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Efficacy of a Methylphenidate Transdermal System Versus t.i.d. Methylphenidate in a Laboratory Setting

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Abstract

Objective: To test the efficacy and tolerability of the methylphenidate transdermal formulation (MTS) against immediate-release methylphenidate (IR MPH) and placebo in a 12-hr analog classroom setting. **Method:** A total of nine boys ages 6 to 9 years, medicated with MPH for ADHD, complete a within-subject, double-blind study. For the purpose of the study, the boys are administered a dose of 20 cm^2 MTS, a matched dose of IR MPH 10 mg TID, and placebo. ADHD symptoms and frequency counts of classroom rule violations and the number of math problems completed are assessed hourly, during three consecutive analog classroom sessions. **Results:** Findings show that, across measures and throughout the day, both treatments significantly differentiated from placebo ($p < .05$) but not from each other. It is also observed that the MTS produced more consistent results across the day but had a delayed onset versus IR MPH. Both medications are well tolerated with only mild reductions in sleep onset. **Conclusion:** The MTS demonstrates comparable efficacy and tolerability to TID IR MPH.

Keywords

ADHD, Methylphenidate, transdermal

The CNS stimulants, in particular immediate-release methylphenidate (IR MPH), have extensive data supporting their efficacy for the treatment of ADHD. However, due to its narrow window of effect, maximum effectiveness is typically not achieved across the entire school day even with repeated dosing of IR MPH (Pliszka, 2007). Efficacy is further reduced by poor adherence to multiple times per day dosing (Gau et al., 2006; Pliszka, 2007). Because ADHD produces impairment outside of school, there has been a growing trend to medicate after school (Pliszka, 2007), necessitating an additional dose of IR MPH. These factors have given rise to the development of longer-acting extended-release (ER) formulations.

Noven Pharmaceuticals and Shire Pharmaceuticals developed a transdermal delivery system containing MPH in a multipolymeric adhesive platform, as a means of providing more sustained levels of MPH that has been approved for the treatment of pediatric ADHD (Pierce, Dixon, Wigal, & McGough, 2008). Other studies have documented the efficacy and tolerability of the methylphenidate transdermal system (MTS; McGough et al., 2006; Pelham, Burrows-MacLean et al., 2005, Pelham, Manos et al., 2005). However, similar to most trials of ER stimulants, they did not employ an active comparator. Only one published trial has evaluated the MTS against other ADHD medications. Findling and colleagues (2008) completed a 7-week between-group trial of MTS versus OROS MPH. However, efficacy was assessed weekly with

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Table 1. Demographic Characteristics

				Teacher DBD scores					
ID #	Age	IQ score	Race	IN	H/I	ODD	CD	ODD CD	Prior MPH dose (in mg)
101[a]	9.5	104	B	1.33	1.11	1.13	0.75	Yes	20
102	9.3	99	W	2.67	2.67	1.63	0.63	Yes	60
103	7.9	83	W	2.33	1.33	0.13	0.00	Yes	20
104	8.10	89	W	1.78	1.56	0.50	0.08	No	20
105	7.3	109	O	2.33	2.75	1.86	2.20	Yes	20
106	9.7	93	N	1.88	1.89	0.20	0.00	No	15
108	8.8	84	W	2.78	2.67	1.50	0.17	Yes	25
109	8.10	101	W	2.78	2.22	1.25	0.00	Yes	20
110	6.4	107	B	2.89	2.67	2.00	1.43	Yes	30
112	8.10	84	O	1.67	0.67	0.38	0.00	Yes	10
Average	8.6	95.3	—	2.2	2.0	1.1	0.5	—	24
SD	1.1	9.9	—	0.6	0.8	0.7	0.8	—	13.7

Note: W = White; B = Black; N = Native American; O = Other (two participants were of mixed race); DBD = Disruptive Behavior Disorders Rating Scale; IN = inattention; H/I = hyperactivity/impulsivity; ODD = oppositional-defiant disorder; CD = conduct disorder. Under the Column, "Age," numbers after the decimal point indicate months.
a. Not included in analyses

parents rating behavior only on weekends, when activities vary widely and do not reliably include any academic tasks. Teacher ratings covered the period between 10 a.m. and 2 p.m., limiting the ability to assess efficacy at the beginning and end of the day, which is relevant as a delayed therapeutic onset of the MTS has been reported (Pelham, Manos et al., 2005).

This first clinical trial of the MTS compared the efficacy of 20 cm^2 MTS applied for 24 hr to a standard TID regimen of 10-mg IR MPH in a double-blind, placebo-controlled study in children with ADHD. Assessments were gathered from parents and teachers in a laboratory classroom spanning a 24-hr period that included efficacy ratings throughout 12 hrs. In addition to traditional symptom measures, we employed objective frequency counts of classroom behaviors and productivity as well as direct observation of sleep onset to better detect differences in efficacy and tolerability across treatments.

Method

Participants

A total 10 boys between the ages of 7 to 9 years with ADHD enrolled in the study (see Table 1). Girls were eligible but none enrolled. Participants were diagnosed using the *DSM-IV* version of Diagnostic Interview Schedule for Children Parent Interview (Shaffer, Fisher, Lucas, Dulcan, & Schwab-Stone, 2000) and the parent and teacher Disruptive Behavior Disorders (DBD) Rating Scale. The DBD measures all *DSM-IIIR* and *IV* symptoms for oppositional-defiant disorder (ODD), conduct disorder (CD), and ADHD on a 4-point Likert-type scale (0 = *not at all* to 3 = *very much*; Pelham, Gnagy, Greenslade, & Milich, 1992). Interviews were completed by a graduate-level research assistant supported by a PhD investigator (LBM) who confirmed all diagnoses. There was 100% agreement among raters. A total of 8 participants were diagnosed with the combined subtype of ADHD and 2 with the inattentive subtype. The average ADHD symptom severity on the DBD was in the moderate range (see Table 1). Eight participants also met criteria for ODD or CD. All participants were receiving a stable dose of IR MPH before enrollment, but none had previously been treated with ER stimulants. For intake, the current MPH dose was suspended for 48 hr so that parent and teacher DBD ratings were collected off medication.

Participants had an estimated full-scale IQ of at least 80 using the block design and vocabulary subtests of the Wechsler Intelligence Scale for Children–III (Wechsler, 1991). Exclusionary conditions included skin sensitivity or any significant dermatological disease, atypical electrocardiogram results or hypertension, and atypical blood and urine test results or evidence of other medical condition that could be worsened by stimulant usage. Participants taking other psychotropics besides MPH were excluded from the study as were participants with psychopathology other than ADHD/ODD/CD severe enough to merit additional treatment. All families signed Institutional Review Board-approved consent forms and were compensated monetarily.

Design and Medication Conditions

This study consisted of a practice week followed by a 3-week, within-subject, random crossover of placebo, 10 mg IR MPH TID, and two 10 cm^2 MTS worn for 24 hr. The MPH dose in the 10 cm^2 patch is identical to the amount contained in the commercially available 12.5 cm^2 MTS. The doses of IR MPH and MTS were deemed to be equivalent based on data from the development of the MTS (33 mg/24 hr for MTS vs.

30 mg/24 hr for IR MPH). Double dummy procedures were used so all children received patches and capsules each day, with applicable placebos. Two 10 cm^2 MTS were applied to the buttock, with sides alternating daily.

Baseline and Practice Procedures

On the Saturday prior to the study, parents received a week's supply of placebo MTS. During the week, parents practiced MTS application and completed dosing diaries and ratings. Participants were admitted to the study site on Friday evening and participated in a practice Saturday laboratory session as described in the following section.

Weekday Procedures

Participants remained in their regular home and school environments Monday through Friday. Parents administered patches and capsules each morning, completed dosing records, and monitored drug tolerability. School personnel gave the lunchtime capsules. Parents and children were admitted to the study site on Friday evening and stayed through Sunday morning. Friday night, staff measured temperature, weight, blood pressure, and pulse; rated adverse events and concomitant medications; collected dosing and adhesion records; and performed skin exams.

Saturday Procedures

Children spent the entire Saturday in the laboratory setting. The MTS patches and morning IR MPH dose were administered between 7:00 and 7:30 a.m. The second and third IR MPH capsules were administered between 11:00 and 11:30 a.m. and between 3:00 and 3:30 p.m. At each dose, adhesion of the MTS was evaluated. IR and MTS doses occurred at the same times each week.

Twelve hourly assessments of classroom behavior and productivity were completed, beginning at 7:30 a.m. Each 30-min session included a 10-min, timed math activity. Violations of classroom rules and numbers of math problems attempted and completed correctly were recorded. Vital signs were taken at 0, 4, 8, and 24 hr after the first dose. Between assessments, children participated in recreational activities and had meals. At approximately 7:30 p.m., children were released to their parents, who stayed overnight with them at the study site.

Efficacy Measures

The number of classroom rule violations served as the primary outcome variable. For this, and the secondary measure—number of math problems completed correctly per classroom session—children's scores were averaged across the 12 hourly assessments per condition. These measures have been shown to detect treatment effects of pharmacological and behavioral interventions for ADHD with adequate interrater reliability (Pelham, Burrows-MacLean et al., 2005; Pelham et al., 1993; Pelham, Manos et al., 2005) and may be a more reasonable proxy of impairment than symptom ratings (Pelham, Massetti, & Fabiano, 2005). For comparisons with earlier MTS studies, the laboratory classroom teacher also completed an IOWA Conners scale after each classroom session (Loney & Milich, 1982). IOWA scores were also averaged across the day to compute a final mean score.

Tolerability Ratings

Parental ratings of their child's sleep, appetite, and other adverse events during the past week were collected Friday evening. On Friday and Saturday nights in the laboratory setting, nursing staff monitored the children hourly between 9:00 p.m. and midnight, recording the time they fell asleep. Other adverse events were assessed through spontaneous report on Saturday evening and Sunday morning. Nurses trained by one of the study physicians (MH) assessed each MTS application site for skin irritation before application and at 0.5, 12, and 24 hr after MTS removal. Skin irritation was rated as *none* (0), *very slight- no defined edge* (1), *mild with a well-defined edge* (2), *moderate* (3), or *severe* (4).

Data Analyses

Since raw data for rule violations and math problems were not normally distributed, values were log transformed before analyses. Efficacy ratings (number of classroom rule violations, math problems correctly completed, IOWA ratings) were aggregated across the 12 classroom periods and analyzed using a repeated-measures analysis of variance. Follow-up within-subject contrasts were conducted between the following conditions: (a) placebo versus MTS, (b) placebo versus IR MPH, and (c) MTS versus IR MPH. Effect sizes (ES) for the primary outcome variable (classroom rule violations) were computed for each classroom period by subtracting the placebo mean across children from each treatment mean and dividing by the placebo standard deviation (Pelham et al., 1993). Sleep onset was averaged across nights in each condition and was analyzed using a repeated-measure ANOVA. Other side-effects data did not occur at a frequent enough rates for analysis so these data are presented descriptively. A within-subject paired *t* test was used to compare mean skin irritation ratings between the MTS and placebo patches.

Results

Efficacy Measures

One participant discontinued the study in the first week due to worsening behavior on placebo and was not included

Table 2. Results of Efficacy Measures

Measure	Placebo *M* (*SD*)	MTS *M* (*SD*)	TID MPH *M* (*SD*)	Placebo versus MTS *F*(1, 8)	Placebo versus t.i.d. MPH *F*(1, 8)	MTS versus TID MPH *F*(1, 8)
Rule violations	81.3 (62.1)	40.4 (52.4)	45.3 (41.3)	9.96, $p = .01$	15.59, $p < .01$	0.35 NS
Math correct	21.6 (25.0)	29.6 (22.7)	34.3 (29.7)	5.14, $p = .05$	30.86, $p < .001$	1.12 NS
IO rating	9.7 (5.1)	5.8 (4.9)	6.0 (4.3)	8.83, $p = .02$	8.50, $p = .0195$	0.02 NS
OD rating	9.0 (5.0)	4.8 (5.3)	4.7 (4.3)	9.18, $p = .02$	12.24, $p < .01$	0.00 NS

Note: IO = inattention/overactivity teacher rating; OD = oppositional–defiant teacher rating; MTS = methylphenidate transdermal system; NS = nonsignificant; TID MPH = 3 times a day immediate-release methylphenidate.

in analyses; all other 9 participants completed the study. Results are presented in Table 2. For classroom rule violations (primary outcome) and teacher IOWA ratings, the two active medications both separated from placebo but did not differ from each other. As illustrated in Figure 1, there were clear positive effects of both conditions for the duration of the 12-hr period but with differential onset of effect. Inspection of means shows that IR MPH produced sizably larger reductions in rule violations 1-hr post dose. ES for rule violations were similar between the drugs used, averaging between 0.6 and 0.8; however, the ES for IR MPH decreased to 0.2-0.4 near the end of the morning and afternoon dosing intervals.

For math problems attempted, IR MPH significantly differed from placebo, but the MTS narrowly failed to separate ($p = .05$). The time course of effects (Figure 1) was similar to that seen for rule violations, with the MTS having a delayed initial onset but producing larger gains approximately 3 to 4 hr after the first and second IR doses.

Adverse Events

All participants receiving at least one dose of medication were included in the safety analysis. A total of 36 adverse events were reported, equally distributed across treatments. The most commonly reported events were appetite reduction ($N = 8$), headache ($N = 5$), abdominal pain ($N = 4$), and cold/flu symptoms ($N = 3$). For both IR MPH and the MTS, parents reported that 33% of participants experienced appetite reduction versus 22% on placebo. There was only one case of emotional lability reported which occurred during MTS usage. Five events were recorded as moderate in severity, one for IR MPH (malaise), none for MTS, and four in the placebo condition (vomiting, stomach ache, faintness, and flu-like symptoms); none was severe. The study physician judged that 57% of reported adverse events were unrelated to medication, 3% were unlikely related, and 40% were possibly related, with equivalent numbers in each treatment condition.

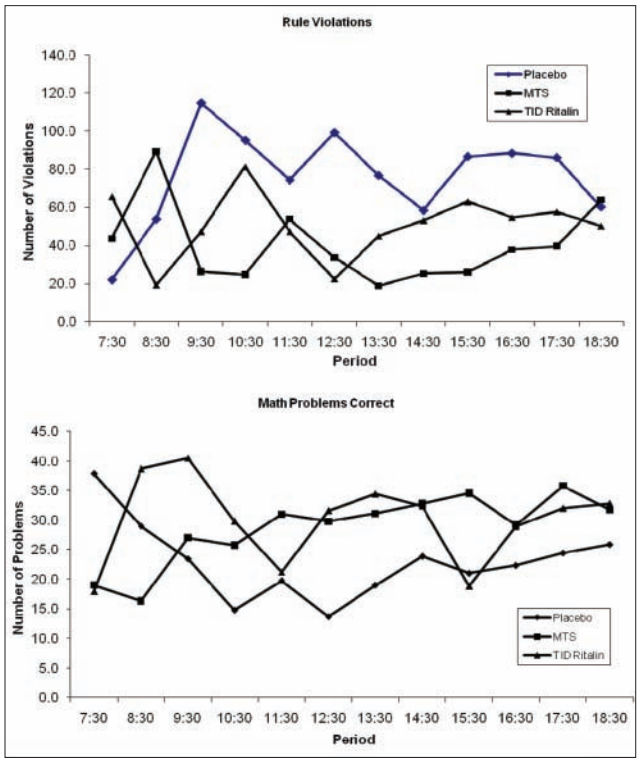

Figure 1. Frequency counts for classroom measures across the 12-hour laboratory day (Top= number of classroom rule violations; Bottom= number of math problems completed correctly).
Note: (MTS = Methylphenidate Transdermal System, TID Ritalin = 3 times a day immediate-release methylphenidate)

Within-subject analysis of variance conducted on the time children fell asleep in the laboratory showed no significant differences among the three conditions; they fell asleep between 9:30 and 10:30 p.m. on average in all conditions. The patches were well tolerated with mean skin irritation ratings in the mild range for both the MTS and placebo patches and no significant difference between conditions ($t = 1.6$ ns). There were no severe skin reactions and

only three moderate reactions that lasted under 12 hr. None precipitated a dose change or patch removal.

Discussion

There have been few head-to-head comparisons of different ADHD medications, leaving clinicians to extrapolate findings across studies to determine whether newer ER medications offer meaningful benefits over the original IR preparations. The one previous study comparing the MTS to another stimulant (Findling et al., 2008) is limited by reliance on parent and teacher ratings which can be prone to rater bias (Waschbusch, Pelham, Waxmonsky, & Johnson, 2009). Moreover, between-group studies like the Findling trial that use weekly assessments are limited in their capacity to define drug onset and duration precisely, which are often the main differences between stimulants (Pliszka, 2007; Weisler, 2007). Analog classroom studies were designed to address these limitations and have become the preferred design for comparing stimulant formulations (Swanson et al., 2002). Ours is the first study to compare the MTS to other MPH products in an analog classroom setting.

Both medications produced significant improvements over placebo across the entire 12-hour session on symptom ratings and objective measures of functioning that are highly sensitive to drug effects (Pelham, Burrows-MacLean et al., 2005; Pelham et al., 2001). The MTS marginally failed to separate from placebo on measures of classroom productivity. However, the improvements in rule violations and the IOWA ratings were comparable to other stimulant trials set in analog classrooms (Pelham, Burrows-MacLean et al., 2005; Pelham et al., 2001), suggesting our failure to find a significant effect was due to the small sample.

The MTS showed a more consistent effect during the day, whereas the TID condition showed a "scalloping" effect that is typically associated with IR MPH (Figure 1). These results are not surprising as the MTS produces increasing *d*-MPH blood levels for 8+ hr, while IR MPH has a half life of 2 to 3 hr (Pierce et al., 2008). For children experiencing symptom exacerbations between IR doses, the MTS may lead to improved effects. However, there was little evidence for superiority of the MTS over IR MPH on the 12-hr composite results (Table 2). Findings are consistent with prior analog classroom trials comparing different stimulants across a 12-hr time span (Muniz et al., 2008; Pelham et al., 2001; Swanson et al., 2004). The one study showing that ER stimulants produced greater symptom control than IR MPH was an unblinded trial using monthly behavior ratings. Although adherence was better with the ER product, the differential rates of medication usage limited the ability to assess the comparative efficacy of the two agents (Steele et al., 2006). Hence, for children compliant with their current medication regimen, switching to MTS is unlikely to lead to improved symptom control.

Both medications exerted effects for up to 12 hr after application, lasting from before breakfast until dinnertime. However, Figure 1 shows an apparent delay in onset of action for MTS as compared to TID IR MPH, with the MTS not reaching peak effectiveness until 120 min after application versus 60 min (the first postdosing assessment) for IR MPH. Another study found a similar delay in the therapeutic onset of the MTS (Pelham, Manos et al., 2005).

Adverse event rates were similar between the treatment conditions with no reports of serious adverse events. The MTS worn for 24 hr had equivalent tolerability to that IR MPH, with only mild reductions in sleep onset or appetite from either drug. However, participants fell asleep between 9:30 and 10:30 p.m. on the laboratory days, and hence the rates of insomnia may be different on school nights when many children have earlier bedtimes. Moreover, all participants had previously been receiving MPH, and this protocol employed a dose below the Federal Drug Authority (FDA) -prescribed maximum for the MTS (37.5 cm^2), which may explain the lower side effects rates versus other MTS studies (McGough et al., 2006; Pelham, Burrows-MacLean et al., 2005; Pelham, Manos et al., 2005). For known MPH responders, it appears that MTS is well tolerated and that inadvertent failure to remove the patch after 9 hr is unlikely to lead to marked disturbances in sleep, appetite, or other serious adverse events. In addition, results suggest that participants tolerating a stable dose of IR MPH can be switched to an equivalent daily dose of MTS without a lengthy titration. The MTS caused only minor skin irritation after an extended wear time, similar to that seen with the placebo patches. Nonetheless, the MTS would not be advisable for children with skin sensitivities.

Limitations

The study's primary limitation is its small sample; nevertheless, the power was improved by the use of a crossover design. This limitation is highlighted by the MTS's marginal failure to separate from placebo ($p = .05$) on the number of math problems completed, even though participants finished more than 33% more problems on the MTS-administered condition versus placebo condition. Similarly, differences between the two drugs at specific time points might have achieved significance in a larger sample. However, inspection of raw means in Table 1 suggests this would not be the case for the composite 12-hr ratings.

All participants were male and 80% had comorbid ODD/CD. All participants were also previously stabilized on MPH. In smaller studies such as this, it is not uncommon to have mostly male samples with high rates of ODD/CD, given the epidemiology of ADHD (Plizska, 2007). Hence, results are not surprising but do limit the ability to generalize findings.

The commercially available version of the MTS has been modified since this trial. The 10 cm^2 patch used in this study contains an identical amount of MPH as the commercial 12.5 cm^2 MTS, and the dose used in this study has a similar pharmacokinetic profile to that of the commercial 25 cm^2 patch (Pierce et al., 2008). These study results were utilized to improve the MTS prior to FDA approval. Any modifications made to the MTS poststudy did not affect the pharmacokinetic or pharmacodynamic properties of the agent (Shire, data on file).

The MTS was applied for 24 consecutive hr that exceeds the FDA-approved wear time of 9 hr (Shire, 2009). As all participants were previously stabilized on MPH, one cannot generalize the tolerability findings to stimulant naïve children.

Clinical Implications

The MTS was found to be an efficacious and tolerable treatment for ADHD, producing sustained effects over a 12-hr period. Although results need to be replicated in larger comparative trials, there was no evidence that the MTS led to improved efficacy or tolerability over IR MPH except for more consistent therapeutic effects across the day. This benefit comes at the price of delayed onset versus IR MPH and likely greater cost as well. For children with poor compliance or midday symptom rebound on IR MPH, conversion to the MTS is a reasonable consideration. For children in whom MPH products are ineffective or intolerable or those well controlled on oral preparations, there appears to be little additional utility in switching to the MTS.

Declaration of Conflicting Interests

Dr. Pelham has served as a consultant for Shire, McNeil, Noven, Celltech/Medeva, Novartis and Abbott Laboratories, received honoraria from Shire and Janssen and research support from Shire, Alza, Eli Lilly, Noven and Cephalon and holds common stock in Abbott Laboratories. Dr. Waxmonsky has served on the Speaker's Bureau for Novartis, and has received research support from Eli Lilly and Shire Inc. Dr. Hoffman has served on the advisory board and Speaker's Bureau for Shire Pharmaceuticals and the Speaker's Board for McNeil. Dr. Ballow has received research support from GlaxoSmith-Kline, Panacos, Boehringer Ingelheim, Pharmasset, Jacobus and Pharmena. Dr. Schentag has served as a consultant for or received support from Noven, Wyeth, Daiichi, Targanta therapeutics, and Astellas. Dr. Gonzalez is a full time employee of P'Kinetics International, Inc. There are no other known current conflicts of interest. Since completion of the study, several authors have left the University of Buffalo. Dr. Meichenbaum is now with Summit Academy, Dr. Panahon with Gwynedd-Mercy College, Dr. Tresco with The Children's Hospital of Philadelphia, Dr. Forehand with Portland State University, Dr. Andy-Lopez Williams is practicing in Utica, NY, and Dr. Coles is with the University of Maine.

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Bios

William E. Pelham, PhD, ABPP, is a SUNY distinguished professor in the Departments of Psychology, Pediatrics, and Psychiatry at the State University of New York at Buffalo (UB) and the director of the Center for Children and Families at UB. His summer treatment program for ADHD children has been recognized by the APA, SAMHSA, and CHADD as a model program and is widely recognized as the state of the art in treatment for ADHD. He has authored or coauthored more than 285 professional papers dealing with ADHD and its assessment and treatment—psychosocial, pharmacological, and combined.

James G. Waxmonsky, MD, is an assistant professor of psychiatry at the State University of Buffalo. His research focuses on the tolerability of stimulant medications and the interface between ADHD and bipolar disorder. He also runs a private practice specializing in the treatment of ADHD in adults.

Jerome Schentag, PharmD, is professor of pharmaceutical sciences and pharmacy, University at Buffalo, the State University of New York (SUNY), New York, and Fellow, Center for Entrepreneurial Leadership, School of Management, University at Buffalo, SUNY, New York. His research interests include the effects of diseases on the pharmacokinetics of antibiotics and the relationship between pharmacokinetics and toxicity of medications in critically ill patients. He has authored or coauthored more than 350 publications.

Charles H. Ballow, PharmD, FCCP, is a director at the Buffalo Clinical Research Center. He holds a BS in chemistry from the University of North Carolina–Chapel Hill and an MS in pharmacology and PharmD from the University of Maryland. Currently, he is the director of the Buffalo Clinical Research Center where his activities are focused in the area of Phase I Pharmacology research. He has over 20 years of research experience in all phases of clinical research.

Carlos J. Panahon, PhD, is an assistant professor in the school psychology doctoral program at Minnesota State University, Mankato. He received his PhD in school psychology from Syracuse University. His research focuses on school consultation, developing academic and behavioral interventions for children with emotional/behavioral disorders, and the effects of noncontingent reinforcement on academic performance.

Elizabeth M. Gnagy, BS, is a senior research support specialist at the Center for Children and Families, University at Buffalo. She earned her BS from Westminster College.

Martin T. Hoffman, MD, is an associate professor of clinical pediatrics, director of the Pediatric Center for Learning and School Success at the University at Buffalo School of Medicine and Biomedical Science and medical director of the Center for Children and Families at the University. Additionally, he is an attending

physician at the Women and Children's Hospital of Buffalo, New York, and a consulting physician at Bertrand Chaffee Hospital, Springville, New York. He has been working with children who have school and learning problems and ADHD since 1986 and has more recently been involved in clinical research.

Lisa Burrows-MacLean, PhD, is the clinical director of the CCF and clinical assistant professor of psychology and pediatrics. She is particularly interested in the dissemination of evidence-based treatment for disruptive behavior disorders and is actively involved in providing consultation on program development and implementation for several community mental health agencies and schools.

David L. Meichenbaum, PhD, is the clinical director of Consulting Services at Summit Educational Resources. He provides consultative support and training to school districts, both regionally and nationally, to facilitate the academic, social, emotional, adaptive, and behavioral development of students with autism spectrum and disruptive behavior disorders.

Gregory L. Forehand, MSW, is a researcher at the Northwest Regional Educational Laboratory. He is also a research and evaluation advisor for the child and family program at the Northwest Lab; he provides methodological and analytical support for a variety of evaluation and research projects, including the evaluation of the Montana Parental Information and Resource Center. He is currently working to complete his PhD in social work and social research at Portland State University and has taught research methods and data analysis to master's degree students in the social work department at Portland State.

Gregory A. Fabiano, PhD, is an assistant professor of counseling, school, and educational psychology at the University at Buffalo. His research has focused on evidence-based assessments and treatments for children with ADHD.

Katy E. Tresco, PhD, is a postdoctoral fellow of psychology at the Children's Hospital of Philadelphia. She received her doctorate in school psychology from Lehigh University and is currently a postdoctoral psychology fellow in the Center for the Management of ADHD at Children's Hospital of Philadelphia. Her research and professional interests include intervention and long-term behavioral, academic, and social outcomes for students with ADHD and other related behavior problems.

Andy Lopez-Williams, PhD, is the founder and director of ADHD & Autism Advocates in Utica, New York—a specialty clinic for children, adolescents, and adults. He also serves as a consultant to The Arc, Oneida-Lewis Chapter and is a member of the advisory board at Pathfinder Village and the Kennedy–Willis Center on Down Syndrome in Edmeston, New York.

Erika K. Coles, PhD, is currently an assistant professor in the Department of Psychology at the University of Maine. She received her doctoral degree in clinical psychology from the University at Buffalo and completed her predoctoral clinical internship at the University of Mississippi Medical Center. Her research interests focus on behavioral interventions for children with ADHD and other disruptive behavior disorders.

Mario A. González, PhD, is president of P'Kinetics International, Inc. specializing in biopharmaceutics and pharmacokinetics research. His research has concentrated on the pharmacokinetic and pharmacodynamic evaluation of extended-release oral and transdermal drug delivery systems as well as *in vitro/in vivo* correlations.