first half of the study and 65% for the second half) regardless of the probe condition (see Table 16 & Figure 19 below). Although observation data were not available for each week, Ss#8 was scored as on-task for 3% to 44% fewer intervals than the comparison child each week observations were obtained.

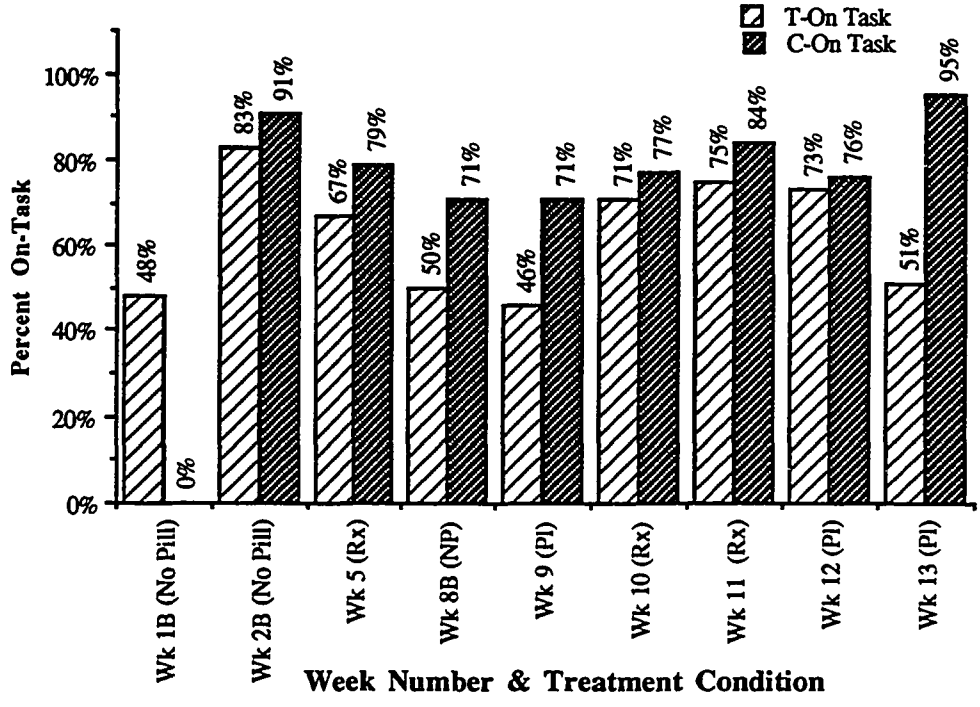
Table 16

Classroom Observation Data for Ss#8 & a Comparison Child

Week Number	Treatment Condition	Target Child Data		Comparis Child Data		% #8 was On Task vs. Compar	Number of observat per week
		On-Task	Off-Task	On-Task	Off-Task		
Week 1B	No Pill	48%	53%	NA	NA	NA	1
Week 2B	No Pill	83%	17%	91%	9%	8%	2
Week 5	Ritalin	67%	33%	79%	21%	12%	3
Week 8B	No Pill	50%	50%	71%	29%	21%	2.9
Week 9	Placebo	46%	54%	71%	29%	25%	1.9
Week 10	Ritalin	71%	29%	77%	23%	6%	3
Week 11	Ritalin	75%	25%	84%	16%	9%	2.88
Week 12	Placebo	73%	27%	76%	24%	3%	3
Week 13	Placebo	51%	49%	95%	5%	44%	2
Overall Average		65%	35%	80%	20%	15%	21.68
Ave for study	1st half of	65%	35%	87%	13%	22%	8
Ave for of study	2nd half	65%	35%	76%	24%	11%	13.68

Table entries depict weekly averaged percentages of on- and off-task behaviors as recorded by undergraduate students during direct classroom observations of the subject's and the comparison child's behavior for each week in the protocol according to whether the child was taking: medication (RX=protocol Ritalin), placebo pills (PL), or no pill at all (NP). The number of observations made for that week are recorded to the right as well as the percentage difference between the subject and the comparison child's on-task behavior, the overall average for on- and off-task behavior for both the target and comparison child, and the overall average for the first and second half of the protocol. A graphic depiction of averages from this table can be seen in figure 19.

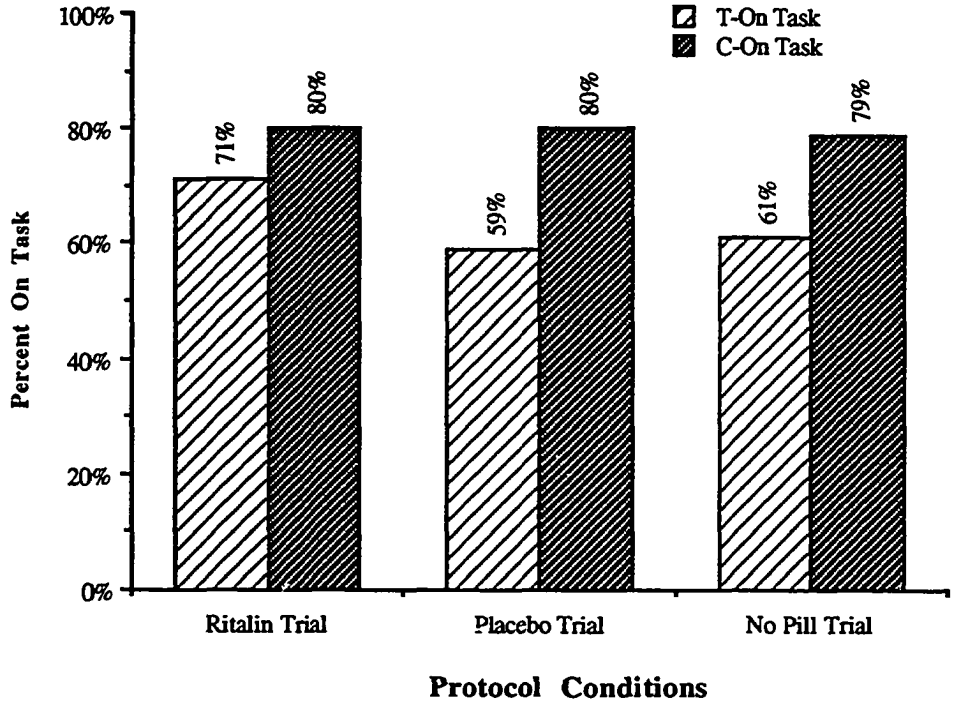
In examining Figure 19 and Table 16, Ss#8's on-task behavior was highest during week 2B (no pill) but this may have occurred reactively due to the newness of the observation situation. It appeared Ritalin was able to increase his on-task behavior, though maybe not to the extent his parent and teacher desired (e.g., they expected a 90% improvement in his on-task behavior) and the placebo was able to maintain his behavior for a relatively short period of time, suggesting it is not as useful as actual Ritalin.



Direct classroom observations of Ss#8's (T=target) and the comparison child's ("C") behavior as recorded by undergraduate students during direct classroom observations by percentage of observation intervals the children were observed to be on-task doing assigned work. A total of 21.9 observations conducted almost weekly throughout the 12 weeks of the protocol are averaged and only the percentage of on--task intervals are recorded in graph format in this figure. Data are presented for weeks during which the target child was taking the protocol trial of Ritalin, placebo, and no pill. Actual numbers of observations made are listed in Table15. There was no comparison child for week 1B.

Figure 19. In-Class Observations of Ss#8 vs. Comparison Child's On-Task Behavior by Weeks in Protocol.

Figure 20 graphically depicts Ss#8's scored on-task intervals while under the two double-blinded treatment conditions (Ritalin and placebo) as well as the (unblinded) no pill condition. Although these observations were made during different weeks, each probe's weekly data (as seen in Table 16) were summed and averaged for this Figure. In examining differences in Ss#8's on-task behavior under the three conditions, it appears that Ritalin was more effective than either the placebo and no pill conditions in maintaining on-task behavior (e.g., there was a 12% difference between Ritalin and placebo and a 10% difference between Ritalin and no pill).



Direct classroom observations of Ss#8's and a comparison child's on- task behavior as recorded by undergraduate students in which all treatment conditions were added together and averaged by observations made while the subject was on the protocol taking Ritalin, placebo and no pill.

Figure 20. Average On-Task Behavior of Ss#8 & a Comparison Child Across Protocol Conditions.

The comparison child's on-task behavior was consistently higher than Ss#8's but the discrepancy between the two children's on-task behavior was halved in the Ritalin probe condition (i.e., 9% under Ritalin conditions versus 21% under placebo and 18% under no pill conditions). This suggests that Ritalin is differentially more effective than either no pill or placebo probe conditions. Because the discrepancy between the two children's behavior was halved, but not eliminated, Ritalin should be considered as part of a more comprehensive behavior management program.

Zung Depression Scale

The parent endorsed depressed mood throughout the study (i.e., mood-marked) and rated her mood in the severe-extreme range during week 9. It did not appear that the parent rated Ss#8's behavior any differently based upon her mood level because her mood was ratings fell within a restricted range throughout the study. The teacher indicated these questions were too personal and irrelevant to Ss#8's behavior and chose not to complete this particular set of questions.

Marial Happiness & Teacher Satisfaction Scales

The parent rated herself mildly happy/satisfied with her role as a parent (i.e., scores ranged between 55 to 67). These ratings on this scale did not seem to covary with her ratings on the Conners or ADD Evaluation Scales because her self-ratings fell within a restricted range. The teacher chose not to complete these questions for the same reasons as given for the Zung Depression Scale.

Discussion of Protocol Findings for Ss#8

There were nine double-blinded probe conditions. The parent was correct on two of three guesses made and the teacher was correct twice out of five guesses made, even though she responded placebo each time she guessed. It is difficult to estimate how expectancies affected parent and teacher symptom ratings on the Conners and ADD Evaluation Scales because the parent guesses were infrequent and teacher guesses were skewed in one direction. It appeared that both might have been influenced by their belief that Ss#8 was not taking a high enough dose of Ritalin. Thus, neither indicated he was taking Ritalin and both rated his behaviors as symptomatic not only to indicate that his behavior had not changed but also to perhaps "prove" he needed a higher dose of Ritalin. Both also had high expectations of Ritalin for Ss#8 (i.e., both were positive towards Ritalin use and both hoped Ritalin would improve his behavior by 90%). This might have negatively influenced rating any improvements seen in his behavior. Neither teacher nor parent observed enough difference in Ss#8's behavior to differentially detect between placebo and Ritalin conditions and note those differences on the rating scales provided.

The parent rated her child's symptomatic behavior as consistently a problem on both the Conners Scale and ADD Evaluation Scale, regardless of the probe conditions in effect. The teacher rated Ss#8's symptoms as hyperactive on the Conners every week except for week 4 (blinded placebo). On the ADD Evaluation Scale, she rated his behavior impulsive every week, hyperactive 11 out of 12 weeks (all except weekly probe 4=placebo), and as inattentive on 9 out of 12 weekly probes (all except weeks 4=pl, 5=Rx, & 6=Rx).

Direct classroom observation data indicated that Ss#8 was on-task for 65% of the intervals observed but averaged 15% less on-task than the comparison child

throughout the evaluation protocol (see Figure 16). Ss#8's behavior was scored consistently less on-task than the comparison child but the discrepancy was halved between the pair's on-task behavior when Ss#8 was taking Ritalin (see Figure 20).

Ss#8's on-task behavior was slightly better during the no pill condition than the placebo condition (see Figure 19). Ss#8's on-task behavior did appear to improve under the Ritalin conditions. Based on the direct behavior observation data, Ss#8 appeared to benefit with Ritalin.

However, Ritalin probes did not improve Ss#8's behavior according to the parent and teacher symptom ratings as well as their verbal reports. Furthermore, both parent and teacher appeared to believe that there was a serious behavior problem with Ss#8 (as suggested by the consistently clinically significant scores on the Conners and ADD Evaluation Scales). Observer data, in contrast, indicated that Ritalin did improve on-task behavior both in relation to the other probe conditions as well as in relation to the comparison child's on-task performance. The discrepancy between the target's and comparison child's on-task behavior was halved when the protocol child was in the Ritalin probe condition. Finally, observations indicated that Ss# 8 was not as seriously off-task as perhaps both teachers and parents indicated as evidenced by the fact that there were only a few weeks during which Ss#8 was observed to be on-task less than 60% of the intervals observed (i.e., during two no pill and two placebo weeks). During the other weeks he was observed to be on-task between 67% to 83% (mean = 74%) of the intervals observed (see Figure 19).

The results on the post-Medication Attitude Survey appeared to support Whalen and Henker's (1980) descriptive study because Ss#8 verbally attributed improved behavior to the effect of medication even though his parent and teacher had not noticed any change in his behavior. Only a 10% and 12% improvement was detected in his behavior while in Ritalin versus both no pill and placebo probes (respectively), which

is not close to the 100% improvement in behavior he believed Ritalin was responsible for. This supports Whalen and Henker's concern that children may take less responsibility for their behavior, attributing better behavior to factors outside their control.

Protocol Recommendations for Ss#8

Ritalin appeared to improve Ss#8's behavior based on in-class observations of his on-task behavior. Perhaps the dose was not high enough to yield behavior changes that would have altered parent and teacher opinions that his behavior had improved. He might be given a trial higher dose of Ritalin. However, due to the potential bias of both the parent and teacher, in-class observations of his behavior should be continued during this trial.

Because Ritalin will not improve Ss#8's symptomatic behavior in all areas or even by 90%, it is recommended that Ss#8 be instructed so that he could better control his behavior during those times when he is at risk to be more hyperactive, impulsive, or inattentive. Ss#8 should be taught to take personal responsibility for controllable negative events and dissuaded from self-blame for uncontrollable negative events. It would be important to identify controllable behaviors and set up contingencies for rewarding increased attention and decreased impulsivity and hyperactivity. Parent and teacher participation in this matter would be strongly encouraged.

Furthermore, increases or decreases in structure and task demands may have a marked effect on his on- and off-task behavior whether on Ritalin at a higher dose or not. Ss#8 should be given clear and consistent contingencies for his behavior. The desirability of the rewards as well as the specificity of the contingencies should not be over-looked. The more he wants the reward, the more successful the contingencies

will be in affecting his on-task behavior and the more consistent the demands are for participation, the more likely he will be to engage in the tasks.

Due to Ss#8's complex family background history and current family make-up, it is recommended that family therapy continue but structure and clear contingencies may be even more important to emphasize for Ss#8. Because he tends to believe no one wants him and that he has to "prove" himself to others, he likely needs a significant amount of reassurance coupled with understanding and patience. Involvement in extracurricular activities may help in this matter (e.g., big brothers, soccer) as well as allow him another outlet for his energy. He likely has high expectations of himself which are increased by the expectations of others. Thus, a careful exploration of his academic skills and learning capabilities may be helpful (e.g., psychological and academic evaluations).

CHAPTER VII

INDIVIDUAL PROTOCOL FINDINGS FOR SS#9

Referral Source and Reason for Protocol Enrollment

Ss#9's mother was concerned about her daughter's tendency to be generally inattentive and "absent minded." Neither she, nor the teacher thought Ss#9 was hyperactive but they were concerned about her lack of focus. A psychiatrist at a local psychology clinic made the diagnosis of ADHD and referred Ss#9 for this medication evaluation protocol.

Social History and Background

Ss #9 was a 10-year-old, Caucasian girl who attended 5th grade during the drug evaluation protocol. Her mother was an unemployed cook with a high school degree. Her father quit high school after 9th grade and worked 40+ hours a week as a baker. Ss#9 lived with her mother, father, and her nephew. Her nephew, Ss#8 was also in the medication evaluation protocol. Both Ss#8 & 9 attended the same school but were in different classrooms.

Protocol Findings for Ss#9

Ss#9 completed all twelve weeks of the drug evaluation protocol with the "break" (please refer to Ss#4's report for clarification see: Background; Note) in the protocol occurring between weeks 3 and 4. However, during weeks 5 (RX) and 6 (PL), Ss#9 took a morning dose only because she did not want to take the pills given her. Thus, she took the dose given her by her mother before school but then did not go

to the nurse during lunch time at school to take her afternoon dose. Because there was only one extra week available before the end of the school year, the pharmacist randomly chose an additional week of placebo to make up for at least one of these weeks lost. Therefore there were 5 placebo conditions, 5 no pill conditions (an additional week occurred during the break), and 4 Ritalin conditions. There were 14 completed parent and teacher weekly data sheets except for the Conners Rating Scales, for which there were 15 completed parent and teacher forms (this included the pre-protocol Conners). Finally, there were between two to five classroom observations per week for all 13 protocol weeks.

Pre- & Post-Protocol Findings for Ss#9

Pre-Protocol Medication Attitude Responses

On the pre-protocol survey, Ss#9's mother indicated the psychiatrist diagnosis of ADHD just confirmed what she already believed to be true but she wasn't sure how taking Ritalin would help her daughter. However, she stated the psychiatrist "convinced" her to at least give it a try, stating that if there were side-effects or if it didn't work they could change the medication. The mother acknowledged knowing that a diagnosis of ADHD is a life-long disorder and that it thus qualifies for disability (Note: the parent requested that this examiner send verification of Ss#9's diagnosis for a disabilities claim the mother filed shortly after her child was diagnosed and entered the drug evaluation protocol).

The mother indicated she believed Ritalin would improve her daughter's behavior by 75% (e.g., help her stay on task, be attentive, and get her school work done). The mother listed the following behaviors as the most distressing: Ss#9 always had to be touching and hanging onto her mother, she didn't get her homework done,

and she had difficulty following directions. The mother reported that other children were more outgoing, followed instructions, and were more independent and had more self-confidence.

The teacher admitted to just finding out that Ss#9 was diagnosed ADHD but agreed with the diagnosis, stating that Ss#9 fit the "classic ADD diagnosis." She indicated that she was happy for Ss#9 because she had seen Ritalin work for other children. She believed Ritalin would improve Ss#9's behaviors by 80% (e.g., help her become better behaved, be able to sustain her attention, improve her organizational skills, and help her turn in her homework). In comparison to other children, the teacher believed Ss#9 was an average student who was well behaved and sensitive to others.

Ss#9 wasn't questioned during the pre-test since she hadn't taken Ritalin before and thus couldn't answer the questions in an informed manner.

Post-Protocol Medication Attitude Responses

After the protocol was completed, Ss#9's mother and teacher were again questioned but only the teacher acknowledged a positive attitude toward Ritalin; the mother and daughter both acknowledged negative attitudes. The mother indicated she hoped for a different reaction and stated there was 0% improvement in her daughter's behavior. She hoped Ss#9 would be more outgoing. Instead, she reported her daughter didn't tell the whole truth and left things half-finished. Furthermore, she indicated that her daughter's mood changed dramatically from one second to the next but acknowledged that part of this was probably due to Ss#9's age. She indicated Ss#9 had to be constantly reminded to take Ritalin but that despite this, the mother had seen, "absolutely no change in her except that she's moodier now." The mother stated Ss#9 was "really shy" but she had been "mouthy with her grandparents," something she had

never done before. The mother indicated that maybe her daughter needed a different medication because she caught Ss#9 trying to throw the pill away and indicated her daughter wouldn't always take her pill. The mother indicated some of Ss#9's most distressing behaviors were that she constantly asked who her natural father was and that she wet the bed all the time (Note: she started wetting the bed about 8-9 months before the medication evaluation protocol began). Compared to other children, Ss#9 was reported by her mother to be withdrawn, shy, and she stated "its like pulling teeth to get her to participate."

The teacher indicated on the post-protocol survey that she was concerned that the dosage was never changed. "I'm not sure that we've discovered anything...because she didn't get a higher dosage." She stated there was only a slight, if any change, in Ss#9's behavior (i.e., 5-10% improvement at the most) but there were a few isolated incidents in which Ss#9 surprised her teacher (e.g., she was able to readily follow along in reading when called on three times in one day and she completed an assignment and turned it in on time). The teacher indicated Ss#9's most distressing behaviors were that she didn't pay attention, didn't follow along with the rest of the class, didn't keep track of, or complete her assignments, had low self-esteem, and lacked friends. Her description of how Ss#9 compared to other children was very similar to the most distressing behaviors. That is, she indicated that compared to other children, Ss#9 didn't pay attention, didn't stay on-task or remain focused, and didn't complete her work.

Ss#9 knew the name of the medication she was taking, stated her mother told her it was to help her stay awake in class and not daydream. She said she missed assignments because she looked (actually more like stared or daydreamed about) at the teacher. Although she acknowledged wanting to take Ritalin at first, she said she didn't believe the adults who told her Ritalin was good for her and that she definitely wanted

to stop taking it. She acknowledged believing she would have to take Ritalin for the rest of her life because she said that's what her mother and doctor told her. She stated she wouldn't mind taking it if it were in a chewable or liquid form but that she didn't like to swallow pills..."it got hard to swallow because I had to take it all the time." If she had to take Ritalin, she indicated a preference to take it at home..."so mom doesn't have to go to school to make sure I take it." She stated that before taking Ritalin she "ignored everybody" and that Ritalin improved her behavior by 100% "once in a while." "I'm outgoing when I take it...sometimes it makes me more sleepy...sometimes I get my work done, sometimes I don't." She indicated wanting to do better in math as a behavior in herself that she would like to change. When asked how she saw herself in comparison to other children, she said other children don't get into trouble, "I got into trouble for talking yesterday." She stated that what might help her was counseling and trying a different medication.

Summary of Medication Attitude Survey

Since Ss#9 had not been on Ritalin before, the parent and teacher were asked to predict how effective it would be for Ss#9 once she started taking it. On a pre-protocol survey, the parent and teacher believed Ritalin would be beneficial. The parent indicated she believed Ritalin would improve Ss#9's behavior by 75% and the teacher believed it would improve by 80%. Ss#9 had not yet taken any Ritalin tablets so wasn't questioned but she did acknowledge a pre-protocol positive attitude towards Ritalin when she was questioned later on the post-protocol survey.

The parent had a negative attitude towards the use of Ritalin for Ss#9 on the post-protocol survey. She indicated a desire to try a different medication and believed there was 0% improvement in Ss#9's behavior while on Ritalin. The teacher's attitude about Ritalin remained positive on a post-protocol survey although she did not believe it

helped Ss#9 much (i.e., she acknowledged Ritalin helped improve Ss#9's behavior by 5-10% "at most"). She stated she would have liked to see Ss#9 on a higher dose of Ritalin. Ss#9 indicated a negative attitude towards Ritalin on the post-protocol assessment but this appeared mainly due to her aversion to swallowing pills and possible embarrassment about having to take medication at school. However, she did admit that Ritalin improved her behavior by 100% "once in a while."

Norwicki-Strickland Locus of Control

This assessment measured the subject's locus of control or tendency to believe that external forces outside her personal control caused her problems. Internality is associated with academic achievement, persistence, higher self-esteem, higher self-concept, higher moral development, greater popularity, more honesty, shorter delay of gratification, lower anxiety, and less interpersonal distance. External scores are associated with emotional, physical, or mental handicaps, psychological maladjustment, vulnerability to sickness and accidents, and hyperkinesis/aggression in boys.

Ss#9 responded "yes" to 48% of the questions (i.e., 19 out of 40 questions), both during the pre- and post-test, suggesting she believed in her own ability to manage her behavior and may have felt that Ritalin had less ability to control her behavior than she did herself. This seemed to be supported by her post-test answers on the Medication Attitude Survey in which she indicated Ritalin improved her behavior by 100% "once in a while" and that sometimes she got her work done but other times she didn't. Ss#9 indicated she did not believe the adults who told her Ritalin was good for her which may have explained her ambivalence towards Ritalin. She didn't seem to be attributing any one cause for her behavior and seemed to believe that sometimes she was in control of her behavior and other times, Ritalin was.

Of note is that Ss#9 was not taking her afternoon dose of medication during one week of the protocol. Since she did take her morning dose, Ss#9 could have had the advantage of comparing her behavior before and after taking Ritalin much more closely than anyone else in this study. Therefore, she may not have been "fooled" by expectations or beliefs about the medication's potential effects on her behavior but rather saw the actual effects on her body.

Weekly Probe Findings for Ss#9

Conners Rating Scale

Applying the cut-off score of 1.20 or more for parent ratings and 1.34 or more for teacher ratings on the Hyperkinetic Index of this scale, ratings by Ss#9's parent reached criterion to qualify Ss#9's behavior as hyperactive 15 times out of 15 weeks in which data sheets were collected (see Table 17). On the other hand, ratings by her teacher never reached criterion for hyperactivity for 15 out of 15 weeks in which data were collected.

Figure 21 also graphically depicts this information. Parent and teacher ratings of the child's behavior on the Conners Scale did not appear to correlate with a particular treatment condition (see Figure 21) and, in fact, seemed to remain consistent throughout the duration of the protocol evaluation.

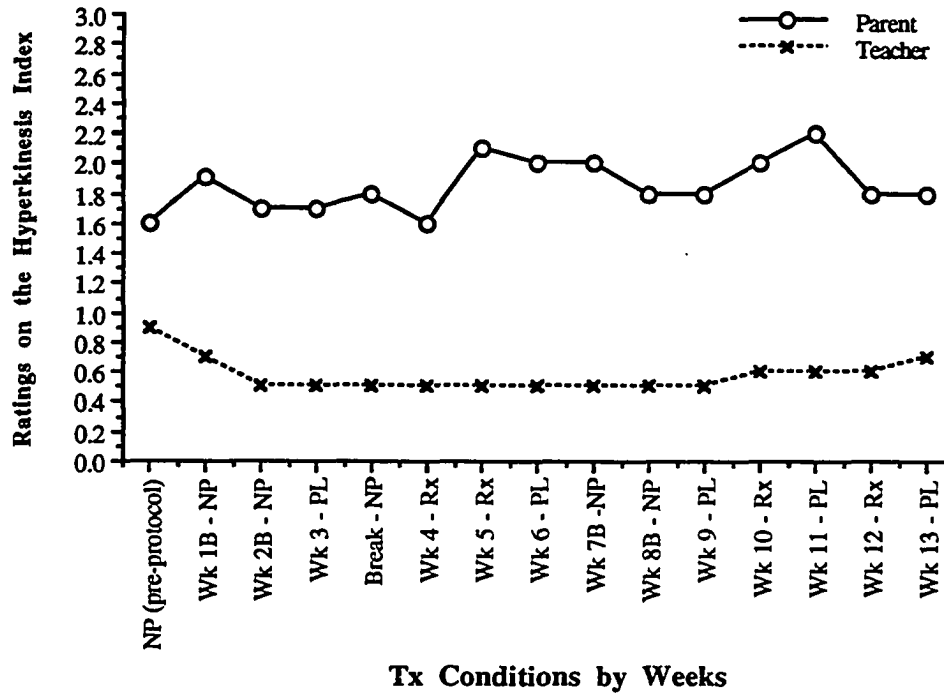
The parent ratings seemed unusually high especially in light of the fact that both parent and teacher admitted on a pre-protocol survey that they believed Ss#9 was not hyperactive but rather was inattentive. It is not clear why Ss#9 was rated so vastly different by these two raters. Several possibilities exist, however. Perhaps the mother wanted to emphasize the importance of her daughter's problem, or maybe there was secondary gain (i.e., disability claim), or possibly the two raters really saw different

Table 17

Parent & Teacher Ratings on the Conners Rating Scale
for Ss#9 by Treatment Conditions

Week Number	Actual Tx Condit	Told re: Tx Condit.	Parent Belief re: Tx Condit.	Teacher Belief	Parent Hyper. Index	Teacher Hyper. Index
Pre-Test	NP	NP	NP	NP	< *1.6* >	.9
1-B	NP	NP	NP	PL	< *1.9* >	.7
2-B	NP	NP	NP	PL	< *1.7* >	.5
3	PL	RX	RX	DK	< *1.7* >	.5
BREAK	NP	NP	NP	DK	< *1.8* >	.5
4	RX	RX	RX/NP	DK	< *1.6*>	.5
5	RX	PL	DK	RX	< *2.1* >	.5
6	PL	PL	DK	PL	< *2.0* >	.5
7-B	NP	NP	NP	RX	< *2.0* >	.5
8-B	NP	NP	NP	RX	< *1.8* >	.5
9	PL	RX	DK	PL	< *1.8* >	.5
10	RX	RX	DK	DK	< *2.0* >	.5
11	PL	PL	DK	DK	< *2.2* >	.6
12	RX	PL	DK	DK	< *1.8* >	.6
13	PL	PL	DK	DK	< *1.8* >	.7
Parent:	correct=1/9	DK = 7/9		Teacher:	correct=3/9	DK = 6/9

(Note: Scores of 1.20+ for the parent and 1.34+ for the teacher suggest ADHD behavior.) Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Rating Scale across three treatment conditions: NP = no pill (no medication or tablet administered), PL = placebo pill (protocol condition), RX = Ritalin (protocol condition). Scores in brackets indicate significant scores which are indicative of hyperactive behavior. "Actual Tx condition" represents what the child was actually administered; "Told re: Tx condition" indicates what the teacher and parent were told the child was taking; and "Belief re: Tx condition" indicates what the teacher and parent acknowledged to be their belief about what the child was actually taking (DK= Don't know). Ss#9 did not take an afternoon dose during weeks 4 & 5 and the parent indicated RX/DK to reflect this. Out of 9 protocol conditions, the parent guessed twice, was correct once, and guessed DK 7 times. The teacher answered DK 6 times and was correct all three times she made a guess during the protocol conditions.



(Note: scores of 1.20+ for the parent and 1.34+ for the teacher suggest ADHD behavior on this scale.) Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Rating Scale across three treatment conditions: NP = no treatment control (no medication or tablet administered), PL = placebo pill (protocol condition), RX = Ritalin (protocol condition).

Figure 21. Parent & Teacher Ratings on the Conners Hyperkinesis Index Subscale by Treatment Conditions & Weeks Before & During Protocol for Ss#9.

behaviors. Alternatively, they could have just interpreted the questions on the forms differently.

ADD Evaluation Scale

This scale uses raw scores (i.e., specific behaviors needing to be addressed in a treatment plan), subscale standard scores (i.e., obtained by converting raw scores into age-appropriate standard scores which are then used to discriminate between ADD vs. "normal" behaviors), and a percentile score (i.e., derived from the sum total of the

subscale standard scores and are used to compare the child being assessed with those of the standardization sample).

The standard scores have a mean of 10 and a standard deviation of 3. Standard scores of 7 through 13 are within one standard deviation above or below the mean and indicate the child behaves no differently than most of the children in the standardization sample. However, standard scores below 7 indicate that the child behaves far more inappropriately than the majority of the students in the normative sample and a specialized intervention program is recommended to address these behaviors. A standard score of 4 or below is two or more standard deviations below the mean and indicates a serious level of concern. A standard score of 4 or below is considered the point at which a diagnosis of ADHD can be made (along with documentation from other instruments) and a formal treatment plan to address the student's inappropriate behaviors is recommended.

As can be seen by looking at Table 18, the parent rated Ss#9 behavior extremely inattentive and impulsive (4 or below) 14 out of 14 weeks but rated her behavior hyperactive only 3 out of 14 weeks. This is quite different than her previous Conners ratings in which all her ratings indicated hyperactive behavior. Ratings by the teacher reached criterion for extreme inattention 14 out of 13 weeks but she did not rate Ss#9's behavior impulsive or hyperactive during any week. Since both the parent and teacher agreed on the pre- and post-protocol survey that Ss#9's main problem is her inattention and not her hyperactivity or even impulsivity, the teacher's rating may be a more objective and accurate reflection of Ss#9's true problems.

Percentile scores for the ADD Evaluation Scale were determined from the subscale standard scores found in Table 18 above. Percentile scores allow for the comparison between the subject's behavior ratings and those of the standardization sample for this scale. For example, the parent rated Ss#9's behavior in the 6th

percentile during the RX condition. This means she rated Ss#9's behavior lower than 94% of the students in the ADD Evaluation Scale's standardization sample. Whereas

Table 18

Parent & Teacher Ratings on the Attention Deficit Disorders Evaluation Form for Ss#9

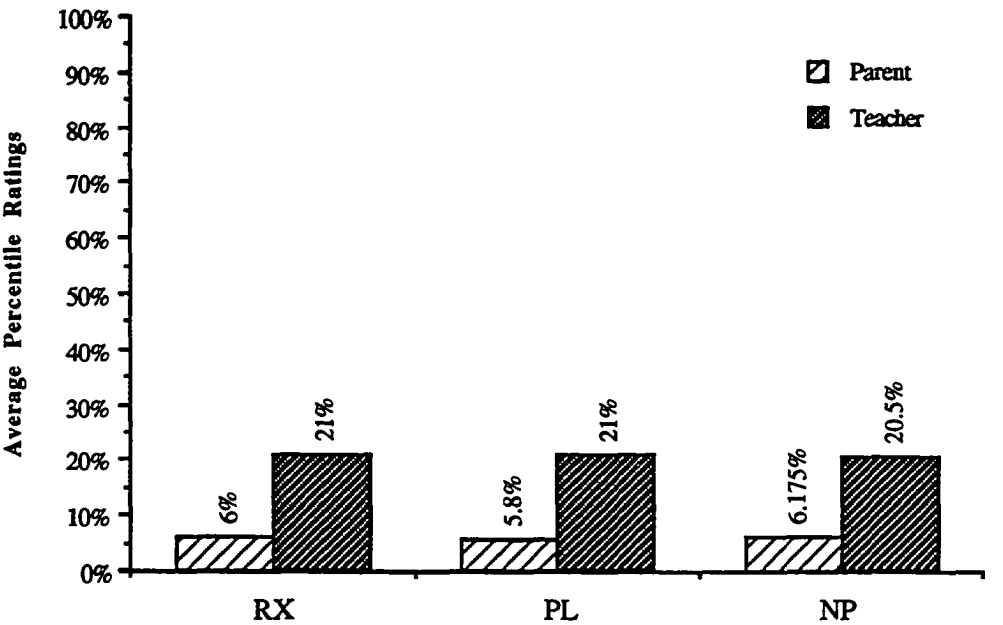
	Parent				Teacher		
Week #	Inattentio	Impulsive	Hyperact	Tx Condit	Inattentio	Impulsive	Hyperact
1-B	<3>	<3>	9	NP	<3>	10	10
2-B	<0>	<2>	<5>	NP	<4>	11	10
3	<4>	<3>	9	PL	<4>	11	10
Break	<2>	<4>	12	NP	<4>	11	10
4	<2>	<4>	12	RX	<4>	10	10
5	<1>	<0>	11	RX	<4>	10	10
6	<0>	<0>	10	PL	<4>	10	10
7-B	<1>	<1>	10	NP	<4>	10	10
8-B	<0>	<0>	10	NP	<4>	10	10
9	<0>	<0>	10	PL	<4>	10	10
10	<0>	<0>	11	RX	<4>	10	10
11	<0>	<0>	10	PL	<4>	10	10
12	<0>	<0>	<2>	RX	<4>	10	10
13	<0>	<0>	<2>	PL	<4>	11	10

Note: On any of the three subscales (Inattention, Impulsivity, Hyperactivity), a standard score of below 7 represents significant behavior deviance and scores 4-0 represent extreme behavior. Scores in brackets indicate clinically significant scores. Parent and teacher scores are listed next to the actual medication, placebo or no pill conditions which were administered to the child for that week in the protocol.

the teacher for this same pre-protocol condition rated the subject's behavior lower than 79% of the children in this standardization sample. In Figure 22, weekly percentile scores were summed and averaged according to the protocol condition in effect at the time the ADD Evaluation Scales were filled out.

Table 18 is useful in determining specific areas being more or less affected and needing specific attention. Figure 22 averages this information so that one can see if, on the whole, Ss#8's behavior was affected by Ritalin as compared to the other two treatment conditions. As can be seen in Figure 22, Ss#9's behavior in all conditions was rated as at least one standard deviation below the mean. The parent rated the child

two standard deviations below the mean under all conditions suggesting extremely inappropriate behaviors needing a formal treatment plan.



The ratings in this graph were determined by adding the sum of the subscale standard scores (as found in Table 18) and converting them to percentile scores. These percentile scores were then summed and averaged for ease of inspection. The percentile scores in the above Figure indicate how the subject being rated compares to children in the ADD Evaluation Scale's standardization sample. Note: RX=protocol (blinded) Ritalin; PL=placebo (no active medication administered); and NP=no pill (no tablet was administered). No ratings were obtained from the teacher during week 4 (NP) but scores were averaged based only on the scores actually obtained.

Figure 22. Average ADD Evaluation Scale Percentile Ratings From Parent & Teacher Across Actual Protocol Conditions for Ss#9.

It appeared that Ss#9's behavior was unaffected by the protocol conditions in effect at the time of the parent and teacher ratings. The teacher ratings were generally higher than the parent's ratings, suggesting a less severe (perhaps more tolerant) interpretation of Ss#9's behavior. The parent and teacher's ratings were equally high

during all three protocol conditions, suggesting Ritalin did not effectively differentially help Ss#9's behavior.

Accuracy of Parent and Teacher Reported Beliefs

Out of the nine double-blinded protocol conditions, the parent guessed with 11% accuracy. She was correct only one time out of the two times she made a guess regarding which protocol condition she believed Ss#9 to be in (see Table 16 above for a display of the treatment conditions and the corresponding parent and teacher beliefs). She answered "don't know" 67% of the time (6/9 times). She was incorrect in all but one time she made a guess. From Table 16 it can be seen that the teacher guessed three times and was correct all three times. However, she responded "don't know" 67% of the time (6/9 times).

In sum, it appears that the teacher and parent noted problems in Ss#9's behavior but there did not appear to be enough of a dramatic difference in Ss#9's behavior during the various treatment conditions to enable the parent or teacher to discern differences in Ss#9's behavior, either on the rating scales or in making guesses regarding actual treatment conditions. Their ratings of the child's behavior on the Conners Parent and Teacher Rating Scale did not appear to correlate with a particular treatment condition (see Figure 21) and, in fact, seemed to remain consistent throughout the duration of the protocol evaluation. Unfortunately there was not enough data on the parent and teacher beliefs to analyze this portion of the study any further.

Interobserver Agreement for Classroom Observations

Out of 38.72 observation sheets collected on Ss#9 for on- and off-task classroom behavior, inter-observer agreement (i.e., two observers watched the subject at the same time) checks were available for 14.92. Although there were actually 20

observation sheets, not all intervals on all the sheets were completed so just the number of intervals were counted. Thus, inter-observer reliability was obtained on 39% of the total number of intervals observed (1788/4644) for Ss#9.

As can be seen in Table 19, the agreement indexes obtained for Ss#9 and the comparison child (combined) for individual weeks (e.g., the percent agreement on the total of the individual daily observation sheets) averaged 86% (column 4, row 18) and ranged between 71% to 97% (column 4). Broken down further by child per week, the overall (on- and off-task) percentage of agreement for Ss#9 (e.g., the percent agreement between one observers' on- and off-task total with the other observer's on- and off-task total scores) ranged between 69% to 99% (column 2) with a mean of 86% (column 2, row 18) and for the comparison child, the percentage agreement ranged between 73% to 96% (column 3) with a mean of 86% (column 3, row 18).

Table 19 also displays interval-by-interval agreement indexes for both the target and comparison child for combined on- and off-task behavior (e.g., comparing each observer's scores on each interval the target and comparison child were observed). Reliability obtained through this manner is necessarily lower than the overall reliability because the proportion of disagreements to agreements increases when you compare total numbers of disagreements with subcategories of agreements. With this in mind, the total percentage of on-task agreement per week and by condition for both target and comparison child (column 9) ranged between 33% to 97% (mean = 83%, row 18) and off-task agreement (column 10) ranged from 13% to 85% (mean = 57%, row 18). The agreement indexes for on- and off-task behavior by child and week are also listed in Table 19 (columns 5 through 8). On-task agreement reliability is substantially higher than off-task agreement. This is expected because on-task is scored by default when either no behavior is observed or a behavior is missed by one or the other observers.

Table 19

Inter-Observer Reliability of Classroom Observations
for Ss#9 (Target) and a Comparison Child

		Percentage of Agreements								
		Overall On- & Off-Task Agreements			***Separated by Child & On-/ Off--Task Records (Interval-by-Interval)***					
		Targ Child	*Com Child*	*Ave Daily Agree*	*Targ Child %*	*Targ Child %*	*Comp Child %*	*Comp Child %*	*T+ C On-Task*	*T+ C Off-Task*
	Week #r	*Ave Agree*	*Ave Agreee*	*On+Of T + C*	*Agree On-Task*	*Agree Off-Task*	*Agree On-Task*	*Agree Off-Task*	*Aver Agree men*	*Aver Agree me*
	COL 1	COL 2	COL 3	COL 4	COL 5	COL 6	COL 7	COL 8	COL 9	COL10
ROW 1	Wk 1B	79%	93%	86%	70%	59%	91%	80%	81%	67%
ROW 2	Wk 5	93%	83%	88%	92%	31%	82%	26%	87%	28%
ROW 3	Wk 6	83%	83%	88%	81%	28%	81%	36%	81%	32%
ROW 4	Wk 6	84%	83%	83%	83%	21%	82%	5%	83%	13%
ROW 5	Wk 8	83%	85%	84%	81%	38%	84%	28%	83%	33%
ROW 6	Wk 8	70%	77%	73%	44%	61%	13%	76%	33%	69%
ROW 7	Wk 8	87%	89%	88%	81%	70%	85%	72%	83%	71%
ROW 8	Wk 9	81%	75%	78%	4%	81%	69%	44%	57%	70%
ROW 9	Wk 9	92%	95%	93%	90%	63%	95%	0%	93%	52%
ROW10	Wk 9	74%	77%	75%	56%	62%	69%	53%	63%	58%
ROW11	Wk 9	97%	96%	96%	97%	75%	95%	70%	96%	72%
ROW12	Wk 10	81%	83%	82%	68%	68%	81%	28%	76%	56%
ROW13	Wk 10	95%	96%	95%	94%	82%	96%	0%	95%	71%
ROW14	Wk 11	99%	95%	97%	99%	96%	94%	74%	97%	85%
ROW15	Wk 12	80%	81%	81%	78%	25%	79%	39%	79%	32%
ROW16	Wk 12	98%	95%	97%	98%	95%	95%	40%	96%	84%
ROW17	Wk 12	69%	73%	71%	35%	63%	68%	34%	56%	54%
ROW18	Avg.:	86%	86%	86%	81%	64%	84%	46%	83%	57%
ROW19	Total	Overall	Percent	Reliab	for the	whole	study	=86%		

Table 19-Continued

Ss#9 (T=target child) and a comparison child (C), were observed by undergraduate students and inter-observer reliability data were collected for 14.92 of the 38.72 observations. Table 19 depicts percent agreements between two observers recording on- and off-task behavior independently of each other. The first three columns represent overall agreement for the whole observation session (not interval by interval) for the target and comparison child (columns 2 & 3); and the overall percentage of agreement (combined scores for on- and off-task as well as for target and comparison) for that observation week (column 4). In the last six columns inter-observer agreements were broken down into percent agreement on an interval-by-interval basis for on-task and off-task behavior for target and comparison child separately (columns 5 through 8) and the average agreement for on-task & off-task behavior for both target and comparison child combined (columns 9 & 10). Row 19 represents the percent agreement for the whole study and row 18 represents the averages for each column.

On the other hand, inappropriate behavior must be seen in order to score the interval as off-task.

The overall (on- and off-task) inter-observer agreement obtained for Ss #9 and the comparison child (combined) was 86% (row #19). Thus, the overall reliability appears to be satisfactory and it is expected that the observation data gathered for this subject is reliable and can be used in making assumptions about the subject's behavior under various treatment conditions.

Classroom Behavior Observations

Ss#9 was recorded as on-task for roughly 72% of the intervals observed (80% for the first half of the study and 64% for the second half) which averaged 11% less on-task than the comparison child (see Table 20 & Figure 23 below). Although observation data were not available for each week, Ss#9 was recorded as on-task 2% to 31% less than the comparison child each week observations were made except for two weeks in which she was on-task the same amount of time as the comparison child (i.e., week 5=Ritalin and week 13=placebo).

In examining Figure 23 and Table 20, Ss#9's on-task behavior was best (i.e., there was less than a 10% difference between the comparison child's on-task behavior and that of Ss#9's) during weeks 3, 4, 5, 6, 8B, 10, 11, and 13. These weeks comprised four placebo weeks, three Ritalin weeks and one no pill week. However,

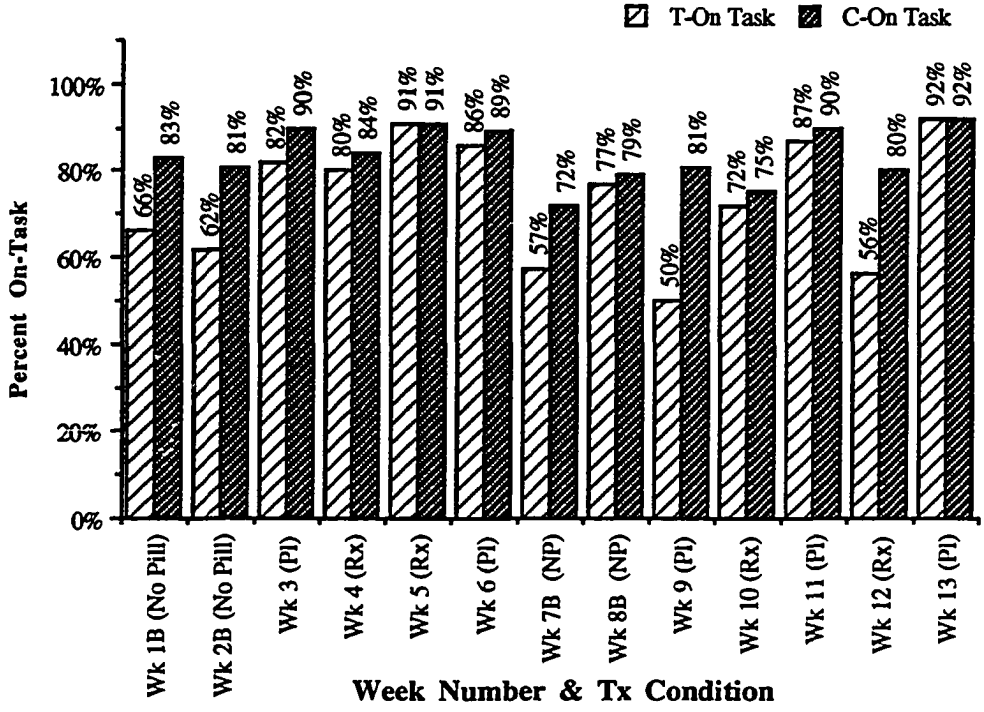
Table 20

Classroom Observation Data for Ss#9 & a Comparison Child

Week Number	Treatment Condition	Target Child Data		Comparis Child Data		% #9 was On Task vs. Compar	Number of observs per week
		On-Task	Off-Task	On-Task	Off-Task		
Wk 1B	No Pill	66%	34%	83%	17%	17%	4
Wk 2B	No Pill	62%	38%	81%	19%	19%	2
Wk 3	Placebo	82%	18%	90%	10%	8%	2
Wk 4	Ritalin	80%	20%	84%	16%	4%	2
Wk 5	Ritalin	91%	9%	91%	9%	0%	2.9
Wk 6	Placebo	86%	14%	89%	11%	3%	3
Wk 7B	No Pill	57%	43%	72%	28%	15%	4.9
Wk 8B	No Pill	77%	23%	79%	21%	2%	2.6
Wk 9	Placebo	50%	50%	81%	19%	31%	3.6
Wk 10	Ritalin	72%	28%	75%	25%	3%	3
Wk 11	Placebo	87%	13%	90%	10%	3%	4
Wk 12	Ritalin	56%	44%	80%	20%	24%	2.72
Wk 13	Placebo	92%	8%	92%	8%	0%	2
Overall	Average	72%	28%	83%	17%	11%	38.72
Ave for of study	1st half	80%	20%	87%	13%	7%	19.9
Ave for of study	2nd half	64%	36%	78%	22%	14%	18.92

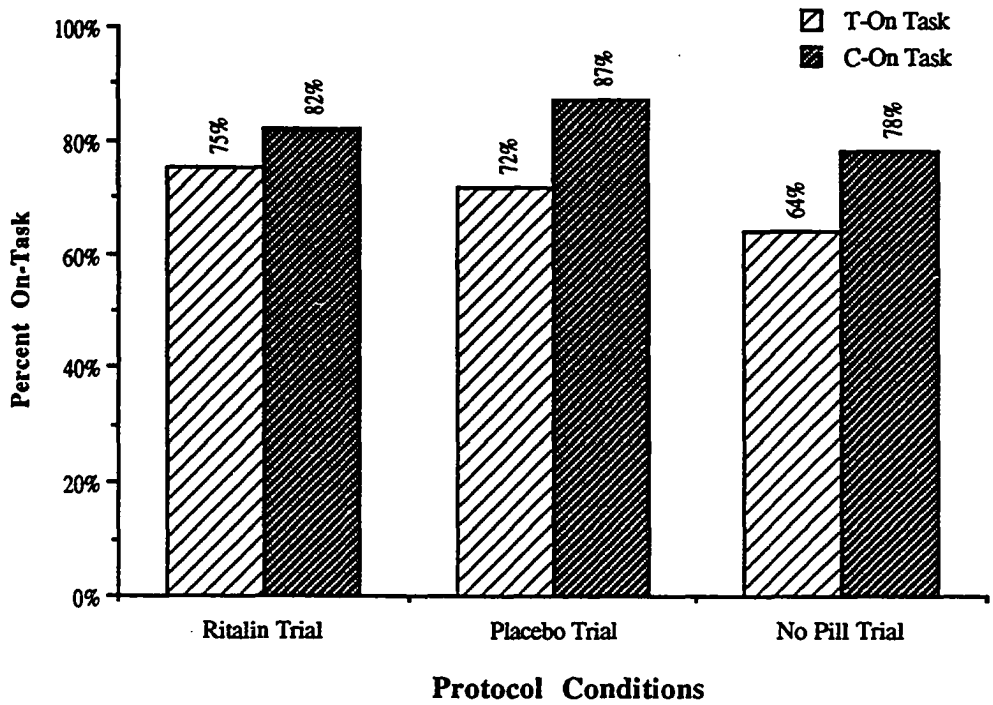
Table entries depict weekly averaged percentages of on- and off-task behaviors as recorded by undergraduate students during direct classroom observations of the subject's and the comparison child's behavior for each week in the protocol according to whether the child was taking: medication (RX=protocol Ritalin), placebo pills (PL), or no pill at all (NP). The number of observations made for that week are recorded to the right as well as the percentage difference between the subject and the comparison child's on-task behavior, overall average for on- and off-task behavior for both the target and comparison child, and the overall average for the first and second half of the protocol. A graphic depiction of averages from this table can be seen in Figure 23.

when added together and averaged across the duration of the protocol evaluation, as in Figure 24, Ss#9's on-task behavior was slightly better under the Ritalin condition but was only 3% better than her on-task behavior under the placebo condition and was 11% better than when under the no pill condition. Furthermore, there was less difference between the comparison and target child's on-task behavior under the Ritalin condition (i.e., 7% under Ritalin, 15% under placebo and 14% under no pill). Thus, on the whole, it appears Ss#9's on-task behavior was better when she took Ritalin.



Direct classroom observations of Ss#9's (T=target) and the comparison child's ("C") behavior as recorded by undergraduate students during direct classroom observations by percentage of observation intervals the children were observed to be on-task doing assigned work. A total of 38.72 observations conducted almost weekly throughout the 13 weeks of the protocol are averaged and the percentage of on- task intervals are recorded in graph format in this figure. Data are presented for weeks during which the target child was taking the protocol trial of Ritalin (Rx), placebo, and no pill. Actual numbers of observations made are in Table 20. Data is displayed by weeks in the medication evaluation protocol.

Figure 23. In-Class Observations of Ss#9 vs. Comparison Child's On-Task Behavior by Weeks in Protocol.



Direct classroom observations of the subject's on- task behaviors as recorded by undergraduate students in which all treatment conditions were added together and averaged by observations made while the subject was on the medication evaluation protocol taking Ritalin, placebo and no pill.

Figure 24. Average On-Task Behavior of Ss#9 & a Comparison Child Across Protocol Conditions.

Zung Depression Scale

The parent acknowledged depressed affect throughout the study (i.e., mood-marked) and rated her mood in the severe-extreme range during weeks 9 and 10. However, it did not appear that the parent rated Ss#9's behavior any differently based upon her mood level since her self-ratings were so consistent. The teacher indicated these questions were too personal and irrelevant to Ss#9's behavior and, because we

could not explain how it was relevant without giving out too much information about the study, she chose not to complete this particular set of questions.

Marital Happiness & Teacher Satisfaction Scales

The parent rated herself mildly to moderately happy/satisfied with her role as a parent. Her scores ranged between 37 to 55 (out of a total of 110). Her ratings on this scale did not seem to correlate with her ratings on the Conners or ADD Evaluation Scales, most notably because her ratings on these scales were so consistent. The teacher completed all but three weeks of this scale, indicating she was moderately satisfied with her job as a teacher (e.g., her scores ranged between 64 to 78).

Discussion of Protocol Findings for Ss#9

Out of nine double-blinded protocol conditions, the parent was incorrect in all but one week she made a guess (out of three times) and the teacher was correct all three times she guessed. It was not possible to estimate how expectancies affected the parent and teacher ratings on the Conners and ADD Evaluation Scales because the parent and teacher guesses were infrequent.

Neither the teacher nor the parent observed enough of a difference in Ss#9's behavior to differentially discriminate between placebo and Ritalin conditions and to report these differences on the rating scales provided. The parent verbally indicated Ss#9 was inattentive which was supported by her ratings on the ADD scale and, although she indicated verbally that Ss#9 was not hyperactive, she rated her as such each week on the Conners and three times on the ADD evaluation scale. Thus, the parent appeared to rate her child's behavior severe regardless of the protocol condition in effect for that week.

The teacher did not rate Ss#9's behavior hyperactive either on the Conners Teacher Rating Scale or on the ADD Evaluation Scale (see Tables 16 & 17 and Figure 21) neither did she rate Ss#9's behavior impulsive; but she did rate Ss#9's behavior extremely inattentive in 14 out of 14 weeks. Thus, both teacher and parent agreed that Ss#9's behavior was inattentive but the parent appeared to rate her daughter's behavior severe in all areas on both rating scales.

It is not clear why Ss#9 was rated so vastly different by these two raters. Several possibilities exist however. The mother may have wanted to emphasize the importance of her daughter's problem, there might have been a secondary gain motivating her responses (i.e., disability claim), the two raters really might have seen different behaviors or perhaps they just interpreted the questions on the forms differently. Whatever the reason, both at least agreed on one thing: Ss#9 was not being helped by the current medication and that she needed a higher dose.

Although Ss#9's behavior did not appear to be improved by Ritalin when examining parent and teacher data, according to the observers, Ss#9's on-task behavior did change and it seemed to change in a positive direction under the Ritalin conditions (see Figures 22 & 23 and Table 20). Ss#9's behavior averaged 75% on-task during the intervals observed while Ss#9 took Ritalin. There was only a 3% difference between the placebo and Ritalin conditions, 8% between the no pill and placebo conditions and only 11% between Ritalin and no pill conditions but these differences became enhanced when examining the comparison data. That is, Ss#9's on-task behavior was only 7% different than the comparison child's behavior when she took Ritalin versus 15% when taking placebo and 14% when taking no pill. Furthermore, Ss#9 may not have been as off-task as the parent and teacher believed her to be. She was on-task less than 60% of the intervals observed three times but the rest of the time she was on-task 62% to 92% of the intervals observed (mean = 80%).

The reason for the parent and teacher's unanimous opinion that Ritalin did not help Ss#9's behavior did not appear to be due to a negative attitude towards medication since both expected somewhat dramatic improvements in Ss#9's behavior once she started taking Ritalin. On the other hand, it could be that because both parent and teacher had high expectations for improvement under Ritalin conditions they may have been unable to see less dramatic improvements in Ss#9's behavior, maybe even more so once they decided between themselves that Ss#9 needed a higher dose. This appears to emphasize the importance of a more objective evaluation of the subject's behavior since there may be many reasons why changes in the subject's behavior are not noted by parents and teachers.

Protocol Recommendations for Ss#9

It appeared Ritalin was beneficial for Ss#9 based upon in-class observations of her on-task behavior. In order to determine if, in fact, she could increase her on-task behavior, she should be given a higher dose trial of Ritalin. This would also help to enlist the support from the parent and teacher who believe in the necessity of a higher dose. However, due to the bias of both the parent and teacher, in-class observations of her behavior should be continued during this trial so that changes in Ss#9's behavior could be compared to changes observed in this evaluation.

Since it is not expected Ritalin would improve Ss#9's behaviors in all areas or even by 75-80% (i.e., the parent and teacher stated desired level of change), it was recommended that Ss#9 be instructed on how to maintain her focus of attention, learn some organizational skills, and become less distracted by internal stimuli (i.e., daydreaming). Ss#9 should be taught to take personal responsibility for controllable negative events and dissuaded from self-blame for uncontrollable negative events. It would likely be important to identify controllable behaviors and to set up contingencies

for rewarding increased attention and decreased impulsivity and hyperactivity. Parent and teacher participation in this matter should be strongly encouraged.

Furthermore, increases or decreases in structure and task demands may likely have a significant affect on her on- and off-task behavior whether she takes Ritalin at a higher dose or not. Ss#9 should be given clear and consistent contingencies for her behavior. The desirability of the rewards as well as the specificity of the contingencies should not be over-looked. The more she wants the reward, the more successful the contingencies will be in affecting her on-task behavior and the more consistent the demands are for participation, the more likely she will be to engage in the tasks.

Because Ss#9 would like to continue psychotherapy and the skills listed above can be taught in individual and family therapy sessions, it was recommended that Ss#9 receive some type of therapy. A careful exploration of her capabilities might also be helpful (e.g., psychological and academic evaluations) to help set clear and reasonable expectations for her behavior.

CHAPTER VIII

INDIVIDUAL PROTOCOL FINDINGS FOR Ss#10

Referral Source and Reason for Protocol Enrollment

A psychiatrist at a local psychology clinic diagnosed Ss#10 as ADHD syndrome and prescribed Ritalin. Her teacher and parents were concerned about Ss#10's aggressiveness and tendency to ignore adult requests. Although the mother did not want her daughter on medication unless it was necessary, she did believe medication might help manage her daughter's behavior. Both the psychiatrist and parent felt more comfortable giving Ss#10 Ritalin when they knew she would be participating in this medication evaluation protocol.

Social History and Background

Ss #10 was a 4.7-year-old Caucasian girl who attended kindergarten during the drug evaluation protocol. Her mother was a housewife who had a newborn baby at home. Her father completed the 11th grade in high school and worked full-time at a printing store.

Ss#10 had received Ritalin (5-10mg) for a month about three or four months before entering this protocol. Because Ss#10 had already been taking Ritalin, she was observed under her pre-protocol prescription of Ritalin which was followed by another week (which was split, see Results below, first paragraph) in which she did not take any pills. Furthermore, during the first half of the drug evaluation protocol (i.e., weeks 6 & 8), Ss#10 took 10mg twice a day. She took 5mg twice a day for the second

half of the protocol (i.e., weeks 11 & 12). However during week 12, the label on the prescription bottle was mismarked and the mother believed her daughter was taking 10mg of Ritalin when Ss#10 was actually receiving 5mg of Ritalin.

Protocol Findings for Ss #10

Ss#10 completed all twelve weeks of the drug evaluation protocol with the "break" (please refer to Ss#4's report for clarification see: Background; Note) in the protocol occurring between weeks 4 and 5. Because the end of the school year was approaching, the baseline weeks were split so that data were collected twice in one week but counted as two weeks sample of data (i.e., during week 2B and 3B as well as week 9B and 10B). However, neither the teacher nor parent turned in data sheets for week 2B so data were collected only once during week 3B.

Another complicating factor was that the drug protocol probe conditions were not evenly distributed. That is, there were supposed to be two probe conditions in which the information told the parents and teachers matched what the child actually received (i.e., two times the parent and teacher were told placebo and Ss#10 actually received placebo and two times when they were told Ss#10 was taking Ritalin and this was true and two conditions in which the information told was different than what the child actually received. However, Ss#10 actually received three placebo-placebo conditions, three Ritalin-Ritalin conditions, and only one placebo-Ritalin and Ritalin-placebo condition (see Table 20, columns 2 and 3 for illustration of the protocol conditions).

The parent did not turn in data sheets for weeks 2B, 4, 5, 6, and 7. Thus, there were 9 parent and 13 teacher weekly data sheets except for the Conners Rating Scales, for which there were 10 parent and 14 teacher completed forms (this included the pre-

protocol Conners). Finally, there were between one to four classroom observations per week for 13 out of 14 protocol weeks.

Pre- & Post-Protocol Findings for Ss#10

Pre-Protocol Medication Attitude Responses

On the pre-protocol survey, Ss#10's mother indicated that the psychiatrist was reluctant at first to administer Ritalin but did so more willingly when he knew Ss#10 was going to be in this drug evaluation protocol. The mother appeared to view Ritalin positively. She indicated Ss#10 did as she was told when taking Ritalin, "she stays upstairs and plays with her toys now." The mother estimated that Ritalin improved her daughter's behavior by 30%. She indicated that Ritalin helps her "settle down...she's too active." The mother indicated that Ss#10's most distressing behaviors are that she hits and swears and that she "charges after" her mother. The mother believed that, in comparison to her daughter, other children are, "a lot better and at other times they are terrible...she goes in streaks...she's great at the baby-sitter's but at home she's a tornado." The mother believed her daughter would have to take Ritalin until she turned 11 years old, at which time she expected her to be "better." In the mean time, she believed Ss#10's behavior would improve if she had someone to talk to (note: an adult volunteer actually did come to Ss#10's classroom 1-2 times a week to talk individually with her).

The teacher indicated she was pleased with the protocol because it meant Ss#10 was receiving some help. She indicated having some of the same problems with Ss#10 as her mother had reported. She agreed that Ss#10 needed to get help early before it became a "school problem" instead of just a home problem. She estimated Ritalin would help Ss#10's behavior by 75% (e.g., make her more attentive, keep her on-task

longer, help her become more flexible and less demanding: "once she gets an idea in her head, she won't budge off of it"). When asked what were Ss#10's most distressing behaviors, the teacher responded that although Ss#10 is bright, she is also defiant and cooperates only as long as you don't turn your back on her (e.g., she unzips her coat as soon as you turn away), she is argumentative, bossy, strong-willed and generally doesn't get along with her peers. She indicated that Ss#10 "plays games...she manipulates adults by getting them side-tracked onto something else....She likes to hug and she uses that to diffuse anger....She does a lot to get attention...." Other children in comparison to Ss#10 were seen as "kinder" (e.g., not as bossy or rude), less argumentative, less strong-willed, less opinionated, and as academically further ahead in letter recognition and sounds. The teacher believed that Ss#10 needed a stable environment, consistency at home with rules, and needed to develop social skills: "...I'd like to see her be less aggressive toward her peers."

Ss#10 was too young and did not understand the questions so there was no completed pre- or post-protocol survey for this subject.

Post-Protocol Medication Attitude Responses

After the protocol had been completed, Ss#10's mother and teacher were again questioned but only the teacher acknowledged a positive attitude toward Ritalin. The mother indicated she didn't like her daughter on Ritalin because it made her too "whiny." She stated Ss#10, "was more whiny towards the end of the study and for the last month she was crying and whining." In fact, she did not give her daughter her pills for the last two days of week 14 because she believed Ss#10 was too whiny. (Note: the parent found Ss#10 to be particularly whiny during the last month of the protocol and she attributed this behavior to the medication. That is, the parent believed Ss#10 received 10mg of Ritalin when she was actually taking 5mg. Furthermore, the

5mg dose of Ritalin was followed by two weeks of placebo. Because she was not aware that Ss#10 was receiving a lower dose for two weeks and no dose of Ritalin at all during the other two weeks, the parent became convinced her daughter was worse on Ritalin than off of it. This may have been a reasonable assumption had Ss#10 not done as well on the placebo or low dose of Ritalin. Finally, prior to the protocol, the mother had almost no tolerance for her daughter's behavior. However, on a post-protocol survey, she expressed a higher tolerance for her daughter's non-medicated behavior. That is, she stated a preference for her daughter's non-medicated behavior after the protocol was completed. This may have resulted from her belief that Ritalin was not working.)

The mother indicated she would rather not have her daughter on medication and that during week 14, Ss#10 was less whiny but more aggressive and hadn't been going to bed until midnight for the previous two weeks. She stated that once, when she gave her daughter her medication, she acted like she received speed: she wouldn't stop talking and she didn't settle down until 60 to 90 minutes later. However, she did estimate Ritalin improved her daughter's behavior by 50% (e.g., settling her down, stopped her from romping around the house, didn't scream as much) but that how Ritalin affected her varied. The parent indicated that the most distressing behaviors Ss#10 exhibited were not listening: "If I say 'no,' she'll do it anyway...she's bound and determined to get her own way." Compared to other children, the mother believed Ss#10 was more "wild" and that she "didn't mind as well."

The teacher indicated on the post-protocol survey that she agreed with the diagnosis of ADHD and that Ss#10 was lucky to have the help that comes from knowing what is wrong. She stated that in her opinion, Ss#10 needed Ritalin and that it improved her behavior by 75% (e.g., she was able to sit still and listen better, was less distracted, was quieter, more centered, more focused, less up-and-down in her

seat, and was nicer to be around). "If she would just concentrate, listen to all the directions, and wait before performing, she would do better...she's very restless."

The teacher stated that Ss#10's most distressing behaviors were that she distracted other students, that she pushed and tested the limits, and that at times she got out of control. However, the teacher indicated that once Ss#10 knew the limits, she was fine. The teacher believed Ss#10 needed family discipline and a very structured home life, "mom needs to take some time with her and let her understand the rules."

Summary of Medication Attitude Survey

On a pre-protocol survey, the parent and teacher both believed Ritalin would be beneficial. The parent estimated Ritalin would improve Ss#10's behavior by 30% and the teacher estimated it would improve by 75%. Ss#10 was too young to question before and after the protocol.

The parent expressed a negative attitude towards the use of Ritalin for Ss#10 on the post-protocol survey. She indicated her daughter's behavior was too "whiny" when taking Ritalin and that she had stopped giving her pills the last two days of the protocol. The teacher's attitude about Ritalin remained positive on a post-protocol survey and she still estimated that it improved Ss#10's symptomatic behavior by 75%.

Norwicki-Strickland Locus of Control

This assessment measured the subject's locus of control or tendency to believe that external forces outside her personal control caused her problems. Internality is associated with academic achievement, persistence, higher self-esteem, higher self-concept, higher moral development, greater popularity, more honesty, shorter delay of gratification, lower anxiety, and less interpersonal distance. External scores are associated with emotional, physical, or mental handicaps, psychological

maladjustment, vulnerability to sickness and accidents, and hyperkinesis/aggression in boys.

Ss#10's pre- and post-test scores were very similar. She responded "yes" to 65% of the questions (i.e., 26 out of 40 questions) on the pre-test and 60% (24) on the post-test, suggesting a tendency towards an external score. This suggests a susceptibility to believing in external causes and resolutions for her problems rather than in her own acts to either resolve or cause her problems. Unfortunately Ss#10 was too young to be questioned on the Medication Attitude Survey so that her verbal responses couldn't be compared to her test scores on this measure. It is likely, however, that Ss#10 did not expect any differences in her behavior when she took a pill versus when she didn't because she likely understood very little about how Ritalin worked and why she had to take it.

Weekly Probe Findings for Ss#10

Conners Rating Scale

Applying the cut-off score of 1.90 for parent symptom ratings and 2.08 or more for teacher symptom ratings on the Hyperkinetic Index of this scale, ratings by Ss#10's parent never reached clinical criterion to qualify Ss#10's behavior as hyperactive during any of 10 weeks in which data were collected (see Table 21 below). Symptom ratings by the teacher met clinical criterion for hyperactivity for 3 out of 15 weeks in which data were collected (i.e., once while Ss#10 was taking 10mg of Ritalin and twice while taking a placebo).

Figure 25 graphically illustrates the data in Table 21. In looking at this Figure, the most striking teacher symptom ratings occurred during the pre-protocol evaluation and the last two weeks of the protocol. The pre-protocol rating may have resulted from

Table 21

Parent & Teacher Ratings on the Conners Rating Scale
for Ss#10 by Treatment Conditions

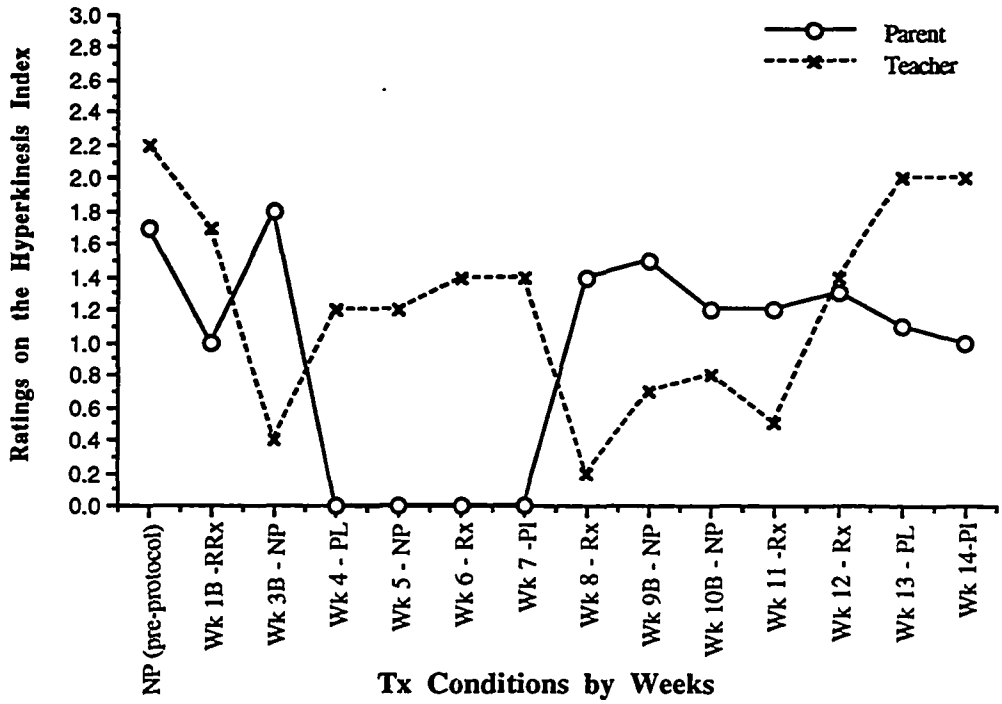
Week Number	Actual Tx Condition	Told re: Tx Condit.	Parent Belief re: Tx Condit.	Teacher Belief	Parent Hyper. Index	Teacher Hyper. Index
Pre-Test	RRX	RRX	RRX	RRX	1.7	< 2.2 >
1-B	RRX	RRX	PL	PL	1.0	1.7
2-B	NP	NP	N/A	N/A	N/A	N/A
3-B	NP	NP	NP	RX	1.8	.4
4	PL	PL	N/A	PL	N/A	1.2
BREAK	NP	NP	N/A	N/A	N/A	N/A
5 - Holiday	NP	NP	N/A	PL	N/A	1.2
6	RX	RX	N/A	PL	N/A	1.4
7	PL	RX	N/A	RX	N/A	1.4
8	RX	PL	DK	RX	1.4	.2
9-B	NP	NP	NP	PL	1.5	.7
10-B	NP	NP	N/A	PL	1.2	.8
11	RX	RX	DK	RX	1.2	.5
12	RX	RX	RX	PL	1.3	1.4
13	PL	PL	RX	PL	1.1	<2.0>
14	PL	PL	RX	PL	1.0	<2.0>
Parent:	correct = 1/8	DK = 2/8		Teacher:	correct =5/8	DK = 0/8

(Note: Scores of 1.90+ from the parent and 2.08+ from the teacher suggest ADHD behavior.) Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Rating Scale across three treatment conditions: RRX= pre-protocol (unblinded) Ritalin; NP = no pill (no medication or tablet administered), PL = placebo pill, RX = Ritalin (protocol double-blinded condition). Scores in brackets indicate clinically significant scores which are indicative of hyperactive behavior. "Actual Tx condition" represents what the child was actually administered; "Told re: Tx condition" indicates what the teacher and parent were told the child was taking; and "Belief re: Tx condition" indicates what the teacher and parent acknowledged to be their belief about what the child was actually taking (DK= Don't know). Weeks 2B and 3B combined were actually only one week as was 9B and 10B (thus there were actually only 12 weeks of the protocol). Note: Ss#10's prescription bottle was marked 10mg on week 12 although she received only 5mg that week. Out of 8 double-blinded protocol conditions, the parent guessed 3 times, was correct once and responded DK twice. Out of these same 8 protocol conditions, the teacher guessed 8 times, was correct 5 times and never responded DK.

the teacher's unfamiliarity with the scale as well as the teacher's initial frustration and intolerance of Ss#10's behavior. In addition, the teacher may have rated Ss#10's symptoms as more severe because she had less tolerance for Ss#10's behavior due to frequent and frustrating attempts to alter Ss#10's behavior prior to the protocol.

Although some hypotheses can be made about the teacher's higher symptom ratings in the initial protocol probes, it is unclear why the last two weeks would have been rated as significantly hyperactive in contrast to the previous weeks which were (blinded) placebo probes (i.e., weeks 4 & 7). During the first probe in which Ss#10 did not take any pill (i.e., week 3B), the teacher rated hyperactivity less symptomatic than for any other week, and second only to week 8 (blinded Ritalin). Furthermore, the teacher rated Ss#10's hyperactivity levels as similar across the five consecutive weekly probes 4 through 7, which included all probe conditions (i.e., two blinded placebo probes, two unblinded no pill probes, and one blinded Ritalin probe). Teacher hyperactivity symptom ratings across the following four weekly probes likewise were fairly consistent, but lower (i.e., "better"), whereas the last three weekly probe ratings suggest a dramatic deterioration in Ss#10's hyperactivity levels which did not seem to be affected by Ritalin because the week 12 hyperactivity rating was just as poor during the previous two placebo weeks (weeks 4 & 7) as well as during the no pill probe (week 5).

The parent's symptom ratings on the hyperactivity scale were fairly consistent over time except for two high scores reported during weeks 1B & 3B. However, hyperactivity symptom ratings during weeks 9B and 10B were not as high as week 3B.



(Note: Ratings given by the teacher of 2.08+ and 1.90+ for the parent suggest ADHD behavior on this scale). Parent and teacher ratings of child behavior problems on the Hyperkinetic Index of the Conners Parent (Revised 48-item) and Teacher (Revised 28-item) Rating Scale across three treatment conditions: NP = no treatment control (no medication or tablet administered), PL = placebo pill (protocol condition), RX = Ritalin (protocol condition). The parent did not turn in data sheets for weeks 4 through 7.

Figure 25. Parent & Teacher Ratings on the Conners Hyperkinesis Index Subscale by Treatment Conditions & Weeks Before & During Protocol for Ss#10.

ADD Evaluation Scale

This scale uses raw scores, subscale standard scores (i.e., obtained by converting raw scores into age-appropriate standard scores which are then used to discriminate between ADD vs. "normal" levels of behaviors), and a percentile score (i.e., derived from the sum total of the subscale standard scores and used to compare the child being assessed with those of the standardization sample).

The standard scores have a mean of 10 and a standard deviation of 3. Standard scores of 7 through 13 are within one standard deviation above or below the mean and indicate that the child behaves no differently than most of the children in the standardization sample. However, standard scores below 7 indicate that the child behaves more inappropriately than the majority of the students in the normative sample and a specialized intervention program is recommended to address these behaviors. A standard score of 4 or below is two or more standard deviations below the mean and indicates a serious level of concern. A standard score of 4 or below is considered the point at which a diagnosis of ADHD can be made (along with documentation from other instruments) and a formal treatment plan to address the student's inappropriate behaviors is recommended.

As can be seen by looking at Table 22 below, the parent rated Ss#10's behavior inattentive for 7 out of 9 weeks (i.e., 78% of the time) but rated her behavior *extremely* (4 or below) inattentive only for week 3-B (i.e., 11% of weekly ratings, and under a no pill probe condition). In addition, she rated Ss#10's behavior impulsive every week (9 out of 9 weeks) but rated her behavior *extremely* impulsive only for the two weeks 1-B and 3-B (i.e., 22%, under pre-protocol Ritalin and no pill probe conditions). Finally, the mother rated Ss#10's behavior *extremely* hyperactive almost every week (i.e., 8 out of 9 weeks or 89% of the weeks for which data were returned). By comparison, the mother tended to rate Ss#10's behavior more severe and more symptomatic of ADHD syndrome behavior on the ADD Evaluation Scale than on the Conner's.

The teacher rated Ss#10's behavior as inattentive 7 out of 13 weekly probes (54%), with only two weekly ratings falling into the extreme range. She rated the subject's behavior as impulsive 9 out of 13 weeks (69%) and 7 of these (or 54%

overall) fell into the extreme range. She rated the Ss' behavior hyperactive during 10 of 13 weeks (77%), 8 of which fell into the extreme range. As did the parent, the teacher

Table 22

Parent & Teacher Ratings on the Attention Deficit Disorders Evaluation Form for Ss#10

	Parent				Teacher		
Week #	Inattent	Impulsive	Hyperact	Tx Condit	Inattent	Impulsive	Hyperact
1-B	<5>	<1>	<0>	RRX	<5>	<2>	<2>
2-B	N/A	N/A	N/A	NP	N/A	N/A	N/A
3-B	<3>	<2>	<0>	NP	8	7	<5>
4	N/A	N/A	N/A	PL	8	<4>	<3>
BREAK	N/A	N/A	N/A	NP	N/A	N/A	N/A
5 - Holiday	N/A	N/A	N/A	NP	7	<6>	<5>
6	N/A	N/A	N/A	RX	<6>	<2>	<1>
7	N/A	N/A	N/A	PL	7	9	8
8	<6>	<5>	<3>	RX	10	8	9
9-B	7	<5>	<3>	NP	<4>	<4>	<3>
10-B	<6>	<6>	<3>	NP	<6>	<5>	<3>
11	<5>	<6>	<4>	RX	9	9	7
12	7	<6>	<4>	RX	<5>	<2>	<0>
13	<6>	<6>	<5>	PL	<5>	<1>	<0>
14	<6>	<6>	<4>	PL	<3>	<1>	<0>

Note: On any of the three subscales (Inattention, Impulsivity, Hyperactivity), a standard score of below 7 represents clinically significant behavior deviance and scores 4-0 represent extreme behavior deviance. Scores in brackets indicate clinically significant scores. Parent and teacher scores are listed next to the actual medication, placebo or no pill conditions which were administered to the child for that week in the protocol. Parents and teachers were requested not to turn in data sheets during the break in the study which lasted only a week.

rated the child's behavior as more symptomatic of ADHD syndrome on the ADD Evaluation Scale than on the Conner's Scale, across probe conditions.

The parent ratings were consistently severe and symptomatic across probe conditions and so were not helpful in detecting differences in Ss#10's reported

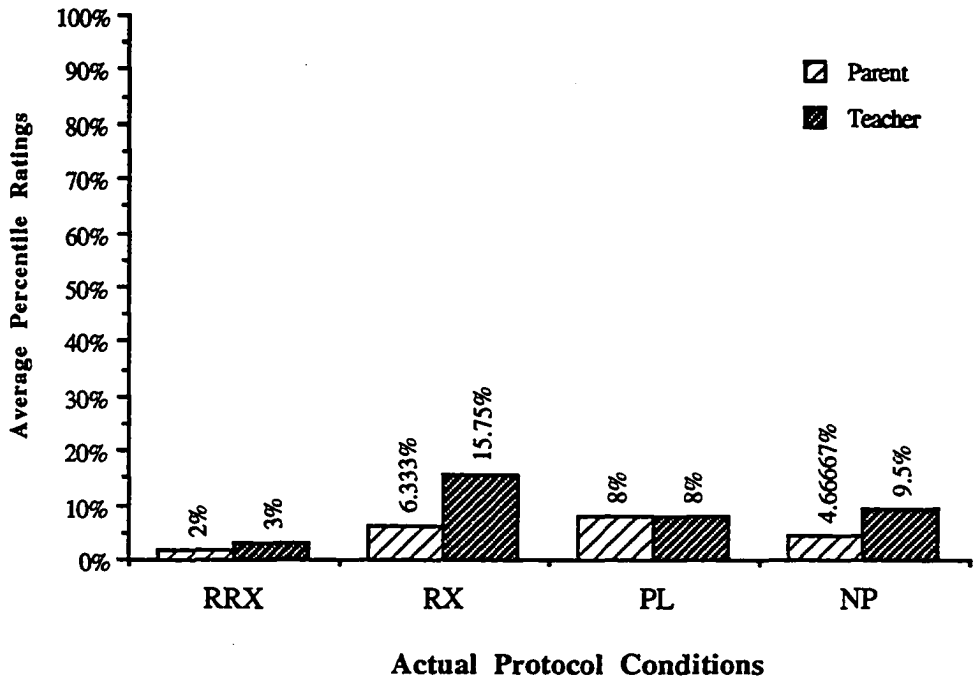
behavior under various protocol conditions. Furthermore, the teacher rated Ss#10's behavior as less severe across all three conditions of the ADD Evaluation Scale only three times (twice under Ritalin and once under placebo conditions). Thus, neither parent nor teacher ratings appeared to vary with the protocol conditions nor did they even appear to agree with each other except that both rated Ss#10 as more hyperactive and impulsive than inattentive. Data interpretation was made more difficult because the parent did not turn in data sheets for 6 of 14 weeks.

Percentile scores for the ADD Evaluation Scale were determined from the subscale standard scores found in Table 22 above. Percentile scores allow for the comparison of the symptom ratings of the patient with data in the standardization sample for this scale. In Figure 26 below, weekly percentile scores were summed and averaged according to the protocol condition in effect at the time the ADD Evaluation Scales were filled out. Percentiles below 16% fall one standard deviation below the mean on the normal curve, whereas scores below 3% fall about two standard deviations below the normal curve mean. For example, the parent rated Ss#10's behavior in the second percentile during the RRX condition. This means she rated her child's behavior lower than 98% of the students in the ADD Evaluation Scale's standardization sample and the teacher rated Ss#10's behavior lower than 97% of the children in this standardization sample for this same pre-protocol condition (i.e., third percentile).

Table 22 is useful in determining specific symptom areas being more or less affected and needing attention. Figure 26 below averages this information so that one can see if, on the whole, Ss#10's behavior was affected by Ritalin as compared to the other two probe conditions. As can be seen in Figure 26, Ss#10's behavior in all probe conditions was rated at least one standard deviation below the mean.

It appeared that only the teacher rated Ss#10's symptoms as improved under any probe condition, and this was the RX condition. However, both parent and teacher

rated Ss#10's symptoms as worse (two standard deviations below the mean) during the pre-protocol RRX condition. There also was only *one* opportunity for rating during the RRX condition compared to four each for the other probe conditions.



The ratings in this graph were determined by adding the sum of the subscale standard scores (as found in Table 22) and converting them to percentile scores. These percentile scores were then summed and averaged for ease of inspection. The percentile scores in the above Figure indicate how the subject being rated compares to children in the ADD Evaluation Scale's standardization sample. Note: RRX=pre-protocol (unblinded) Ritalin; RX=protocol (blinded) Ritalin; PL=placebo (no active medication administered); and NP=no pill (no tablet was administered). No ratings were obtained from the parent during weeks 4,(PL), 5B (NP), 6 (RX), 7 (PL) but scores were averaged only on the scores actually obtained.

Figure 26. Average ADD Evaluation Scale Percentile Ratings From Parent & Teacher Across Actual Protocol Conditions for Ss#10.

It appeared that the parent and teacher ratings were in agreement during the

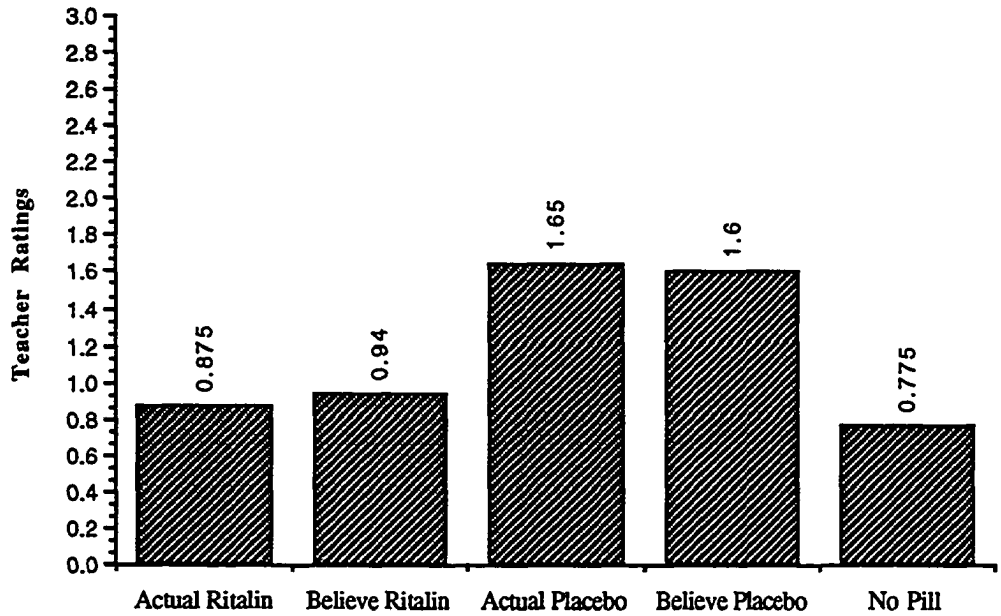
RRX and PL conditions but the teacher rated Ss#10's behavior more favorably than the parent during the RX and NP conditions. The teacher rated Ss#10's behavior relatively the same during the PL and NP probe conditions while the parent rated Ss#10's behavior best under the PL condition followed closely by the RX and NP probe conditions. Thus, it is not clear whether or not Ritalin effectively differentially helped Ss#10's symptomatic behavior. Contextual information gathered by observers (sign data) as described in the next section may help to clear up some of this ambiguity.

Accuracy of Parent and Teacher Reported Beliefs

Out of the eight double-blinded protocol conditions, the parent correctly guessed the probe condition only once (i.e., 13% accuracy). She attempted only three weekly guesses (see Table 20 for a display of the treatment conditions and the corresponding parent and teacher beliefs) and was correct once (i.e., during week 12). She answered "don't know" twice and did not turn in data sheets three out of eight weeks. From Table 20 it can be seen that the teacher guessed eight times and was correct five times (63% accuracy). Unlike the parent, the teacher did not respond in only one direction. She guessed placebo five weeks and Ritalin three weeks for the blinded protocol conditions. In sum, it appears that the teacher was much better identifying actual probe conditions than was the parent. Furthermore, because she made more guesses, her expectations and ratings can be examined further.

The teacher did not rate Ss#10's behavior as hyperactive consistently according to the actual protocol probe conditions. She rated Ss#10's behavior as markedly hyperactive only three weeks on the Conners (out of at least eight weeks that data sheets were turned in) during which Ss#10 was within placebo, no pill and pre-protocol Ritalin probe conditions. On the ADD Evaluation Scale, teacher ratings seemed mixed about the effect of Ritalin. She rated Ss#10's behavior problematic

twice while Ss#10 was taking Ritalin (i.e., weeks 6 and 12) but rated Ss#10's behavior within a "normal" or average range for Ss#10's age group the other two weeks Ss#10 took Ritalin (i.e., weeks 8 and 11). Furthermore, the parent and teacher ratings of Ss#10's behavior on the Conners Parent and Teacher Rating Scale did not appear to consistently agree with any particular probe condition (see Figure 25).



Actual Protocol Conditions & Teacher Beliefs

The numbers in this graph represent teacher ratings when the teacher believed Ss#10 took Ritalin, Placebo, or No Pill and when these conditions actually occurred. Teacher ratings on the Conners Teacher Rating Scale were averaged first by the actual protocol conditions in effect at the time the teacher rated the subject on this scale and then ratings were averaged according to what the teacher believed the subject to be taking when she rated the subject on this scale. The "Believe Placebo" condition has ratings which occurred while the subject was in a "no pill" condition because the teacher never acknowledged a "no pill" condition and, instead, acknowledged either "placebo" or "Ritalin" every time.

Figure 27. Teacher Ratings on the CTRS by Actual Protocol Conditions & Teacher Beliefs for Ss#10.

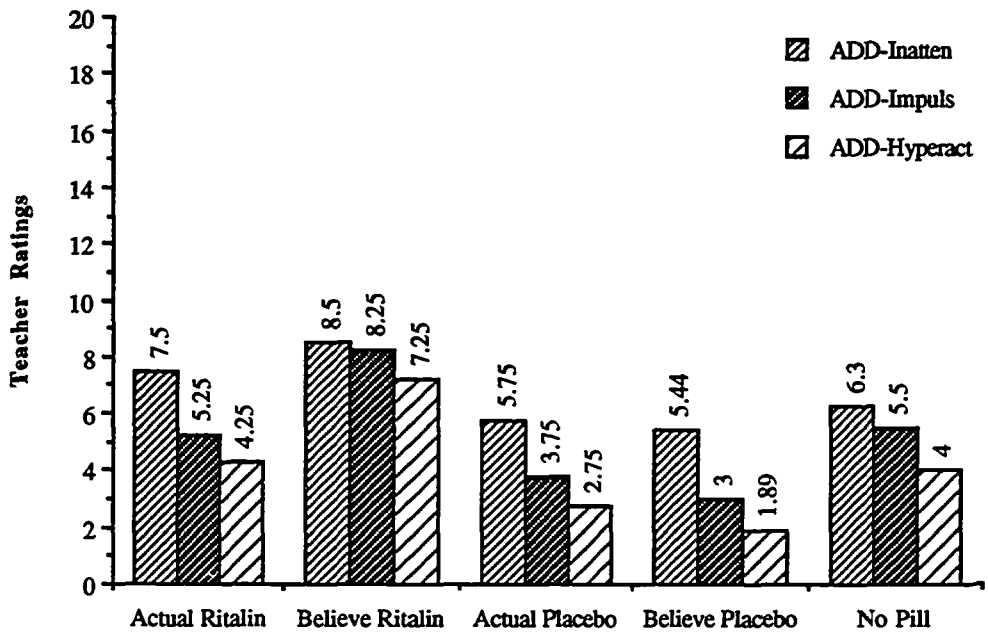
The teacher's ratings did not appear to be influenced by her beliefs about the

protocol conditions on the Conners Teacher Rating Scale. The teacher rated Ss#10's behavior similarly on the Conners Scale both when she believed Ss#10 to be taking Ritalin or placebo as well as when Ss#10 was actually taking Ritalin or placebo (see Figure 27). However, on the ADD Evaluation Scale, the teacher appeared to be influenced by her belief in Ritalin. She rated the patient's behavior similarly when she "believed" the subject to be taking placebo as she did when Ss#10 was actually taking placebo. The teacher's ratings were slightly higher (which is a more favorable or "average" score) when she "believed" the subject to be taking Ritalin than when Ss#10 actually took Ritalin (see Figure 28).

Interobserver Agreement for Classroom Observations

Out of 27.38 observation sheets collected on Ss#10 for on- and off-task classroom behavior, 15.28 included inter-observer agreement checks (i.e., two observers watched the subject at the same time). There were actually 17 inter-observer observation sheets but not all intervals on all the sheets were completed. Only the number of intervals were counted. Thus, inter-observer reliability was obtained on 52% of the total number of intervals observed (2901/5541) for Ss#10.

As can be seen in Table 23, the agreement indexes obtained for Ss#10 and the comparison child (combined) for individual weeks (e.g., the percent agreement on the total of the individual daily observation sheets) averaged 81% (column 4, row 18) and ranged between 64% to 93% (column 4). Broken down further by child per week, the overall (on- and off-task) percentage of agreement for Ss#10 (e.g., the percent agreement between one observers' on- and off-task total with the other observer's on- and off-task total scores) ranged between 65% to 97% (column 2) with a mean of 79% (row 18) and for the comparison child, the percentage agreement ranged between 59% to 100% (column 3) with a mean of 83% (row 18).



Teacher ratings on the school version of the Attention Deficit Disorders Evaluation Scale were averaged first by the actual protocol conditions in effect at the time the teacher rated the subject on this scale and then ratings were averaged according to what the teacher believed the subject to be taking when she rated the subject on this scale. The "Believe Placebo" condition has ratings which occurred while the subject was in a "no pill" condition because the teacher never acknowledged a "no pill" condition and, instead, acknowledged either "placebo" or "Ritalin" every time. Note: Ratings of 7+ are considered "normal" or average. Ratings which are below 7 suggest some behavioral deviance.

Figure 28. Teacher Ratings on the ADD Evaluation Scale by Actual Protocol Conditions & Teacher Beliefs for Ss#10.

Table 23 also displays interval-by-interval agreement indexes for both the protocol and comparison child for combined on- and off-task behavior (e.g., comparing each observer's scores on each interval the target and comparison child were observed). Reliability obtained through this manner is necessarily lower than the overall reliability because the proportion of disagreements to agreements increases

Table 23

Inter-Observer Reliability of Classroom Observations
for Ss#10 (Target) & a Comparison Child

Percentage of Agreements										
		Overall On- & Off-Task Agreements			*Separated by Child & On-/Off--Task Records (Interval-by-Interval)*					
		Targe Child	*Com Child*	*Ave Daily Agree*	*Targe Child % Agree On-Task*	*Targe Child % Agree Off-Task*	*Com Child % Agree On-Task*	*Com Child % Agree Off-Task*	*T+ C On-Task Averag Agree*	*T+ C Off-Task Averag Agree*
	Week #	*Ave Agree*	*Ave Agree*	*On+Of T + C*						
	COL 1	COL 2	COL 3	COL 4	COL 5	COL 6	COL 7	COL 8	COL 9	COL10
ROW 1	Wk 1B	69%	79%	74%	62%	40%	77%	27%	70%	35%
ROW 2	Wk 2B	65%	100%	83%	59%	29%	100%	100%	79%	46%
ROW 3	Wk 2B	70%	78%	74%	61%	42%	74%	41%	68%	42%
ROW 4	Wk 4	77%	93%	85%	70%	48%	92%	44%	82%	47%
ROW 5	Wk 4	81%	75%	78%	68%	68%	65%	52%	66%	61%
ROW 6	Wk 6	91%	88%	89%	89%	67%	87%	12%	88%	47%
ROW 7	Wk 6	83%	81%	82%	81%	39%	80%	23%	80%	31%
ROW 8	Wk 6	81%	89%	85%	73%	61%	87%	58%	81%	60%
ROW 9	Wk 7	75%	78%	76%	71%	35%	76%	21%	74%	29%
ROW10	Wk 7	97%	88%	93%	96%	60%	87%	50%	92%	53%
ROW11	Wk 8	93%	93%	93%	92%	40%	92%	25%	92%	33%
ROW12	Wk10B	80%	76%	78%	74%	56%	69%	48%	71%	52%
ROW13	Wk 11	68%	59%	64%	60%	39%	51%	29%	56%	34%
ROW14	Wk 12	86%	86%	86%	84%	48%	86%	6%	85%	34%
ROW15	Wk 12	68%	78%	73%	63%	29%	76%	30%	69%	29%
ROW16	Wk 13	83%	93%	88%	78%	54%	93%	0%	86%	45%
ROW17	Wk 14	77%	76%	76%	69%	53%	74%	28%	71%	43%
ROW18	Avg.:	79%	83%	81%	75%	46%	81%	36%	78%	42%
ROW19	Total	Overall	Percent	Reliab	for the	whole	study	=81%		

Table 23-Continued

Ss#10 (T=target child) and a comparison child (C) were observed by undergraduate students and inter-observer reliability data were collected for 15.28 of the 27.38 observations. Table 23 depicts percent agreements between two observers recording on- and off-task behavior independently of each other. The first three columns represent overall agreement for the whole observation session (not interval by interval) for the target and comparison child (i.e., columns 2 & 3); and the overall percentage of agreement for that observation week (i.e., combined scores for on- and off-task as well as for target and comparison; column 4). In the last six columns inter-observer agreements were broken down into percent agreement on an interval-by-interval basis for on-task and off-task behavior for target and comparison child separately (i.e., columns 5 through 8) and the average agreement for on-task & off-task behavior for both target and comparison child combined (i.e., columns 9 & 10). Row 19 represents the percent agreement for the whole study and row 18 represents the averages for each column.

when you compare total numbers of disagreements with subcategories of agreements. With this in mind, the total percentage of on-task agreement per week and by condition for both protocol and comparison child (column 9) ranged between 56% to 92% (mean = 78%, row 18) and off-task agreement (column 10) ranged from 29% to 61% (mean = 42%). The agreement indexes for on- and off-task behavior by child and week are also listed in Table 23 (columns 5 through 8). On-task agreement reliability is substantially higher than off-task agreement. This is expected because on-task is scored by default when either no behavior is observed or a behavior is missed by one or the other observers. On the other hand, inappropriate behavior must be seen in order to score the interval as off-task.

The overall (on- and off-task) inter-observer agreement obtained for Ss #10 and the comparison child (combined) was 81% (row #19). Thus, the overall reliability appears to be high enough to make guarded treatment decisions based on these data, especially when these are monitored through the continuing course of treatment and modified as needed.

Classroom Behavior Observations

Ss#10 was recorded as on-task for roughly 70% of the intervals observed (73% for the first half of the study and 75% for the second half) which averaged 10% less on-task than the comparison child (see Table 24 & Figure 29 below). Although observation data were not available for each week, Ss#10 generally was recorded as on-task 1% to 22% less than the comparison child across weekly probes except for week 10B (no pill) in which she was recorded on-task the same number of intervals as the comparison child, and for weeks 7 (placebo) and 12 (Ritalin) in which she was recorded on task for 4% to 8% more intervals than the comparison.

In examining Figure 29 and Table 24, Ss#10's on-task behavior was least discrepant (i.e., there was less than a 10% difference between the comparison child's intervals of on-task behavior and that of Ss#10's) during weeks 6 through 12. These weeks contained four Ritalin probes, one placebo probe, and two no pill probes. When added together and averaged across the duration of the protocol evaluation (see Figure 30) Ss#10's appeared to be on-task slightly more under the Ritalin condition, with 7% more intervals on-task than in the placebo probe condition, and 6% more intervals on-task than when in the no pill probe condition. Placebo and no pill probe conditions differed by only 1% of intervals scored on-task. Furthermore, the comparison and target child's on-task behavior was less discrepant under the Ritalin condition (i.e., 2% under Ritalin, vs. 12% under placebo and 10% under no pill). Thus, on the whole, it appeared Ss#10's on-task classroom behavior was observed to be slightly improved in the Ritalin probe.

Table 24

Classroom Observation Data for Ss#10
& a Comparison Child

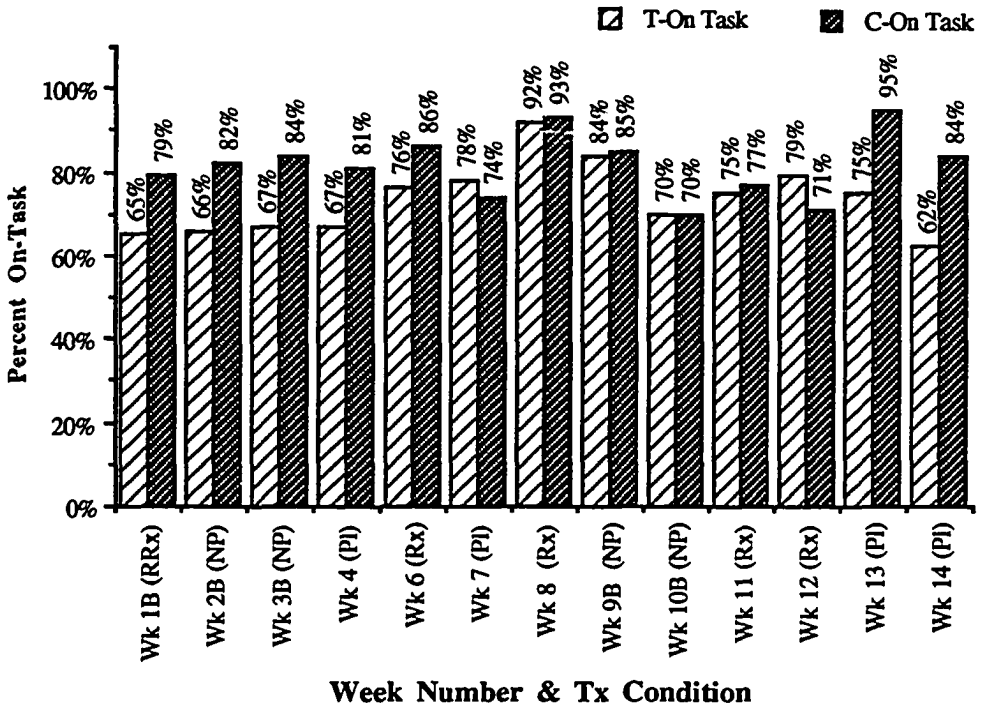
Week Number	Treatment Condition	Target Child Data		Comparis Child Data		% #10 was On Task vs. Compar	Number of observat per week
		On-Task	Off-Task	On-Task	Off-Task		
Wk 1B	RRX	65%	35%	79%	21%	14%	.92
Wk 2B	No Pill	66%	34%	82%	18%	16%	1.6
Wk 3B	No Pill	67%	33%	84%	16%	17%	2
Wk 4	Placebo	67%	33%	81%	19%	14%	2.7
Wk 6	Ritalin	76%	24%	86%	14%	10%	3.2
Wk 7	Placebo	78%	22%	74%	26%	<+4%>	2.7
Wk 8	Ritalin	92%	8%	93%	7%	1%	1
Wk 9B	No Pill	84%	16%	85%	15%	1%	2
Wk 10B	No Pill	70%	30%	70%	30%	0%	.89
Wk 11	Ritalin	75%	25%	77%	23%	2%	3.5
Wk 12	Ritalin	79%	21%	71%	29%	<+8%>	3
Wk 13	Placebo	75%	25%	95%	5%	20%	2
Wk 14	Placebo	62%	38%	84%	16%	22%	1.87
Overall	Average%	70%	30%	80%	20%	10%	27.38
Ave for	1st half of study	73%	27%	82%	18%	9%	14.12
Ave for of	2nd half study	75%	25%	80%	20%	5%	13.26

Table entries depict weekly averaged percentages of on- and off-task behaviors as recorded by undergraduate students during direct classroom observations of the subject's and the comparison child's behavior for each week in the protocol according to whether the child was taking: medication pre-protocol Ritalin (RRX); protocol Ritalin (RX); placebo pills (PL), or no pill at all (NP). The number of observations made for that week are recorded to the right as well as the percentage difference between the subject and the comparison child's on-task behavior, overall average for on- and off-task behavior for both the target and comparison child, and the overall average for the first and second half of the protocol. The two scores in brackets indicate that the target child was 4% and 8% more on-task than the comparison. A graphic depiction of averages from this table can be seen in Figure 29.

Zung Depression Scale

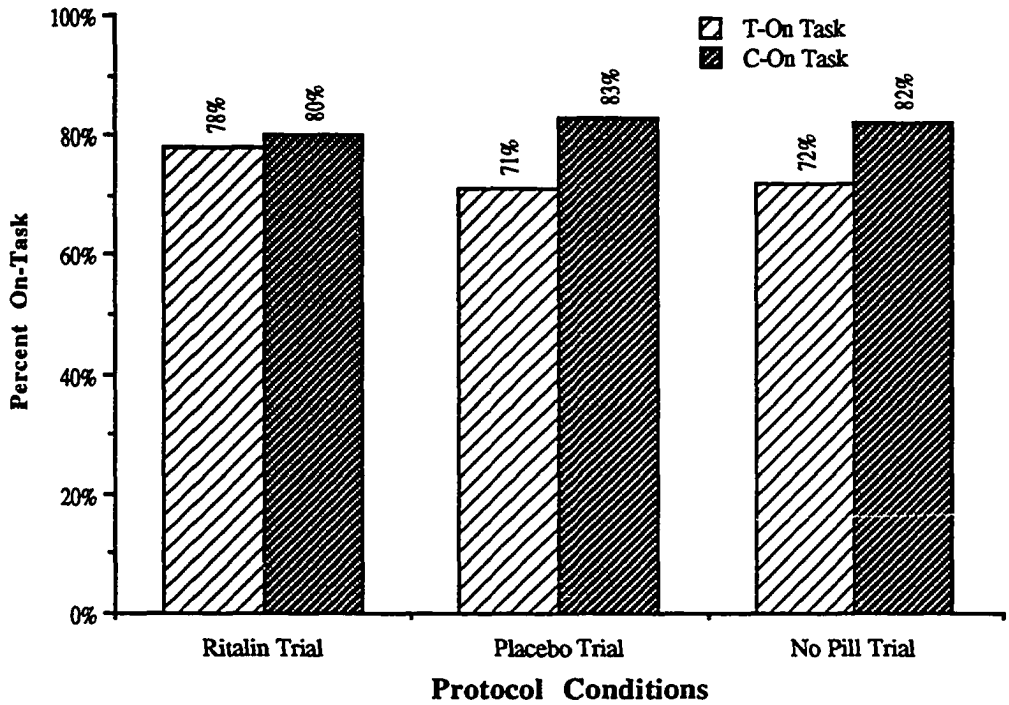
The parent acknowledged depressed mood (i.e., minimum to mildly depressed

mood level) during weeks 1B (RRX), 3B (NP), 8 (RX), 9B (NP), and 12 (RX) and rated herself in the normal mood range during weeks 10B (NP), 11 (RX), 13 (PL), and 14 (PL). It did not appear that the parent's rating of Ss#10's behavior was related to her weekly mood ratings, because her ratings of child behavior were fairly consistent regardless of her current mood rating.



Direct classroom observations of Ss#10's (T=target) and the comparison child's ("C") behavior as recorded by undergraduate students during direct classroom observations by percentage of observation intervals the children were observed to be on-task doing assigned work. A total of 27.38 observations conducted almost weekly throughout the 14 weeks of the protocol were averaged and the percentage of on- task intervals were recorded in graph format in this figure. Data are presented for weeks during which the target child was taking the pre-protocol (RRX) and protocol (RX) trial of Ritalin, placebo (PL), and no pill (NP). Actual numbers of observations made are in Table 24. Data is displayed by weeks in the medication evaluation protocol.

Figure 29. In-Class Observations of Ss#10 vs. Comparison Child's On-Task Behavior by Weeks in Protocol.



Direct classroom observations of the subject's and comparison child's on- task behaviors as recorded by undergraduate students in which all treatment conditions were added together and averaged by observations made while the subject was on the medication evaluation protocol taking Ritalin, placebo and no pill.

Figure 30. Average On-Task Behavior of Ss#10 & a Comparison Child Across Protocol Conditions.

The teacher indicated these questions were too personal and irrelevant to Ss#10's behavior. Because we could not explain how this scale was relevant without giving out too much information about the study, she chose not to complete this particular set of questions.

Marital Happiness & Teacher Satisfaction Scales

The parent rated herself mildly to moderately happy/satisfied with her role as a parent. Her scores ranged between 45 to 51 (out of a total of 110). Her ratings on this scale did not seem to covary with her ratings on the Conners or ADD Evaluation

Scales, most notably because her ratings on these scales did not vary much across probe conditions.

The teacher's ratings suggested she was highly satisfied with her job as a teacher (e.g., her scores ranged between 93 to 107 but 93 occurred only once and 107 occurred most often). Like the parent, the teacher scores on this scale did not covary with her ratings on the ADD and Conners Scales.

Discussion of Protocol Findings for Ss#10

Out of 8 double-blinded protocol probe conditions, the parent guessed the actual probe condition with 13% accuracy whereas the teacher guessed with 63% accuracy. The improved teacher accuracy may well be due to the fact that she attempted a guess every week whereas the parent guessed only three times. The teacher detected protocol conditions at above chance levels. Whether or not the teacher's symptom rating scores were influenced by her beliefs about which condition was in effect will be discussed below.

The parent rated Ss#10's symptomatic behavior as hyperactive on the ADD Evaluation Scale but not on the Conners. The teacher rated Ss#10's symptomatic behavior as hyperactive three weeks on the Conners but 8 out of 11 weeks on the ADD Evaluation Scale. Furthermore, on the other two subscales of the ADD Evaluation Scale, parent and teacher symptom scores did not agree with each other. The mother's symptom scores reached severity criterion on the ADD Evaluation Scale 100% of the weeks (i.e., 9 out of 9 weeks) for impulsive behavior and 78% of the weeks (i.e., 7 out of 9 weeks) for inattention. On the other hand, the teacher's symptom scores met clinical criterion for severe impulsive behavior 69% of the weeks (i.e., 9 out of 13 weeks) and 54% (i.e., 7 out of 13 weeks) for inattention.

Evaluating the effectiveness of Ritalin for this child would have been made more difficult if only parent or teacher symptom data were available, or if one had only the Conners symptom data. When looking just at parent symptom scores, it appeared that Ss#10's behavior never varied across probe conditions, but when looking at the teacher symptom scores, it appeared that Ss#10's behavior did vary with probes. Perhaps the teacher's symptom scores are more useful in determining the effectiveness of Ritalin because she had optimal exposure to Ss#10 when she took Ritalin. Compared with the parent, the teacher's ratings of Ss#10's symptomatic behavior varied across probe conditions, more data sheets were obtained, and teacher symptom ratings appeared to be consistent with the findings from direct classroom observations (sign data).

According to the in-class observations, Ss#10's was on-task behavior for slightly more intervals within the Ritalin probe. Although the differences between intervals scored on-task under all three probe conditions was minimal (i.e., between 1% to 7% difference) discrepancy scores were notable between the protocol and comparison child (i.e., there was only a 2% of intervals on-task discrepancy between the target and comparison under the Ritalin condition: see Figures 28 & 29 and Table 24).

Although teacher symptom and observer sign data both suggest Ritalin was more effective for Ss#10's on-task behavior than either placebo or no pill, it should be cautioned that, on at least one symptom rating scale, teacher ratings appeared to be subjectively, and possibly personally, biased in favor of Ritalin (see Figure 28). Of further cautionary note is that teacher symptom ratings made during the no pill condition appeared very similar to those obtained during the actual Ritalin conditions on both symptom rating scales (see Figures 26 and 27). Thus, it is not clear if, or to what extent, personal bias may have influenced the teacher's rating data.

Both parent and teacher symptom ratings on the Conners scales did not indicate that Ss#10 was clinically hyperactive. Had only these symptom data been available, they would not support verbal reports that Ss#10 was "hyperactive." The psychiatrist might have been confronted with the problem of determining which source of data (symptom or sign) should carry more weight when making clinical decisions.

Parent and teacher behavior symptom ratings did not differentiate among the protocol probe conditions, yielding inconclusive data on whether Ritalin was effective. However, the observation data did suggest improvement within the Ritalin probe. Ss#10 was scored as on-task during 78% of the intervals while taking Ritalin, but this was only 7% more intervals than placebo and only 6% more than no pill probes. Support for the therapeutic effect of Ritalin may be seen when discrepancy data are including from the comparison child (i.e., 2% difference between the target and comparison under Ritalin versus a 12% discrepancy when under placebo and a 10% discrepancy when under no pill). In addition, Ss#10 did not appear to engage in as much off-task behavior as the parent and teacher ratings might have suggested (i.e., she was scored on-task 62% to 92% of the intervals observed, with a mean of 70%).

Prior to the protocol the parent had a low tolerance for Ss#10's unmedicated behavior but developed a belief that Ritalin caused "whiny" behavior and then preferred Ss#10's behavior while not taking a pill. She did not give her daughter a pill during the last two days of the protocol evaluation even though Ss#10's behavior, according to the parent, had not changed much since the start of the protocol. Thus, beliefs may affect medication endorsement in either direction . This only underlines the importance of obtaining objective and multiple evaluations of the patient's behavior under (blinded) medication and non-medication conditions.

Protocol Recommendations for Ss#10

Ritalin may have a beneficial effect for Ss#10 based upon both the in-class observations of on-task behavior as well as teacher symptom rating data. However, the parent was convinced Ritalin was not benefiting her daughter due perhaps to the fact that the parent thought her daughter was taking Ritalin when she was not. This demonstrated the importance of the double-blind control, but the parent's resulting attitude will now have to be addressed. This could be done by showing her the data from the protocol and allowing her the option of observing her child's behavior under unblinded Ritalin conditions.

Despite a recommendation to continue taking Ritalin, Ss#10 still needs to be taught to take personal responsibility for controllable negative events and dissuaded from self-blame for uncontrollable negative events. It would likely be important to identify controllable behaviors and to set up contingencies for rewarding increased attention and decreased impulsivity and hyperactivity. Parent and teacher participation in this matter would be strongly encouraged.

Furthermore, increases or decreases in structure and task demands may likely have a significant affect on her on- and off-task behavior. Ss#10 should be given clear and consistent contingencies for her behavior. The desirability of the rewards as well as the specificity of the contingencies should not be over-looked. The more she wants the reward, the more successful the contingencies will be in affecting her on-task behavior. The more consistent the demands are for participation, the more likely she will be to engage in the tasks.

Psychotherapy and social skills training may also be beneficial due to Ss#10 aggressiveness and tendency to "push the limits." Family therapy is encouraged to help the parents set clear and enforceable limits on her behavior as well as help the parents

follow through with contingencies for Ss#10's behavior. A careful exploration of her academic skills and learning capabilities may also be helpful (e.g., psychological and academic evaluations) to help set clearer expectations for her behavior.

CHAPTER IX

SUMMARY OF INDIVIDUAL PROTOCOL FINDINGS

Referral Sources & Reasons for Enrollment in Protocol Evaluation

Four subjects (i.e., Ss# 4, 7, 8, and 9) had never taken Ritalin or psychostimulants before this protocol and two subjects (i.e., Ss# 3 and 10) had taken Ritalin. At the time of referral, Ss#3's mother and psychiatrist questioned whether or not Ss#3 still needed to take Ritalin and asked for the drug evaluation to help them make this determination. Ss#10 was referred because the psychiatrist questioned the administration of Ritalin in a child so young.

All subjects were diagnosed as ADHD syndrome by the same psychiatrist and found to qualify for a drug evaluation of Ritalin. All parents and teachers as well as the school principals agreed to participate in this protocol prior to its implementation for each subject.

Social Histories and Backgrounds

All children were Caucasian except Ss#4 who was an African American. Ss#3 was a 13 year old male in the second grade; Ss#4 was a 9 year old male in the third grade; Ss#7 and Ss#10 were 5 and 4.7 years old respectively and both were in kindergarten; Ss#8 was a 7 year old male in the second grade; and Ss#9 was a 10 year old girl in the fifth grade. Ss#3 and 4 were in special classes for learning disability.

Four other subjects dropped out of the protocol because the principal or teacher were unwilling to participate in the protocol (i.e., questions asked were

believed to be too personal, lengthy, or irrelevant and they did not want observers in the classroom).

Data were collected for only seven weeks from teacher 3b and for only eight weeks from teacher 3c and Ss#3's parent. Ss#3 had less data because his teachers no longer wanted to participate since they believed Ss#3 was becoming worse by not being on his medication. The remainder of the subjects completed all 12 weeks of the protocol and all teachers turned in at least 12 weeks or more of data but the parent for Ss#10 turned in only 10 weeks of data. Teachers for Ss#9 and 10 turned in 15 and 14 weeks of data respectively. The parent for Ss#7 (i.e., 7a) turned in 12 weeks, 8a turned in 15 weeks of data and 9a turned in 15 weeks of data. Despite the unequal numbers of weekly probe data sets collected, some analysis was possible because the data were analyzed individually. The following will present group trends and overall findings for use of this evaluation protocol.

Pre- & Post-Protocol Findings

Medication Attitude Survey

Because expectancies were unsuccessfully influenced, ADHD evaluation forms completed by parents and teachers did not covary with expectancies. This survey became of little use except as a description of how the participants' attitudes changed or stayed the same as a function of enrolling in the protocol. (Please refer to the section entitled, "Accuracy of Parent and Teacher Reported Beliefs" for more detailed information about expectancies and the following two sections for results of the ADHD evaluation forms.) Results thus were used mainly to determine how well received Ritalin would be if it were prescribed for a particular child. These results were listed in

the individual progress reports for each subject. The following describes a general picture of the results found for this survey.

One child, Ss#4, changed his attitude about Ritalin during a post-protocol evaluation (i.e., from a pre-protocol positive attitude to a post-protocol negative attitude), one child's attitude, Ss#10, remained neutral before and after the protocol, and one child's attitude, Ss#3, remained positive before and after the protocol (see Table 25). Three subjects were not able to answer the pre-protocol questionnaire (i.e., subject numbers 7, 8, and 9). However, Ss#7 and Ss#8 had positive attitudes about Ritalin on the post-test and Ss#9 had a negative attitude about Ritalin.

The parents for Ss#3 and 7 had positive attitudes about Ritalin for their children, whereas the parent for Ss#4 had a neutral attitude about Ritalin, both before and after the protocol. Although Ss#8 and 9 had the same parent, the parent changed her attitude about Ritalin in different directions. At the start of the protocol she believed Ritalin was what Ss#8 needed but wasn't sure that Ritalin would be effective for Ss#9. She initially had a positive view of Ritalin for Ss#8 but during the post-protocol evaluation expressed a more neutral view of medication for her child. This same parent for Ss#9 had an initially neutral view of Ritalin for Ss#9 which changed to a negative view at the end of the protocol evaluation. The parent for Ss#10 changed the most dramatically, from positive to a negative view of medication for her daughter. The remaining two parents did not change attitudes.

The teachers for Ss#3, 4, 9, and 10 all had positive attitudes about Ritalin both before and after the protocol. The teacher for Ss#7 changed his attitude from an initially neutral view to one that was more positive. The teacher for Ss#8 changed from a positive to a neutral attitude about Ritalin.

Only Ss#7's teacher expressed an improved attitude towards Ritalin. The attitudes of five teachers, two parents and one child remained positive both before and

after the protocol. One parent's attitude remained neutral but the attitude of one child, two parents, and one teacher became less favorable at the end of the protocol. Most participants in this evaluation continued to have a positive opinion about Ritalin. None had a negative opinion at the start of the evaluation but four did not like Ritalin at the end of the evaluation and a small portion maintained a neutral attitude about Ritalin both before and after the protocol (see Table 25).

Table 25

Group Summary of Responses to Medication Attitude Survey

Pre-Test		Pre- Test			Post- Test	
Missing	Positive	Neutral	Negative	Positive	Neutral	Negative
	3,3a,3b/c			3,3a,3b/c		
	4, 4b	4a		4b	4a	4*
7	7a	7b		7,7a,7b*		
8	8a, 8b			8	8a*, 8b*	
9	9b	9a		9b		9, 9a*
10 & post	10a, 10b			10b		10a*
Totals	12	3	0	11	3	4

Child, parent, and teacher attitudes about Ritalin both before & after the protocol are listed in this table (i.e., a = parent, b = teacher, c = teacher; plain numbers represent the child in the evaluation). Subject numbers 7, 8, and 9 did not complete a pre-protocol evaluations survey. Ss#10 was too young to complete either a pre- or post-attitude survey. Asteriks indicate changed attitudes on post-test evaluation.

Norwicki-Strickland

Internality is associated with academic achievement, persistence, higher self-

esteem, higher self-concept, higher moral development, greater popularity, more honesty, shorter delay of gratification, lower anxiety, and less interpersonal distance. External scores are associated with emotional, physical, or mental handicaps, psychological maladjustment, more vulnerable to sickness and accidents, and hyperkinetic/aggressive boys were more external than a comparably aged group of kids.

On this measure, the higher the number of "yes" responses, the more external the score. Five subjects had a lower post-test score (i.e., less "yes" responses) and one subject's post-test score matched the pre-test score (i.e., mean pre-test score was 62% or 25 "yes" answers and the mean post-test score was 51% or 21.5 "yes" answers). Furthermore, all the subjects except Ss# 3 and 4 closely matched their estimated true score (see Table 26). Thus, the majority of the subjects' responses were less external on the second administration of the test. However, these differences were insignificant for four subjects. Their post-test scores changed from 0% to 5% (i.e., Ss#7, 8, 9, and 10). The other two subjects showed the most dramatic change (i.e., Ss#3 and 4) changed 35% and 20% respectively (see Figure 31 and Table 26).

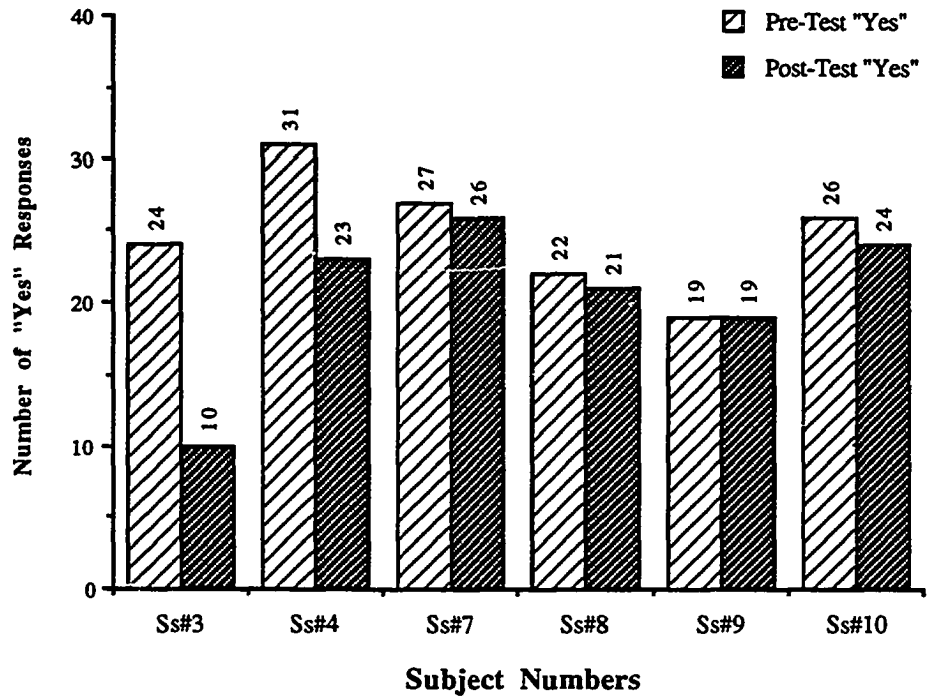
None of the subjects' scores moved toward the external zone after the protocol (i.e., no one answered "yes" more frequently on the post-test). These results thus seem to contradict Whalen and Henker's (1980) findings because external attributions did not change. However, this may have had to do with the design of this protocol in which at times subjects did not take any pills and therefore had to rely on their own resources to manage their behavior and perhaps had less opportunity to become psychologically dependent on the medication.

Table 26

Group Differences Between Post-Protocol Scores & Estimated True Scores on the Norwicki-Strickland

	Pre-Protocol	*Post-Protocol*		*Difference Between*
Subject Number	*Number / Percent Yes*	*Number / Percent Yes*	*Estimated True Score*	*Post v. ETS Percent Difference*
3	24 / 60%	10 / 25%	22*	12 / 35%
4	31 / 78%	23 / 58%	27*	4 / 20%
7	27 / 68%	26 / 65%	24	2 / 3%
8	22 / 55%	21 / 53%	21	0 / 2%
9	19 /48%	19 / 48%	18	1 / 0%
10	26 / 65%	24 / 60%	23	1 / 5%
Range	19 - 31 48% - 78%	10 -26 25% - 65%		0 - 12 0% - 35%
Mean	24.8 / 62%	**20.5 /51.5%**		**3.2 / 10.8%**

Note: Raw scores for each subject were recorded for the pre- and post-protocol. Percent scores were obtained by dividing the raw score by the total number of ":yes" answers. The difference between the pre-protocol percent scores were then subtracted from the post-protocol percent scores and were recorded as "Percent difference". The Estimated True Score (or ETS) was calculated by adjusting the raw score for error in this test (test-re-test reliability: r=.63 for 3rd graders). This ETS is the score the child could be expected to obtain if s/he simply re-took the test, regardless of any intervention. The difference between the ETS and the raw score is recorded in the far right-hand column. Only Ss#3 & 4 had large difference scores.



The higher the number of "yes" scores, the more external the score. For example, Ss#3 had 24 "yes" responses on the pre-test, indicating 60% of his responses were in the external direction. This means most of the time he believed external forces were responsible for his behavior and that he himself had little control over the outcome. In contrast, his post-test score suggested he believed he had control over the outcome of his behavior (i.e., that he was responsible for what happened to him) since only 25% of his responses were in the external direction.

Figure 31. Group Summary of the Pre- & Post–Test Child Self-Ratings on the Norwicki-Strickland Locus of Control Scale.

Weekly Probe Findings

Conners Rating Scale

Parents for Ss#3 and 10 and teachers for Ss#4 and 9 never rated the children's symptoms as severe enough to meet clinical criteria as hyperactive on the Conners Rating Scale during any probe week. Parents for Ss#8 and 9 and the teacher for Ss#8

rated their children's symptoms at clinically significant levels for hyperactivity on the Conners Rating Scale each probe week. There were only a few parents and/or teachers

Table 27

High (Hyperactive) vs. Low ("Normal") Scores for All Parents on the Conners Parent Rating Scale

Ss#	RRX		RX		PL		NP		Total	Total
	High	Low	High	Low	High	Low	High	Low	High	Low
3a	0	3	0	2	0	2	0	1	*0*	*8*
4a	1	1	0	4	2	2	0	3	*3*	*10*
7a	0	0	2	1	1	3	3	2	*6*	*6*
8a	0	0	4	0	5	0	6	0	*15*	*0*
9a	0	0	4	0	4	0	7	0	*15*	*0*
10a	0	2	0	3	0	2	0	3	*0*	*10*
Total	1	6	10	10	12	9	16	9	*39*	*34*
%	*14%*	85%	*50%*	50%	*57%*	43%	*64%*	36%	*53%*	*47%*

Note: Parent scores on the Conners Parent Rating Scale were counted as either "High" (i.e., meeting the cut-off criteria for Hyperactivity) or "Low" (i.e., anything not meeting the cut-off criteria). These scores were then added according to when in the protocol ratings were given (i.e., either during conditions of unblinded Ritalin = RRX; blinded Ritalin = RX; Placebo =PL; or No Pill = NP).

who varied their symptom ratings across weeks (see Tables 27 and 28). Ss#4's parent rated her child's behavior as hyperactive during one Ritalin week and two placebo weeks. Ss#7's parent rated her child's behavior as hyperactive during the first six weeks of the protocol, except for week 4, a placebo week. The teacher rated Ss#7 as

hyperactive only during two weeks (i.e., one no pill week and one Ritalin week). The teacher for Ss#10 rated her as hyperactive during one Ritalin and two placebo weeks.

Table 28

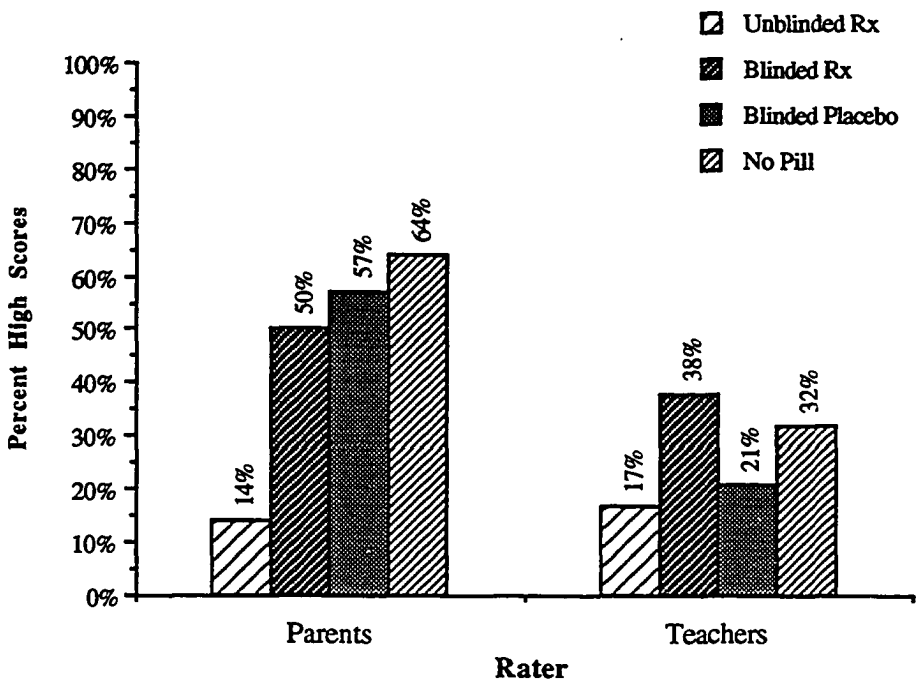
High (Hyperactive) vs. Low ("Normal") Scores for All Teachers on the Conners Teacher Rating Scale

Ss#	RRX		RX		PL		NP		Total	Total
	High	Low	High	Low	High	Low	High	Low	High	Low
3b	1	2	1	0	0	2	0	1	*2*	*5*
3c	0	3	2	0	2	0	1	0	*5*	*3*
4b	0	4	0	2	0	4	0	4	*0*	*14*
7b	0	0	1	3	0	5	1	4	*2*	*12*
8b	0	0	4	0	1	1	7	0	*12*	*1*
9b	0	0	0	4	0	5	0	6	*0*	*15*
10b	1	1	0	4	2	2	0	4	*3*	*11*
Total	2	10	8	13	5	19	9	19	*24*	*61*
%	17%	83%	38%	62%	21%	79%	32%	68%	*28%*	*78%*

Note: Parent scores on the Conners Parent Rating Scale were counted as either "High" (i.e., meeting the cut-off criteria for Hyperactivity) or "Low" (i.e., anything not meeting the cut-off criteria). These scores were then added according to when in the protocol ratings were given (i.e., either during conditions of unblinded Ritalin = RRX; blinded Ritalin = RX; Placebo =PL; or No Pill = NP).

The lack of variation in scores often led to low correlations between teacher and parent ratings (see Table 29). However since approximately the same number of parents and teachers did not vary their scores, all ratings were included in Figure 32.

According to Figure 32, parent ratings indicated children were 7% less hyperactive under the blinded Ritalin condition than placebo, 14% less hyperactive under blinded Ritalin than no pill and 7% less hyperactive under placebo than no pill.



Binary scores (i.e., "high"= Hyperactivity) were used as cut-off points based on each subject's norm-related "high" scores. Each probe condition ratings were totaled by probe condition and then divided by how many ratings were in the "high" versus "low" category (only high scores were included in the graph since low scores were simply the inverse of high scores). Number of data points for each probe condition are listed in Tables 27 and 28.

Figure 32. All Parent & Teacher Ratings on the Conners Rating Scale by High (Hyperactive) Cut-Off Scores & Probe Conditions.

However, when examining teacher ratings, the opposite can be seen. That is, teachers rated children 17% more hyperactive under blinded Ritalin than placebo, and 6% more hyperactive under blinded Ritalin than no pill. Of the blinded conditions, the placebo probe was rated as less hyperactive (i.e., 11% less than no pill). Thus, parent and

teacher ratings did not appear to be equally sensitive to the probe conditions and different clinical decisions might be made depending on which person was completing the rating scale.

Table 29

Agreements & Correlations Between Parents & Teachers on the Conners Rating Scale by Subject Number

Subject Number	Agreement on Cut-Off Levels	Correlation on Raw Scores
Ss #3	3a vs. 3b = 72% 3a vs. 3c = 38% 3b vs. 3c = 43%	3a vs. 3b = .302 3a vs. 3c = -.646 3b vs. 3c = .250
Ss #4	75%	-.459
Ss #7	58%	.445
Ss #8	92%	.466
Ss #9	0%	-.252
Ss #10	70%	-.338

Binary (i.e., High = Hyperactivity and Low = "Normal") scores were use as "cut-off" points based on each subjects' norm-related "high" score. Parent high and low scores were then compared to teacher high and low scores and each weekly score was rated as either "agreement" or "disagreement." Correlations present the average relationship among the weekly raw scores for teachers with those of scores for parents.

In addition, parent and teacher scores agreed between 0% to 92% (agreement = both ratings were at the norm-related cut-off score for hyperactivity or both ratings were below this score for the same week; see Table 29). Furthermore, two teachers, who taught Ss#3 during the same weeks (they alternated dayes) agreed only 43% of the time. Symptom ratings from the two teachers for Ss#3 agreed with each other during

only one week in which data were obtained. Teacher 3b rated Ss#3 as hyperactive during only two weeks (i.e., week B-2 = RRX and week 6 = RX) whereas teacher 3c rated Ss#3 as hyperactive on the Conners during weeks 3 through 7, which consisted of one no pill week and two each of the placebo and Ritalin conditions. Although the parent and one teacher ratings agreed 72% of the time, the parent and teacher 3c agreed only 38%. Although this is only one case example with a small "n," it calls into question the utility and reliability of this measure across observers and should be more closely examined in future studies.

A critical finding relating to the importance of the double-blind is illustrated in the difference between the unblinded Ritalin conditions and the probes. Both parents and teachers rated the children less hyperactive during the unblinded Ritalin condition than during any of the other probes (i.e., 36% and 21% difference respectively). Thus, on this measure, there was some lack of agreement between parents and teachers as well as between teachers, negative correlations between some ratings, and a definite improvement in ratings when parents and teachers were not blinded to treatment conditions.

It was interesting to explore whether parent and teacher ratings were lower on second administration of the Conners since Milich et al. (1980) noted that statistical regression could explain improvements in the performance of children as usually assessed by the Conners scales. Seven raters (i.e., three parents and four teachers) rated the subjects' behavior more severe (i.e., they gave them a higher hyperactive score) during the first rating, four raters (three parents and one teacher) rated the subject higher on second administration, and two teacher ratings did not change from first to second administration of the Conners. Thus, it appeared that no strong trends could be determined in either direction.

ADD Evaluation Scale

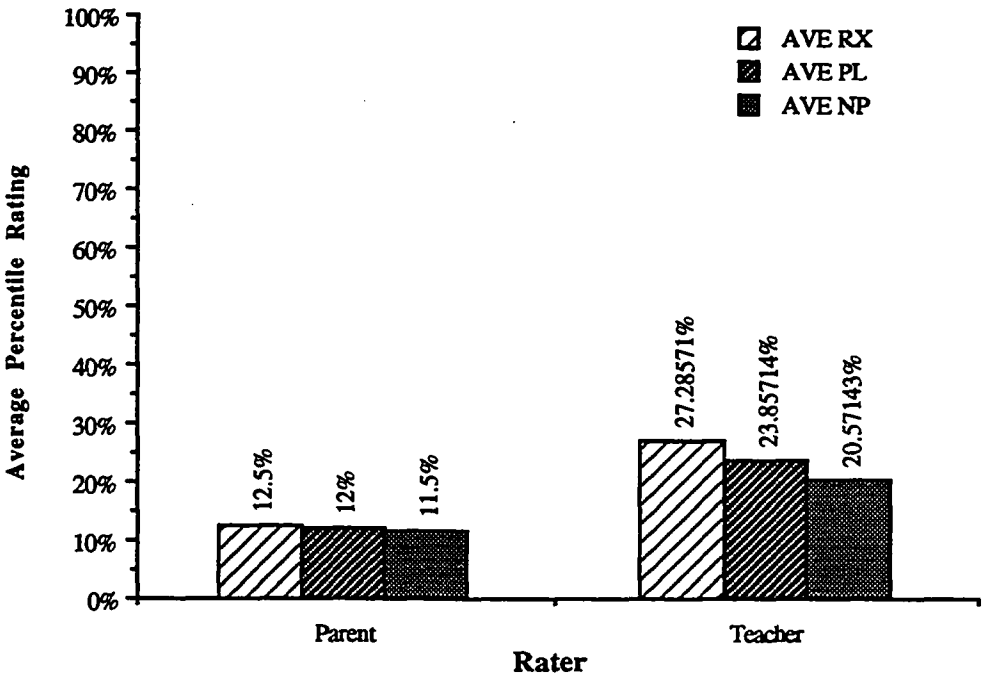
Ratings by parents and teachers on this measure showed no clear individual differences between protocol conditions. Individually, parent and teacher ratings of the subjects did not covary with the protocol condition in effect. When variations in scores were present, they were evenly distributed across all probe conditions (i.e., no pill, placebo and Ritalin). However, when ratings were grouped (as in Figure 33), subjects were rated slightly better under the blinded Ritalin condition (Note: Children were not observed during the unblinded Ritalin conditions.)

As can be seen in Figure 33, teachers appeared to discriminate between conditions slightly better than parents and the greatest differences appeared between the Ritalin and no pill probe conditions. However, no teacher was individually able to differentially discriminate between conditions (see individual progress reports for more detailed results).

The overall agreement between parent and teacher scores on the ADD Evaluation form was slightly better than those achieved with the Conners (72%, Table 30). Nevertheless, agreements varied from 0% to 100%. Agreements were highest when parents and teachers were rating the children on the hyperactivity index (85% overall agreement versus 64% and 68% for inattention and impulsivity respectively). There was a generally poor correlation between parent and teacher weekly ratings (i.e., range = +.67 to -.57; see Table 31).

Accuracy of Child Reported Beliefs

Children were asked to fill out a weekly form in which they indicated whether or not they believed they had received the medication (see appendix). Children were asked on a weekly basis whether or not they benefited from the medication that week,



The ratings in this graph were determined by adding the sum of the subscale standard scores for all subjects for each protocol condition (i.e., RX= protocol (blinded) Ritalin; PL=placebo (no active medication administered); and NP=no pill (no tablet was administered) and converting them to percentile scores. The teachers appeared to discriminate between conditions slightly better than the parents and the greatest difference appeared between the Ritalin and no pill conditions. However, no teacher was individually able to differentially discriminate between conditions.

Figure 33. Average Percentile Scores from All Parent & Teacher Ratings on the ADD Evaluation Scale.

to assess whether or not they knew if they received medication, and also to assess the integrity of the design.

However, the children were not mature enough to understand that they may or may not be receiving active medication and most became confused when they were told to "guess" whether or not they were taking medication. For the most part, the children did not have an opinion one way or another and the parents were the ones filling out the

child forms. Therefore, this part of the protocol evaluation was dropped for all children.

Table 30

Percent Agreement Between Parent & Teacher Ratings on the ADD Evaluation Scale

	Inatten	%	Impuls	%	Hypera	%		
Ss#	#Agree ments	Agree ments	#Agree	Agree ments	#Agree	Agree ments	Total #	Tot Agree
3a v b	4/5	80%	2/5	40%	3/5	60%	9/15	60%
3a v c	6/6	100%	5/6	83%	4/6	67%	15/18	83%
3b v c	4/5	80%	1/5	20%	4/5	80%	9/15	60%
3a v b/c	10/11	90%	7/11	63%	7/11	63%	24/33	73%
4	0/12	0%	11/12	92%	12/12	100%	23/36	64%
7	7/11	63%	11/11	100%	11/11	100%	29/33	88%
8	9/12	75%	12/12	100%	11/12	92%	32/36	89%
9	14/14	100%	0/14	0%	11/14	78%	25/42	60%
10	4/9	44%	6/9	67%	7/9	77%	17/27	63%
Totals	44/69		47/69		59/69		150/207	
% Tot		64%		68%		85%		72%

Parent high and low scores (i.e., Low = behavior deviance (scores 6 and below) and High = "normal") were compared to teacher high and low scores and each weekly score was rated as either "agreement" or "disagreement." Percent total in last row included totals from 3a vs. 3b/c only.

Table 31

Correlations Between All Parent and Teacher Symptom Ratings on the ADD Evaluation Scale

Subject #	Inattention	Impulsivity	Hyperactivity
3a vs. 3b	-.233	-.571	-.480
3a vs. 3b	-.286	.207	-.321
3b vs. 3c	-.215	.469	.281
4a vs. 4b	.456	.316	.208
7a vs. 7b	.441	.560	.673
8a vs. 8b	-.090	.042	-.003
9a vs. 9b	-.449	.418	0
10a vs. 10b	-.460	-.050	-.236

Correlations present the average relationship among the weekly Sub Scale scores for teachers with those of scores for parents.

Accuracy of Parent and Teacher Reported Beliefs

In examining only the blinded protocol conditions, it was apparent that parents and teachers were unable to discriminate placebo from Ritalin weeks as indicated by their records of guessing whether or not each week was a medication trial (see Table 32). Parents often did not guess and when they did, they were poorer guessers than the teachers. Parents attempted guesses only 30% of the time (i.e., 14 out of 47 double-blinded protocol conditions) whereas teachers attempted guesses 58% of the time (i.e., 30 of 51 double-blinded protocol conditions; four more conditions were added because there were two teachers for Ss#3 yielding four protocol conditions for this subject). One parent and three teachers responded in one direction every time they

made a guess (i.e., the parent and teacher for Ss#8 responded placebo every time and the teachers for Ss#4 and 7 responded Ritalin every time).

Table 32

Accuracy of All Teacher & Parent Reported Beliefs

	Total Correct		Total "Don't Knows"		Total # Guesses		Total # of
Subject Number	Parent # Correct	Teacher # Correct	Parent # DK's	Teacher # DK's	Parent # Guesses	Teacher # Guesses	Protocol Condition
Ss#3	0	b: 0/ c: 1	4	b = 4 / c = 3	0	b = 0 / c = 1	b = 4 / c = 8
Ss#4	3	4	5	1	3	7	8
Ss#7	0	2	6	3	3	6	9
Ss#8	2	2	6	3	3	5	9
Ss#9	1	3	7	6	2	3	9
Ss#10	1	5	2	0	3	8	8
Totals	7	17	30	17 / 20	14	30	47 / 51
(% out of the actual # of protocol condits)	7/47 =15%	17/51 =33%	30/47 =64%	20/51 =39%	14/47 =30%	30/51 =58%	
(% out of the # of guesses made)	7/14 =50%	17/30 =36%					

Parents correctly guessed the double-blinded protocol conditions with 15% accuracy (7 out of 47 conditions) and guessed with 50% accuracy when considering the actual number of guesses attempted (7 out of 14). For these same conditions, teachers guessedwith 33% accuracy (17 out of 51 conditions; 4 more conditions were added since there was an extra teacher for Ss#3, allowing for 4 more guesses) and 36% accuracy respectively (17 out of 30). Parents did not offer a guess and indicated "don't know" when asked under which condition they believed their child to be in 64% of the time (30 out of 47 conditions) and teachers answered "don't know" 39% of the time (20 out of 51 conditions). Parents made a guess 30% of the time and teachers guessed 58% of the time. Note: three data sheets were missing from the parent of Ss#10 and one from the teacher of Ss#8.

The majority of parent responses to this question was "I don't know." Parents answered "don't know" 64% of the time (i.e., 30 out of 47 double-blinded protocol conditions) and teachers answered "don't know" 39% of the time (i.e., 20 out of 51 double-blinded protocol conditions). (Note: three data sheets were missing for the parent of Ss#10 and one was missing from the teacher for Ss#8.) When parents and teachers did guess, parents correctly guessed the protocol conditions 50% of the time (i.e., 7 out of 14 guesses actually attempted) while teachers guessed correctly 36% of the time (i.e., 17 out of 30 guesses actually attempted). However, these percentages dropped considerably when all double-blinded conditions were considered (i.e., there were 47 double-blinded protocol conditions for parents and 51 for teachers). Thus, using this data, parents correctly guessed 15% of the time (i.e., 7 out of 47 conditions) and teachers correctly guessed 33% of the time (i.e., 17 out of 51 conditions). All other times they either guessed inaccurately or said: "don't know." Only Ss#10's teacher guessed above chance levels (i.e., 63% accuracy) and she was also the only one to attempt a guess every week.

Interobserver Agreement for Classroom Observations

The overall reliability for the study appeared to be acceptable for treatment decision making purposes (i.e., between 81% to 88%) except for one overall reliability of 69% for Ss#3 (see Table 33). However, several reliability checks completed for Ss#3 were never turned in which, if they had been found, might have improved the reliability for Ss#3. With most subjects, reliability checks were conducted about half the time the subject was observed. More specifically, 56% of observations were made without a second observer and 44% of observations were made with a second observer. A total of 158.61 observation sheets were turned in (88.3 for observations

made without a reliability observer and 70.31 for observations made with two observers). Furthermore, observations were equally distributed during the first half of the study and the second half (i.e., 71.12 and 73.16 respectively).

Table 33

Inter-Observer Agreement Across All Subjects

Subject #	# Observer Sheets	#Agreement Checks	# Intervals	% that are Reliab checks	Overall Reliab
3	14.33	2	228/1893	12%	69%
4	21.9	9.4	1126/2650	42%	80%
7	34.6	18.6	2238/4158	54%	88%
8	21.68	10.28	1228/2596	47%	82%
9	38.72	14.92	1788/4644	39%	86%
10	27.38	15.28	2901/5541	52%	81%

This table summarizes observation data collected for each subject throughout the protocol. For each subject as listed in the far left corner, there is a listing of how many actual observation sheets were turned in by the observer, the total number of times these were observations made by two people (agreement checks), the number of intervals there were two observers over the total number of intervals for which data was collected and the corresponding percent reliability (i.e., the percent of observations which were reliability checks) and the overall reliability for the whole study.

Classroom Behavior Observations

When averaging percent on-task for all children, target children were on-task 71% of the intervals observed during the blinded Ritalin probes; 64% during placebo probes and 59% during the no pill probe condtions. Furthermore, the differences between the target and comparison children were less during the double-blinded Ritalin probe (13% difference between the target and comparison child's on-task behavior) than during the placebo (19%) or no pill (23%).

When looking at individual subject data as they compare between each subject (Figure 34), all subjects showed measurable improvements in on-task behaviors when they took Ritalin versus the placebo or no pill probe conditions. However, the amount of on-task behavior observed in the Ritalin probes varied from subject to subject (i.e., from a minimum of 3% improvement over placebo to a maximum of 12%, with a mean improvement of 6.2%; see Table 34). For every subject, the discrepancy between the on-task behavior levels of the protocol and comparison child were reduced when the target child was in the Ritalin versus a placebo or no pill probe condition (i.e., from a minimum of 1% reduction in on-task behavior while taking Ritalin versus placebo to a maximum of 12%, with a mean of 6.17%; see Table 35). It is unclear whether these small differences would be clinically significant in the classroom.

Table 34

Average Percent Target Children were On-Task
by Probe Conditions

Ss#	Rx vs. PL	Rx vs. NP	PL vs. NP
3	3%	3%	0%
4	6%	6%	12%
7	6%	7%	13%
8	12%	10%	2%
9	3%	5%	8%
10	7%	6%	1%
Mean % On-Task	6.2%	6.2%	6%

Compared average percent differences in on-task behavior for each target child across probe conditions.

In examining individual data, it can be seen that the average on-task

performance of the target children, regardless of protocol condition, ranged between 54% to 75% throughout the evaluation and the average performance for the comparison children ranged between 80% to 85% on-task. The target children were on-task between 1% to 56% *less* than the comparison children during any given week. Although there were times that a target child was on-task as much or more than their respective comparison child, these times did not appear to correspond with any particular protocol condition (e.g., Ss#3's best week was during a pre-protocol Ritalin observation; Ss#4's was during a no pill week; Ss#7's occurred twice, once during a placebo week and once during a Ritalin week; Ss#8's was during a no pill week; Ss#9's was during a Ritalin and placebo week; and Ss#10's occurred once each during no pill, placebo, and Ritalin weeks).

Table 35

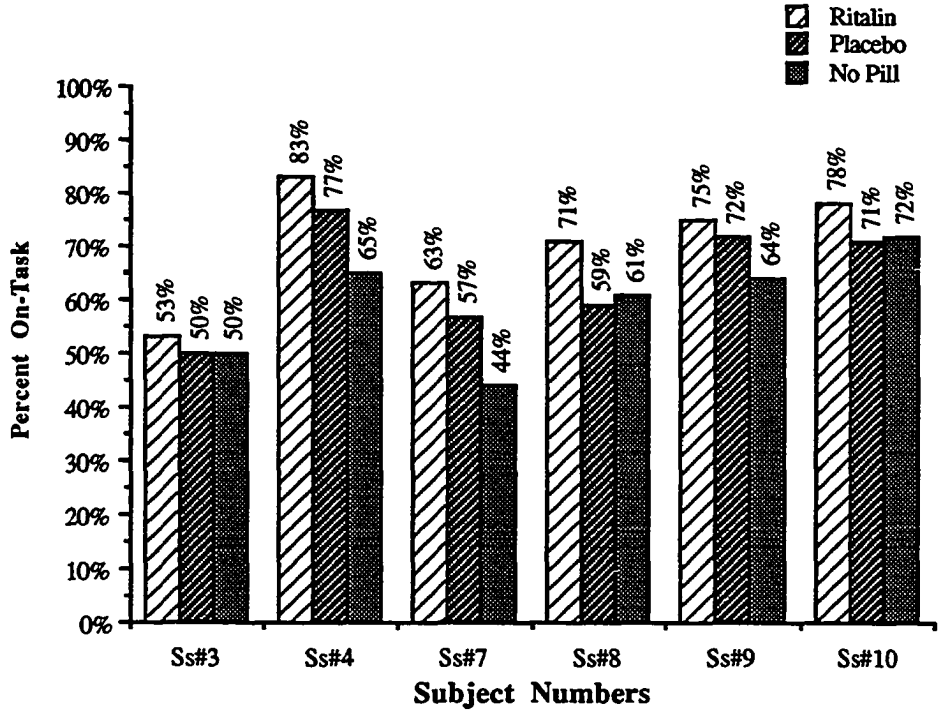
Average Percent Difference Between Target & Comparison Children by Probe Conditions

Ss#	Rx vs. PL	Rx vs. NP	PL vs. NP
3	5%	15%	10%
4	1%	1%	0%
7	1%	23%	22%
8	12%	9%	3%
9	8%	7%	1%
10	10%	10%	2%
Mean Difference	6.17%	10.83%	6.33%

Compared average differences between comparison and target children with equal number of probe conditions between probes but within subjects.

The comparison child was identified by the classroom teacher as being an

average student, matching the target child in age and gender but not in behavior. That is, the comparison child's performance was considered to be generally non-problematic by the teacher and the closer the target child's on-task performance matched the comparison child's, the better the target child's on-task performance was considered to be. Thus, even if the target child's on-task behavior was not high, if it closely matched the comparison child's behavior it was considered to be non-problematic within the context of that classroom and with that teacher.

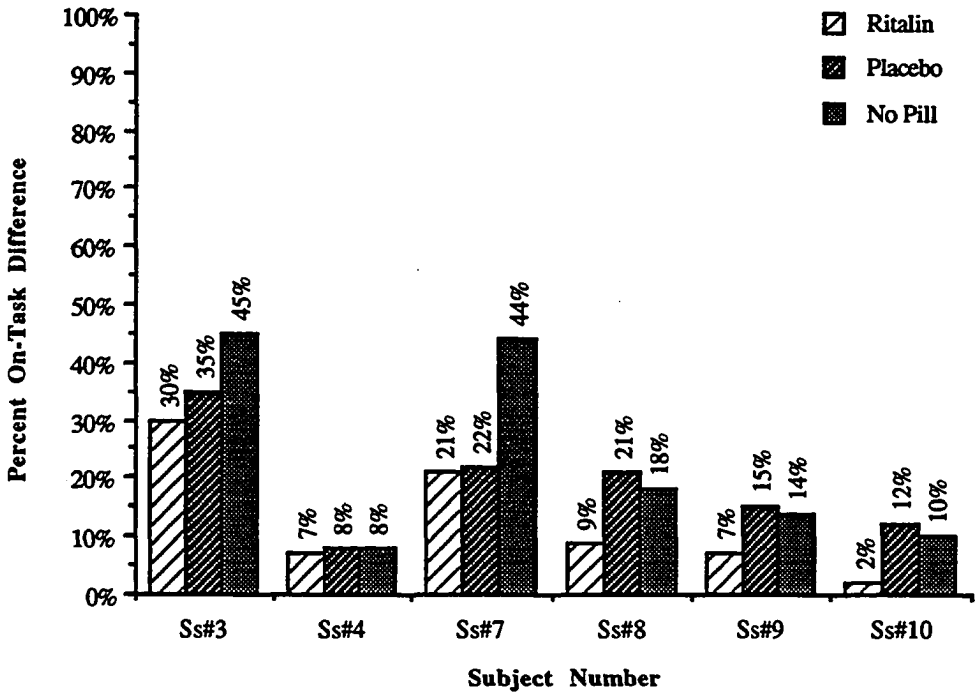


Classroom observations of each of the target children's on-task performance under the three protocol conditions.

Figure 34. Percent Target Children were On-Task During Each Protocol Condition.

Figure 35 displays the average differences between the target and comparison

child's on-task performance under the three protocol conditions. The group data indicated less difference between the protocol and comparison children's



The average differences between the on-task performance of the target and comparison child while under three protocol conditions. Numbers were obtained by averaging the percent on-task and subtracting this from the average on-task performance of the comparison child for each subject.

Figure 35. Average Differences Between Target & Comparison Children's On-Task Performance Under Each Protocol Condition.

on-task performance when in the Ritalin versus placebo or no-pill probe conditions. Individually, however, the differences varied dramatically.

Ss#10's on-task observations under (blinded) Ritalin conditions appeared to differ least in relation to the comparison child's on-task performance (i.e., there was an average 2% difference between the target and comparison child's on-task performance under the Ritalin conditions). On the other hand, the greatest differences between target

and comparison child's on-task performances was seen in Ss#3's and Ss#7's on-task performance within the no pill condition (i.e., 45% and 44% respectively).

In general, it appeared that Ss#3's on-task behavior was worse than the comparison child's, almost regardless of the treatment condition; whereas Ss#4's on-task performance was almost as good as the comparison child's, regardless of protocol condition. Ss#7's on-task behavior appeared similar whether taking Ritalin or a placebo but was vastly different taking no pill. There appeared to be less of a difference between target and comparison children's on-task behavior while Ss# 8, 9, and 10 were in the Ritalin probe when compared to their on-task behavior when in both the no pill and placebo conditions. These data proved helpful when making decisions about whether or not the target child should continue taking Ritalin (please refer to individual progress reports sections for more detailed information about the actual decisions made).

Zung Depression Scale

All teachers rated themselves with normal mood except for teachers 3c and 4b who each rated themselves during one week with minimal to mildly depressed mood (i.e., below 50=normal affect). The teachers of Ss#8, 9, and 10 did not fill out the questionnaires because they thought the questions were too personal. Only the parent for Ss#4 rated herself within normal mood ranges throughout the entire protocol evaluation. Parents of Ss#7, 8, and 9 rated their mood as depressed throughout the whole evaluation. The parents for Ss#3 and 10 rated their mood in the depressed range half the time and within the normal mood range the other half. These mood rating changes did not covary with the probe conditions. The parent for Ss#3 rated her mood in the minimal to mildly depressed range while Ss#3 was taking pre-protocol Ritalin (week B-1), placebo (week 5), and twice during the protocol Ritalin (weeks 6 and 7).

The parent for Ss#10 rated her mood in the minimal to mildly depressed range during a pre-protocol Ritalin week (i.e., week 1-B), two no pill weeks (3-B and 9-B), and two Ritalin weeks (8 and 12).

Marital Happiness & Teacher Satisfaction Scale

Parents for Ss# 4, 7, and 10 rated themselves happy with their role as a parent. However, the parents for Ss# 3, 8, and 9 rated themselves in the moderate to low satisfaction range every time. All teachers except 9b rated themselves satisfied with their role as a teacher. The teacher for Ss#9 rated herself as moderately satisfied. Two teachers, 8b and 10b, did not complete the forms because they believed the questions to be too personal. There were just as many significant ratings on the Conners and ADD Scales when parents rated themselves unhappy as they did when they rated themselves happy.

CHAPTER X

DISCUSSION AND CONCLUSIONS

Discussion

As noted in the beginning of the Results section, six students were referred but unable to participate in this study because the teachers, principals, or school board did not want to be over-burdened with the forms and observations, despite parental persistence to include their child in the evaluation protocol. Furthermore, it was difficult to recruit and maintain the six subjects who participated in this clinical trials series, as illustrated by Ss#3's withdrawal after only six weeks in the protocol (at the teachers' request).

It seemed ironic that so many teachers were more willing to accept that their students were taking psychostimulant medication than they were for that same child to be evaluated for the drug's actual therapeutic effect on the child's behavior. Because Ritalin and other psychostimulants are so widely used, especially in Kalamazoo, it may be seen as a harmless drug. Having a child who takes a psychostimulant in the classroom may appear to be completely ordinary. Because most children don't suffer from serious side-effects, children and adults may have become desensitized to psychostimulant use. Psychostimulants then appear to be as harmless as vitamins or aspirin rather than seen as a potentially dangerous psychotropic medication.

In fact Methylphenidate (Ritalin) is classed along with other amphetamines as a Schedule II drug according to the federal Comprehensive Drug Abuse Prevention and Control Act. The Act lists drugs according to their "abuse potential" and medical use. Drugs listed range from Schedule I (i.e., "high potential for abuse" and "no currently

accepted medical use"; e.g., heroin, LSD) to Schedule V (i.e., "minimum abuse potential" and minimal controls on its use; e.g., antiussives, antidiarrheals). The controls for Schedule II drugs include: prescribed amounts for no more than one month; no refills without face to face examination by a physician (i.e., prescriptions cannot be called in by phone); prescriptions must be made in triplicate (a copy must be kept in the physician's files and one sent to Washington and the other to the state capital of the state in which they were written); prescriptions must be filled within three days of issue; and the drugs must be stored in the pharmacist's vault (Goode, 1989; pp. 35-37). It seems unlikely that the federal government would use such stringent precautions with a drug as "harmless as aspirin."

A drug requiring such precautions for prescription should also require similar precautions in subsequent evaluation of efficacy for each individual child for which it is prescribed. Teachers, principals, school boards, and parents should require thorough and objective drug evaluations for continued psychostimulant use for each child. This dissertation attempted to formulate such a protocol but could have been more successful with greater cooperation by more professionals. Another group of experimenters did have greater cooperation and their conclusions were similar to those of the present study.

Gadow (1993) described a protocol similar to this one. His program, entitled, "A School-Based Medication Evaluation Program" (SBME), is described as a structured method to evaluate stimulant drug responsiveness in school settings. The SBME lasted 6 weeks and incorporated both placebo-controlled and double-blind conditions. It was developed within the Child Psychiatry Outpatient Service at the State University of New York at Stony Brook. The SBME was reportedly a pioneering approach to the evaluation of stimulant medication therapeutic effects with ADHD syndrome children because it incorporated both symptom rating scales completed by

parents and teachers as well as direct observations of the child's behavior in the classroom.

Gadow emphasized that,

> ...with such a variety of drug response measures and assessment models to choose from (both community- and hospital-based), there is no defensible reason to explain why some type of scientifically valid medication evaluation procedure cannot be established for all clinical settings in which stimulant drugs are routinely prescribed for hyperactivity. The challenge for the next decade is to formulate a less ambiguous rationale for treatment and to 'fine tune' clinical management (p. 209).

Although such a protocol as the one described in the present report and by Gadow require people, money, and cooperation from a relatively large number of people, it is possible. As Gadow (1993) insists, "There does not seem to be any reason why licensed health care providers (e.g., psychologists, social workers, psychiatric nurses) or their supervisees could not conduct direct observations in collaboration with a community-based physician. The expenses incurred for such evaluations can be billed as part of the diagnostic workup (baseline) and treatment plan" (p. 207). Gadow speculated that parents would be more than willing to pay out-of-pocket if insurance reimbursement were not available.

Gadow acknowledged several limitations of the SBME which were also present in the current investigation: (a) it is expensive; (b) time-consuming; (c) requires the collaboration of a relatively large number of professionals; (d) it requires considerable amount of clinical judgment in certain cases; (e) it assesses drug effects on a relatively small number of clinically significant target behaviors; (f) behavior rating scales are only of secondary importance to the decisions made in the SBME; (g) it requires further investigation to determine its clinical and societal validity; and (h) it should be expanded to incorporate the diagnostic and follow-up phases of drug therapy (p. 208-209). However, the SBME and the present study were presented as alternative protocols to be further tested and validated.

The value of this protocol and the one designed by Gadow is that the emphasis is on making treatment decisions based on the child's observed behavioral reaction to the medication rather than to the parent and teacher verbal reports about how they think Ritalin may or may not be helping the child.

It appears crucial to include evaluations of school performance because that is typically the setting in which most of the child's inappropriate behaviors are problematic and can be most closely observed. As Gadow (1993) pointed out, it is indeed ironic that,

> The school, which has traditionally been conceptualized as the most clinically troublesome setting for hyperactive children, is only occasionally considered a potential source of answers to many of the hotly debated issues concerning the diagnosis and treatment of this disorder (p. 210).

Some additional critical features which would be important to include in future protocol evaluations are: (a) behavior observations during different times of the day and while children are involved in different activities (e.g., in the classroom, lunchtime, recess); (b) behavioral observations of a comparison child; (c) double- (or triple-) blind procedure; (d) the integrity of the double-blind should be checked whether the protocol is used in research or practice; (e) parents and teachers should be required to answer either "yes" or "no" to the question of whether or not they believed their child/student was taking Ritalin or placebo; (f) children should be assessed during their regular medication regimen (i.e., unblinded Ritalin trial); (g) the psychiatrist/M.D. involved should vary the medication dose according to standard medical practice; (h) regardless of protocol outcomes, behavioral interventions should be considered in addition to, or as alternatives to, medication treatment; (i) when skills improve with behavioral intervention, another medicaiton evaluation should be conducted to compare behavior improvements against no-drug and drug conditions in order to increase confidence in the continued use of Ritalin medication.

Current clinical decisions regarding the use or non-use of Ritalin as well as the procedures used to vary the dose of medication, are not based on standardized norms with objective criteria for evaluating the therapeutic effectiveness of Ritalin. Because this study involved a small number of subjects, no standardized, objective criteria can be promoted. However, some suggestions for future study can be made.

Because this study found an overall improvement of less than 10% for blinded Ritalin over placebo probes, the question then becomes: "At what point is medication treatment clinically significant?" If the protocol indicates less than 10% improvement of Ritalin over placebo probes (either as indicated by behavioral observations in the classroom or by symptomatic rating forms) is it worth continuing medication treatment (i.e., in light of the continued cost of medication, doctor visits, physiological and psychological side-effects) versus alternative treatments such as behavioral interventions?

The ultimate decision made regarding the above question may have to balance ethical against business concerns. That is, as a business, the focus is on the parent/teacher and their concerns as a consumer/customer. However, professional ethics dictate focusing on the best interests of the patient (in this case the child). If the parent and teacher rating scales agree or are consistent with each other, there may be no ethical delemma. However, if there are inconsistencies either between the parent and teacher symptomatic ratings and/or between these ratings and in-class observations, it may indicate that the forms and observations are measuring the "wrong" behaviors (i.e., teachers or parents may be more upset about the intensity, frequency, duration, or absence of certain behaviors which are not quantified in the observations or forms used to assess the child). Another explanation may be that the problem is not be with the child but instead with the family or teacher belief system. It is up to the clinician to examine the situation further and determine the "real" problem.

The ethical delemma results when there are inconsistencies in data and parents and/or teachers are insistent on one particular type of treatment (e.g., either they want Ritalin or not) which may be different from what the clinician believes. If the parent or teacher are not satisfied (i.e., if the child is not given Ritalin when parents or teachers strongly believe the child should have it), they may then be "forced" to "doctor shop" to get what they want (e.g., psychostimulant treatment). The professional may then be soon out of business (for not "satisfying the customer") as well as behaving in an unethical manner because the child did not receive the most effective treatment according to the clinician's professional opinion (i.e., because the child ultimately received psychostimulant medication from another professional). The resolution may be a compromise (which is distinguished from "caving in" in that the the child's needs are still being met). Psychostimulant treatment can be recommended or continued as long as behavioral interventions are simultaneously included in the treatment package. The ultimate goal would be to resolve the "psychological biases" with successful behavior management. Once the child's behavior is observed to be improving, the medication evaluation protocol can again be implemented to determine how well the child behaves under his/her regular (unblinded) and blinded psychostimulant treatment as well as during the placebo and no pill conditions.

The biases of parents and teachers may be overcome by providing other means of measuring improved behavior (i.e., instead of measuring just on- and off-task behavior). Thus, parents and teachers can be asked what they believe would indicate that the child's behavior was improved (e.g., completing homework, improved social interactions, decreased aggression towards others). An important distinction to make when parents and teachers talk about particular child behavior problems is between positive and negative symptoms/signs. Positive symptoms and signs are defined as the presence of a behavioral excess whereas negative symptoms and signs are behavioral

deficits. Very oftern what teachers and parents are reacting to are the positive signs or symptoms (e.g., aggression, hyperactivity, impulsiveness) rather than negative signs or symptoms of behavior (e.g., inattention, underachievement, lack of appropriate social skills). Furthermore, psychostimulant treatment generally impacts on the positive, but not negative, symptoms and signs of behavior. The ethical and professional delemma arises when positive symptoms are addressed and the parent or teacher then no longer are concerned about the child's behavior deficits and treatment is prematurely considered "successful." Thus, although the adult complaints are resolved, the child's therapeutic needs still aren't fully realized.

The clinician should therefore tread carefully and address the emotional as well as rational perspectives of the adults involved. The adult may not be amendable to rational comments until they trust and like the clinician. Once a therapeutic alliance is established, the adult might try the clinician's recommendations. This can be compared to treating an agoraphobic who only enters a feared situation because he or she trusts the statements of the clinician who assures the patient that he/she will survive and be O.K. If the patient did not trust the clinician, he or she would run away in fearful situations because their fears/emotions would be stronger than their rational belief in the clinician's judgment and expertise.

Conclusions

The answer to the question regarding Ritalin's effectiveness for a particular child varied depending on which measure was examined. The symptomatic rating scales indicated that parent and teachers did not always agree (or covary). Furthermore, agreement was low even between the two teachers of the same subject. There was higher and more consistent agreement between the in-class observation data

and probe conditions which indicated that subjects were 6.2% more on-task under the blinded Ritalin than placebo probes.

It appeared that parents and teachers did not break the double-blind due to their low accuracy on the belief forms (i.e., of the total probes, parents guessed with 15% and teachers guessed with 33% accuracy and only one teacher guessed with 63% accuracy). In addition, symptomatic ratings by parents and teachers did not vary much across probe conditions and in some cases, did not vary at all.

Expectancies/beliefs did appear to influence parent and teacher ratings because there was a 36% difference between parent ratings during the unblinded and blinded Ritalin conditions and a similar 21% difference for teachers on the Conners Rating Scale. Most parents and teachers responded "don't know" to the question regarding what probe condition they believed their child/student to be in. (Note: Because teachers and parents spent at least five hours a day with the children, they should have been able to form some type of opinion. Therefore, the next study should require that the rater always record an opinion and perhaps include a rating of how much they believe that opinion.) Child beliefs were excluded from examination because the parents were too heavily involved in the children's responses.

Further support for the impact of expectations/beliefs had on symptomatic ratings comes from ancedotal data. One parent (of Ss#8 and 9) who verbally requested an increased dose of Ritalin for her children consistently rated Ss#8 and 9 hyperactive even though Ss#9 was not noted by the psychiatrist, teacher, or even the parent herself at the start of the study, as exhibiting symptoms of hyperactivity. By contrast, the parent of Ss#10, who believed Ritalin caused her child to be more "whiney," rated her child's behavior consistently low (i.e., not meeting the "cut-off" criteria for hyperactivity). During the last week in the evaluation the parent actually stopped giving her child the capsules. The parent appeared to be misled about the probe conditions and

actually believed her child was taking Ritalin, when she was in fact receiving placebo. Thus, she developed the belief that it was Ritalin which caused her child to be "whiney" but this behavior actually occurred more often during placebo weeks.

Locus of Control as assessed with the Norwicki-Strickland scale did not indicate that the children became more externally focused during the medicaton treatment as previous reserach has suggested. Furthermore, the opposite appeared to be true. All of the children's post-protocol scores decreased (became more internal) and the scores from only two subjects were clinically significant. Scores from Ss#3 and 4 dropped 35% and 20% on post-protocol evaluation which were 12 and 4 points (respectively) less than their expected true scores. Ss#3 and 4 were the only two subject who had been taking Ritalin for longer than a year. It may have been that this protocol caused them to have less belief in the medication leading the children to attribute more internal causes for their behavior. However, it should be emphasized that children may give different reasons/causes for their behavior depending on how and when the questions are asked which should be evaluated in future studies.

Contrary to previous studies, the current protocol did not appear to be contaminated by mood or job/marital satisfaction. This may have occurred because the parents and teachers believed the information was too personal to answer candidly, the forms may not have been sensitive enough, or it may have been too much effort to answer carefully. In any case, the responses on the Zung Depression Scale, Marital Happiness and teacher satisfaction scales showed a restriction in range.

Pre-protocol attitudes about Ritalin (i.e., the Medication Attitude Survey) were not compared with parent and teacher ratings on the Conners and ADD Scales because the raters were unwilling to be influenced by what the experimenters told them as well as because the ratings on the Conners and ADD Scales did not covary with differing protocol conditions. Perhaps the reason for the lack of detection using these scales was

due to the fact that the patients' behaviors were not severe enough or that the medication prescribed was not at an effective dose.

However, the medication dose prescribed was determined by the physician based on clinical response and not by this protocol. The children's symptomatic behaviors were seen as severe enough by the parents and teachers to warrant an evaluation by the psychiatrist who then confirmed symptom severity, diagnosed ADD syndrome, and prescribed medication. The medication procedure followed was the typical one used clinically by the psychiatrist involved in this study. Furthermore, part of the lack of parent and teacher satisfaction with the current dose of medication for Ss# 8 and 9 may have related to the fact that they simply expected too much from these children (as noted by the lack of severe discrepancies between the target and comparison children). Thus, without conducting an objective evaluation of the child's performance in relation to a comparison child in the same classroom, this belief may have lead to erroneous prescriptions and treatments when less drastic measures could have been taken. Therefore, it appeared the psychiatrist was wise to not want to increase the dosage of medication until the results of the protocol were known.

In making the final recommendations for treatment, direct classroom observations (sign data) appeared to be the most helpful in determining the effectiveness of Ritalin over placebo or no pill for each individual child. Although the differences between protocol conditions were slight, the observations at least more consistently detected one condition over another. Furthermore, the inclusion of comparison children in the observations was helpful in determining changes in the subjects' behavior while maintaining a control for daily and task related variations in environmental demands.

In-class behavior observations, however, are not without problems. Observers can miss recording some behaviors, the child may be particularly good on the days the

observers come to the classroom (through luck or intention), and the child is observed for a very limited sample of time and behaviors. Thus, behavior observations may present the problem of looking at the "trees and missing the forest." The observers are limited in time and what they watch.

Furthermore, because the observation sheets did not have a relative scale, all off-task behaviors were rated equally disruptive (i.e., any behavior which was not on-task was automatically off-task, regardless of how disruptive or intolerable the behavior was). Thus, teachers and parents might have viewed more severe or serious off-task behaviors such as "howling" (i.e., a termination response in which the teachers or parents needed to stop what they were doing and immediately react to the behavior) less tolerable than an off-task behavior such as daydreaming (i.e., a passive off-task behavior). Although this protocol evaluation attempted to address this issue by dividing off-task behaviors into passive, motor, verbal, and termination off-task behaviors, the reliability obtained were not of high enough quality to make the data useful to discriminate less severe from more severe off-task behavior (i.e., because the observers weren't trained well enough, the protocol wasn't sensitive enough, and/or the categories were not defined well enough). Future studies might focus on refining the behavior observation procedures to allow for a closer examination of off-task behaviors. For example, examining positive versus negative symptoms and signs (e.g., completion of homework, improved academic grades, decreased reports of aggression). It may be that what observers in this protocol were seeing was not what they should have been measuring.

As noted at the end of each individual progress report, the choice of Ritalin use or non-use is not the only option available to the children referred. It is important to emphasize that just because Ritalin may have been recommended for a particular child does not mean that minor re-structuring of the classroom (for example) wouldn't work

better or equally well. Medication may be an important component in the treatment plan for some children but environmental stimuli and behavior management of that environment may be equally important components. It can't be stressed enough that a thorough evaluation and observation of the child's behavior be conducted before, during, and after medication is prescribed or discontinued because what one believes he or she observes may not actually be occurring. Or it may not be occurring at the same frequency, intensity, or duration that one may think.

Recommendations for Future Studies

There are several recommendations for future studies. A summary of recommendations for future studies is as follows:

1. Teachers & Parents resisted being "fooled" once they were fully informed. To truly test expectations they needed to believe in what they were being told (precluding Human Review standards of fully informing participants).

2. Teachers and parents should be pushed to express a belief about which probe was in effect to determine how sensitive they were to behavior changes caused by probes (i.e., give them a forced choice response).

3. Include an evaluation of social interactions with peers (as modeled in Gadow's School-Based Medication Evaluation Program, 1993).

4. Track parent and teacher requests for increased doses and monitor child responsiveness as well as parent and teacher satisfaction. How useful are their comments to the psychiatrist for dose decisions?

5. Don't include depression or satisfaction/happiness scales since teachers see these forms as intrusive and no useful information was gathered from using these forms.

6. Collect parent and teacher data weekly. Ask them if they noticed anything different that week.

7. Record all anecdotal information. Interview parents and teachers on a weekly basis to get a clearer picture of what they are seeing. Parents and teachers may put more thought into talking to someone than they would in filling out a form they see every week.

8. Teachers may agree to participate and then engage in a variety of activities to stop the protocol. Several options are possible for teachers is to complain/inform to higher administration or the school board that "research" is being conducted in classrooms without prior approval. Or to complain to the local teacher's union that non-certified people are in their classrooms.

9. Therefore, teachers should always have an easy way out if they do not want to participate. Teachers may say "yes" to parents maintain good rapport but resist cooperating with the protocol.

10. There should be two fixed windows for enrolling children in the protocol. Start before October 1st and/or by January 15th so there are enough weeks left in the year to make up for weeks lost.

11. Check every week or more often to make sure children are taking their medication at school and parents are continuing to give in the morning.

12. Use the smallest capsule/tablet possible since some children do not like swallowing pills which may affect whether or not they go to the nurse to take their daily pill.

Recommendations for Working With Observers

In addition, after working with observers in the school classroom, several recommendations should also be noted for future research:

1. Set minimum criteria for advancing onto next stage of observing solo.

2. Offer special incentives for observing more than the minimum number of observations per week.

3. Make observers turn in observation sheets every day or every other day to decrease the possibility of losing a major portion of observation data.

4. Have undergraduate students help with data entry and keep weekly summaries of child progress in a locked file for the "experimenter's eyes only."

5. Keep an accurate count of how many in-class observations are occurring vs. reliability checks per week. Are the times of observation being varied?

6. Give clear objectives to observers (e.g., indicate how many observation sessions and reliability checks they need for an "A"; what happens to their grade if they lose data; what happens if they miss sessions they were scheduled to attend, especially if it is a reliability session; how many absences are they allowed per week, month, semester before their grade is affected; how many "excused" absences are allowed; how much advanced notice do they need to give another observer or the experimenter if they can't observe when scheduled)

Appendix A

Consent to Release Information

WESTERN MICHIGAN PSYCHOLOGY DEPARTMENT
CONSENT TO RELEASE INFORMATION
TO THE BEHAVIORAL PEDIATRICS LAB

I understand that the Behavioral Pediatrics Lab at WMU is evaluating the effects of expectations of parents, teachers and children when children are treated with ritalin and placebo tablets. Ann Thompson, a doctoral level student at WMU, and Dr. Galen Alessi, a professor and supervisor of the research project at WMU, would like to ask for your voluntary participation in a study to improve the current methods used to assess and treat children like yours who have been diagnosed with ADHD.

If you decide to participate, we would ask for a 12 week committment from you and your child. You would need to fill out weekly questionnaires, give us permission to talk to your child's teacher and allow us to conduct weekly 20 minute behavioral observations of your child during school hours. In return, your child's medication would be provided free of cost to you throughout the duration of this study and your child's psychiatrist/physician would be given more accurate information regarding your child's individual needs.

☐

Yes, I am interested in finding out more information about this study and I give _____ permission to contact Ann Thompson about my interest.

☐

No, I am not interested in finding out more information about this study and I do not give _____ permission to contact Ann Thompson about me or my child.

_____ _____
Signature of Parent/Guardian Date

_____ _____
Signature of Witness Date

_____
Name of child

_____ _____
Name of person to contact Phone number

_____ _____
Name of child's school teacher Phone number

_____
Name of school child attends

Appendix B

Informed Consent

WESTERN MICHIGAN PSYCHOLOGY DEPARTMENT
INFORMED CONSENT FOR PARTICIPATION IN A
RESEARCH STUDY

You and your child are invited to take part in a study. We are studying the impact of expectations of parents and teachers when children diagnosed with attention deficit-hyperactivity disorder are treated with medication or placebo tablets. Studies have shown that placebo tablets (sugar pills containing no active medication) can sometimes have beneficial effects without risking the potential side-effects seen with active medication. We would like to determine if your child is one who would respond better to placebo tablets than to Ritalin, a drug commonly prescribed to treat ADHD children.

We have asked a pharmacist to vary placebo (sugar pills) and Ritalin tablets so that even we do not know when your child will be receiving placebos and when he/she will receive Ritalin. The pharmacist will give us a list of the dates that will be correct sometimes but not at others. We will share this information with you but we will not always be right in what we tell you.

At the end of the study, the pharmacist will give us the list of dates which accurately reflect when your child was taking Ritalin. With the permission of, and consultation with, your physician, we will track how well your child does under these different conditions. We will evaluate your son or daughter's progress and at the end of the study will tell you under which conditions he/she performs best.

There are few risks involved in this study. Your child may be misled sometimes into thinking that he/she is receiving the medication when he/she is not, and you may be inconvenienced if your child responds well to a particular condition (no pill, placebo, or medication) and occasionally does not receive that condition. However, when the study is over, we will be better able to tell under which condition your child performs best. We will report to you the results of the assessments obtained and tell you which condition appeared to have the "best" effect on your child.

You will be asked to complete several questionnaires about yourself and your child. These questionnaires will help us assess a variety of areas which may influence your child's ADHD behavior. Questionnaires regarding your home life and your

current mood are included because these have been known to affect parents' responses to ADHD children. If you find any item on the questionnaires given to you to complete, too personal, you may chose not to answer it. These forms are included here for your review and so that we can answer any questions you may have about them.

We would like to observe how your child behaves during times he is not taking a pill as well as during times when he is taking a pill and compare the differences. This added information will allow us to evaluate your child's performance more accurately. Therefore, when we start the study, your child will not take any pills for two weeks. Then he/she will take pills for four weeks and at week 7 and 8 he/she will not take any pills. Weeks 7 and 8 will be "wash-out" weeks so we can observe how your child behaves when he/she is no longer taking pills. This also allows time for the medication to leave his/her system before another trial of medication is introduced and the psychiatrist or physician can determine if a new (higher or lower) dose of medication needs to be prescribed. We will ask you to continue to complete questionnaires during the times your child is not taking pills.

All information obtained in this study will be held in confidence. Names will be kept confidential on all of the questionnaires and recording forms. Only the researchers involved in this project will have access to this information.

By signing this Informed Consent you give us permission for the data found in this study to be used in scientific presentations and publications, provided that the data are presented in such a manner that it is impossible to identify the responses of any individual.

Your participation in this study is voluntary; your decision to participate or not in the current study will not in any way affect your relations with your physician, psychiatrist, or pediatrician, your child's school, or with Western Michigan University. We request that you talk this over with your child and receive his/her assent to participate.

It is recommended that you and your child participate in the entire project once you sign below. However, if at any time you wish to stop participating, you are free to do so. The study will last a total of 12 weeks.

Questions or complaints regarding this research project may be directed to Ann Thompson (doctoral student heading this project) 345-3966, Dr. Galen Alessi (supervisor of the project) 387-4470, or to the chair of the WMU Psychology Department, Dr. Richard Tsegaye-Spates 387-4484.

Your signature below indicates that you understand the above information and have decided to participate in this study. You will receive a copy of this form.

_____ _____

Signature of Parent/Guardian Date

_____ _____

Signature of Witness Date

_____

Witness' Printed Name

_____ _____

Physician's Name Physician's Phone #

Physician's Address: _____

_____

c: guardian
psychiatrist
pharmacist
researchers

Appendix C

Informed Assent

WESTERN MICHIGAN PSYCHOLOGY DEPARTMENT
INFORMED ASSENT FOR PARTICIPATION
IN A RESEARCH STUDY

I understand that I will be receiving a pill and I will not know whether the pill will contain medicine or no medicine. I also understand that I will have to fill out some forms at different times during this study.

I understand that to be in this study I will take my pills every day and I will fill out certain forms on a weekly basis.

I understand that if at any time I wish to stop participating in this study I can do so.

Participant's signature or printed name Date

Witness' signature that this form was read to, and understood by, the participant Date

c: Guardian
Psychiatrist
Pharmacist
Researchers

Appendix D

School Release Form

BEHAVIORAL PEDIATRICS CLINIC
WESTERN MICHIGAN UNIVERSITY

CONSENT FOR RELEASE OF CONFIDENTIAL INFORMATION

I authorize_____ at _____
(Name of Teacher and/or Principal) (Name of School)

to mail to Ann Thompson, a doctoral level student at Western Michigan University, a completed behavioral rating scales (Conners Teacher Questionnaire & the ADD Evaluation Scale) an Attitudes Survey, a weekly believability check sheet, the Happiness Scale, Zung Depression Scale and a disciplinary record of the student. I further authorize Ann Thompson and/or her research assistants to observe my child in class and to converse with my child's teacher regarding my child's in class behaviors.

From the records of of:_____
First Name of Student Middle Last

To: Ann Thompson, Doctoral Student at WMU for the purpose of data analysis to use in the ADHD research project evaluating expectancy effects.

This consent is effective from:_____to _____ after which time it will expire. month / day / year month / day / year

My signature means that I have read this form and/or have had it explained to me so that I understand what information will be released, to whom, and for what purpose. I realize that I am under no obligation to give this consent, and may withdraw my consent at any time prior to the above expiration date by notifying the above authorized individual or school.

_____
Parent/Guardian Signature Relationship to student Date

_____
Address Zip Code

_____
Witness' printed name Signature Date

c: Guardian
School Administrator
Researchers

Appendix E

Calendar of Weekly Probe Conditions

March 1992

Sun	Mon	Tue	Wed	Thu	Fri	Sat
1 Medication	2 *Pick up parent forms* Placebo	3 Placebo	4 Placebo	5 Placebo	6 *Pick up Teacher forms* Placebo	7 Placebo
8 Placebo	9 Medication *Pick up parent forms*	10 Medication	11 Medication	12 Medication	13 Medication *Pick up Teacher forms*	14 Medication
15 Medication	16 *Pick up parent forms* Placebo	17 Placebo	18 Placebo	19 Placebo	20 *Pick up Teacher forms* Placebo	21 Placebo
22 Placebo	23 No Pill *Pick up parent forms*	24 No Pill	25 No Pill	26 No Pill	27 No Pill *Pick up Teacher forms*	28 No Pill
29 No Pill	30 No Pill *Pick up parent forms*	31 No Pill				

Appendix F

Medication Attitude Survey for Parents, Teachers, & Children

Code #:_____ Date:_____

Interviewer:_____

ATTITUDE SURVEY FOR PARENTS

1) What were your initial thoughts when the physician/psychiatrist/ psychologist first told you that your child was diagnosed attention deficit disorder (with or without hyperactivity?)

2) What were your initial thoughts when s/he prescribed medication treatment for your child?

3) How have these initial thoughts change since then?

4) What caused you to change your thoughts?

5) What kinds of experiences have you had with medication treatments in the past?

6) Do you think that these previous experiences have influenced your current beliefs about medication treatment for your child?

7) Did you want your child to be on medication?

8) Do you still feel the same way now?

9) What do you know about Ritalin?

10) Is this different than what you knew when you were first told your child would be on Ritalin?

11) Do you know any other child or adult currently taking Ritalin or who took it in the past?

12) Do you believe that Ritalin improves your child's behavior?

13) By how much?

14) In what ways?

15) How can you tell that your child has shown improvement since he has been on medication?

16) What are the most distressing habits or behaviors your child exhibits? (What would you most like to see changed?)

Medication Attitude Survey (con't)

17) Describe how you see other children as compared to yours.

18) Do you think that medication is the only thing that will work for your child?

19) Do you think any other treatment might work (e.g., behavioral techniques, counseling, different teacher, firmer discipline, etc.)?

20) How do you think your child would perform if he did not receive his medication?

21) On a scale of 1 to 5 (1 being the highest level) how would you rate the level of your child's misbehavior when he is not taking medication?

22) ....His activity level?

23) How would you rate his behavior on a scale of 1 to 5 regarding his behavior while taking medication?

24) ...His activity level?

25) Do you have any additional comments about Ritalin, medication, or your student that you would like to share at this time?

Code #:_____ Date:_____

Interviewer:_____

MEDICATION ATTITUDE SURVEY FOR TEACHERS

1) What were your initial thoughts when the physician/psychiatrist/psychologist first told you that your student was diagnosed attention deficit disorder (with or without hyperactivity?)

2) What were your initial thoughts when s/he prescribed medication treatment for your student?

3) How have these initial thoughts change since then?

4) What caused you to change your thoughts?

5) What kinds of experiences have you had with medication treatments in the past?

6) Do you think that these previous experiences have influenced your current beliefs about medication treatment for your student?

7) Did you want your student to be on medication?

8) Do you still feel the same way now?

9) What do you know about Ritalin?

10) Is this different than what you knew when you were first told your student would be on Ritalin?

11) Do you know any other student or adult currently taking Ritalin or who took it in the past?

12) Do you believe that Ritalin improves your student's behavior?

13) By how much?

14) In what ways?

15) How can you tell that your student has shown improvement since he has been on medication?

16) What are the most distressing habits or behaviors your student exhibits? (What would you most like to see changed?)

Medication Attitude Survey (con't)

17) Describe how you see other children as compared to your student.

18) Do you think that medication is the only thing that will work for your student?

19) Do you think any other treatment might work (e.g., behavioral techniques, counseling, different teacher, firmer discipline, etc.)?

20) How do you think your student would perform if he did not receive his medication?

21) On a scale of 1 to 5 (1 being the highest level) how would you rate the level of your student's misbehavior when he is not taking medication?

22) ....His activity level?

23) How would you rate his behavior on a scale of 1 to 5 regarding his behavior while taking medication?

24) ...His activity level?

25) Do you have any additional comments about Ritalin, medication, or your student that you would like to share at this time?

Code #:_____ Date:_____

Interviewer:_____

MEDICATION ATTITUDE SURVEY FOR CHILDREN

1) Are you taking any medication or pills?

2) What is it called?

3) Do you know what it is for?

4) What were you told about what it can do for you?

5) Do you believe what others have told you about its effects?

6) Do you like taking the pill?

7) What do you or don't you like about taking the pill?

8) Who knows that you take the pill?

9) What have other children or adults said about your taking the pill?

10) Do you want to stop taking the pill?

11) How long do you think you will have to take it?

12) Does anyone else you know take the pill?

13) What has s/he said about the pill?

14) When you first started taking the pill, did you want to take it? Has this opinion changed since you started taking the pill?

15) What changed your mind about the pill?

16) Have you ever not taken the pill?

17) How did you react, what was your behavior like, how were you different or the same?

18) Have you ever taken any other medication?

19) What did you think about taking that medication?

Medication Attitude Survey (con't)

20) What kinds of experiences have you had with medication in the past?

21) Do you think that these previous experiences have influenced your current beliefs about medication treatment?

22) What do you know about Ritalin? How does it work? How does it help you? How does it not help you?

22) Do you believe that Ritalin improves your behavior?

23) By how much?

24) In what ways?

25) How can you tell that you have shown improvement since you have been on medication?

26) What are some of the behaviors that you would like to change about yourself? Why?

27) Are these behaviors that others would like to see changed or that you would like to see changed?

28) Describe how you see other children as compared to yourself.

29) Do you think that the pill is the only thing that will work for you?

30) Do you think any other treatment might work (e.g., behavioral techniques, counseling, different teacher, different classroom, different discipline, etc.)?

31) On a scale of 1 to 5 (1 being the highest level) how would you rate the level of your misbehavior when you are not taking medication?

32) ....Your activity level?

33) How would you rate your behavior on a scale of 1 to 5 while taking medication?

34) ...Your activity level?

35) Do you have any additional comments about Ritalin, medication, or your parents or teacher that you would like to share at this time?

Appendix G

Forms to Assess Parent, Teacher, & Child Beliefs Regarding Protocol Conditions

WESTERN MICHIGAN PSYCHOLOGY DEPARTMENT
BEHAVIORAL PEDIATRICS LAB
PARENT BELIEF FORM

Parent Code#: _____ Date: _____Child Code #: _____

1. Please check whichever one of the following sentences that you believe to be true:

_____a. My son received active medication this week.

_____b. My son did not receive any active medication this week.

_____c. I do not know whether or not my son received active medication or not this week.

_____d. Other (please specify)_____

2. What makes you feel this way?_____

_____

3. Please indicate which day(s) this week were your son's best day(s) in terms of his behavior at home

_____

4. Why do you think these day(s) were best?

_____

5. Which day(s) did your son behave the worst?

_____

6. Why do you think these day(s) were worse?

_____

WESTERN MICHIGAN PSYCHOLOGY DEPARTMENT
BEHAVIORAL PEDIATRICS LAB
TEACHER BELIEF FORM

Teacher Code #: _____ Date: _____

Child Code #: _____

1. Please check whichever one of the following sentences that you believe to be true:

_____a. This student received active medication this week.

_____b. This student did not receive any active medication this week.

_____c. I do not know whether or not this student received active medication or not this week.

_____d. Other (please specify)_____

_____

2. Please indicate which day(s) this week your student was on his best behavior

_____

3. Why do you think these day(s) were better?

_____

4. Which day(s) did your student behave the worst?

_____

5. Why do you think these day(s) were worse?

_____

WESTERN MICHIGAN PSYCHOLOGY DEPARTMENT
BEHAVIORAL PEDIATRICS LAB
CHILD BELIEF FORM

Child Code#: _____ Date: _____

Parent Code #: _____

1. Please check whichever one of the following sentences that you believe to be true:

   _____a. I received active medication this week.

   _____b. I did not receive any active medication this week.

   _____c. I do not know whether or not I received active medication or not this week.

   _____d. Other (please specify)_____

2. Please check whichever one of the following sentences that you believe to be true:

   _____a. I believe the pill I took this week helped me.

   _____b. I do not believe that the pill I took this week helped me.

   _____c. Other (please specify)

_____

3. Which day(s) this week do you think you behaved the best?

_____

4. Why do you think you behaved best on these day(s)?

_____

5. Which day(s) do you think you behaved the worst?

_____

6. Why do you think you behaved worse on these day(s)?

_____

Appendix H

Weekly Form Used to Assess Teacher Happiness

Code #_____ Date_____

Teaching Happiness Scale

	Completely Unhappy									Completely Happy
Teaching Responsibilities	1	2	3	4	5	6	7	8	9	10
Interactions with children	1	2	3	4	5	6	7	8	9	10
Peer Support	1	2	3	4	5	6	7	8	9	10
School Supplies	1	2	3	4	5	6	7	8	9	10
School Communications	1	2	3	4	5	6	7	8	9	10
Academic progress of pupils	1	2	3	4	5	6	7	8	9	10
Support from Parents	1	2	3	4	5	6	7	8	9	10
Administrative Support	1	2	3	4	5	6	7	8	9	10
Personal Growth & Development	1	2	3	4	5	6	7	8	9	10
Time allowed for breaks, planning,grading, etc.	1	2	3	4	5	6	7	8	9	10
General Happiness in teaching	1	2	3	4	5	6	7	8	9	10

Appendix I

Confidentiality Statement

WESTERN MICHIGAN PSYCHOLOGY DEPARTMENT
BEHAVIORAL PEDIATRICS LAB

CONFIDENTIALITY STATEMENT

I, _____ understand my ethical responsibility to keep confidential all identifying information about the subjects participating in this research study. I therefore agree to not discuss any identifying information about any subject involved in this research study outside of the research group meetings.

_____ _____

Signature Date

Appendix J

Direct Observation Form

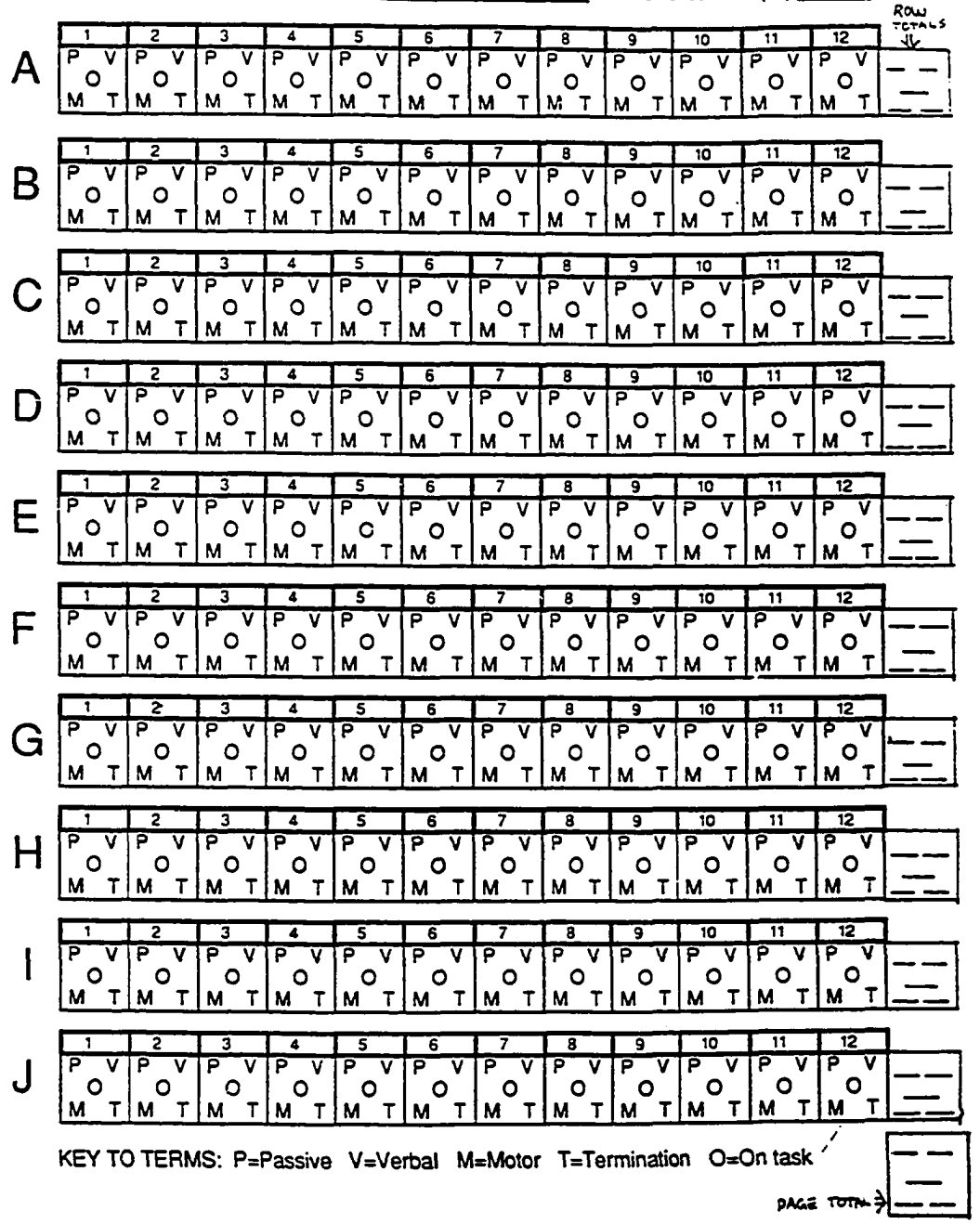
Sheet _____ of ____

Study Project: _____ Manager: _____

Subject Number: _____ Observer : _____ (Check one) Primary _____ Reliability____

Date: _____ Start Time: _____ End Time:_____ Total Time: _____

Condition: _____ Interval :_____ Interval Size: 10" (or) _____



Appendix K

Human Subjects Institutional Review Board Approval Letter

Human Subjects Institutional Review Board

Kalamazoo, Michigan 49008-3899

WESTERN MICHIGAN UNIVERSITY

Date: November 20, 1991

To: Ann Thompson

From: Mary Anne Bunda, Chair

Re: HSIRB Project Number: 91-10-21

This letter will serve as confirmation that your research protocol, "The impact of expectancies when withdrawing methylphenidate from children diagnosed with adhd" has been approved under the exempt* category of review by the HSIRB. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the approval application.

You must seek reapproval for any changes in this design. You must also seek reapproval if the project extends beyond the termination date.

The Board wishes you success in the pursuit of your research goals.

xc: Alessi, Psychology

Approval Termination: November 20, 1992

*Although this project is categorized as a "full review" protocol, the application was reviewed under the exempt category due to prior full board approval of the original protocol submitted by Dr. Alessi.

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