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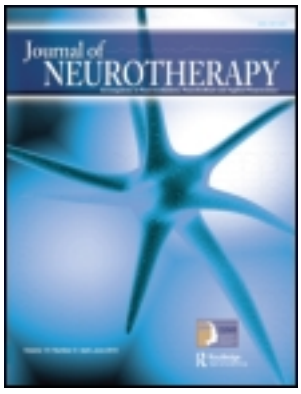

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Ending the Evidentiary & Insurance Reimbursement Bias Against Neurofeedback to Treat ADHD: It Will Take Clinician Action in Addition to the Compelling Science

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EDITORIAL

ENDING THE EVIDENTIARY & INSURANCE REIMBURSEMENT BIAS AGAINST NEUROFEEDBACK TO TREAT ADHD: IT WILL TAKE CLINICIAN ACTION IN ADDITION TO THE COMPELLING SCIENCE

Attention deficit/hyperactivity disorder (ADHD) is the most frequently diagnosed pediatric behavioral health disorder with 11% of American school-aged children (and nearly 20% of high school boys) having been medically diagnosed with ADHD according to the latest report from the Centers for Disease Control and Prevention (Schwarz & Cohen, 2013), a significant increase from the 8% in prior reports (Centers for Disease Control and Prevention, 2010). Stimulant medication and behavior therapy are the two most widely accepted treatments for ADHD, and these treatments are commonly reimbursed by healthcare insurers. Although both are considered to meet the highest standards for the ''evidence-based treatment'' of ADHD, and been recognized as such by the American Academy of Child and Adolescent Psychiatry (AACAP) and CHADD, the leading ADHD advocacy group, the actual evidence is that these treatments fail to result in sustained benefit for the vast majority of children who receive them as demonstrated in the NIMH-funded MTA Cooperative study, the gold standard study in ADHD treatment effectiveness research.

UNDERSTANDING THE MTA COOPERATIVE STUDY

For background, the MTA trial was a ''cooperative'' study that included America's foremost experts in the psychotropic and behavior therapy treatments of ADHD in the design, oversight, and reporting of the study's results. This multicentered, open-label, trial randomly assigned 579 ADHD children to receive systematic medication management (SMM), multicomponent behavior therapy (BT), combined SMM/BT, or simply a referral to community care (CC) in which the referred children/families may or may not have actually followed through and received any treatment (MTA Cooperative Group, 1999). The children and their parents who received SMM, BT, or combined SMM/BT were then referred to community professionals for ongoing care after the end of 14 months of study-directed treatment. Follow-up assessments were then conducted at 10 months (MTA Cooperative Group, 2004a, 2994b), 22 months (Jensen et al., 2007), and 4.83 and 6.83 years (Molina et al., 2009) after the end of study-directed treatment.

The design of the SMM, BT, and combined SMM/BT interventions took a ''spare-no-expense'' approach to ensure that the children received optimal versions of the assigned care, a quality of care for those receiving these interventions that is not obtainable in 99% of real-world treatment settings. As documented in the authors' International Society for Neurofeedback & Research (ISNR)–commissioned white paper, we found that conservative cost estimates in today's dollars for the 14 months of SMM was $4,150, $11,430 for BT, and $16,580 for the integrated SMM/BT treatment (see Table 1). In addition to the open-label nature of the MTA study, the study relied on nonblinded parent and teacher rating scales to evaluate outcomes with these raters systematically involved in the SMM, BT, and SMM/BT treatments (but not for those children referred to CC), thereby inflating the initial reports of outcomes from said treatments in relationship to CC (Hammond, 2011). Despite this built-in inflationary bias in the reporting of BT, SMM,

TABLE 1. Systematic Medication Management and Behavior Therapy Components in the MTA Cooperative Study

Systematic medication management	Systematic medication management (SMM) included: An initial 28-day double-blind, daily switch titration of methylphenidate hydrochloride, using 5 randomly ordered repeats each of placebo, 5 mg, 10 mg, and 15 or 20 mg given at breakfast and lunch with a half dose in the afternoon. Experienced clinicians blindly reviewed graphs of daily-administered parent and teacher ratings of the child's responses to each of the three doses and placebo and by consensus selected his/her best dose. The agreed-on dose (if not placebo) became the child's initial maintenance dose. This was done to yield optimal symptom reduction and minimal side effects for each child. If the child did not obtain an adequate response to methylphenidate during titration, the pharmacotherapist performed nonblinded trials of 3 or more additional medications, and evaluating the effectiveness of each of these trials based on parent and teacher ratings of the child's responses to same. Provided monthly half-hour office visits with the pharmacotherapist to review parent concerns, evaluate progress, and provide advice, support, and recommend readings to the parent. The pharmacotherapist communicated monthly by phone with the child's teachers and readjusted medications if the child was not doing well. **Cost Estimate:** Selection of optimal dose $800 13 half-hour office visits × $110 per visit = $1,430 13 teacher phone calls × $40 per call = $520 14 months of medication × $100 per month = $1,400.00 **Total Cost Estimate:** $800 + $1,430 + $520 + $1,400 = **$4,150.00**
Parent training	Parent training involved 27 group and 8 individual sessions per family. It began weekly on randomization, concurrent with biweekly teacher consultation; both were tapered over time. The same therapist-consultant conducted parent training and teacher consultation. **Cost Estimate:** 27 group sessions × $50 per group = $1,350 8 individual sessions × $120 per session = $960
Child-focused treatment	Child-focused treatment involved an 8-week, 5-days-per-week, 9-hours per-day summer camp using intensive behavioral interventions administered by counselors/aides, supervised by the same teacher-consultants who performed parent training and teacher consultation. Behavioral interventions were delivered in group-based recreational settings, and included a point system tied to specific rewards, time out, social reinforcement, modeling, group problem-solving, sports skills, and social skills training. The summer treatment program included classrooms that provided individualized academic skills practice and reinforcement of appropriate classroom behavior. **Cost Estimate:** $300 per week × 8 weeks = $2,400
School-based treatment	School-based treatment had 2 components: 10 to 16 sessions of biweekly teacher consultation focused on classroom behavior management strategies and 12 weeks (60 school days) of a part-time, behaviorally trained, paraprofessional aide working directly with the child. The aides had been counselors in the summer camp, and the program continued in the fall, to help generalize treatment gains made in the camp into the classroom. Throughout the school year, a daily report card linked home and school. The daily report card was a 1-page teacher-completed checklist of the child's successes on specific preselected behaviors, and was brought home daily by the child to be reinforced by the parent with home-based rewards (e.g., television time, snacks). **Cost Estimate:** 16 teacher consultation sessions × $120 per session = $1,920 60 days of in-school aide × $80 per day = $4,800 **Total Cost Estimate for BT:** $1,350 + $960 + $2,400 + $1,920 + $4,800 = **$11,430**
Combined SMM and BT	Combined SMM/BT treatment provided all of the treatment components outlined above in an integrated manner. Information was regularly shared between the behavioral psychologist/teacher-consultant and pharmacotherapist. Manualized guidelines determined if and when an adjustment in one treatment should be made versus first intervening with the other first. **Cost Estimate:** Information sharing and ongoing psychologist/pharmacotherapist consultations $1,000.00 **Total Cost Estimate:** $1,000 + $4,150 + $11,430 = **$16,580**
Additional treatment	The SMM, BT, and combined SMM/BT groups were authorized up to 8 additional sessions to use when needed to address clinical emergencies and/or instances of possible dropout from the study. At the end of the 14 months of study-directed treatment, these children/families were also provided with recommendations for ongoing treatment as warranted combined with referrals to medical and behavioral health professionals practicing in their community.
Referral to community care	Parents of children assigned to community care were provided a report of the initial study assessments along with a list of community mental health resources and may or may not have followed through with treatment. Two-thirds of the community care children received attention deficit/hyperactivity disorder medications from their own provider during at least part of the 14 months.

Note. BT = behavior therapy.

and SMM/BT outcomes relative to CC, our review of the five initial and follow-up MTA outcome articles found the following:

- Multicomponent BT failed to result in any significant reduction in core ADHD symptoms beyond those achieved by subjects who had simply been referred to CC;
- Combined SMM/BT failed to separate from SMM on any direct comparison of the primary ADHD outcomes at the end of study-directed treatment and all follow-up assessments. In several secondary analyses, there was modest evidence that at the end of study-directed treatment (but not in the follow-up assessments) the children in the combined SMM/BT group did somewhat better than those receiving only SMM;
- Although both SMM and SMM/BT separated from BT and CC on the primary ADHD outcomes at the end of study-directed treatment, their effect size was cut in half (.6 to .3) at the 10-month follow-up assessment and disappeared entirely in the 22-month, and 4.83 and 6.83 year, follow-up assessments thereby making it difficult to argue that 14 months of comprehensive behavior therapy, either alone or in combination with SMM, conferred any advantages to the children assigned to these exceedingly costly and time-intensive interventions;
- Even after 14 months of free, intensive multicomponent BT combined with SMM followed by referral to community-based professionals for continuing care, ADHD was found to be an ongoing debilitating illness and the societal costs that are associated with it included 10.4% of such ''optimally treated'' children requiring psychiatric hospitalization one or more times during follow-up. The psychiatric hospitalization rate for those receiving multicomponent BT without medication was even higher at 12.3%. Surprisingly though, only 8.3% of those who had simply been referred to community care required psychiatric hospitalization during follow-up, and many of these children received little to no actual treatment for their ADHD; certainly not the 14 months of high-cost and optimally administered ''evidence-based'' treatments that the other subjects received; and
- The study authors concluded, ''Finally, a previous analysis of the MTA data through 3 years did not provide evidence that subject selection biases toward medication use in the follow-up period accounted for the observed lack of differential effects. Thus, although the MTA data provided strong support for the acute reduction of symptoms with intensive medication management, these long-term follow-up data fail to provide support for long-term advantage of (continued) medication treatment beyond 2 years for the majority of children'' (Molina et al., 2009, pp. 496–497).

Given the findings from this seminal study, the evidence is clear that even gold-plated versions of these commonly recognized and reimbursed ''evidence-based'' treatments fail to result in sustained benefit for the vast majority of ADHD children who receive them. It is therefore disappointing that although both AACAP and CHADD vigorously endorse stimulant medication and behavior therapy as the two leading evidence-based treatments for ADHD, these organizations fail to acknowledge the troubling findings from the MTA study that expose the profound inadequacies of these treatments.

NEUROFEEDBACK AS AN EVIDENCE-BASED TREATMENT FOR ADHD

Neurofeedback (NFB) is a form of behavior therapy with more than 40 years of basic and applied research combining real-time measurement of neuronal electrical activity with the scientifically established principles of operant conditioning to teach trainees how to better self-regulate brain functioning. As such, NFB is uniquely suited to treat the neuronal dysregulation that is common in people diagnosed with ADHD.

Beginning in the early 1960s, neuroscientists demonstrated that decreases in the motor activity of cats was associated with increased 12–16 Hz neuronal electrical activity in the sensorimotor cortex, an activity pattern that Professor Barry Sterman named the sensorimotor rhythm (SMR). Professor Sterman and his colleagues found that when hungry cats were fed contingent upon the increase in SMR activity, the cats ''became very alert'' and displayed ''an almost intense cessation of movement,'' behaviors seldom seen in children with ADHD (Sterman & Wyrwicka, 1967). Building on Dr. Sterman's findings, in the mid-1970s using a scientifically rigorous research design in which both the child subjects and raters of ADHD behaviors were blind to the experimental condition and the children acted as their own experimental controls, Drs. Lubar and Shouse demonstrated both (a) the functional relationship between SMR and the manifestation of the core behaviors associated with ADHD and (b) that through real-time feedback of SMR activity levels paired with operant conditioning, children diagnosed with ADHD learned to self-regulate SMR with the resulting improvements or worsening in their core ADHD symptoms based on whether they were being reinforced to increase or decrease their level of SMR (Lubar & Shouse, 1976; Shouse & Lubar, 1979).

Building on the neuroscience research foundation provided by Professors Barry Sterman and Joel Lubar, NFB's evidence-base has continued to grow with more than 50 peer-reviewed articles published to date documenting its effectiveness in treating ADHD's core symptoms. Our ISNR paper reviews in detail the controlled studies published during the past decade evaluating NFB's effectiveness in treating children and adolescents with ADHD. Our review documents that not only has NFB been found to be superior to a variety of experimental control group conditions, but also in three studies NFB was found to be equivalent to stimulant medication in treating the core symptoms of ADHD. Furthermore, we found five studies that assessed whether NFB resulted in sustained benefits after treatment ended, including two studies with 2-year follow-up assessments. In each of these follow-up assessments, the gains from NFB were maintained after treatment had ended, and in one study had increased further during the 2-year follow-up such that half of the children no longer meet the diagnostic criteria for ADHD (Gani, Birbaumer, & Strehl, 2008).

In contrast to the positive reports of sustained benefit following termination of NFB treatment, stimulant medications' beneficial effects commonly cease when the medication is stopped, and as found in the MTA Cooperative study, the authors concluded that there was *no evidence* to support the ''long-term advantage of (continued) medication treatment beyond 2 years for the majority of children'' (Molina et al., 2009, p. 497). Similarly, a 2010 Australian government-funded study of the long-term outcomes from stimulant medication treatment found no significant differences in outcomes for ADHD youth based on medication status (Smith, Jongeling, Hartmann, Russell, & Landu, 2010). Finally, the just published results from the NIMH-funded Preschool Attention-Deficit/Hyperactivity Disorder Treatment Study (PATS) found that ''medication status during follow-up, on versus off, did not predict symptom severity,'' and despite optimal parent training and systematic medication management at the study's outset, the authors concluded that

> ADHD in preschoolers is a relatively stable diagnosis over a 6-year period. The course is generally chronic, with high symptom severity and impairment, in very young children with moderate-to-severe ADHD, despite treatment with medication. Development of more effective ADHD intervention strategies is needed for this age group. (Riddle et al., 2013, p. 264)

So although the MTA, PATS, and Australian study findings, along with 50 years of research and clinical practice, clearly document the short-term effectiveness of stimulants, these large taxpayer-funded studies have each failed to find *any evidence* of sustained benefits from taking these medications, and the long-term

risks from taking them are still not fully known. Furthermore even during the near-term, one third or more of children do not respond adequately to ADHD medications and/or have significant adverse side effects from them, heightening further the need for effective treatment alternatives that are made widely accessible through insurance coverage.

Besides the findings from our review, independent evaluations of NFB's evidence-base increasingly validate NFB's effectiveness in treating the core symptoms of ADHD. A recent 2012 meta-analysis found NFB to be more than twice as effective in treating the core symptoms of ADHD, with an average weighted effect size of .21 compared to effect sizes of only .09 or less for the other six included treatments, with working memory training, behavior modification, school-based behavior therapy, behaviorally based parent training, and behavioral self-monitoring treatments each having negative effect sizes compared to the control group conditions. The negative effect size findings prompted the authors to conclude that these five commonly utilized—and often insurance reimbursed—treatments for ADHD ''cannot be deemed to be efficacious'' (Hodgson, Hutchinson, & Denson, 2012). This meta-analysis did not even include four recent controlled NFB studies, each finding NFB to be a highly effective treatment for ADHD and involving a total of 301 ADHD child and adolescent subjects, because these studies were published after the cutoff date for study inclusion. Furthermore in October 2012, the company that maintains the American Academy of Pediatrics' ranking of research support for psychosocial treatments awarded NFB the highest level of evidence-based support for the treatment of ADHD (Practice-Wise, 2012).

CONFRONTING EVIDENTIARY BIAS

In the appendix to our ISNR paper, the first author addresses in detail the critics of NFB, the most long-standing and prominent of whom is Russell Barkley (Barkley, 1992; Loo & Barkley, 2005). In their 2005 review article, Drs. Loo and Barkley stated that for NFB to be considered a ''legitimate treatment'' it must be not only found effective but also demonstrated in ''studies that are scientifically rigorous'' that

- ''Changing the EEG is the mechanism of change in ADHD symptoms'';
- The treatment effects must also ''generalize to non-treatment settings'' and ''persist over time''; and furthermore
- ''Even with such demonstrations, it must also be shown that treatment is cost effective in managing the symptoms of ADHD relative to the prevailing empirically supported approaches'' (p. 73).

Logically, if we accept Loo/Barkley's evidentiary standards for NFB, the same standards should be applied to all psychological and pharmaceutical treatments for ADHD in order to minimize bias when evaluating their evidence base. When applied even-handedly though, the simple fact is that there are no psychosocial *or* pharmaceutical treatments for any behavioral health disorder that meet Loo/Barkley's evidentiary standards.

Dr. Barkley himself flagrantly violates his own ''treatment legitimacy'' standards. Although Barkley has been a strong proponent of stimulant medications to treat ADHD ever since completing his dissertation on this topic in 1977, and receiving near-continuous funding from pharmaceutical companies in the ensuing years, despite billions of dollars spent in ''scientifically rigorous'' research over the past 40-plus years, we still do not know what are the mechanisms of change from stimulants that account for the observed short-term improvements in ADHD symptoms. Every psychoactive medication has a statement similar to ''presumably works by'' or ''is thought to . . . '' when describing a Food and Drug Administration–approved drug's hypothesized ''mechanism of change,'' yet Barkley fails to hold stimulants to the same evidentiary standard that he asserts is necessary for NFB to meet before it can be considered a legitimate treatment. Take methylphenidate,

for example—the most commonly prescribed drug for ADHD:

> The mode of therapeutic action in humans is not completely understood, but methylphenidate presumably activates the brain stem arousal system and cortex to produce its stimulant effect. Methylphenidate is thought to block the reuptake of norepinephrine and dopamine. ...There is neither specific evidence which clearly establishes the mechanism whereby Methylin produces its mental and behavioral effects in children, nor conclusive evidence regarding how these effects relate to the condition of the central nervous system. (Food and Drug Administration, n.d., p. 1)

Furthermore, it is well known that the effects of stimulant medications do not ''persist over time'' when treatment is stopped. Barkley himself emphasizes this point on his website. Regarding cost-effectiveness, medication-based treatment is quite expensive given the fact that in the attempts to sustain effectiveness, people have to take the medication(s) on an ongoing basis and, for many, at ever higher doses and/or with intermittent medication changes and new drug augmentation due to the tolerance effects that commonly develop to the originally prescribed medication(s). This reality is seen in the PATS study. By Year 3, an antipsychotic had been added to 8.3% of the preschoolers' medication regimen (*M* age = 7.4 years), and by Year 6, 12.9% were taking an antipsychotic (*M* age = 10.4 years). The loss of efficacy in ADHD medications likely accounts for the majority of the dramatic increase in prescribing antipsychotics to children. In a 2012 article published in *Archives of General Psychiatry*, Olfson, Blanco, Liu, Wang, and Correll reported that between 1993–1998 and 2005–2009, the rate of antipsychotics prescribed to children increased by more than 750% (from 0.24 to 1.83% of all outpatient visits to general practitioners and psychiatrists). Their analysis found that disruptive behavior disorders (primarily ADHD) were the most common diagnoses in children that were prescribed an antipsychotic accounting for 63% of such cases, and that in 54.1% of the outpatient visits, whenever an antipsychotic was prescribed there was also an ADHD medication prescribed to the same child.

The combination of open-ended treatment by medication(s), and the associated physician fees for overseeing the prescribing of these drugs, makes drug-centric treatment for ADHD very expensive with a poor cost–benefit return on investment as demonstrated by the MTA study authors' own conclusion that they found *no evidence* to support the ''long-term advantage of (continued) medication treatment beyond 2 years for the majority of children,'' a conclusion identical to that found in the PATS and Australian studies. The simple fact is that the available evidence from these large, taxpayer-funded studies indicates that not only do the effects of stimulant medications not ''persist over time'' after treatment is stopped, but there is no evidence from these long-term follow-up studies of a sustained benefit even when these drugs continue to be taken for the vast majority of ADHD children and teens.

On the behavior therapy front, behaviorally based parent training of the type developed by Barkley (1987) and included as one-leg of the multicomponent behavior therapy treatment used in the MTA study, and classroom BT, have not been subjected to rigorous controlled trials in which the specific aspects of the interventions were shown to be the mediating mechanisms of change and that the observed changes generalized to other settings and persisted over time. In fact, we know that the effects of such behavioral strategies for ADHD do not generalize to other settings nor persist over time, as even Barkley himself acknowledges on his website, stating,

> Psychological treatments, such as behavior modification in the classroom and parent training in child behavior management methods, have been shown to produce short-term benefits in these settings. However, the improvements ... do not generalize to other settings that are not included in the management program. Moreover, recent studies suggest, as with the medications discussed above, that the gains

> obtained during treatment may not last once treatment has been terminated. (Barkley, n.d., p. 5)

Although Barkley, among others, holds NFB to far higher evidentiary standards than they apply to their preferred ''legitimate treatments,'' the irony is that NFB comes far closer to meeting these evidentiary standards for the effective treatment of ADHD than either stimulant medications or behavior therapy. As documented in our ISNR paper,

- By using a reversal research design, the very first NFB studies by Lubar and Shouse demonstrated that ''changing the EEG is the mechanism of change in ADHD symptoms'' and Barkley conveniently fails to reference these seminal studies in each of his reviews;
- In addition to the initial Lubar studies, Lubar, Swartwood, Swartwood, and O'Donnell (1995) demonstrated that ADHD children who learned to decrease their theta/beta ratios through NFB training showed improvement on multiple outcome measures, whereas nonlearners did not improve. Furthermore, there are now seven new studies demonstrating that NFB resulted in protocol-specified ''changes in the EEG'' and these improvements in EEG self-regulation persisted when reassessed at 6 months and 2 years after treatment termination with associated sustained improvement in ADHD core symptoms. In addition, four studies have correlated the extent of changes in subjects' EEG to ADHD symptom improvement and found that those subjects who were most successful in learning to self-regulate their EEG had the greatest improvement in ADHD symptoms, thereby providing additional strong evidence that ''changing the EEG is the mechanism of change in ADHD symptoms'';
- In numerous studies, NFB is shown to result in significant improvements in both parent-rated and teacher-rated core symptoms of ADHD compared to control group conditions, thereby providing strong evidence that unlike behavior therapy, the gains from NFB treatment ''generalize to nontreatment settings'' (i.e., both home and school); and finally
- In five follow-up studies, NFB resulted in significant improvement in core ADHD symptoms that were sustained when reassessed at 6 months and 2 years after treatment termination thereby providing strong evidence that unlike stimulant medications and behavior therapy, the gains from NFB treatment ''persist over time'' following treatment termination.

Perhaps the most common criticism of NFB research by Barkley and other reviewers is that it has not been demonstrated as efficacious in placebo-controlled ''triple-blinded'' trials in which the NFB clinicians, subjects, and outcome raters are blind to whether the subjects were receiving real EEG or sham feedback. Similar to Loo/Barkley, though, the authors of these reviews do not apply the same evidentiary standards when evaluating the effectiveness of their preferred treatments. For example Nicholas Lofthouse, the lead author in three of these reviews (Lofthouse, Arnold, Hersch, & Hurt, 2012; Lofthouse, Arnold, Hersch, Hurt, & Debeus, 2012; Lofthouse, McBurnett, Arnold, & Hurt, 2011) identifies BT and cognitive behavior therapy (CBT) as evidence-based treatments for ADHD (Lofthouse et al., 2011) while asserting that NFB fails to achieve this designation; yet neither of these treatments have ever been shown to be effective in placebo-controlled studies in which the treating clinician was blind to the experimental condition. In fact, it is widely recognized that these learning-based treatments are not suitable for such research designs because it is impossible to blind the clinician to the treatment condition. In research on learning-based treatments, the clinician follows behaviorally based treatment procedures to optimize the targeted skills for learning and this cannot be done using *blind* clinicians. The same is true for NFB because it is the operant conditioning of the EEG and requires a trained clinician to maximize the learning effect by monitoring and ensuring that the desired

brainwave pattern is in fact being reinforced. NFB is not analogous to a pill in which one can evaluate its effectiveness by simply comparing it to an inert/sugar pill version of it. NFB is a learning-based treatment and, like other forms of behavior therapy, requires oversight by a skilled clinician to ensure that the desired brainwave pattern is in fact being learned.

Advocates, such as Lofthouse, Eugene Arnold, and their Ohio State colleagues, for blinding clinicians to the treatment condition typically cite the availability of auto-thresholding NFB software that minute-to-minute resets the reinforcement threshold using ''fuzzy logic based on the immediately preceding EEG'' because such software does not ''require a 'NF coach' to guide trainees'' (Arnold et al., 2012, p. 3). The logic of these advocates though is indeed fuzzy and displays a profound lack of understanding on their part to the most basic principles of operant conditioning on which NFB is based. As emphasized in an article coauthored by many of NFB's leading experts including Drs. Sterman and Lubar, ''the learning principle of shaping is completely violated in the auto-thresholding procedure'' since

> if the learner begins to fatigue, lose interest, or even stop actively participating in the training, the reward signals continue to be provided irrespective of whether they are producing the desired behavior. They are, in fact, being rewarded for only changing the (EEG) behavior based on the previous averaged time period, which may not be an actual change from the starting behavior point. Even worse, it may actually be in the opposite direction than the desired training parameter. (Sherlin et al., 2011, p. 298)

Given the inherent problems of applying to NFB a research methodology that is not suited for learning-based treatments, the onus is on the advocates of blinding NFB clinicians to first demonstrate that

- There is an equivalent level of success in subjects learning to self-regulate the targeted EEG when comparing non-blinded to blinded clinicians overseeing the NFB training;
- The sham feedback is in fact shown to be inert on the targeted EEG pattern that is the focus of training in the NFB group; and furthermore
- If the researchers deviate from accepted NFB best practices by using methodologies such as auto-thresholding, they need to first demonstrate that these procedures result in equivalent or superior effects on the targeted EEG as do those NFB practices that have proven effective in more than 40 years of research.

Furthermore, although we acknowledge the importance of blinding raters to the treatment condition when assessing outcomes, NFB's critics routinely fail to acknowledge the common breaking-of-the-blind in ''gold standard'' placebo-controlled psychotropic drug trials. As Harvard professor Irving Kirsch (2009) documented, the blind is routinely broken in placebo-controlled studies by both the physicians overseeing treatment and the experimental subjects due to the informed consent process in which the subjects (and if underage, the subjects' parents) are given a detailed description of potential side effects, which are then reported to the physicians during the ongoing study visits. High rates of side effects are common in psychotropic medications; particularly fast-acting stimulant drugs with their frequent side effects of insomnia, loss of appetite, dizziness, headaches, and stomachaches, among others. As Professor Kirsch documented, the often marginal (if any) superiority of the active medication over the inert placebo commonly disappears when an active placebo is used, that is, a placebo that produces side effects similar to the study medication and thereby reducing the incidence of breaking-the-blind. Little wonder, then, that side effect–producing placebos are virtually never used in the gold standard ''double-blind placebo-controlled'' drug trials.

It is troubling that published reviews by authors without any NFB expertise demonstrate clear bias by holding NFB to far-higher evidentiary standards than the treatments they

advocate for as being ''evidence-based.'' Furthermore, the authors of these reviewers consistently fail to acknowledge the MTA study findings that expose the profound inadequacies of even optimized versions of their preferred treatments. The 2012 meta-analysis of non-pharmacological ADHD treatments, which applied the same standard of scientific rigor across treatments necessary for study inclusion, did not even include Drs. Lofthouse and Arnolds' ''evidence-based'' CBT in its analysis—*as no such CBT study exists that met their scientific standards for inclusion—NONE*. Similarly, the independent evidence-based rankings completed for the American Academy of Pediatrics gave CBT a Level 5, *NO SUPPORT* ranking for treating ADHD compared to a Level 1, *HIGHEST SUPPORT* ranking for NFB; yet Drs. Lofthouse and Arnold assert that CBT is an evidence-based treatment for ADHD (Lofthouse et al., 2011), a baseless assertion with no research support, while their reviews deny this designation for neurofeedback and thereby display their profound evidentiary bias in how they evaluate treatments.

THE NEED FOR CLINICIAN ACTION TO END INSURANCE REIMBURSEMENT BIAS

Although NFB's science is compelling, particularly when evaluated even-handedly according to the same evidentiary standards as other learning-based treatments, it will take clinician action to end the insurance reimbursement bias against it in America. Starting in 2011, ISNR's board sponsored the development of a clinician toolkit to support such an effort by the first and fourth authors. The toolkit includes letter templates for both in and out-of-network NFB clinicians, and those they treat, to use in appealing the denial of coverage for neurofeedback. These letter templates incorporate key provisions of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (''the Parity Act''). For example, the Parity Act prohibits insurers from applying a higher level of scientific evidence to mental health and substance abuse treatments than those applied to commonly reimbursed medical procedures. In this regard, an analysis of 2,711 practice recommendations in cardiology found that only 11% were based on evidence from more than one randomized controlled trial, whereas 48% were based simply on expert opinion, case studies, or standards-of-care (Pierluigi, Allen, Kramer, Califf, & Smith, 2009). Similarly, a 2011 analysis of the levels of evidence behind the Infectious Diseases Society of America's practice guidelines found that only 14% were based on evidence supported by randomized controlled trials, whereas more than half (55%) were supported only by expert opinion (Lee & Vielemeyer, 2011). As made clear in the appeal letter templates (and documented in our ISNR review), neurofeedback has far more evidentiary support than most commonly reimbursed medical procedures. These letter templates also incorporate aspects of the Parity Act's regulatory procedures designed to ensure compliance by insurers. The Parity Implementation Coalition (PIC; a coalition of 13 national Mental Health and Substance Use Disorder provider and consumer advocacy groups) has been working to improve the enforcement of the parity law and has advocated for a Final Regulation that will close some loopholes in the current Interim Final Regulation, which was issued in 2010. In January 2013, the Obama administration announced that it would promulgate a final rule in a few months. PIC has found that providers and consumers who appealed denial decisions by referencing the parity law have won numerous appeals based on the Interim Final Regulation and parity statute. PIC expects that with the issuance of the final rule, enforcement will improve further. The ISNR-commissioned evidence review should be a major asset in proving that insurance companies that label NFB as experimental are applying a more restrictive standard to this effective treatment as compared to many of their commonly reimbursed medical and surgical treatments.

The Affordable Care Act (ACA) provides an additional avenue to secure reimbursement for NFB in that it mandates the right of external

review if the insurer denies coverage after internal appeal. This right provides additional leverage in securing NFB coverage because ACA mandates that insurers must pay for these independent external reviews (which are not cheap) regardless of the external review's decision. By making clear how the medical necessity criteria are not being applied even-handedly, combined with the MTA, PATS, and Australian studies' documentation of the poor long-term outcomes from the currently reimbursed ADHD treatments, the toolkit's letters should significantly increase the likelihood of having coverage denials overturned when externally reviewed, thereby making insurers pay twice for their bias, and ultimately change their discriminatory reimbursement policies, which harm ADHD children by paying only for inferior care.

CONCLUSION

In reviewing pharmacotherapy's current status, psychiatrist and National Institute of Mental Health (NIMH) director Dr. Thomas Insel (2009) noted that repeatedly in NIMH-funded comparative effectiveness studies, second-generation antidepressants, mood stabilizers, and antipsychotics have been found to be no better than their first-generation cousins from the 1950s and 60s; and despite the dramatic increased use of these second-generation drugs, he stated there is ''no evidence that the morbidity or mortality of mental disorders has dropped substantially in the past decades'' (p. 704). In a moment of clarity, Dr. Insel then went on to state, ''The unfortunate reality is that current medications help too few people to get better and very few people to get well'' (p. 704).

Although Dr. Insel's acknowledgment of the 50-plus-year failure to improve outcomes from psychotropic treatment was largely based on the numerous studies finding no difference in outcomes from first and second-generation medications (other than differences in side effect profiles); this same conclusion clearly applies to ADHD ones as well. Given Dr. Insel's comments (which reflect the views of many in the research and clinical community of the significant limitations resulting from relying exclusively on psychopharmacological treatments), it was surprising to read NIMH's conclusions drawn from the recently published PATS study that they funded. The press release noted that after 6 years there was high symptom severity and impairment for these children, with 89% still meeting the diagnostic criteria for ADHD regardless of whether they were ''on or off'' medication during follow-up (and remember, each preschooler's parents had also received extensive parent training at the study's outset). Despite the clear implications from these findings, and those from the MTA Cooperative study, for the need to dedicate research dollars into investigating alternatives to ADHD medications, the press release's What's Next section states, ''In an effort to improve outcomes for these children, *more research is needed on the effects of ADHD medications on preschoolers over the long term, as well as the effects of combining different medications* [emphasis added]'' (NIMH, 2013).

Although we support the search for more effective treatments for ADHD, including pharmacological ones, we do not understand why NIMH does not allocate more funds to support research-based alternative interventions for this debilitating illness. With almost 40 years of research establishing NFB's effectiveness, we don't understand the reluctance of U.S. research agencies to not fund comparative research evaluating NFB's effectiveness relative to the established treatments of stimulants and behavior therapy. In this regards, Duric, Assmus, Gundersen, and Elegen (2012) recently published a large randomized controlled trial comparing NFB to stimulant medication and combined NFB/medication. This Norwegian study found that NFB was as effective as the other two treatments in reducing ADHD's core symptoms. Furthermore, although not reaching statistical significance, the researchers found that standalone NFB treatment averaged more than twice the improvement in parental ratings of attention than the other two treatments, and NFB's effect size was larger than them both on the Inattention and Hyperactivity subscales as well as the ADHD total score measure. The

contrast between the MTA study's findings and those from Duric et al. are telling. Whereas in the MTA study, 14 months of intensive multicomponent BT combined with SMM failed to provide any additional benefit over medication alone in reducing ADHD's core symptoms; in the Duric study, stimulant medication combined with NFB failed to provide any additional benefit in reducing ADHD's core symptoms over a mere 30 sessions of NFB as a stand-alone treatment.

It is a testimony to NFB researchers worldwide that they have accomplished this level and scope of research with no U.S. taxpayer funding other than the recent small feasibility study in which *none* of the nine study authors had any prior NFB expertise as evidenced in their biographies at the end of the article (Arnold et al., 2012). We doubt that NIMH has ever before funded researchers with no expertise in the treatment that they were investigating (and this was certainly not the case in the MTA and PATS studies). This lack of expertise resulted in the Ohio State University researchers using auto-thresholding software for conducting NFB, a method that is rejected by NFB's leading scientists because it violates the most basic principles of operant conditioning on which NFB is based. NFB is the only treatment that combines the real-time measurement of brain functioning, with the scientifically established principles of operant conditioning, to treat the underlying neuronal dysregulation that is commonly found in those diagnosed with ADHD, and it therefore warrants NIMH funding to enhance further NFB's efficiency and effectiveness.

Almost 40 years after the seminal reversal design studies by Drs. Lubar and Shouse demonstrated that neurofeedback was the ''mechanism of change'' resulting in the clear reduction of ADHD's core symptoms, NIMH, NFB's critics, and healthcare insurers still classify it as an ''experimental'' treatment while clinging to their preferred ones that have repeatedly been found not to result in sustained benefit for those who have ADHD. ADHD children and their families cannot wait any longer. It will take concerted action by NFB clinicians and those they treat, using the provisions of the Parity Act and ACA, to end the evidentiary and reimbursement bias against NFB, and thereby facilitate its widespread adoption as an effective treatment for ADHD. To aide this effort, ISNR's board has posted on its website our evidence-based review and the letter templates to use in appealing insurers' denial of coverage for neurofeedback.

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