

Case #6099 (07/18/17)

Neurocore, LLC

Neurocore Brain Performance Centers

Challenger: *National Advertising Division*

Product Type: *Drugs/Health/Health Aids*

Issues: *Express Claims*

Disposition: *Modified-Discontinued*

- **Health-related efficacy claims should be supported by competent and reliable scientific evidence.**

Basis of Inquiry: As part of its ongoing monitoring program, NAD reviewed certain advertising claims made by Neurocore, LLC (“Neurocore” or the advertiser) for its Neurocore Brain Performance Centers. The following are representative of the type of claims that served as the basis for this inquiry:

Express Claims:

ADHD:

81% of children who come to us on ADHD meds and complete our program are able to reduce or eliminate their use of medications upon program completion

76% achieve non-clinical status; 90% report improvement

Anxiety:

Control your anxiety without medication

78% achieve non-clinical status; 90% report improvement

Autism:

25% reduction in reported symptoms on the autism evaluation checklists

Depression:

Strengthen your brain to fight depression without medication.

73% achieve non-clinical status; 91% report improvement

Memory:

You’ll experience improved memory, as well as better sleep, focus, mood, mental clarity and overall cognitive performance.

Migraines:

A natural remedy for migraines.

Sleep:

Sleep soundly without medication.

Testimonials:

The advertiser uses testimonials which make claims that need substantiation if made directly by the advertiser.

Advertiser's Position:

Neurocore explained that its Brain Performance Centers administer neurofeedback, a form of neurotherapy that measures the electric activity in the brain with frequency bands mapped from the brain to a computer. This mapping allows the computer to monitor and manipulate the activity of the brain in order to teach the brain to regulate certain functions. According to the advertiser Neurofeedback works like physical therapy for the brain: it rehabilitates, regulates, and normalizes optimal brain functions by conditioning the brain to regulate itself.

Neurocore maintained that its advertising claims are supported by competent and reliable scientific evidence and that its use of testimonials on its website is consistent with Federal Trade Commission ("FTC") guidance on the use of testimonials in advertising. Neurocore explained that the science behind neurofeedback and neurotherapy dates as far back as the 1930 and has grown and evolved over time. Today, neurofeedback is used by many practitioners, is widely discussed in medical and scientific literature and the subject of vast research and study.

Neurocore was founded in 2004 and specializes in data-driven, brain-based assessments and drug-free treatment to help children and adults improve concentration, sleep better, and manage stress. It operates nine centers in the US, seven in Michigan and two in Florida. Neurocore uses quantitative electroencephalography ("QEEG") along with other evaluation tools, to map the electrical functions of the brain and identify specific brain wave functions to target using neurofeedback. Neurocore uses a combination of neurofeedback and biofeedback to train the brain to operate more efficiently.

I. Assessment

Neurocore explained that its service begins with an initial assessment of new clients. Clients complete a series of forms including (1) the Achenbach System of Empirically Based Assessment ("ASEBA") form, a collection of behavioral questionnaires to assess competencies, strengths, adaptive functioning and behavioral, emotional and social problems of individuals from 18 months to 90 years old, (2) the Pittsburgh Sleep Quality Index ("PSQI"); and (3) the Insomnia severity Index ("ISI"). Neurocore explained that the ASEBA renders numerical results as a "T Score" and those numerical results link to various mental health conditions recognized by the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, 5th Edition. The reliability of the ASEBA has been scientifically validated and is well-recognized as a mental health diagnostic tool.

A Neurocore employee then provides each client an overview of the initial assessment.

In addition, clients complete a series of biofeedback tests that provide readings on the client's heart rate, blood pressure, and breathing pattern. The client also takes the Integrated Visual and Auditory Continuous Performance Test ("IVA"), which is an EEG validated, computerized test that measures both visual and auditory impulsivity and inattention. Finally the client undergoes a nineteen-site QEEG reading. The data is compared to the Neuroguide Database, which contains the universe of QEEG results, to determine the "normalcy" range of the client's QEEG reading. The report compares the client's electrical footprint to the "normal" range and outlines specific brain waves to target for neurofeedback. Neurocore prepares an in-depth summary of its testing for its client to review with a Neurocore employee who is either a licensed mental health professional or social worker. The Neurocore employee then provides an overview of the potential results the client may experience as a result of the Neurocore program.

II. The Neurocore Program

The Neurocore program consists of thirty sessions of biofeedback and neurofeedback. The program begins with a meeting to go over the program including setting individualized goals. The goals are evaluated after ten, twenty and thirty sessions in meetings between the client and a Neurocore employee and changes to the training protocol may be recommended to ensure optimal results.

Each session begins by connecting the client to equipment which monitors breathing, as the biofeedback portion of Neurocore, requires deep breathing exercises to achieve optimal breathing. After three minutes of biofeedback, the client is connected to the neurofeedback sensors, placed on the ears and head, and then begins a 40 minute neurofeedback session. Both the neurofeedback and biofeedback use visual cues to train clients who watch a movie on a computer screen. When a client's breathing rhythm is out of the optimal range, the computer display shrinks, prompting an adjustment in breathing pattern until the computer display returns to normal. Similarly, neurofeedback monitors and measures the client's brainwave activity while the client views a movie. If the brainwaves function outside the normal limits, the movie will pause, giving both an audio and visual cue.

Neurocore maintained that by using these audio and visual cues, clients learn to optimize their brain activity to remain in the normal range. Over the course of thirty sessions, new brain connections and pathways are formed and strengthened. After each session, data for the EEG is recorded and logged. This information is used to determine the treatment parameters for subsequent sessions. After completing thirty sessions the client completes a full post assessment that is identical to the initial assessment. Data collected during the program is reviewed with the client and the client is given a detailed printout of progress.

Neurocore explained that it collects data on the results of clients who complete its 30-week program. To demonstrate the efficacy of its program when completed, it compiles and compares this internal data to determine the magnitude of change each client experiences as a result of the program. The advertiser contended that its advertising clearly and conspicuously discloses that its claims are based on assessments of its clients who complete 30 sessions.

Neurocore also submitted a report from its clinical biostatistician Kayleah Groeneveld. Ms. Groeneveld explained that the outcome percentages reported by Neurocore are based upon a review of the internal data (through October 2016) of the entire Neurocore population who began treatment with scores in the clinical range for ADHD, Anxiety, or Depression, based on the ASEBA scales. Her statistical report explained that this data is not inferential statistics but descriptive. Descriptive statistics describe or summarize data in a meaningful way but do not allow conclusions beyond the data analyzed. Ms. Groeneveld explained that the retrospective review of internal data from the Neurocore population reports these results but does not imply the results are part of a clinical trial. She argued that the public release of these results can be used to inform judgments about program quality, personnel or educational programs.

III. Evidence in Support of Neurocore's Advertising Claims

Neurocore contended that it has competent and reliable scientific evidence to support its claims. Specifically the claim that 81% of children who come to us on ADHD meds and complete our program are able to reduce or eliminate their use of medication upon program completion and "75% achieve non-clinical status; 90% report improvement" are supported by internal data collected by Neurocore and analyzed by its biostatistician.

Neurocore performed a study in collaboration with Priority Health Insurance Company in 2012 of 127 children covered by Priority Health insurance. 48 children began the program on medication prescribed to manage the symptoms of ADHD. Following completion of the program 39 of those 48 (81%) either eliminated or reduced their dosage of ADHD medication. Additionally, Neurocore performed a study in October, 2016 ("Neurocore 2016 Study") using data collected from clients who completed its 30-session program with a T-score of 70 or higher on the ASEBA index, a score considered "clinical," a total of 296 clients. Of those 296, 224 (76.7%) lowered their T-score below 70, and 265 (89.5%) lowered their T-Score by at least one point on the ASEBA index.

As for its claims related to anxiety, "Control your anxiety without medication" and "78% achieve non-clinical status; 90% report improvement," Neurocore asserted that these claims are supported by scientific literature and studies that have found neurofeedback effective in controlling the symptoms of anxiety. Additionally, Neurocore's internal data supports its quantified claim. Its clients were able to lower their ASEBA index anxiety scores by completing the 30-session program. The Neurocore 2016 Study found that of the 196 clients considered "clinical" with T-scores of 70 or higher on the ASEBA, 226 (90%) lowered their T-score by at least one point on the ASEBA index.

The autism claim, that neurofeedback results in a "25% reduction in reported symptoms on the autism Treat Evaluation Checklists" comes from findings of three independent scientific studies. The authors of these three different studies found positive results in connection with neurofeedback as a treatment for autism spectrum disorder ("ASD") symptoms. One study demonstrated a 26% reduction in reported symptoms on the Autism Treatment Evaluation Checklists after neurofeedback treatments. A second study found that ASD patients who

received neurofeedback treatment improved executive functions. The third study noted that parents of children with ASD reported improved communication and social skills following neurofeedback treatment. Neurocore noted that its website also discloses that there is no cure for ASD.

Neurocore asserted that its claim that it can “Strengthen your brain to fight depression – without medication” and “73% achieve non-clinical; 91% report improvement” is supported by a combination of scientific literature regarding the effectiveness of neurofeedback and biofeedback in combatting the symptoms of depression as well as the Neurocore 2016 Study. Neurocore explained that studies on depression demonstrate that a combination of neurofeedback and biofeedback, through breathing training and heart regulations, have had positive impacts on depression symptoms. Additionally, the Neurocore 2016 Study found that among clients who completed the program and were considered “clinical” due to the severity of their depression symptoms, 71.6% (266 of 292) made a significant improvement so that their T-scores were below clinical levels on the ASEBA index.

Neurocore explained that the claims related to memory loss, migraines and sleep disorders, “you’ll experience improved memory, as well as better sleep, focus, mood, mental clarity and overall cognitive performance,” “a natural remedy for migraines,” and “sleep soundly without medication,” are supported by scientific literature and studies on the effectiveness of neurofeedback and biofeedback in combatting the symptoms of memory loss, migraines and sleep disorders. Additionally, the Neurocore 2016 Study demonstrates that its clients experienced fewer occurrences of memory loss, migraines and/or sleep disorder following completion of the program.

Neurocore maintained that it provided numerous studies in support of its claims, including the Neurocore 2016 Study, the 2012 Neurocore Study, performed in conjunction with Priority Healthcare, as well as many published studies on neurofeedback, meta-analyses of the studies on neurofeedback, and scientific literature related to neurofeedback.

In addition, Neurocore relied upon the expert reports of Dr. Robert. Thatcher, Founder, president and CEO of Applied Neuroscience, which creates the leading software that reads and measures brainwaves used in neurofeedback including the neurofeedback program used by Neurocore. Dr. Thatcher’s first expert report concludes that neurofeedback is grounded in science that is well-accepted by the scientific community and that Neurocore follows the best industry standards for neurofeedback. Dr. Thatcher maintained that neurofeedback leads to changes in the brain that lead to the reduction in symptoms of various conditions. Dr. Thatcher explains that compelling and legitimate scientific evidence, including a 2016 randomized controlled trial on ADHD symptoms, exists to show that neurofeedback can help people address the symptoms of numerous conditions including ADHD, anxiety, depression, memory loss and insomnia, and benefits consumers.

The Neurocore 2016 Study showed that children who underwent neurofeedback therapy for ADHD experienced improvements in ADHD rating scales. The behavioral changes were paralleled by physiological changes in their EEG readings in a similar manner and magnitude to

a comparison group of children taking ADHD medication. Within the neurofeedback group, greater reductions in EEG theta activity were associated with greater improvements in ADHD symptoms.

Dr. Thatcher also directed NAD's attention to several studies, including randomized controlled clinical trials, which assess neurofeedback's impact on ADHD, anxiety, depression memory loss and insomnia. The clinical trials show neurofeedback results in improvements in all of these conditions. Dr. Thatch argued that neurofeedback evidence has been admitted as evidence in court, and met the court's high standards for admissibility and is trusted and used by the United States Army, as well as many institutes of higher education, and is reimbursable by some insurance companies.

III. Testimonials

Neurocore explained that its consumer testimonials reflect the honest beliefs of its clients. Each client is asked to complete a survey regarding their experience at Neurocore and informed that Neurocore regularly uses client endorsements in its marketing campaigns. Neurocore also maintained that the testimonials it uses in its advertising discuss results which are typical of what the average consumer can expect to experience after completing the Neurocore program.

Decision:

This matter concerns advertising claims made by Neurocore, LLC for its Neurocore Brain Training Centers which it claims relieves symptoms of difficult to treat conditions like ADHD, anxiety, depression and autism spectrum disorder. The advertiser provided evidence in support of its claims including studies of its own internal data, as well as articles, clinical studies, and meta-analysis on the use of neurofeedback in treating these conditions. The volumes of research on neurofeedback demonstrate that there is continued debate about the effectiveness of neurofeedback in treating conditions like ADHD, anxiety, depression, autism spectrum disorder, migraines, memory and sleep disorders. It is not NAD's purview to review whether neurofeedback is a validated, scientifically proven method for treating ADHD or any other condition. NAD's review is limited to whether the evidence provided is a good fit for the advertising claims made here. NAD will review, the messages reasonably conveyed by Neurocore's advertising, the evidence provided in support of these claims and determine whether there is good fit between the two.

I. Neurocore's Advertising

Neurocore's website includes a tab labeled, "Who We Help" with a menu allowing users to click on ADHD, Adult ADHD, Anxiety, Autism, Depression, Memory, Migraines, Sleep, Stress and Teen ADHD. Clicking on any of these conditions, will lead to a page with strong health-related claims about what the Neurocore program can do. For example, Neurocore claims:

“Overcome ADHD – without drugs;”
“How to Overcome Adult ADHD Drug-free (and Improve Your Daily Life in the Process);”
“Control your anxiety without medication;”
“Drug-free program to help curb the symptoms associated with Autism;”
“Strengthen your brain to fight depression – without medication;”
“Stay sharp for years to come;” “Don’t miss out on life’s precious moments,” and
“Stop migraines before they start.”

These are strong health-related advertising claims promising that the Neurocore program can treat these challenging conditions and reduce or eliminate the need for medication.

For the conditions ADHD, anxiety, and depression, Neurocore makes quantified claims about its outcomes for these conditions, (e.g. “our ADHD outcomes”). These claims are based on results from Neurocore’s internal data analysis, the Neurocore 2016 Study, discussed below, which tracks the before and after results of Neurocore clients who complete their 30-session program. For example, the ADHD outcomes are listed as:

90% report fewer or less frequent ADHD symptoms
85% experience a “clinically important” reduction of ADHD symptoms
76% achieve non-clinical status
54% no longer meet symptomatic thresholds for ADHD

NAD determined that consumers viewing advertising which makes claims based on Neurocore’s program results could reasonably take away the message that they are likely to experience the same results if they complete the Neurocore program. These strong health-related claims that all or nearly all of its clients see significant differences in symptoms of ADHD, anxiety or depression reasonably convey the message that each new client is just as likely to experience the same results after completing 30 sessions of the Neurocore Program.

II. Advertising Claim Support

Health-related efficacy claims, like the claims Neurocore makes that its 30 session program relieves symptoms of ADHD, Anxiety, Depression, Autism, and improves migraines, memory and sleep disorders, must be supported by competent and reliable scientific evidence. Generally, for health-related claims, competent and reliable scientific evidence are human clinical trials that are methodologically sound and statistically significant to the 95% confidence level with results that translate into meaningful benefits for consumers that relate directly to the performance attributes promised by advertising.¹ In evaluating whether this evidence constitutes competent and reliable scientific evidence to provide a reasonable basis for this claim, it is relevant to consider the claim, the consequences of a false claim, the benefits of a truthful claim, the cost of

¹ POM Wonderful v. FTC, (DC Circuit Court of Appeals 2015) at https://www.ftc.gov/system/files/documents/cases/pom_dc_circuit1_0.pdf; InterHealth Nutraceuticals, Inc. (Zychrome), Report #5569, *NAD/CARU Case Reports* (April 2013).

developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable.²

The advertiser provided its internal client data analysis (“Neurocore 2016 Study”) as well as third party scientific evidence, including published clinical trials, on neurofeedback’s use in treating symptoms of ADHD, anxiety, depression, autism, as well as improving memory, sleep and migraines.

A. Neurocore’s Internal Data Analysis

As support for its claims that the Neurocore Program is effective in treating ADHD, Anxiety and Depression the advertiser submitted its internal data analysis, the Neurocore 2016 Study, which evaluates the results of every Neurocore client. The study uses Neurocore’s internal client assessments before they begin treatment and compares them with their internal assessments after 30 treatments. The assessments are based upon each clients’ completion of a series of forms including the ASEBA, the Pittsburgh Sleep Quality Index and the Insomnia Severity Index and an initial QEEG reading both before beginning the Neurofeedback program and after 30 treatments. The ASEBA is a diagnostic tool for mental health disorders and gives scaled “T scores” which, when they fall within a certain range, are consistent with specific mental health disorders like ADHD, anxiety and depression. Additionally, the initial QEEG reading is compared to a universe of QEEG readings to determine a “normalcy” range. Before beginning treatment, clients meet with a Neurocore employee, a social worker or licensed mental health professional, who summarizes Neurocore’s initial assessment. The Neurocore employee also explains what results the client can expect after undergoing Neurocore’s program.³

The advertiser contended that its use of internal efficacy outcomes is sound. It is based on pre and post assessment data of those who complete 30 sessions, using reliable, validated and credible assessment tools, the ASEBA, and used statistical protocols to determine outcomes. Further it argued that collecting and analyzing internal data is an important accountability system, widely accepted in institutions which are publicly funded.

NAD was concerned, however, that studies analyzing internal assessment data, while important for internal or external accountability, does not provide competent and reliable scientific evidence in support of health-related advertising claims, particularly the strong claims the advertiser makes here. Neurocore advertises its ADHD, anxiety, and depression outcomes, based on clients who completed 30 sessions, making claims that nearly all clients report fewer symptoms, most experience a ‘clinically important’ reduction in symptoms and achieve non-

² *Pfizer, Inc.*, 81 F.T.C. 23 (1972); *see also* FTC Policy Statement Regarding Advertising Substantiation. The level of evidence required to support an advertising claim is driven by the messages reasonably conveyed by the claim. UltraBotanical, LLC (UltraCur Dietary Supplements), Report #6052, *NAD/CARU Case Reports* (February 2017). ³ Neurocore also submitted its 2012 Study which it performed in collaboration with Priority Health Insurance Company of 127 children with ADHD who completed the Neurocore program that were covered by Priority Health insurance. The analysis regarding the Neurocore 2016 Study applies equally to the 2012 Study which was also based on internal assessment data from Neurocore’s clients based on self-assessment data or parent assessment data.

clinical status and that more than half no longer meet symptomatic thresholds for these conditions, which are all based on internal assessment data.

As Neurocore's own statistical expert report explains, there is a difference between clinical studies and observational studies like the 2016 Study on Neurocore's population. A randomized controlled trial can be used to make inferences from the sample tested on to a broader population. Observational studies, like Neurocore's review of internal data, provide information on the treatment of a particular group of people. Nonetheless, they do not provide a basis for inferring or projecting how another population will respond to the same treatment. As Neurocore's statistician explained, "descriptive statistics do not, however, allow us to make conclusions beyond the data analysed."⁴

Consumers rely on advertising to make decisions about what a product or service does and whether it is worthy of their time and resources – here whether the Neurocore program will be effective for them or their children in treating ADHD, anxiety and depression. Data that is not reliable for projecting how another population will respond to the treatment is not reliable as support for advertising claims. As Neurocore's expert statistician acknowledges, its observational data is not reliable for projecting the same results on a different population.

Further, the Neurocore 2016 Study bases its results on their client's own assessment data. The clients are told what improvements they can expect from the Neurocore program after they complete their initial assessment forms. During the course of the program, progress is reviewed with the clients at specified intervals, and changes in QEEG results are reviewed. Once the program is completed each client completes the same assessment again, which is the basis for measuring improvement. Providing information about what a specific treatment is likely to do before treatment begins is likely to bias results. Additionally, the clients who choose to begin the Neurocore program and complete all thirty sessions are not representative of the general population. Using only Neurocore's clients, who have made a decision to invest their time and substantial financial resources in the thirty session program, is likely to bias results in favor of Neurocore. As NAD has noted in prior cases, a study which introduces a bias by telling participants how a product should perform, as well as testing a population that was predisposed to believe in the efficacy of the product, is not reliable support for advertising claims.⁵ For the all of the foregoing reasons, NAD concluded that the Neurocore 2016 Study, as well as the Neurocore 2012 Study, did not provide reliable support for Neurocore's advertising claims.

B. Clinical Studies

In addition to its internal studies on the Neurocore program, the advertiser submitted multiple studies and articles on neurofeedback and its use in treating symptoms of ADHD, anxiety, depression, autism, as well its effect in improving memory, sleep and migraines. The most

⁴ Supplemental Internal Statistical Expert Report at 3 *quoting* Statistics.Laerd.com.

⁵ Prestige Brands, Inc. (Monistat Stay Fresh Gel), Report #5955 *NAD/CARU Case Reports* (May 2016) ("NAD was concerned that both the bias introduced by telling participants how the product should perform before use, as well as using a survey population that included only participants who found the marketing materials persuasive, undermined the reliability of this survey when used to support product efficacy claims. ")

reliable form of evidence to support health-related advertising claims is randomized controlled trials which compare results from using the product at issue (here a thirty session Neurofeedback and biofeedback program) to a control so that the results from the neurofeedback can be distinguished from a placebo. A placebo control is particularly important for evaluating the effectiveness of neurofeedback because the placebo effect may be heightened when each person sees a clinician, uses expensive, technologically advanced equipment and is exposed to numerous training sessions.⁶ Further, it is always important that the tested treatment – whether it is a dietary supplement, a medical device or a multi-faceted brain training program – be the same or sufficiently similar to the one for which the advertising claims are made.⁷ As the FTC has cautioned, “claims that do not match the science, no matter how sound that science is, are likely to be unsubstantiated.”⁸

The research submitted by Neurocore uses a variety of different neurofeedback protocols, while Neurocore uses a specific type of neurofeedback, “Z Score” neurofeedback which has only been used in more recent studies.⁹ Prior to the use of Z Score neurofeedback, neurofeedback related to either alpha and theta rhythms, with different protocols for providing neurofeedback signals to study participants. The advertiser’s expert report explains the mechanism of action of Z-Score neurofeedback and explains why it is an improvement over prior methods, but an expert opinion cannot substitute for randomized controlled trials on the new method itself.¹⁰ While there are some randomized-controlled trials on Z-Score neurofeedback, there appear to be different methodologies associated with Z-Score neurofeedback.¹¹ Additionally, the few studies on Z-Score neurofeedback are small, scale, pilot studies or not well-controlled.¹²

⁶ Sitaram, R., et al., *Closed-Loop Brain Training: The Science of Neurofeedback* 18 *Nature Reviews* 86 (February 2017).

⁷ See e.g., Novartis Consumer Health, Inc. (Benefiber), Report #5873, *NAD/CARU Case Reports* (August 2015); *aff’d* NARB Panel #206 (December 2015)(the advertisers claim was not substantiated when there was no testing on the correct fiber, in the correct dosage, on the relevant population demonstrating statistically significant results.)

⁸ *Dietary Supplements: An Advertising Guide for Industry*, Federal Trade Commission (April 2001), available at <http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry> at p. 16.

⁹ Although the advertiser provided a list of articles and studies regarding Z-Score neurofeedback, it did not provide NAD with copies of each of the articles and studies on Z-Score neurofeedback. Further, the articles and studies listed in the expert report make clear that the research on Z-score neurofeedback does not include controlled trials on robust study populations. While a few studies appear to be clinical trials, they appear to be case studies or pilot studies which also cannot serve as competent and reliable scientific evidence to support health-related advertising claims.

¹⁰ See Good Health Naturally, Report #5441, *NAD/CARU Case Reports* (March 2012) citing <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm073200.htm>; <http://www.ftc.gov/bcp/menus/resources/guidance/adv.shtm>. (An abstract or informal summary of an article is less reliable, because such documents usually do not give the reader enough insight into how the research was conducted or how the data were analyzed to objectively evaluate the quality of the research data and the conclusions drawn by the authors. Moreover, the mere fact that the study was published does not necessarily mean that the research is competent and reliable evidence adequate to substantiate a particular claim.)

¹¹ See e.g., Stokes, D.A., *Neurofeedback and biofeedback with 37 migraineurs: a clinical outcome study* 6:9 *Behavioral and Brain Functions* 1 (2010).

¹² In the Advertiser’s Supplemental response to NAD it included an expert report from Dr. Robert Thatcher which cites studies on Z Score Neurofeedback. Although the advertiser did not provide NAD with the studies themselves, and, as a result, NAD could not rely on the studies, the citations include only a few clinical trials some of which are labeled as “pilot” studies; see also Hammer, B., et al., *Neurofeedback for Insomnia: A Pilot Study of Z-Score SMR*

In addition, to NAD's concern that the specific type of neurofeedback used in the Neurocore program has not been subject to robust clinical trials, to the extent there is clinical testing regarding the effectiveness of neurofeedback on a variety conditions including ADHD, the results are mixed. A February 2017 article evaluating how neurofeedback is being used in both clinical and experimental settings notes that while there are randomized controlled trials regarding improvements in ADHD symptoms, meta-analyses of these studies have yielded inconsistent findings.¹³ It noted that "ADHD is one of the most well-investigated clinical neurofeedback applications, however, we still lack definitive evidence of efficacy for neurofeedback mediated treatment of this condition."¹⁴ As the FTC notes, "wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions about the adequacy of an advertiser's substantiation."¹⁵ Inconsistent evidence regarding a claimed effect may affect the strength of the claim, or whether a claim can be made at all. Evidence on the efficacy of neurofeedback on all of these conditions is mixed. As a result, NAD had substantial concerns about whether this body of research supports the strong, health-related claims made for Neurocore.

1. ADHD

Neurocore claims, "Overcome ADHD – without drugs" which is followed by claims about "Our ADHD Outcomes" which make the quantified claims that 90% report fewer or less frequent ADHD symptoms," "85% experience a 'clinically important' reduction in ADHD symptoms," "76% achieve non-clinical status," and "54% no longer meet symptomatic thresholds for ADHD." To support these strong, quantified efficacy claims, the advertiser relies on results from several randomized controlled trials.

The Gevensleben Study evaluated 102 children with ADHD before and after 36 sessions of neurofeedback with a control group who completed computerized attention skills training. After treatment, both parent and teacher ratings of the children who completed neurofeedback were superior to the control group. The study found that about 52% of the neurofeedback group responded to training, but that there was a high percentage of non-responders.¹⁶ Further, in the follow up to the Gevensleben Study, a high percentage of the participants, 18% of the neurofeedback group and 17.1% of the control group, started medication during the follow up

and Individualized Protocols 36 Appl. Psychophysiol Biofeedback 251-264 (2011)(Eight participants completed the randomized, parallel group, single blind study).

¹³ One found that neurofeedback was efficacious while the other found that neurofeedback was ineffective when assessed with blinded measures, while another concluded that it was more effective than active control conditions. See Sitaram, R., et al., *Closed-Loop Brain Training: The Science of Neurofeedback* 18 Nature Reviews 86 (February 2017).

¹⁴ Sitaram, R., et al., *Closed-Loop Brain Training: The Science of Neurofeedback* 18 Nature Reviews 86 (February 2017).

¹⁵ <https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf>

¹⁶ Gevensleben, H., *Neurofeedback training in children with ADHD: A randomized controlled clinical trial*, 50/7 J. Child Psychology and Psychiatry 780 (2009).

interval, before being evaluated at 6-months post-treatment, although the study concluded that the behavioral effects were maintained overall.¹⁷

The Janssen Study evaluated 112 children with a diagnosis of ADHD before and after thirty sessions of neurofeedback and compared their results to control groups who completed physical activity and another control group on stimulant medication.¹⁸ The Janssen Study primarily evaluated EEG changes in the neurofeedback group but noted that, for the behavioral assessments pre and post treatment, teachers did not notice a change in behavior while parents reported only small behavioral improvements (though not more than the control group that participated in physical activity.) The Meisel study evaluated 23 children with ADHD after 40 neurofeedback sessions and compared their results to a control group on stimulant medication.¹⁹ This study observed differences in reported ADHD symptom improvement depending on who was evaluating improvement. Immediately post-treatment, mothers observed improvements in ADHD symptoms which were statistically significant, whereas fathers and teachers reported no statistically significant improvements. (Improvements in some other measures were observed.) Further, by the second follow up, 8 of the 12 children in the neurofeedback group had begun stimulant medication.

These results of these studies demonstrate that on some measures, some reported improvement, but the inconsistency in the results calls into question whether the results can support the strong efficacy claims made by Neurocore. These study results are not consistent with the claims that 90% of Neurocore's clients report fewer ADHD symptoms or that the Neurocore Program allows consumers to "Overcome ADHD -- without drugs."

2. Anxiety and Depression

With respect to the effect of neurofeedback on symptoms of anxiety and depression, the body of evidence on neurofeedback is smaller. Neurocore relied upon several, small-scale trials of neurofeedback which were not well-controlled.²⁰ Although one small scale study on anxiety and neurofeedback had a control group, it was not blinded.²¹ Some of the studies cited by Neurocore for the effectiveness of neurofeedback on anxiety and depression actually study the effect of

¹⁷ Gevensleben, H., *Neurofeedback training in children with ADHD: 6-month follow-up of a randomized controlled trial* 19 Early Child. Adolesc. Psychiatry 715 (2010) (Of the neurofeedback group who had been classified as responders, almost half (5 out of 11) began medication during the follow up period. Of those who did not begin medication during the follow up interval, 50% showed a reduction in the primary outcome measures.)

¹⁸ Janssen, T., et al., *A randomized controlled trial into the effects of neurofeedback, methylphenidate, and physical activity on EEG power spectra in children with ADHD* 57-5 J. of Child Psychology and Psychiatry 633 (2016)

¹⁹ Meisel, V., *Neurofeedback and standard pharmacological intervention in ADHD: A randomized controlled trial with six-month follow-up.* 94 Biological Psychology 12 (2013).

²⁰ Dreiss, S.M., et al. *Using Neurofeedback to Lower Anxiety Symptoms Using Individualized qEEG Protocols: A Pilot Study*, 2(3) NeuroRegulation 137-48 (2015)(14 subjects without a control group); Walker, J., *QEEG-Guided Neurofeedback for Anger/Anger Control Disorder*, 37(2) Biofeedback 67-70 (2013)(19 subjects with a 4 person control group which included only patient who declined neurofeedback training.)

²¹ Linden, D.E.J., *Real-Time Self-Regulation of Emotion Networks in Patients with Depression*, 7(6) PLoS ONE e38115 (2012)(Study authors noted that the study of 16 subjects was for proof of concept, not to demonstrate clinical effectiveness that that "further formal tested in randomized trials with blinded assessments is needed in order to assess the clinical efficacy.")

neurofeedback on different conditions, including Obsessive-Compulsive Disorder,²² anxiety associated with Post-Traumatic Stress Disorder,²³ and anger/anger control disorder.²⁴ These studies are not sufficiently reliable to support the strong, quantified health-related claims that the Neurocore program can control anxiety or depression without medication and that a high percentage of clients who complete the Neurocore program will see an improvement in their anxiety (90%) or depression (91%) and that many will achieve non-clinical status (anxiety 78% depression 73%).

3. Autism

The advertiser submitted articles and studies related to using neurofeedback to treat symptoms of autism. An article Neurocore submitted which reviewed both published and unpublished studies on neurofeedback and Autism Spectrum Disorder reached the conclusion that the research supports a determination that neurofeedback is “possibly efficacious.”²⁵ Neurocore makes the claim that neurofeedback results in a “25% reduction in reported symptoms on the autism evaluation checklists.” This claim is based upon the Jarusiewicz Study which found that after neurofeedback, study subjects demonstrated a 26% reduction in reported symptoms on the Autism Treatment Evaluation Checklists.²⁶ This was a small scale, unblinded study, with only 12 children in the neurofeedback group completing the study. Eight children dropped out before completing the minimum number of 20 sessions of neurofeedback. Further, the outcomes were based on upon parent reports of improvement, without any objective measures.

In addition, the advertiser cites two other studies, the Kouijzer Study and the Pineda Study.²⁷ Neither study provides support for the specific claim made here that neurofeedback results in a 25% reduction in reported symptoms. (Both did note improvement in some symptoms associated with Autism Spectrum Disorder.) Both studies, however, were very small scale. The Kouijzer Study had only 14 total participants, it was not randomized or blinded, and improvement was evaluated only by parents of the children in the study. The study authors noted that the neurofeedback training can influence the results parents’ perceive, as they get “advice, encouragement, support and compliments” from the neurofeedback trainers which “raise expectations of improvement.” The Pineda Study was also an unblinded study on a small population with assessments of behavioral improvements by parents, which the study authors also recognized could influence results. It lacked a real control, in that it used typically

²² Koprivova, J. *Prediction of Treatment Response and the Effect of Independent Component Neurofeedback in Obsessive-Compulsive Disorder: A Randomized Sham-Controlled, Double-Blind Study*, 67 *Neuropsychobiology* 210-223 (2013).

²³ Walker, J., *Anxiety Associated with Post-Traumatic Stress Disorder – The Role of Quantitative Electroencephalograph in Diagnosis and in Guiding Neurofeedback Training to Remediate Anxiety*, 37(2) *Biofeedback* 67-70 (2009).

²⁴ Walker, J., *QEEG-Guided Neurofeedback for Anger/Anger Control Disorder*, 17(1) *J. of Neurotherapy* 88-92 (2013)(This study lacked a control and the number of sessions of neurofeedback varied by participant.

²⁵ Cohen, R., *Neurofeedback for Autism Spectrum Disorder: A Review of the Literature*, 10:1007 *Appl. Psychophysiol. Biofeedback* 10484-009 (2010).

²⁶ Jarusiewicz, B., *Efficacy of Neurofeedback for Children in the Autistic Spectrum: A Pilot Study*, 6:4 *Journal of Neurotherapy: Investigations in Neuromodulation, Neurofeedback and Applied Neuroscience* 39(2002).

²⁷ Pineda, J. *Neurofeedback training produces normalization in behavioral and electrophysiological measures of high-functioning autism*, *Phil. Trans. R. Soci. B* 369:20130183 (2014).

developing children as a control. These small scale, unblinded studies, which lack strong controls are insufficient to support the strong, quantified claims Neurocore makes here related to autism.

4. Memory, Migraines and Sleep

Neurocore claims that its clients will “experience improved memory, as well as better sleep, focus, mood, mental clarity and overall cognitive performance,” that Neurocore is a “natural remedy for migraines” and will allow its clients to “Sleep soundly without medication,”

With respect to the memory claims, NAD had a number of concerns with the studies presented. First, Neurocore’s advertising targets consumers with age-related memory loss. It introduces its performance claims by stating, “With every passing year, it can be difficult not to fret about future memory loss . . . we now know it is possible to grow your brain and address the effects of aging in a few month’s time.” To the extent that Neurocore targets its advertising to consumers concerned about age-related memory loss, it should provide testing on subjects with age-related memory loss. Both the NARB and NAD have routinely recognized that studies must be tested on the relevant population to reliably support advertising claims to that population.²⁸

The three studies Neurocore cites do not assess age-related memory loss. One tested memory in healthy subjects with an average age of 23.²⁹ The other tested memory improvement in subjects with traumatic brain injury and specific learning disabilities which were compared to a control group of healthy adults without memory issues.³⁰ The third study tested elderly subjects with

²⁸ See e.g., Intracuticals, Inc. (Aroxelne Skin Care Products), Report #5953, *NAD/CARU Case Reports* (May 2016)(without analysis of the representativeness of the population were insufficient to support strong efficacy claims); Nootrobox, Inc. (Nootropics), Report , *NAD/CARU Case Reports* (human clinical trial on dietary ingredient insufficient to support cognitive performance claims where the study population was not representative of targeted advertising); Chattem, Inc. (Nasacort Allergy 24 HR), NARB Panel # 207 (2016)(NARB Panel found “studies of subjects outside the advertisements’ target population do not provide strong evidence as to the preference of people within the target population; Den-Mat Corp. (Rembrandt Toothpaste), NARB Panel # 75/75 (1994) (study that evaluated specialized population insufficient for claim support because “at best, the results were significant for the population studied, but not for the general population covered by the claim made.”); see also FDA, Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act 2008), at <https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm>. Further, the FTC has further stated that “advertisers should not rely on research based on a specific test population for claims targeted at the general population without considering first whether it is scientifically sound to make such extrapolations.” FTC, *Dietary Supplements: An Advertising Guide for Industry*, Example 23.

²⁹ Guez, J., *Influence of electroencephalography neurofeedback training on episodic memory: A Randomized Sham-Controlled Double-Blind Study*, 23(5) *Memory* 683-94 (2014) (The study authors acknowledged that their results would not necessarily be the same for older adults, “Since the present study was conducted on young adults, further research must determine if the elderly, too, could benefit” from neurofeedback.)

³⁰ Thornton, K., *The Relation Between Memory Improvement and QEEG Changes in Three Clinical Groups as a Result of Neurofeedback*, 17(2) *J. of Neurotherapy: Investigations in Neuromodulation, Neurofeedback and Applied Neuroscience* 116-131(2013). NAD noted that this was not a clinical study but a retrospective review of past patients QEEG and cognitive performance data. Further, it evaluated a multi-faceted program which included neurofeedback as well as additional memory training activities. To the extent that Neurocore’s Memory Bootcamp, a supplement to its 30-session Neurocore program, is the same or similar to the multifaceted program studied, Neurocore’s advertising claims would have to make clear that it is advertising the Neurocore Memory Bootcamp.

mild cognitive impairment, not age-related memory loss.³¹ Mild cognitive impairment is a diagnosis recognizing cognitive changes that are greater than normal age-related memory loss.³² This study is an uncontrolled observational study on participants in a specific brain training protocol. Without controls, it is impossible to determine whether improvements were the result of the placebo effect or the brain training activities that included neurofeedback.

With regard to testing on sleep, the advertiser relies on three small scale studies on neurofeedback and sleep – one study had 17 participants,³³ another study had 8 participants,³⁴ and the third had 10 participants.³⁵ None of these small-scale trials was of sufficient size to provide reliable support for the claim that the Neurocore program will allow consumers to “sleep soundly without medication.” Each study has significant shortcomings in addition to the sample size, including lack of placebo controls. In order to support the strong health-related claim that Neurocore clients will “sleep soundly without medication,” the advertiser would need controlled testing, on a robust sample size demonstrating its program aids sleep as well or better than sleep medication.

The testing the advertiser submitted related to the impact of neurofeedback on migraines was also insufficient to support the advertiser’s strong health-related claims. While one study included a control group, the control group consisted of individuals without headaches.³⁶ Another study was an unblinded study without any control group.³⁷ The third study included a control group, but was not blinded and participants could either elect to opt in or out of the neurofeedback group.³⁸ These studies lacked sufficient controls to provide competent and reliable scientific evidence to support the advertiser’s strong claim that the Neurocore program will “Stop Migraines before they start.”

³¹ Fotuhi, M., *A Personalized 12-week “Brain Fitness Program” for Improving Cognitive Function and Increasing the Volume of Hippocampus in Elderly with Mild Cognitive Impairment*, 2 J. of Prevention of Alzheimer’s Disease 1 – 5 (2016)(This uncontrolled study also used a multi-pronged approach to memory loss including cognitive skills, training, meditation, and treatment for medical conditions.)

³² USPSTF, *Screening for Cognitive Impairment in Older Adults: An Evidence Update for the USPSTF*, (2013). MCI is cognitive decline as either self-reported, caregiver or clinician reported. It is an impairment on objective cognitive tasks and/or evidence of decline over time on objective tasks, but does not meet the clinical criteria for dementia. Bischoff, et al., *Mild Cognitive Impairment – a review of prevalence, incidence, and outcome according to current approaches*, 106 Acta Psychiatr. Scand 403 (2002) at <http://www.columbia.edu/cu/biology/faculty/kelley/city-seminar/papers/Bischoff%20et%20al.pdf>; see also Alzheimer’s Association, *Mild Cognitive Impairment* (October 2015), at http://www.alz.org/dementia/downloads/topicsheet_MCI.pdf.

³³ Cortoos, A., et al., *An Exploratory Study on the Effects of Tele-neurofeedback and Tele-biofeedback on Objective and Subjective Sleep in Patients with Primary Insomnia*, 35 Appl. Psychophysiol. Biofeedback 125-134 (2010).

³⁴ Hammer, B. et al., *Neurofeedback for Insomnia: A Pilot Study of Z-Score SMR and Individualized Protocols*, 36 Appl. Psychophysiol. Biofeedback 251-64 (2011).

³⁵ Schabus, M., et al., *Enhancing sleep quality and memory in insomnia using instrumental sensorimotor rhythm conditioning*, 95 Biological Psychology 126-34 (2014).

³⁶ Gass, J.J., et al., *Autonomic Dysregulation in headache patients*, 38 Applied Psychophysiol. Biofeedback 257-63 (2013).

³⁷ Stokes, D.A., et al., *Neurofeedback and Biofeedback with 37 migraineurs: a clinical outcome study*, 6(9) Behavioral and Brain Functions 1-10 (2010).

³⁸ Walker, J.E., *QEEG-Guided Neurofeedback for Recurrent Migraine Headaches*, 42 (1) Clinical EEG and Neuroscience 59-61(2011).

III. Testimonials

Neurocore's claims about ADHD, anxiety, depression, autism, and memory, migraines and sleep are interspersed with testimonials from Neurocore clients claiming improvements after completing the program. In addition, the website includes an entire webpage with client reviews. Many of the testimonials claim that the Neurocore program reduced or eliminated the need for medication and provided a solution or even a cure for these challenging conditions.

Testimonials, like those on the Neurocore website, which endorse a product or service by describing personal experiences are likely to be interpreted by consumers to mean that they too can expect to have the same experience. As a result, consumer testimonials which make performance claims must be substantiated, in the same way that such claims would need to be substantiated if made directly by the advertiser. The Federal Trade Commission has provided specific guidance that consumer testimonials about the efficacy of a product should be backed by adequate substantiation that the testimonial experience is representative of what consumers will generally achieve when using the product. Therefore, unless the advertiser can independently substantiate that the consumer endorser's claims are typical of most users, the FTC cautions that "the advertiser should either state what the generally expected results would be or indicate that the consumer should not expect to experience the attested results. Vague disclaimers like "results may vary" are likely to be insufficient."³⁹

NAD recommended that the advertiser discontinue its testimonials which claim that Neurocore clients have reduced or eliminated the need for medication for ADHD, Anxiety, Depression, memory problems, migraines or sleep disorders, (e.g., "I have cut my medicine in half," "I am off my depression meds") and further cautioned the advertiser to discontinue its use of testimonials which make claims that are not supported by the evidence on neurofeedback.

Conclusion:

NAD concluded that the advertiser's evidence was insufficiently reliable to substantiate the strong health-related advertising claims including,

- Overcome ADHD – without drugs;
- 81% of children who come to us on ADHD meds and complete our program are able to reduce or eliminate their use of medications upon program completion;
- 76% achieve non-clinical status; 90% report improvement;
- Control your anxiety without medication;
- 78% achieve non-clinical status; 90% report improvement;
- 25% reduction in reported symptoms on the autism evaluation checklists;
- Strengthen your brain to fight depression without medication;
- 73% achieve non-clinical status; 91% report improvement;

³⁹ <https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry>; see also *Flora, Inc. (Udo's Oil 3-6-9 Blend)*, #5389 NAD Case Reports (October 2011); *The Elations Company, LLC (Elations Liquid Supplements)*, Report #5196, NAD/CARU Case Reports (July 2010).

You'll experience improved memory, as well as better sleep, focus, mood, mental clarity and overall cognitive performance;
A natural remedy for migraines;
Sleep soundly without medication.

As a result, NAD recommended that all of the challenged claims be discontinued. NAD also recommended that the advertiser discontinue its testimonials which claim that Neurocore clients have reduced or eliminated the need for medication for ADHD, Anxiety, Depression, memory problems, migraines or sleep disorders, (e.g., "I have cut my medicine in half," "I am off my depression meds") and further cautioned the advertiser to discontinue its use of testimonials which make claims that the advertiser could not support.

Advertiser's Statement:

While we appreciate NAD's efforts in evaluating Neurocore's advertising, Neurocore will appeal the decision to the NARB. Neurocore takes pride in being able to offer a viable, non-chemical alternative to treat symptoms of mental and behavioral conditions that impact millions of consumers. Neurocore stands firmly behind the accuracy and integrity of the results reported by the clients who complete its program, and strongly believes that the testimonials of its clients are truthful, accurate, and representative of the typical client experience.

The claims made by Neurocore constitute truthful and valuable commercial speech. The public has the right to receive accurate information about viable alternatives to the chemical treatment of symptoms for mental and behavioral conditions. **(#6099 LB, closed 07/18/2017)**