

November 12, 2019

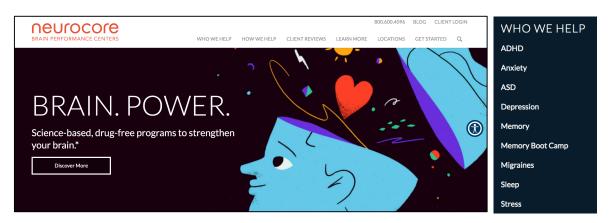
VIA EMAIL AND OVERNIGHT MAIL

Andrew Smith, Director, Bureau of Consumer Protection Mary Engle, Associate Director, Division of Advertising Practices Federal Trade Commission 600 Pennsylvania Ave. N.W. Washington, D.C. 20580

Re: Neurocore, LLC's Use of Unsubstantiated Medical Treatment Claims

Dear Mr. Smith and Ms. Engle:

We write to file a complaint with the Federal Trade Commission against Michigan-based "brain training" company Neurocore, LLC for its unrelenting use of unsubstantiated medical treatment claims despite prior admonishment by the National Advertising Division (NAD) and the National Advertising Review Board (NARB), and the company's representations that it would cease making such claims. Notwithstanding this history, Neurocore continues to market itself as providing "Science-based, drug-free programs to strengthen your brain" in order to treat numerous medical conditions, including ADHD, anxiety, autism, depression, migraines, memory loss, and insomnia, without competent and reliable scientific evidence to support such treatment claims.



Neurocore – Overview

Founded in 2004, ¹ Neurocore has three Brain Performance Centers located in Michigan and Florida. ² The company claims – without adequate substantiation – that neurofeedback, a form of biofeedback that uses a reward-based system to allegedly change the electrical activity of the brain, ³ can treat numerous medical ailments and can eliminate the need for physician-prescribed medications. ⁴

At Neurocore Brain Performance Centers, new customers first complete an initial brain diagnostic assessment, which is a one-time two-hour appointment that consists of questionnaires, biofeedback tests (heart rate, blood pressure, and breathing pattern), and a quantitative electroencephalography reading that maps electrical functions in the brain.

Rather than being conducted by psychiatrists, psychologists, neurologists or other neurofeedback experts, such medical assessments are done by social workers.

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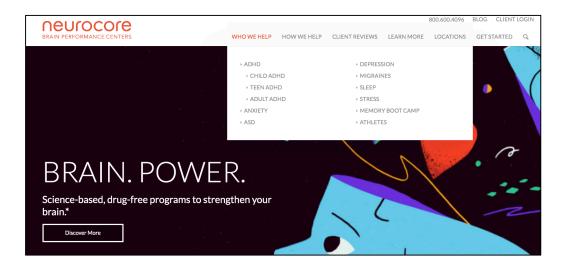
These assessments are then used by Neurocore staff to diagnose individuals with conditions such as ADHD⁷ and depression. Treatment consists of 30 neurofeedback sessions administered by technicians, which cost approximately \$2,000.8 Each session entails being connected to neurofeedback sensors placed on the ears and head for approximately 45 minutes while watching a movie on a computer screen. The movie pauses or shrinks depending upon the client's breathing patterns and brainwave activity. According to Neurocore, this process forms and strengthens new brain connections and pathways ultimately resulting in the "non-invasive treatment" of "ADHD and ADD, stress disorders, anxiety, panic attacks, Asperger's, depression, headaches, migraines, concussions, some forms of memory concerns, and sleep issues." ¹⁰

In addition to targeting patients with learning disabilities and psychiatric disorders, Neurocore also targets the elderly with its Memory Boot Camp Program: its "comprehensive, integrated memory program to assess and treat aging brain and related memory issues." Much like Neurocore's treatment program for other ailments, the Boot Camp program consists of an initial two-hour assessment followed by 30 sessions that include, among other things, participating in "active brain training through precision neurofeedback sessions." ¹²

Neurocore primarily markets its services on its website and through its social media accounts. Medical experts have warned that the company's advertising harms vulnerable patients, such as children with autism, by, among other things, diverting resources away from medically supported therapies. Other experts have cautioned that Neurocore's neurofeedback could, in certain circumstances, actually worsen the brain's functioning, something that is not disclosed in any of the company's marketing. 14

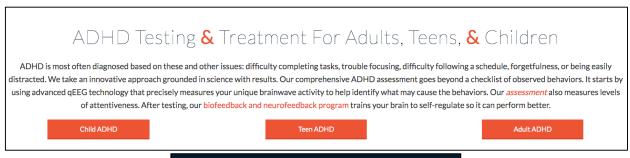
Neurocore's Medical Treatment Claims

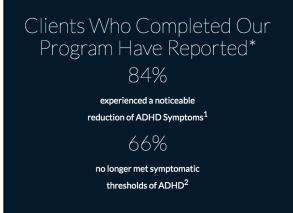
The first tab on the homepage of Neurocore's website – neurocorecenters.com – is labeled "Who We Help," which drops down to a menu that allows users to click on ADHD, anxiety, autism, depression, and migraines, among other things.¹⁵



Clicking on any of the listed medical conditions leads to a page that further claims Neurocore can treat the condition at issue.

For example, Neurocore's ADHD page states: 16





Similarly, Neurocore's anxiety page states: 17





The company's website also includes numerous testimonials that make similar treatment claims. For example: 18

"My daughter was struggling with severe depression. She had days when she couldn't get off the couch. Her personality changed — my sweet, kind child became angry, self-loathing, and withdrawn. My husband and I didn't know what to do...

My daughter no longer suffers from depression. She has literally transformed. She is the same kid as before her depression only more vibrant. This program was a game changer for her and for our family. By session 10 we could see real improvements, and by session 25 or so I'd say she was nearly symptom free.

The staff here has been incredible. They have gone above and beyond to make my daughter feel supported and welcomed. Very professional and helpful."

Lucille C.

West Bloomfield, September 2017

"My daughter was experiencing debilitating headaches nearly every day. She is a highly motivated and high achieving kid putting a lot of pressure on herself resulting in anxiety and stress. After just five sessions, her headaches were significantly reduced and at the end of thirty sessions, she is nearly headache free."

Anonymous

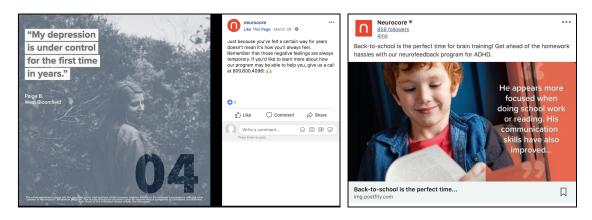
"I have Bipolar II, anxiety, PTSD, and ADD which leave me with daily symptoms of at least one of those at any given time. I was looking for a drug-free alternative or at least supplement to the low dose of medications and current coping skills that I use.

I feel I'm less stressed, and I notice less daily symptoms. I'm also more educated in overall wellness now. It's incredibly fascinating to see the science behind things I've dealt with mentally for a long time. It's near impossible to find treatment for my diagnoses that can give a clear indication of improvement. Every single person I have interacted with at this office has been nice, compassionate, and professional. A great team here!"

Lauren T.

Sterling Heights Center, June 2019

Such claims are also present in other company marketing materials, including its social media pages. For example,



TINA.org has compiled more than 170 current examples of webpages and marketing materials, all of which are available at https://www.truthinadvertising.org/neurocore-database/, in which Neurocore claims it can treat or alleviate the symptoms of medical disorders that include ADHD, anxiety, autism, depression, migraines, memory loss, and insomnia. https://www.truthinadvertising.org/neurocore-database/, in which Neurocore claims it can treat or alleviate the symptoms of medical disorders that include ADHD, anxiety, autism, depression, migraines, memory loss, and insomnia. https://www.truthinadvertising.org/neurocore-database/, in which Neurocore claims it can treat or alleviate the symptoms of medical disorders that include ADHD, anxiety, autism, depression, migraines, memory loss, and insomnia. https://www.truthinadvertising.org/neurocore-database/.

The issue with such claims is that there is not competent and reliable scientific evidence to substantiate these marketing claims making them deceptive and in violation of the FTC Act.²⁰

Neurocore's Proffered Substantiation is Inadequate

To support its medical treatment claims, Neurocore relies on (1) internal client data analyses, (2) third-party studies, and (3) an expert report. However, none of this evidence provides adequate substantiation for the health claims being made.

First, Neurocore's internal client data analyses are simply descriptive, observational studies that provide information on the treatment of a particular group of people but do not allow for conclusions to be made beyond the data analyzed. In other words, unlike randomized, controlled clinical trials, internal, anecdotal client-data analyses cannot be

used to make inferences from the sample tested on to a broader population. In addition, Neurocore's internal data analyses were conducted by Neurocore employees and thus potentially influenced by experimental bias.²¹

Similarly, the third-party studies on which Neurocore relies all contain one or both of the following flaws:

- The study examined a different type of neurofeedback than that used by Neurocore (i.e., Z-score neurofeedback);
- The study examined Z-score neurofeedback but it was a small, pilot study and/or was not well-controlled (e.g., not blinded, not an appropriate test population).

In addition, the results of the third-party studies are mixed as to the effectiveness of neurofeedback in treating conditions such as ADHD, anxiety, depression, and autism. While some concluded that neurofeedback is efficacious in treating such disorders, others did not and noted the need for further studies.²²

Finally, regarding Neurocore's expert opinion, such documentation cannot substitute for randomized, controlled clinical trials.²³

Further, in recommending that Neurocore stop using medical treatment claims in its marketing materials, NAD explained in a comprehensive July 2017 report that the company's scientific evidence is insufficient to substantiate the health claims at issue. NAD's conclusions were mirrored in NARB's June 2018 report that affirmed NAD's conclusions. Neurocore did not dispute NARB's findings and represented that it would "comply with the NARB panel's recommendations." Neurocore

Need for Enforcement Action

Neurocore's deceptive marketing is used to attract vulnerable consumers, many of whom struggle with difficult psychiatric disorders, are caring for children who struggle with such disorders, or are seniors dealing with age-related memory loss, to its Brain Performance Centers. The consumer harm associated with deceiving these susceptible populations is of great concern and must be stopped.²⁷ For the foregoing reasons, TINA.org urges the FTC to open an investigation of the claims being made by Neurocore and take appropriate enforcement action.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq. Legal Director

Truth in Advertising, Inc.

Bonnie Patten, Esq. Executive Director Truth in Advertising, Inc.

6

Cc via email: Mark Murrison, CEO, Neurocore Laura Brett, Director, National Advertising Division

¹ According to the Michigan Secretary of State, the company changed its name to Neurocore, LLC from 139 Education, LLC in February 2015.

Neurocore is primarily funded by Dick and Betsy DeVos's privately-held investment management firm The Windquest Group. https://www.neurocorecenters.com/careers.

² https://www.neurocorecenters.com/neurological-treatment-brain-performance-centers#locations.

³ https://www.neurocorecenters.com/; https://www.neurocorecenters.com/neurofeedback-training.

⁴ TINA.org has also filed a complaint letter with the U.S. Food and Drug Administration regarding Neurocore's failure to obtain FDA premarketing approval for its neurofeedback equipment. *See* https://www.truthinadvertising.org/wp-content/uploads/2019/11/11 12 19-Neurocore-complaint-letter-to-FDA.pdf. Biofeedback equipment is a Class II device, which is only exempt from FDA premarket notification procedures "when it is a prescription battery powered device that is indicated for relaxation training and muscle reeducation and prescription use." *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=882.5050. Not only does Neurocore's equipment fail to meet these conditions, but equipment similar to Neurocore's that is used solely to assist in the diagnosis of ADHD, rather than treat it, required premarket approval. http://alert.psychnews.org/2013/07/fda-approves-device-to-help-diagnose.html.

⁵ https://www.neurocorecenters.com/blog/neurocores-frequently-asked-questions; Report of NARB Panel 225, Appeal of NAD Final Decision Regarding Claims by Neurocore, LLC for Neurocore Brain Performance Centers, dated June 4, 2018.

⁶ Betsy Devos Invests in a Therapy Under Scrutiny, The New York Times, Jan. 30, 2017, https://www.nytimes.com/2017/01/30/us/politics/betsy-devos-neurocore-brain-centers.html.

ADHD is a clinical diagnosis generally made by a licensed health care professional. *See* FDA Approves Device to Help Diagnose ADHD in Children, Psychiatric News Alert, July 16, 2013, http://alert.psychnews.org/2013/07/fda-approves-device-to-help-diagnose.html ("ADHD is a clinical diagnosis and is very clearly defined that way in *DSM-5*... There is no one specific test that can make the diagnosis of ADHD... No one should ever look at these tools as overriding the clinical diagnosis... On the positive side, [the newly approved FDA device] is noninvasive and could be used to support a clinical diagnosis. But ADHD is a disorder involving particular behaviors in the area of attention, hyperactivity, and impulsivity that must occur in more than one environment—at home, at school, or elsewhere. So parents' observations, for instance, will be an important part of an overall clinical assessment.")

https://www.neurocorecenters.com/neurofeedback-training; https://www.neurocorecenters.com/insurance-and-billing; Betsy Devos Invests in a Therapy Under Scrutiny, The New York Times, Jan. 30, 2017, https://www.nytimes.com/2017/01/30/us/politics/betsy-devos-neurocore-brain-centers.html; Betsy DeVos has invested millions in this 'brain training' company. So I checked it out., The

Washington Post, May 26, 2017, https://www.washingtonpost.com/posteverything/wp/2017/05/26/betsy-devos-neurocore/.

¹³ See, e.g., Betsy Devos Invests in a Therapy Under Scrutiny, The New York Times, Jan. 30, 2017, https://www.nytimes.com/2017/01/30/us/politics/betsy-devos-neurocore-brain-centers.html (Dr. Matthew Siegel, a child psychiatrist at Maine Behavioral Healthcare and associate professor at Tufts School of Medicine, who co-wrote autism practice standards for the American Academy of Child and Adolescent Psychiatry stated, "This [Neurocore] causes real harm to children because it diverts attention, hope and resources. If there were something out there that was uniquely powerful and wonderful, we'd all be using it.")

¹⁴ Betsy DeVos has invested millions in this 'brain training' company. So I checked it out., The Washington Post, May 26, 2017, https://www.washingtonpost.com/posteverything/wp/2017/05/26/betsy-devos-neurocore/ ("It's also not totally clear that unusually slow or fast brain activity is a symptom of a disorder. It could be a sign of your brain compensating for something – maybe a past injury – and so trying to get your neural activity to look more 'normal' could actually make your brain function worse," quoting Russell Barkley, a psychiatry professor Virginia Commonwealth University and specialist in ADHD).

¹⁵ While this investigation and complaint focus on Neurocore, similar claims are also made on the company's related website neuropeakpro.com, which is geared toward professionals looking for an "edge."

For example, the Neuropeak Pro website includes the following claims regarding ADHD, anxiety, and depression. *See https://www.neuropeakpro.com/*.



⁹ https://www.neurocorecenters.com/neurofeedback-training.

https://www.neurocorecenters.com/neurofeedback. See also https://www.neurocorecenters.com/neurofeedback-training; NAD Case #6099, Neurocore, LLC, July 18, 2017.

¹¹ https://www.neurocorecenters.com/memorybootcamp.

¹² *Id*.



¹⁶ https://www.neurocorecenters.com/treatment/adhd.

¹⁹ TINA.org collected more than 200 examples of Neurocore claiming that it can treat, cure, or alleviate the symptoms of numerous medical conditions. However, TINA.org's sampling was collected over a three-year period (2017, 2018, and 2019) and, over time, some of the collected claims have been taken down or changed. Nonetheless, as of November 2019, more than 170 of the examples collected remain in publication, including prominent claims on the company's website.

It is also worth noting that Neurocore appears to have used influencers to market its services. *See, e.g.,* So, I Got My Brain Assessed at Neurocore Boca Raton, Modern Boca Mom, Oct. 24, 2016, https://modernbocamom.com/2016/10/neurocore-boca-raton/.

Neurocore makes no claims that it can cure any conditions, including any conditions referenced on its website or in print materials, including ADHD, anxiety, autism, depression, traumatic brain injury, post-traumatic stress disorder, migraines, headaches, stress, sleep disorders, Alzheimer's and dementia. If you take prescription medications for any of these conditions, you should consult with your doctor before discontinuing use of such medications.

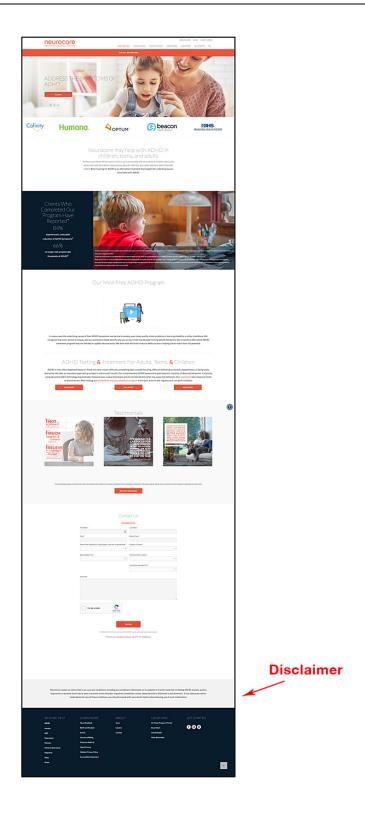
However, as a matter of law, such a disclosure cannot be used as cover for false and deceptive marketing claims. That is to say, Neurocore is not permitted to make medical treatment claims and then post a contradictory disclosure stating that the treatment claims are not actually true. "A disclosure can only qualify or limit a claim to avoid a misleading impression. It cannot cure a false claim. If a disclosure provides information that contradicts a material claim, the disclosure will not be sufficient to prevent the ad from being deceptive. In that situation, the claim itself must be modified." *See* .com Disclosures: How to Make Effective Disclosures in Digital Advertising, https://www.ftc.gov/system/files/documents/plain-language/bus41-dot-com-disclosures-information-about-online-advertising.pdf. As the FTC has repeatedly noted, "what the headline giveth, the fine print cannot taketh away." *See* What the headline giveth, by Lesley Fair, https://www.ftc.gov/news-events/blogs/business-blog/2011/06/what-headline-giveth.

Moreover, not only is the disclaimer legally ineffective, but its placement is such that the vast majority of consumers will never see it.

¹⁷ https://www.neurocorecenters.com/treatment/anxiety.

https://www.neurocorecenters.com/treatment/depression; https://www.neurocorecenters.com/treatment/migraines; https://www.neurocorecenters.com/testimonials-reviews-client-success-stories.

²⁰ Neurocore's website includes an insufficient disclosure at the very bottom of its webpages.



As the Commission has stated, disclosures must be prominent, conspicuous, and "effectively communicated to consumers before they make a purchase or incur a financial obligation." See

.com Disclosures: How to Make Effective Disclosures in Digital Advertising. There can be no dispute that Neurocore's disclaimer is not prominent or conspicuous, as is required by law.

The following is a list of the challenged expressed claims that the NARB recommended discontinuing, alongside some of Neurocore's current marketing claims:

Claims at Issue in NARB Report:	Claim Being Used by Neurocore Today:
"Control your anxiety without medication."	"Medication-Free* Anxiety Treatment With Brain Training"
	"Neurocore's Drug-Free Anxiety Program"
	https://www.neurocorecenters.com/treatment/anxiety
"Strengthen your brain to fight depression without medication."	"Non-Drug* Program to Fight Depression Symptoms"
	"Medication-Free Depression Treatment Program"

²¹ Since NAD's 2017 report and the NARB's 2018 report, Neurocore has released one additional study: a 2019 retrospective study performed by Neurocore scientists and staff, which presents the same reliability issues as those identified by NAD and the NARB. https://www.neurocorecenters.com/learn-more; https://www.nebi.nlm.nih.gov/pubmed/31119405.

²² See also Brain Training: Buyer Beware, Robert Thibault, PhD, https://www.truthinadvertising.org/brain-training-buyer-beware/ (discussing some of the issues with the science regarding neurofeedback: "[N]eurofeedback alone is [not] an effective treatment;" "When we looked at the most comprehensive list of publications on Z-score training, we found that 95% of the authors either practice this technique privately or sell the equipment to do so.")

²³ Advertising claims such as Neurocore's must be supported by competent and reliable scientific evidence. More specifically, when claiming a causal relationship between the advertised product or service and the treatment of any disease or disorder, the advertiser must have at least one randomized, controlled, human clinical trial study demonstrating statistically significant results before making such a claim. *See POM Wonderful, LLC v. FTC, 777 F. 3d 478 (D.C. Cir. 2015).*

²⁴ NAD Case #6099, Neurocore, LLC, July 18, 2017.

²⁵ Report of NARB Panel 225, Appeal of NAD Final Decision Regarding Claims by Neurocore, LLC for Neurocore Brain Performance Centers, dated June 4, 2018.

²⁶ *Id.* NARB recommended that "Neurocore discontinue the challenged express claims, including quantified outcome claims based on Neurocore's internal studies. ... The panel also recommends that Neurocore discontinue advertising testimonials, including those on YouTube, that claim Neurocore clients have reduced or eliminated the need for medication for ADHD, anxiety, depression, memory problems, migraines or sleep disorders. Finally, the panel recommends that Neurocore clearly and conspicuously disclose, in any advertising stating or implying that the Neurocore program is drug free, that consumers who take prescription medication for any condition for which Neurocore offers treatment should consult with their doctor before discontinuing use of such medications."

	https://www.neurocorecenters.com/treatment/depression
"You'll experience improved memory, as well as better sleep, focus, mood, mental clarity and overall cognitive performance."	"Science has shown that with memory exercises, you can take advantage of the brain's ability to change, strengthen it, and improve memory at any age. Using this science, combined with the latest technology, Neurocore has developed an innovative memory exercise program to combat memory loss – Memory Boot Camp This holistic approach is aimed at improving memory, increasing mental sharpness, and enhancing your overall health."
	https://www.neurocorecenters.com/memorybootcamp
"A natural remedy for migraines."	"Our Drug-Free* Migraine Headache Treatment Alternative"
	https://www.neurocorecenters.com/treatment/migraines
"Sleep soundly without medication."	"My life has improved dramatically since I started my Neurocore treatment. I no longer have to take medication to sleep, and I sleep peacefully through the night. I am able to face mental challenges with more ease, as resulted through successfully sitting for an 8-hour exam that I was unable to complete before Neurocore." https://www.neurocorecenters.com/testimonials-reviews-client-success-stories/sleep-treatment-reviews "Clients Who Completed Our Program Have Reported* 73% experienced a noticeable reduction of insomnia symptoms 84% no longer met symptomatic thresholds of insomnia." https://www.neurocorecenters.com/treatment/sleep
"Our Anxiety Outcomes* 90% report fewer or less frequent Anxiety symptoms *** 78% achieve non-clinical status"	"Clients Who Completed Our Program Have Reported* 86% experienced a noticeable reduction of Anxiety Symptoms¹ 67% no longer met symptomatic thresholds of Anxiety.2" https://www.neurocorecenters.com/treatment/anxiety
"Our Depression Outcomes* 91% report fewer or less frequent Depressive symptoms *** 72% achieve non-clinical status"	"Clients Who Completed Our Program Have Reported* 84% experienced a noticeable reduction of Depressive symptoms 67% no longer met symptomatic thresholds of Depression." https://www.neurocorecenters.com/treatment/depression

Our ADHD Outcomes "90% report fewer or less frequent ADHD symptoms *** 76% achieve non-clinical status"	"Clients Who Completed Our Program Have Reported* 84% experienced a noticeable reduction of ADHD Symptoms¹ 66% no longer met symptomatic thresholds of ADHD²" https://www.neurocorecenters.com/treatment/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*. *Results of one research study done in collaboration with a major Midwest insurance company."	"Our Med-Free* Approach to Treating ADHD in Children" https://www.neurocorecenters.com/treatment/child-adhd
"25% reduction in reported symptoms on the autism evaluation checklists."	"Brain therapy to address symptoms of autism spectrum disorder." "we use neurofeedback sessions to train the brain to self-regulate and optimize its performance, resulting in a more calm and focused state." https://www.neurocorecenters.com/treatment/asd
Testimonials that reference reduction or elimination of medication.	Current examples: "Previously having an older child with ADHD and having her on medication and seeing the side effects from the medication, we were very hesitant on putting our son on medication for the same problem. Neurocore was a perfect treatment choice for our son. Prior to coming, he was not able to focus on the task at hand or even sit at the dinner table and make it through dinner without getting up to go do something else. Since starting Neurocore our son now can sit through dinner without leaving the table. He is now able to work on his homework independently without constant redirection." https://www.neurocorecenters.com/testimonials-reviews-client-success-stories/child-adhd-treatment-reviews "I wanted to find a good way to treat depression and
	anxiety without medication. I do feel less anxious, less prone to panic, and I am starting to find it easier not to think negatively, or to keep myself from giving up on life. The Neurocore program itself was not that difficult.

It can be very helpful, so it's worth sticking through to the end"
https://www.neurocorecenters.com/testimonials- reviews-client-success-stories/depression-treatment- reviews

²⁷ It is worth noting that this matter is quite similar to the FTC's 2016 federal court action against Lumosity, a company that was marketing its "brain-training" program as able to treat memory loss, cognitive decline, ADHD, and other ailments through video games. As the FTC stated, "Lumosity preyed on consumers' fears about age-related cognitive decline, suggesting their games could stave off memory loss, dementia, and even Alzheimer's disease...But Lumosity simply did not have the science to back up its ads." Lumosity to Pay \$2 Million to Settle FTC Deceptive Advertising Charges for Its "Brain Training" Program," Jan. 5, 2016 Press Release, https://www.ftc.gov/news-events/press-releases/2016/01/lumosity-pay-2-million-settle-ftc-deceptive-advertising-charges.