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A Critical Review of: *Double-Blind Placebo-Controlled Randomized Clinical Trial of Neurofeedback for Attention-Deficit/Hyperactivity Disorder With 13-Month Follow-Up*

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Abstract

Attention-deficit/hyperactivity disorder (ADHD) is a common neurobehavioral condition affecting children and adolescents impairing academic success, self-esteem, and social interactions. Since there is no cure for ADHD, the public relies on researchers to provide an honest and objective evaluation of treatment options to help those with ADHD manage the disorder. The public's expectation was thwarted when a study was published in the Journal of the American Academy of Child & Adolescent Psychiatry (JAACAP) titled *Double-Blind Placebo-Controlled Randomized Clinical Trial of Neurofeedback for Attention-Deficit/Hyperactivity Disorder with 13-Month Follow-Up* (Arnold et al., 2021). The principal investigator and lead author was L. Eugene Arnold, MD, who referred to his coauthors as a collaborative team. The National Institute of Mental Health funded the study with a $2 million grant. This critical review of Arnold et al. examines various aspects of the study to help us understand why the findings and stated conclusion of the study deviated from a substantial body of research and clinical evidence demonstrating the effectiveness of NFB for treating ADHD.

Keywords: call for retraction; neurofeedback; pharmaceutical biasing

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Introduction

Attention-deficit/hyperactivity disorder (ADHD) is a common neurobehavioral condition affecting children and adolescents impairing academic success, self-esteem, and social interactions. Since there is no cure for ADHD, the public relies on researchers to provide an honest and objective evaluation of treatment options to help those with ADHD manage the disorder. The public's expectation was thwarted when a study was published in the Journal of the American Academy of Child & Adolescent Psychiatry (JAACAP) in August 2021, titled *Double-Blind Placebo-Controlled Randomized Clinical Trial of Neurofeedback for Attention-Deficit/Hyperactivity Disorder with 13-Month Follow-Up* [Hereafter, abbreviated as "study" or "Arnold et al."]. The study intended to evaluate neurofeedback as a treatment for ADHD over a 13-month period. The principal investigator and lead author was L. Eugene Arnold, MD, along with a team of coauthors collectively known as the Neurofeedback Collaborative Group. The study may be accessed in the JAACAP, 2021-07-01, Volume 60, Issue 7, pages 841–855. This study was supported by a $2 million grant from the National Institute of Mental Health (NIMH) #R01-MH100144, by Ohio State University College of Medicine Endowment, and by a Clinical and Translational Science award 8UL18TR000090-05 from the National Center for Translational Sciences. Clinical Trials Identifier: NCT02251743, date of registration: 9/17/2014. The paper is available here:

https://europepmc.org/article/MED/32853703#free-full-text

The Neurofeedback Collaborative Group was cited as coauthors and comprised of the following:

> Martijn Arns, PhD; Justin Barterian, PhD; Rachel Bergman, BA; Sarah Black, PhD; C. Keith Conners, PhD (deceased); Shea Connor, BS; Sudeshna Dasgupta, MD; Roger deBeus, PhD; Teryll Higgins, MA; Laurence Hirshberg, PhD; Jill A. Hollway, PhD; Cynthia Kerson, PhD; Howard Lightstone, B; Nicholas Lofthouse, PhD; Joel Lubar, PhD; Keith McBurnett, PhD; Vincent Monastra, PhD; Kristin Buchan-Page, BA; Xueliang (Jeff) Pan, PhD; Robert Rice, PhD; Michelle E. Roley-Roberts, PhD; Rachel Rhodes, MLAS; Constance Schrader, PhD; Yubo (Jeremy) Tan, MS, MBBS; Craig E. Williams, MD.

Neurofeedback training (NFB) is one of several types of biofeedback, all of which are predicated on the operant conditioning paradigm, wherein spontaneous activity increases when reinforcement is provided. In the specific case of NFB treatment of ADHD, an electroencephalographic (EEG) device is used to continually analyze the child's brainwaves. This device provides auditory and visual signals or rewards within 250 ms of the moment the child's brain shifts into an EEG pattern that is known to correlate with a more attentive state. When these transient moments of heightened alertness are paired with the reward signals, the child learns how to better self-regulate their attention. As the child receives this training, their ability to sustain attention improves and ADHD symptoms decrease.

This critique examines various aspects of the study to help us understand why the findings and stated conclusion of the study deviated from a substantial body of research and clinical evidence demonstrating the effectiveness of NFB for treating ADHD. In addition to identifying errors in the study's design, methodology, and data analysis, information gathered from interviewing several authors revealed deeper issues compromising the reliability and validity of the conclusions. One author described personal surreptitious communication between the authors of the study and a journal editor that indicated the JAACAP journal would publish the study *if* the conclusion stated that NFB was no better than a placebo. In direct contradiction to core ethical principles, the manuscript was subsequently manipulated to conform with the journal editor's predetermined outcome.

Lexchin along with other concerned scientists (2003) have compiled substantial evidence demonstrating that sponsorship of research by the pharmaceutical industry compromises the outcome and quality of research studies. Although investigators are ethically required to disclose conflicts of interest, this fails to reveal the degree to which said conflict impacted the research. This study by Arnold et al. is a prime example of how current ethical requirements fail to reveal critical information. The sheer number of methodological errors alone, not to mention the coercion by editors at JAACAP, demonstrates that incentives to disparage NFB, influenced the evolution and publication of this study to a greater extent than the ethical requirement to provide research that is free of conflicts of interest. Those controlling the authorship and publishing of this study abused their credentialed authority and now must follow ethical requirements to disclose the errors and retract the study. When those who conduct research admit and correct errors, the very nature of scientific inquiry is strengthened along with the public's trust in the conclusions offered by research studies. For future researchers, an admission and retraction of this study will demonstrate the critical nature for adopting strategies to minimize the impact of conflicts of interest by fostering transparency and accountability in their research practices.

Part I. Neurofeedback History

Before discussing specific issues in the study, it is important to understand that the efficacy of NFB treatment for ADHD has already been repeatedly demonstrated. In the 1950s, Kamiya (1968, 1969, 2011) demonstrated successful operant conditioning of the alpha frequency (8–12 Hz). Sterman (1969, 1972, 1974, 2000) completed a series of exemplary studies characterized by rigorous research designs and transparent methodology allowing publication in top-tier scientific journals and replication at independent laboratories. In the 1960s, Sterman conducted research on medication-resistant epilepsy using NFB to increase an EEG frequency called the sensorimotor rhythm (12–15 Hz). This training allowed epileptics to significantly reduce the frequency, intensity, and duration of seizure incidents lasting for many months and even years. Sterman's work with human and animal subjects demonstrated cross-species conditioning thus eliminating any suggestion that the effects produced by NFB might be due to placebo or bias. Lubar et al. (1995) and Zuberer et al. (2015) conducted studies demonstrating the effectiveness of NFB as a treatment for ADHD. Many others contributed to this early efficacy research verifying that NFB was safe

and effective to improve functional abilities for a wide range of physiological and psychogenic disorders.

Part II. Acceptance of Neurofeedback

For the purposes of this critique, *detractor* will be used as a general term to refer to those having direct or indirect ties, are paid by, or receive tangible benefit(s) from their association with the pharmaceutical industry, including, but not limited to, pharmaceutical company employees, members of their Boards of Director, major stockholders, agents such as pharmaceutical company consultants, collaborators, biomedical researchers funded by the industry, and physicians who "have a monopoly over the prescription trade by virtue of their licenses to practice" (Idzik, 1965).

Detractors have created and spread many false beliefs regarding NFB. One such false belief is that key decision-makers at the NIMH have been unwilling to fund NFB studies because they question the legitimacy of NFB. The real reason this major source of funding for research is hesitant to fund NFB research is because the efficacy of NFB has already been scientifically demonstrated. The funding priority of the NIMH, as their mission statement indicates, is to investigate *new* treatments that build upon our knowledge base (see https://www.nih.gov/about-nih/what-we-do/mission-goals).

NFB is not a new treatment, therefore allocating funding to assess efficacy is duplicative and unwarranted. Detractors disregard the fact that NFB has an extensive history of acceptance as a medical procedure illustrated by these selected examples:

a) In 1978, the Current Procedural Terminology (CPT) committee, under the auspices of the American Medical Association, acknowledged that NFB met or exceeded requirements for efficacy and assigned treatment codes indicating it was a legitimate intervention eligible for reimbursement by health insurance companies (https://www.ama-assn.org/amaone/cpt-current-procedural-terminology).
b) In 1976, the U.S. Food and Drug Administration began regulating NFB instruments as Class II medical devices indicating they were safe and effective tools for treatment (https://www.accessdata.fda.gov/cdrh_docs/pdf14/K143031.pdf).
c) The International Society for Neurofeedback (ISNR) supplies the public with a downloadable bibliography of NFB studies. In the section covering NFB research treatment of ADHD (pp. 3–12), the bibliography identifies over 130 studies showing NFB is an efficacious treatment for ADHD as both a standalone treatment or part of a multimodal regimen. In addition, ISNR estimates there are over 15,000 clinicians worldwide using this technology (https://isnr.org/wp-content/uploads/2019/07/download.pdf).
d) Another professional organization, the Applied Psychophysiology and Biofeedback Society (AAPB), recently released the 4th edition of a book titled, "Evidence-Based Practice in Biofeedback & Neurofeedback" (Khazan et al., 2023). Chapter 6 focuses on NFB and ADHD (pp. 121–135) and cites over 40 highly credible studies that were peer-reviewed. Based on the strength of this research, the authors and AAPB determined that the research on NFB for ADHD earned their highest determination of effectiveness: Level 5 – Efficacious and Specific.
e) NFB has been evaluated by various regulatory authorities and is recognized as within the "scope of practice" for psychologists, psychiatrists, physical therapists, nurses, occupational therapists, social workers, and family therapists, among others.
f) NFB developed from well-established foundational studies that have continued to support the growth of the field. The neurofeedback field continues to be supported by ongoing research projects, professional organizations, a dedicated peer-reviewed journal, and a certification program for new providers.
g) Data Bridge Market Research analyzes trends and predicts that the global market for NFB will be USD 1,908 million by 2029 (https://www.databridgemarketresearch.com/reports/global-neurofeedback-market).

Despite these facts and optimistic projections, as this critique discusses, the pharmaceutical industry and detractors who benefit from their association with this industry have a long history of unfairly targeting NFB. This abuse of the public's trust is directly related to the fact that, when people choose nondrug treatments rather than drug therapy, the profit margin of the pharmaceutical industry diminishes. Detractors do more than simply ignore

the mountain of NFB research or write articles to dissuade the public from NFB treatment. Over time, their fear of this intervention has effectively marginalized the entire neurofeedback field. This critique provides evidence that methods and data were manipulated to draw false conclusions that advance the narrative that NFB treatment of ADHD has yet to prove itself as an efficacious treatment. While the neurofeedback field is receptive to legitimate research-based challenges and constructive criticism, these must be scientifically based and take into consideration conclusions derived from previous research and prevailing standards of care. Deviating from ethical scientific procedures undermines the search for evidence-based interventions and unfairly deprives the public of effective treatment options.

Part III. Documenting Errors, Notifying the Authors and the Editor of JAACAP

After the publication of this study, an ad hoc committee of experts in the neurofeedback field gathered to review the study. The committee included Lori Ellison, Henry Harbin, Joy Lunt, Lori Russell-Chapin, Gary Schummer, and Mark Trullinger. The committee identified the list of significant errors (see Part IV below) that severely compromised the study's integrity. Taken together, these errors make any meaningful interpretation of the study's data impossible and prevent the study from being determinative of the efficacy of NFB. Additionally, a "Letter to the Editor" titled *Erroneous Science* in Arnold et al. (2021) was sent to the Editor-In-Chief of JAACAP pointing out the errors. Consistent with ethical standards, the Letter urged the Journal to retract the study and provide an explanation of the nature and extent of the errors. Although the authors appeared to agree with the validity of the errors, to the best of our knowledge, none have asked the Journal to retract the study. Interestingly, the ad hoc committee received a response regarding the Letter from the Editor-in-Chief of the JAACAP stating that he considered the documented concerns but was unwilling to share it with his fellow editors. He ended his response paradoxically and shamelessly stating that our Letter did not meet the journal's standards for publication.

After the errors were made known to the primary authors in the meeting, some of the authors indicated they had not been apprised of the issues. Perhaps this is due to the fact that the study's collaborators were responsible for nonoverlapping aspects of the study and not all were involved in writing the manuscript. As indicated in the support material for the study, tasks were assigned as follows:

> ***Conceptualization***. Arnold, Arns, deBeus, Hirshberg, Hollway, Kerson, Lubar, McBurnett, Monastra; **Data Curation**: Arns, deBeus, Lightstone, Monastra, Buchan-Page, Pan, Rice, Tan; **Formal Analysis**: Arnold, Arns, Black, Conners, Dasgupta, deBeus, Hollway, Kerson, Lofthouse, Monastra, Buchan-Page, Pan, Rice, Roley-Roberts, Rhodes, Schrader, Tan, Williams; **Funding Acquisition**: Arnold; **Investigation:** Arnold, Black, Connor, Dasgupta, deBeus, Kerson, McBurnett, Monastra, Pan, Roley-Roberts; **Methodology**: Arnold, Arns, Barterian, Bergman, Black, Conners, Connor, Dasgupta, deBeus, Higgins, Hirshberg, Hollway, Kerson, Lofthouse, Lubar, Monastra; **Project Administration**: Arnold, Barterian, Bergman, Connor, deBeus, Higgins, Hollway, Kerson, Monastra, Buchan-Page, Roley-Roberts; **Resources**: Arnold, Connor, deBeus, Kerson, Lightstone, Monastra, Buchan-Page, Pan, Tan; **Software**: Lightstone; **Supervision**: Arnold, Barterian, Black, deBeus, Hollway, Kerson, Rhodes, Schrader, Williams; **Validation:** Arnold, Arns, Barterian, Black, deBeus, Hollway, Kerson, Monastra, Buchan-Page, Rhodes, Williams; **Visualization**: Arnold, Arns, Connor, deBeus, Pan, Tan**; Writing – original draft**: Arnold, Arns, deBeus; **Writing – review and editing**: Kerson, Monastra, Pan, Roley-Roberts (https://www.jaacap.org/article/S0890-8567(20)31358-7/fulltext - articleInformation).

Part IV. Errors in Arnold et al. (2021)

Error 1: Hypothesizing After Results Are Known. Abbreviated *HARKing*, Kerr (1998) stated this involves deceptively modifying a study's primary hypothesis after the results are analyzed. HARKing obscures valuable aspects of the truth and engenders a range of issues. Originally, the authors had preregistered a specific primary outcome hypothesis, which they later altered *after* analyzing the results. This shift in hypothesis compromises the integrity of the study and introduces misleading elements into the analysis. The authors of this study stated the following preregistered primary outcome hypothesis:

> Children randomly assigned to NFB will, when assessed in an unmedicated state, show a significantly greater reduction of inattentive ADHD symptoms rated by parents and teachers than those assigned to double-blind placebo sham treatment of equal duration, intensity, involvement, and appearance.

By definition, a sham placebo is designed to have no real effect. However, in this study, the sham placebo *did* show a real effect. The authors stated:

> The control improvement appears comparable to the longer, more intensive MTA behavioral treatment. What this improvement is due to requires further research, but the 13-month durability suggests more than a placebo response.

Therefore, critical data required by the primary hypothesis could not be calculated. Rather than truthfully stating this fact, the authors changed their preregistered primary outcome hypothesis by removing the words *placebo sham* when they presented their conclusion. The authors stated:

> In summary, the primary outcome failed to show a significant advantage of NFB over the control treatment.

Experts well-versed in HARKing have stated that this error typically arises from either investigator incompetence or a deliberate intent to mislead readers into perceiving the study as credible. In this context, the authors knowingly misrepresented the truth or concealed a material fact for reasons we can only speculate. The choice by the Editor of JAACP to publish the manuscript without identifying and insisting this error be corrected is duplicitous and raises questions about the journal's oversight and commitment to maintaining research integrity.

Error 2: There Was No Valid Placebo Sham Control Group. The "control" group was given EEG feedback acquired from subjects of similar ages who were not part of the study. Additionally, this group was provided with real-time electromyographic (muscle tension level) feedback (EMG). EMG feedback was given when a fluctuation in muscle tension was detected. Participants received visual and auditory cues that guided them into a more relaxed state typically associated with lowering muscle tension. Notably, Barth et al. (2017) found that EMG feedback *alone* leads to a reduction in ADHD symptoms, particularly the hyperactivity component. EMG researchers suggest that decreasing muscle tension facilitates the reallocation of physiological resources so attention can be better regulated. Not knowing the literature regarding the impact of EMG biofeedback on ADHD is another indication of the sophomoric approach Arnold et al. (2021) took to conducting this study. Additionally, participants in both the control and treatment groups received guidance about the significance of sleep and nutrition, with a specific emphasis on the importance of breakfast, and were provided with a list of recommended breakfast foods. During each session, all participants were queried about their daily food intake and sleep duration. Given the implementation of these interventions, one could reasonably anticipate that the control group would also exhibit a learning effect, which manifested as a 59% improvement compared to a 67% improvement in the treatment group. The control group therefore did not serve as a true control as they were given an intervention known to directly impact attentional factors. The study's control group was actually an alternative treatment group, and the principal investigators should have been aware of this prior to finalizing the study's method. Lacking a true control group, the title, data analysis, and manuscript should have been corrected to indicate this fact.

Error 3: Type III Error or P-Hacking. The integrity of research findings and their ethical interpretation demand thorough consideration of all possible factors influencing outcomes, particularly when such conclusions impact medical treatments and patients' well-being. Diligent researchers and journal reviewers exercise caution to avoid the Type III error, a misjudgment characterized by rejecting the null hypothesis for an incorrect rationale. Trullinger et al. (2019) indicated that this error occurs when researchers repeatedly select data or apply statistical analyses until nonsignificant results become significant. Astonishingly, the authors of the study, and even more notably, the panel of editors at JAACP, permitted the authors to reach a conclusion that brain-wave-contingent reinforcement was ineffective simply based on the absence of a statistically significant disparity between the treatment and control groups in the EEG domain. This approach highlights a fundamental misinterpretation of statistical significance, overlooking the broader context and potential nuances within the data and was essentially dishonest. Such an oversight calls into question both the methodological rigor of those who analyzed the data and the scrutiny expected from the editorial review process. From the study:

> From baseline to treatment end the primary outcome showed significant ($p < .0001$) improvement for both NFB ($d = 1.51$) and control ($d = 1.47$) but did not show a significant difference between them.

Left unexamined was the very plausible scenario wherein the improvement observed with the control group was not without cause. After all, the "sham treatment" the authors referred to as the control group produced positive results akin to those observed in the NFB group. Of primary importance,

but completely disregarded in the manuscript, the control condition exhibited effectiveness comparable to established treatments for ADHD, including stimulant medication and behavior therapy, as per the primary outcome measure. Consequently, the control condition cannot be cavalierly deemed as inert or a mere placebo. A more scientifically and ethically sound conclusion would be to acknowledge that significant inferences regarding the efficacy of NFB cannot be drawn from this study due to the absence of one of the conditions necessary to conduct a viable double-blind placebo-controlled randomized clinical trial (RCT); that is, the control group must meet the criteria for a neutral placebo. The study's conclusion, as presented, inaccurately portrayed the data. The authors, out of ignorance or deliberate deceit, set this fact aside and presented to the public a false conclusion. Failing to rectify this is not only irresponsible but also ethically indefensible.

Error 4: "False No-Effect" Error. The analysis was not conducted to ascertain whether conditioned theta-beta ratio (TBR) training played a mediating role in driving symptom improvements across both the control and treatment groups. The authors stated:

> Categorically, based on the simple slope direction (up or down), the percentage of TBR "learners" was 59% for controls (9% greater than the 50% expected by chance in the dichotomous classification, p = .22) and 67% for NFB (17% greater than expected by chance, p = .003).

The erroneous assumption of a 50% random chance for TBR learning resulted in a misleading situation where a statistically significant difference between NFB and random chance emerged, rather than between the control and random chance. Additionally, hypothesis testing within this study's data may not accurately determine specificity due to the near-identical number of participants reported as having achieved TBR learning in both the NFB and control groups. This misstep led to the authors committing a "False no-effect" error, as discussed by Head et al. (2015). Experts state that this error can only be attributed to either the researchers' incompetence or deliberate deception. Ethical researchers are careful to avoid this error by employing readily accessible statistical techniques developed to identify this issue thereby allowing investigators to accurately test their hypotheses. Had the authors and/or the editorial staff at JAACAP chosen to identify this error and utilize appropriate corrective measures, the impact of this error would have been mitigated allowing the study to present somewhat more accurate findings.

Error 5: The Authors Stated There Was Only One Deviation From the Registered Protocol, Which Was Dishonest and Deceptive. The authors stated:

> The TBR inclusion threshold was changed from 5.0 (~1.5 *SD* above norms for 6- to 11-year-olds) in the registration protocol to 4.5 (~1.2 *SD* above norms) to increase sample representativeness, *the only change from the registered protocol*. [emphasis added]

The assertion in this statement is inaccurate. In addition, it is the second instance where the authors diverged from their initially preregistered protocol. While it is commendable that the authors acknowledged this deviation from the original design, it prompts one to question why they chose to acknowledge this relatively minor deviation while neglecting to address a major deviation concerning the study's most pivotal aspect—altering the criteria necessary to reach a conclusion. The authors doubled down on this ethical violation by explicitly stating that this deviation represented "the only change," misleading readers into presuming that no other departures from the preregistered protocol existed throughout the study. This selective acknowledgment misguides readers by creating an impression of transparency while concealing more significant deviations from the original protocol. The impact of the author's failure to honestly address all deviations and their implications cannot be overstated. Honest and full transparency, qualities this study lacks, is crucial for maintaining the credibility and reliability of the research process.

Error 6: The Misapplication of the TBR. The authors claimed that the core element of the treatment group was the behaviorally conditioned alteration in the TBR. However, unwarranted assumptions about random changes in the TBR resulted in a misinterpretation of the sham group's efficacy, erroneously suggesting similar outcomes to the treatment group. The evaluation of learning rates for the TBR followed the methodology established by Monastra et al. (2005), having a documented test-retest reliability of 96%. This high reliability indicates that only 4% of participants should exhibit changes due to random chance. Surprisingly, the present study's analysis diverged from this established research on TBR test-retest reliability by assuming that learning would occur in 50% of participants purely due to random chance, without clear justification. Furthermore, employing the TBR as either a dependent variable or considering it as a

possible underlying mechanism of action was a substantial error. Although some research studies have indicated decreases in the TBR following NFB, other research by Janssen et al. (2017) contradicted this finding. Despite studies showcasing significant reductions in ADHD symptoms, Bakhshayesh et al. (2011) and Gevensleben et al. (2009) observed that some participants who improved showed no significant changes in the TBR. In addition, Ogrim and Hestad (2013) noted the persistence of "remarkably stable" power measures in both theta and beta frequencies after 30 sessions of NFB. Given the variance in findings and the lack of a consensus within the scientific community that decreasing the TBR indicates effective NFB, using the TBR in the context of this study was naïve, lacking both scientific validity and reliability.

Error 7: The Focus on the TBR Overlooked More Scientifically Viable Alternatives. The decision to focus on the TBR as a key measure of training indicated that the authors assumed ADHD is a disorder stemming from a frequency imbalance. A much more popular theory, but equally controversial, suggests ADHD is caused by an imbalance of neurotransmitters. Both theories lack scientific validation and have been criticized in the literature. While identifying EEG subtypes based on frequency-specific phenotypic expressions has been shown to have diagnostic utility, there is no consensus among experts that this EEG metric is the best or even a good way to account for all possible expressions of ADHD. A competing theory suggested by clinical data indicates that problems with ADHD are more likely an instability in the vigilance network rather than an issue involving an imbalance in certain frequencies. Since an overarching principle of every NFB session is that this training *always* reinforces neural stability, no matter what frequency bands are trained or where the electrodes are placed, there is significantly more justification to consider metrics that indicate a correlation with NFB. Similar to Sterman's work with epileptics, NFB clinicians have found that the best EEG metrics showing a consistent positive correlation with a reduction in ADHD symptoms are those assessing neural stability. Among the many measures, the most reliable metric in our clinical work has been the coefficient of variation, a statistical measure used to express the relative variability of a dataset. This metric is also known as normalized root-mean-square deviation (NRMSD), Percent RMS, or relative standard deviation (RSD). It is a standardized measure of dispersion of a probability distribution or frequency distribution and is defined as the ratio of the standard deviation (σ) to the mean (μ) or its absolute value, often expressed as a percentage. Of note, the software used in this study calculates the standard deviation for each period of NFB for the treatment group. However, the authors ignored this readily available measure, choosing instead to employ the TBR, a measure lacking validity and reliability.

Error 8: The Training Interval Was Not Consistent With the Best Practice Model. Beginning with the earliest research, it has been consistently understood that the training interval represents a critical consideration in effectively implementing any operant conditioning paradigm. The level of attention an individual devotes to a signal as well as the impact that signal may have on the individual in any environment directly correlates with their capacity to extract crucial information from that signal. The evolution of best practice guidelines within the neurofeedback field is consistent with operant conditioning research and stems from clinical experience. Similar to determining the ideal dosage of medication, the training interval is highly significant in determining the success or failure of NFB. The spacing between training sessions becomes more determinative of the success when treating younger children or at the beginning of treatment. Additional considerations impacting the training session interval involve the severity of ADHD symptoms or if daily events in the child's life are complicated by varying social, mental, or emotional issues. These issues impact clinical recommendations for the spacing of treatment intervals. Generally, we find that treatment outcomes are optimal when the participant or their parent commits to engage in a minimum of three spaced NFB sessions per week *consistently*. Participants undergoing fewer than three sessions weekly tend to experience less favorable outcomes or require a greater number of sessions to achieve maximum benefit from NFB. However, the methodology employed in this study did not require participants to consistently adhere to the three-sessions-per-week guideline. Instead, participants were allowed to attend sessions that yielded them an *average* of three sessions per week. Notably, the authors we interviewed disclosed that certain participants in the treatment group went up to 2 weeks without training. In clinical settings, fewer sessions, especially during the initial stages of treatment, results in significant slowing in progress and, with longer treatment intervals, there is often a substantial regression in progress. The noncompliance of participants or their parents with this critical recommendation sometimes leads them to say the NFB was not effective. This is why some experts in this field have said, "When NFB

fails, it has more to do with factors outside the therapist's control than it does the NFB." In the context of this study, allowing participants to have extended no-training intervals was an avoidable methodological error that undoubtedly compromised the effectiveness of NFB on the treatment group.

***Error 9*: *The Fixed Protocol for Training That Changes on a Fixed Schedule Was Not Reasonable or Optimal*.** The information provided in the text of this study is not transparent on the schedule of NFB, but according to the authors interviewed, a fixed protocol was utilized for training frequencies that changed every five sessions. This signifies a noteworthy deviation from established best practice guidelines. Such a fixed protocol, particularly one with a five-session interval, could potentially introduce inadequate spacing for effective reinforcement, especially for younger children who often require more immediate and frequent rewards. Moreover, considering the nature of ADHD treatment, the training is more effective if the interface of the participant with the instrument is more interactive. A characteristic of ADHD is the difficulty individuals with this condition face in terms of delaying gratification. This inability to defer immediate rewards in favor of longer-term goals contributes to challenges in impulse control, attention regulation, and behavioral self-regulation. This characteristic underscores the complex nature of ADHD and further emphasizes the importance of tailoring treatment approaches to accommodate the age, maturity level, degree of impairment, and specific cognitive and behavioral profiles of those who present for NFB. Furthermore, the conventional process during the initial 3 min of a session involves the NFB device calibrating itself to align with the participant's real-time EEG activity. Subsequently, this calibration is utilized during the session to determine thresholds for providing the feedback rewards. When a more adaptive protocol is used, more focused attention results empowering the child to experience enhanced self-regulation of their attention. The study's adherence to a fixed protocol, without considering the nuances of individuals with ADHD ignores the benefits associated with more fluid and interactive reinforcement schedule. This negatively impacted the treatment group's ability to learn self-regulation of attention.

***Error 10: Placement of the Active Sensor, a Critical Piece of Information, Was Omitted*.** For a study to be ethically reviewed, comprehended, and replicated, ethical guidelines mandate transparent communication of critical information, particularly concerning the methods employed. In clear violation of this principle, the study omitted critically important details regarding the precise placement of active electrodes on each participant. Additionally, a cogent rationale for selecting the specific electrode placements is absent. The process by which these determinations were reached remains enigmatic even to certain authors we interviewed. Typically, NFB involves selecting the optimal electrode placement based on a quantitative EEG (qEEG) assessment and a comprehensive clinical interview. The qEEG is a sensitive diagnostic assessment tool commonly used in clinical settings, neuroscience research, and in fields such as neurofeedback, psychology, neurology, and psychiatry to gain insights into brain function and help to identify potential neurological issues. This software-based application mathematically processes digitally recorded EEG to highlight specific waveform components that transforms the EEG into a format or domain that allows exploration of relevant information and examining the data in a variety of montages which can highlight impairments. In addition, associating numerical results with EEG data facilitates subsequent review, most importantly, allowing the comparison of a participant's data with an age-matched database. For purposes of NFB, the information provided by the qEEG is interpreted by a trained clinician and integrated along with clinical data into an individualized treatment plan. Practitioners are expected to be capable of justifying their chosen electrode placements based on these criteria. It follows that researchers should adhere to, at minimum, this same standard. The extent to which this study deviated from this established best practice guidelines is undisclosed, but any deviation without robust scientific justification is untenable. The lack of transparency in this aspect of the study raises concerns about the overall rigor and integrity of the research process, and by extension, the reliability of the conclusions drawn from the study.

***Error 11: The Study Makes It Clear the qEEG Was Used Diagnostically While Other Protocol Determinative Information Was Disregarded*.** To be eligible for inclusion in the study, each participant's qEEG assessment confirmed the presence of an ADHD phenotype characterized by excessive theta and deficient beta activity. Beyond this baseline criterion, best practice guidelines and clinical expertise have evolved that direct NFB providers to seek convergent validity by utilizing information from several databases. These data in conjunction with data derived from a comprehensive clinical interview are used to inform the optimal NFB protocol. Although the low beta, high theta phenotype may accurately categorize this subtype,

the precise frequency ranges for each participant differs. For example, some might exhibit excessive activity in the 3–7 Hz range, while others could display excesses in the 4–9 Hz range. The qEEG assessments identify the ideal inhibit frequency range for each participant and, when this, more tailored, range is incorporated into the NFB treatment protocol, it significantly impacts the degree and rate of improvement and, of course, the overall success of the treatment. However, in the context of an RCT, we must assume all participants were provided feedback based on a fixed bandwidth. This approach was abandoned years ago in favor of using tailored inhibits; training using tailored inhibits results in a significantly more effective treatment. Explicit information about the choice of inhibit frequency and the failure to provide a robust scientific rationale for their selection is a departure from best practice procedures and ethical research guidelines. This, no doubt, had a negative impact on the NFB treatment group.

Error 12: The Lack of Proper Training for the Technicians. Technicians must be thoroughly trained in proper electrode placement; how to obtain a viable, stable, and reliable EEG signal; how to ensure proper functioning of the amplifier, hardware, and software; and how to optimize participant engagement. Two authors of the study who were well-versed in NFB procedures independently disclosed that the technicians lacked even the most basic skills necessary to fulfill this role. They readily discussed the following: the lack of consistency in how technicians addressed problems that arose during sessions, including solving problematic software or hardware issues and how to proceed or even recognize when, for example, an electrode becomes unseated during a session, or when excessive muscle artifact obliterates the EEG that will later be analyzed and considered an important datapoint. Discrepancies among technicians extended to various aspects, such as differing responses to session interruptions and troubleshooting problems related to the equipment. NFB technicians are expected to do much more than ensure the computer and NFB instrument are functioning properly. Equally significant, technicians were inadequately trained in effectively interacting with participants, which is particularly crucial for minors with ADHD, who are not known for having patience and typically do not respond well to corrective measures. For instance, children with ADHD, particularly after a 6-hour school day, will exhibit fatigue that is often characterized by limited tolerance for remedial or insensitive interactions. Although they may feign attentiveness, they are adept at disengaging from prescribed tasks out of boredom or spite if they perceive their technician is treating them unfairly or is placing unreasonable demands on them. These factors would markedly influence the EEG data used for analysis and undoubtedly had a dramatic impact on the overall treatment outcome. Technicians in this study were neither certified nor provided the *minimum* 6 weeks of training considered necessary in clinical settings. They lacked the skills to properly resolve technical issues and, even more importantly, they lacked interpersonal training to effectively manage ADHD children and adolescents. It was reported the technicians improved as the study proceeded; however, this lack of consistency throughout the course of the study would have impacted the quality and reliability of the data. The lack of proper technician training had implications for the integrity of the data, the ultimate effectiveness of the treatment, the generalizability of the results, and the validity and reliability of the study's conclusions.

Error 13: The Study's Primary Outcome Measure Lacked Ecological Validity. According to standards of scientific inquiry, this study should be reported as a failed trial since the anticipated group differences that were hypothesized did not materialize for the primary outcome measure, as stated. However, scientific reporting standards also necessitate considering the possibility that the primary outcome measure lacked validity in accurately measuring changes related to ADHD. Clinically, it is quite common to see a reduced need for medication during and post-NFB, which is likely attributed to enhanced self-regulation of attention. Interestingly, this study did identify significant differences in the NFB group after 13 months, along with a notably higher rate of remission, as reported in the study (40% in the treatment group compared to 19% in the control group). Curiously, this outcome was overlooked and not presented because the reduction in medication was not designated as a primary outcome measure. Overlooking this common and expected result from NFB centers worldwide shows a lack of sophistication and understanding of how this treatment impacts children and adolescents who use medication to treat their ADHD. Indeed, this finding should have been reported as it raises questions about the ecological validity of statistically significant changes observed in the primary outcome measure. It is likely that the primary outcome measure might not have been sensitive or valid enough to gauge changes in ADHD symptoms. Therefore, it is essential to consider the possibility that statistical significance on the primary outcome measure may not equate to clinical significance.

This is a common consideration in various neurological and neuropsychological disorders. In essence, the divergence between the NFB and control conditions may have held clinical significance even if statistical significance was not achieved in the criterion measure. This underscores the need for a more thorough and inclusive interpretation of results, a recognition that clinical significance holds distinct value from statistical significance in related neurophysiological data. In addition, it indicates that the principal investigators had a less than adequate understanding of how NFB interacts with the use of medications.

Error 14: Including Dual-Diagnosis Participants Confounded the Results. Dual-diagnosis participants have complex clinical profiles. By definition, this unnecessarily introduced confounding variables that affected the accuracy and generalizability of the study's findings. Writing in the Journal of the American Medical Association, Plana-Ripoll et al. (2019) noted that the presence of comorbid disorders alongside ADHD considerably complicates treatment outcomes. The inclusion criteria stipulated the requirement for ADHD to be present, but neither the inclusion nor exclusion criteria specified that ADHD must be the participant's primary disorder. This study allowed participants with primary diagnoses other than ADHD to enroll, as long as they met the criteria for ADHD. Dual-diagnosis individuals often require specialized and integrated treatments to address their issues comprehensively. Had the authors avoided this complexity and minimized confounding influences, the study would have offered a clearer evaluation of the specific impact of NFB on ADHD symptoms and been more generalizable to this group. There exists no sound justification for including participants whose primary concern was not ADHD in a study with this level of funding and support.

Error 15: Failing to Control for Medication Severely Confounds the Results. It is inexplicable and unjustifiable to fail to either control the use of ADHD medication or exclude those who are medicated. The fact that medications chemically produce the same results as the treatment being evaluated should have been enough to convince investigators to exclude medicated participants. In addition, medications are known to alter the EEG, a key measure that was used to evaluate the efficacy of NFB in this study. The degree to which medications impact a particular individual's ability to focus attention varies idiosyncratically depending on multiple factors that make it extremely difficult to control. It is difficult, if not impossible, to accurately apportion changes in these primary measures to the medication or the NFB. Random assignment cannot account for the wide diversity of effects seen with the use of medication as illustrated in this partial list of medication-related issues:

a) Although there are only two major groups of ADHD medications, the stimulants and nonstimulants, within these groups are many medications, all of which have unique EEG profiles, dosing instructions, and duration of effects.
b) There is no dosing formula that can be tracked, such as milligrams per pound of body weight as the dose a child is prescribed varies not only with body mass but also the severity of the disorder.
c) A feature of ADHD is being forgetful making inconsistent medication use difficult to track.
d) Medication has a wide variety of idiosyncratic expressions and side effects as the blood level of the medication increases, peaks, and is removed from the body through metabolism.
e) Likewise, there is a wide variety of distinctive social and emotional differences when blood levels are either increasing or decreasing from medication use.
f) Although the *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; DSM-5; American Psychiatric Association [APA], 2013)] no longer differentiates between ADD and ADHD, the presence or absence of hyperactivity impacts medications that are prescribed and how NFB sessions are conducted.
g) Research shows that when a child is treated with NFB, the need for medication decreases or is eliminated. As the course of NFB progresses, to minimize the possibility that the child experiences medication overdose symptoms, typically a child undergoing NFB is periodically reevaluated by the prescribing physician who will adjust the medication appropriately. This becomes an ethical issue that must be properly addressed in a study utilizing NFB if medication use is not eliminated or controlled.

NFB teaches the participant to self-regulate their attention; therefore, the presence of medication impacts the child's capacity to glean meaningful learning from their interaction with the NFB instrument. Clinically, we see that if a child remains on stimulant medication during NFB, they typically require extending the overall number of sessions

before positive effects are observed. In some cases, stimulant usage can make it impossible for the child to show any improvement. Had the participants not been medicated, the study would have been better focused and yielded a more valid and reliable evaluation of the impact of NFB on the targeted population. Given the substantial prevalence of ADHD, we must conclude that there exists no sound justification for including medicated ADHD participants in a study with this level of funding and support.

> **Note**. While it may be argued that the RCT design accounts for issues such as co-occurring conditions and medications because the effects are randomly distributed and, theoretically, they statistically cancel out over a series of imaginary experiments. However, given the *extremely* wide diversity in how these confounds manifest, the decision not to exclude these individuals means any causality attributed to the treatment could come from imbalances in these confounding issues.

Error 16: Treatment Fidelity Was Inadequate and Unfeasible. The absence of an on-site expert during the sessions who was proficient in all aspects of proper NFB treatment application posed a significant concern in the reliability of each session. The study's method section stated:

> All trainers/technicians received initial reliability training and weekly phone consultations from Dr. Vincent Monastra, who reviewed 287 randomly selected videotapes of treatment sessions and visited each site yearly to observe treatment in person.

The acquisition of skills necessary to promptly address the challenges that invariably arise during NFB demands a substantial investment of time. It is imperative to address problems as they emerge during sessions, rather than addressing them in annual visits by an expert or a weekly phone conversation. If supervision were conducted in such a manner in a clinical setting, it would be considered substantially below the standard of care, inadequate, and negligent. Conversations with the authors revealed a consensus on the gravity of this oversight. Having an expert on site who possesses comprehensive proficiency in all facets of the treatment help to ensure that sessions are conducted with optimal consistency, quality, and effectiveness. Disregarding this crucial "best-practice" guideline represents a notable shortcoming that undoubtedly had a detrimental impact on the validity and reliability of the study's published results.

Error 17: Creating a Valid "Sham" Condition for NFB Has Never Been Demonstrated. Since each time a researcher claims to have created a valid sham, their study concludes that NFB is no more effective than a placebo, it is reasonable to question the neutrality of the ostensible sham condition itself rather than questioning the efficacy of NFB. Researchers have speculated the degree to which NFB's effectiveness is rooted exclusively in the operant conditioning model. Some experts suggest NFB may be more aligned with skill acquisition. This alternate perspective could potentially clarify the elusive search for robust neuromarkers that correlate with positive responses to NFB. Considering the evolution of the human brain, it is evident that natural selection has molded our brain's development to be highly attuned to both conscious and subconscious signals within our environment. As the brain functions as the central control center for an intricate and interconnected system, it is exceedingly unlikely that a sham condition could ever be devised in which physiological input occurs without influencing the distributed attention neural network. Given the challenges in developing a valid placebo equivalent akin to the placebo used in drug studies, a better alternative would be to utilize research designs that do not require this condition (West, 2008). If the authors had a better understanding of the shortcomings of the sham control paradigm in assessing NFB, they might have considered employing more innovative and suitable research designs to more accurately assess the efficacy of NFB.

Error 18: The RCT Study Design Is Not Feasible to Evaluate Neurofeedback Efficacy. The choice by Arnold et al. (2021) to employ the research design known as the double-blind placebo-controlled RCT to evaluate the efficacy of NFB was inappropriate. Despite RCT's "gold standard" reputation, experts state the special status for RCTs is unwarranted and depends on many factors. As Páez et al. (2022) and Shean (2014) have discussed, there are many common and effective treatments, including NFB, that cannot be properly evaluated using the RCT. Surgery, physical therapy, psychotherapy, evaluating diet/exercise programs, novel therapies, or treatments for rare conditions are a few interventions where the RCT research design would be inappropriate to demonstrate efficacy. The imposition of this requirement and its acceptance by the neurofeedback field has been somewhat successful at dismissing the significance of the myriad of past studies that consistently demonstrated the efficacy of NFB. Those studies employed experimental designs such as controlled

trials, ABA design, cross-sectional and longitudinal research, case and observational studies, and meta-analyses. These designs are scientifically valid and, in the opinion of many scholars, are more appropriate research designs to demonstrate the efficacy of NFB. Deaton and Cartwright (2018) explained how the role of RCTs in scientific investigation has been exaggerated. They also point out that RCT's reputation as the gold standard for uncovering truth may even be harmful when, for example, it undermines the obligation of scientific investigation to reconcile RCT's results with other evidence in a process of cumulative understanding. In summary, here are a few selected explanations cited by experts explaining why the RCT design is inappropriate for NFB research:

a) Complexity and individualization make creating a standardized placebo condition that adequately mimics active NFB intervention difficult. NFB is highly individualized and tailored. Therefore, treatment-specific protocols are based on the patient's unique expression of a disorder and their desired goals.
b) Blinding Difficulties – As Lang and Stroup (2020) have pointed out, true blinding is so unhelpful and misleading that researchers should stop using it. In the context of this study, one cannot create a placebo condition that effectively masks the real-time feedback or mimics the changes in brainwave activity associated with the active treatment.
c) Lack of Suitable Sham Control – Finding an analogous placebo or sham control for NFB that convincingly replicates the experience of receiving real-time brainwave feedback is very difficult and simply providing random or irrelevant feedback does not effectively mimic the active NFB intervention.
d) Placebo-controlled studies raise ethical concerns – If NFB is an established and potentially beneficial treatment for several conditions. Therefore, many ethicists contend that withholding the active treatment from participants in the placebo group is not ethically justifiable.
e) RCTs are expensive, time-consuming, and require at least 100 or more, preferably 300 participants.
f) Given this study's target population were children and adolescents with ADHD who often have at least one ADHD parent, the probability of compliance with all requirements of the RCT for the duration of time required is, by definition, extremely low.

Of particular note, the technician's responsibility encompasses real-time observation of both the participant and their raw EEG displayed on their monitor. Achieving true blinding is impossible since the technician can seamlessly correlate the participant's movements with their real-time physiological data (EEG) being displayed on the technician monitor. This is an intrinsic limitation compromising every NFB study that purports to employ a double-blind design, including this study. Mandating this condition creates a conundrum for the technician; that is, the integrity of the double-blind design is inevitably compromised when the technician is adequately fulfilling their role. The investigators of this study should have been aware of this problem and chosen a more appropriate research design that acknowledges the unique challenges of NFB while maintaining scientific rigor.

Error 19: The Double-Blind Study Design Is Not <u>Necessary</u> to Evaluate Neurofeedback Efficacy. To conduct an objective study on the application of NFB to treat ADHD, the most meaningful metric to investigate is the degree to which the treatment impacts ADHD symptoms and the durability of the effects. It is worth noting that drug studies, in their evaluations of efficacy, typically do not rely on an array of physiological measures nor are they required to identify the underlying mechanism of action. Instead, they employ relatively straightforward symptom checklists or simple computerized test to assess attentional factors. Since a significant reduction in the disruptive symptoms of ADHD suffices for determining the effectiveness of medications, the same criterion should apply to assessing the efficacy of NFB. Regrettably, in this study, there was insufficient emphasis placed on validated ADHD symptom reduction metrics.

Part V. The Authors and Journal Editor Colluded to Modify the Data

In a stunning and troubling disclosure, an author divulged to two members of the ad hoc committee that, as the manuscript was being reviewed, editors from the JAACAP contacted the authors to communicate their willingness to publish the manuscript on the condition that the conclusion stated that neurofeedback was no more effective than the placebo. This revelation raised serious concerns about the study's credibility and the integrity of the journal publication process. It also highlighted the extent to which some medical journals go to protect their interests and the existing status quo. The pressure exerted by the journal on the authors meets the definition of coercion and was

the immediate catalyst for the manipulation of data and the presentation of an invalid and deceptive conclusion. However, this behavior by the JAACAP and the willingness of the authors to change their original results illustrates larger contextual factors that have historically targeted nondrug treatments that threaten the financial interests of the pharmaceutical industry and medication prescribers.

Part VI. Conflicts of Interest Compromise Research Integrity

The expectation that an individual will act in ways that benefit their self-interest aligns with disclosures exposing financial ties between vocal critics of NFB and the pharmaceutical industry. Given that these critics influence patient treatments and research funding decisions, the field of neurofeedback faces persistent criticism that precludes fair competition in the healthcare marketplace. Ethical guidelines prioritize treatments that are most effective, least toxic, and have the fewest side effects. If gatekeepers and key decision-makers were to acknowledge the safety and efficacy of NFB, it would likely become the primary treatment for ADHD, replacing drugs as the first-line option. In such a scenario, drug therapy would be reserved for those who either prefer taking medications or fail a trial of NFB.

Given that the authors were apprised of the issues discussed above and to date have taken no action to retract or publicly correct these issues, we are left to speculate and offer opinions as to why the study so egregiously departed from ethical research standards and delivered to the public a contrived and deceptive conclusion. There are three possible explanations for this: incompetence, negligence, or the deliberate intent to deceive. The NIMH carefully screens potential investigators to ensure competency and approves grants to those professionals who possess the highest academic credentials and have demonstrated a history of cautiously overseeing large research projects. Given this rigorous screening procedure, it is unlikely the key investigators of the study were incompetent or negligent. Combining competence with the collusion described above, there is only one rational explanation for this deception—the authors knew exactly what they were doing and made the conscious decision to compromise their ethical responsibility.

The problematic issues identified in this critique could have been avoided were it not for bias, conflicts of interest, and a willingness to pervert the scientific method. Over 10 years before the publication of this study, our office and several other NFB experts were recruited to advise Dr. Arnold on relevant issues regarding the study's design and methods. At that time, the limitations of the RCT research design and the problems associated with developing a blinded placebo-sham condition were discussed. In addition, it was suggested that Dr. Arnold speak with a spectrum of NFB providers and incorporate best practice recommendations derived from their clinical experience into the methods used. Best practice guidelines reflect the most current practices NFB providers have found to help ensure positive treatment outcomes.

In addition, there was a team of coauthors identified as collaborators in the study some of whom were themselves experts in NFB, having many decades of experience. The authors we interviewed stated that each collaborator was assigned responsibility for a specific aspect of the study however there was little opportunity to offer input or suggestions to Dr. Arnold once the methods were determined and the study commenced. Lastly, if there were any gaps in knowledge or competence, Dr. Arnold had access to funds from a $2 million grant to hire experts or consultants as necessary. Had the principal investigator been willing to draw from the wealth of knowledge and resources at his disposal, this research could have met the highest standards of research, garnered widespread respect, and been considered a landmark study. Sadly, the compelling body of evidence outlined in this critique strongly indicates that this study should be retracted and its conclusion ignored.

In his role as the principal investigator, Dr. Arnold was responsible for ensuring the integrity of this research project. Given the breadth of his experience and the availability of NFB experts, he must have been cognizant of the issues negatively impacting the validity and reliability of the study as it unfolded. Considering that many of these issues were brought to his attention long before initiating participant enrollment, and again after the study was published, his decision to do nothing speaks volumes in terms of his commitment to the integrity of the project and to science, in general. This study serves as a reminder of the multifaceted dynamics that can impact scientific research, ranging from biases in authors and journal editors to powerful background forces that offer scientists benefits that would not otherwise be available to them. The benefits flow when researchers align their conclusions with corporate interests. The author's collusion with the publishing journal resulted in a predetermined, although nonscientific, outcome that

frustrates, in particular, the public's ability to discern the best treatment for loved ones with ADHD and harms those who would otherwise have benefited from honest, unbiased research.

To illustrate the duplicity in medication research for ADHD, consider the fact that Dr. Arnold was the principal investigator in an earlier and much larger $17.7 million NIMH-funded study conducted at the University of Buffalo titled Multimodal Treatment of Attention Deficit Hyperactivity Disorder (MTA, 1999). This study compared stimulant medication to behavioral interventions. One conclusion from this study demonstrated that medications had an initial positive effect on ADHD that diminished after 1–2 years. Once the effects of medication lessened, the data indicated behavior therapy became more effective than medications to manage ADHD symptoms. This breakdown in the widely believed fiction that stimulant medications are the only legitimate treatment of ADHD had to be explained and the 3-year follow-up to this study did just that (Jensen et al., 2007). Whereas one might think the diminished response to medication might be due to increased tolerance or adverse drug reactions, which occurs with other drugs. However, the follow-up study blamed the less-than-optimal effects of the medication on poor adherence and persistence of the participants taking the medication. This later study stated, "Precise knowledge of the actual extent of adherence and persistence as well as an understanding of what factors predict treatment adherence has remained somewhat elusive" (Jensen et al., 2007). This suggests that if the participants had simply continued to take the stimulant medication, the results would have shown the superiority of medications. Apparently, to understand any of the reasons why children and adolescents often stop taking stimulants proves to be too "elusive" for the researchers to consider.

The degree to which the MTA study influenced Dr. Arnold's decisions concerning the present study would be pure speculation. However, we know that the prestige and academic acclaim resulting from being a principal investigator overseeing the present study that uses the gold standard of research designs and being funded by the NIMH, coupled with the veneer of legitimacy provided by publication in the flagship journal of psychiatry, the American Academy of Child and Adolescent Psychiatry, was sufficient to convince Dr. Arnold to alter his findings such that they "coincidentally" and unethically aligned with the goals of the pharmaceutical industry and the prescribing community.

Part VII. Uncovering Conflicts of Interest

The very nature of the scientific method separates fact from fiction in order to discern truth. Since research will positively impact some interests and negatively impact others, considering which groups benefit and which are hurt is a reasonable way to assess the degree to which biases and conflicts of interest influence an investigator's conclusions. If NFB efficacy is acknowledged as a treatment for ADHD, the field of psychiatry and the pharmaceutical industry have the most to lose. Although the actual percentage of income child and adolescent psychiatrists derive from diagnosing and treating ADHD varies depending on the focus of individual practices, given the growing numbers of children who are being prescribed an ever-widening formulary of powerful psychotropic drugs to treat ADHD (Watson et al., 2014), it is fair to say that a significant portion of their income is derived from prescribing drugs to treat ADHD. Experts are legitimately concerned that, according to the Centers for Disease Control and Prevention, 1 in 6 children aged 2–8 years have been prescribed at least one medication to treat a behavioral or mental health condition. DEA data shows that in 1 year (2020–2021), the amount of prescription amphetamines, such as Adderall, that were sold in the U.S. jumped by 1.5 tons. More than 41 million prescriptions for amphetamines were filled in 2020—an almost 16% increase over 2019. Alan Schwarz's book, *ADHD Nation: Children, Doctors, Big Pharma, and the Making of an American Epidemic* (2017) paints many industry-funded ADHD "opinion leaders" in an unflattering light and sees their influence as malicious:

> Psychiatry journals teemed with more than a thousand studies on ADHD conducted by pharma-sponsored scientists. The Food and Drug Administration relied upon them when green-lighting medications as safe and effective. Their findings served as the backbone for the lectures that drug companies' key opinion leaders delivered on world tours. The whirlwind created a self-affirming circle of science, one that quashed all dissent.

"The direct-to-consumer model, supported by the pharmaceutical industry, is an inappropriate, potentially dangerous model," warned Crowley et al. (2021), who authored a 2021 research paper that examined the role of profit in the U.S. healthcare system. In a fact-checked, well-referenced, and widely cited article titled, *Big Pharma's Role in Clinical Trials*, Michelle Llamas (2021) discussed a review conducted by the Washington Post of 73 studies of new drugs that were published in The

New England Journal of Medicine. Of those 73 studies, a pharmaceutical company funded 60 of them, 50 had drug-company employees among the authors, and 37 lead researchers had accepted money from a drug company. Given these recent trends, the public should be extremely cautious when considering research that evaluates new or novel treatments, especially nondrug treatments, when the research is conducted by investigators who benefit directly or indirectly from their association with the pharmaceutical industry.

Disclosures for all authors may be found here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7904968/

The principal investigator for this study, L. Eugene Arnold, MD, stated he is a child and adolescent psychiatrist. According to the disclosure cited above, Dr. Arnold has received research funding from Shire, Supernus, Otsuka, Roche/Genentech, and Young Living, has consulted with Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD), Pfizer, and Waypoint, and has been on advisory boards for Ironshore, Novartis, Otsuka, Pfizer, Roche, and Shire (a Takeda company). In addition, Dr. Arnold has received research funding from five pharmaceutical companies, consulted with groups that have historically been extremely critical of NFB and served on the advisory boards for six pharmaceutical companies.

Jureidini and McHenry (2011) disclosed the fact that the Journal of the American Academy of Child and Adolescent Psychiatry has a history of having been criticized for failing to uphold the scientific standards of clinical research by not retracting fraudulent research. Additionally, they indicated that the JAACAP downplayed a trial's negative results in a study sponsored by, and ghostwritten on behalf of, SmithKline Beecham (now GlaxoSmithKline). JAACAP editors declined to retract the article, arguing that the negative results are available in the article, and therefore there were insufficient grounds for retraction. This claim is disputed on the basis that primary and secondary outcomes for efficacy were manipulated and safety results were obscured or omitted.

H. Edmund Pigott (2010, 2011, 2015) spent over a decade documenting a parallel scandal that occurred in a series of NIMH-funded studies published in the *American Journal of Psychiatry*, the *Journal of Clinical Psychopharmacology,* and *Psychological Medicine,* known as the STAR*D study that cost taxpayers $35 million. Pigott presented irrefutable evidence that these industry-supported studies failed to provide an accurate assessment of psychiatric drugs purported to treat depression. Similar to Arnold et al. (2021) the research design used in their clinical trials was biased. Authoring articles in several journals, Pigott exposed how STAR*D investigators manipulated data, minimized adverse events, and failed to report negative effects. The conclusion the STAR*D authors deceptively reported was a cumulative remission rate of depression was 67% when, if the study protocol had been correctly followed, would have only been 35%. Rather than adhere to ethical guidelines and retract the study, the journal editors doubled down on their fraud falsely accusing Pigott and colleagues of being methodologically flawed and having created the problems they documented (https://www.madinamerica.com/2023/12/stard-authors-double-down-fraud/).

There is enough direct and circumstantial evidence to reasonably conclude that there are no ethical barriers and no limit to the number of human lives the pharmaceutical industry is willing to sacrifice to increase the sale of drugs. In addition, there appears to be no shortage of “researchers” who benefit from the sale of drugs and are willing to abandon their oath to “first, do no harm” to advance the sale of drugs. Publishing studies that deceive the public, helps to ensure that the supremacy of drug therapy remains unchallenged. History shows that those who attempt to demonstrate efficacy for nondrug treatments will be rebuffed, disregarded, and forced to confront numerous artificial barriers.

Part VIII. The Impact of This Study

This study’s conclusion has been publicly distributed, widely repeated, and weaponized in statements and articles written usually by psychiatrists or others who benefit from the sale of drugs to treat ADHD. The detrimental effects on the public perception of NFB and the reputation of researchers and providers in the neurofeedback field have been profound. Health insurance companies rely on published research, such as this study, to make coverage decisions. Currently, this study is perceived as authoritative; therefore, the conclusion is cited by adjusters to deny coverage or reimbursement for NFB services. We have spoken with prospective and current neurofeedback providers who have reevaluated their decision to enter or continue in this field. It is possible that, if this study is not retracted, the Current Procedural Terminology (CPT) committee could cite this study to withdraw treatment codes effectively disallowing

providers to receive insurance reimbursement for offering NFB services.

Carlat Publishing claims to be a respected distributor of unbiased psychiatric education. They issued a report on April 1, 2023, stating that, based on the Arnold et al. (2021) study, they do not "recommend referring patients to this expensive treatment until studies show clearer benefit." (https://www.thecarlatreport.com/articles/4357-testing-neurofeedback-for-adhd). A scathing editorial in the American Journal of Psychiatry also referenced Arnold et al. (2021). The author James McGough (2022), a psychiatrist, "coincidentally" served on the Board for Sunovion Pharmaceuticals and was a consultant for Eli Lilly, Takeda, and Tris Pharma. With little understanding of the issues involved in studying NFB, he sarcastically titled his editorial, *Neurofeedback for ADHD: Time to Call It Quits?* As he could not reasonably critique the early NFB studies, McGough glosses over them. Ironically, all the issues he identifies as problematic in more recent NFB research applies to Arnold et al. (2021), including poorly described outcome measures, the use of too few metrics measuring improvement, positive outcomes being attributed to nonspecific effects, and, to no one's surprise, the studies failed to find statistically significant benefits comparing NFB treatment groups to sham-control groups. Naively unaware of his hubris and hypocrisy, McGough writes, "In evaluating these studies, one should be aware of methodological concerns as well as the possibility of financial conflicts of interest."

Arnold et al. (2021) published a flawed conclusion that has had detrimental effects on the parents of minors with ADHD who no longer have valid and reliable information upon which to make an informed decision regarding treatments. Those damaged the most by this study are the children and adolescents who would likely have received lifelong benefits from NFB had the study been conducted properly and its conclusion been ethically sound. If this study is allowed to go unchallenged and is not retracted, money from a variety of entrenched interests will likely continue to undermine NFB along with other treatments that are perceived to negatively impact drug manufacturers due to these interests profiting from treating illness, not curing or preventing illness. If nothing is done to force the retraction of this study, NFB may cease to exist as a treatment option. The choice to do something to support the retraction of this abysmal study or to remain silent about it being published as legitimate research is not social or academic, it is a moral choice.

Part IX. Ethical Considerations

The mission statement for the NIMH calls for the "urgent study and integration of novel brain-based innovative therapies that integrate advances in technology." A major issue impeding the realization of this statement is exemplified in the study criticized here. Those invested in the pharmacological "status quo" are powerfully entrenched and resist the advancement of all technologically-based neuromodulatory interventions such as NFB. Even in the face of overwhelming evidence that NFB is helpful in the treatment of a wide variety of disorders, produces far fewer side effects than medications, has durable results, and is less costly over the long term than drug therapy, recent studies led by medical doctors, including the present study, continue to disparage NFB.

Current ethical guidelines require researchers to disclose all conflicts of interest. However, this guideline does not reveal the most relevant ethical issue—to what extent did the author's conflict of interest impact their research. We are left to surmise this by examining patterns of behavior among researchers or groups they affiliate, or by scrutinizing the implications of their research conclusions; that is, who benefits from their research. Because of this limitation, ethicists have recommended that future guidelines direct researchers to abstain from research projects if there is even the possibility that their conflict could skew the results. At the very least, those having any conflict of interest should never be principal investigators. Forward-thinking ethics such as this are discussed on the Integrity website at https://h2020integrity.eu/integrity/. Considering the issues revealed in this critique, it should be obvious that no one with a direct or indirect association with the pharmaceutical industry can be trusted to fairly evaluate any nondrug treatment.

We would be remiss to overlook the harm done to society when pseudoscientists allow personal biases and conflicts of interest to direct their work. According to a recent survey conducted by Pew Research Center (2022), the percentage of adults in the U.S. who say they have a great deal of confidence in medical scientists to act in the best interests of the public dropped from 40% to 29% *in only the past year*. Almost daily, the news reminds us of unprecedented challenges that, if not dealt with quickly and comprehensively, could end the existence of our species. There is a direct relationship between the degree to which researchers adhere to sound scientific principles and the public's capacity to invest their trust in research

conclusions. Studies that manipulate data to draw false conclusions not only fail to add anything of value to our knowledge base but, more significantly, they erode the public's trust in the scientific method—unarguably humanity's most reliable tool to forge a positive and healthy future.

Part X. Summary

To conform with research ethics, the authors of Arnold et al. (2021) and the editors of JAACAP are urged, once again, to consider the issues in this critique and take responsibility to explain how these errors occurred and retract the study. We fully expect the editors of JAACAP to be argumentative and hostile to any call for retraction and try to blame anyone but themselves for this travesty. Perhaps the main author, Dr. Arnold will decide to issue the call to retract. If not, the team of coauthors, designated the Neurofeedback Collaborative Group, should be aware that each author shares joint responsibility for the study's lack of integrity. At the point an author becomes aware of the issues delineated in this critique, they are ethically required to initiate a formal retraction request to the Editor-In-Chief of JAACAP, even if they were not directly responsible for the errors. Although authorship of a retracted study may have negative implications, given the degree this study departed from ethical guidelines, the failure to call for retraction will likely be viewed by colleagues as being on the wrong side of this issue.

For years, detractors of NFB have shown themselves to be puppets of the pharmaceutical industry by demanding that NFB must, once again, prove it is an effective treatment. However, these detractors insist that the only path for NFB to be considered evidence-based is by employing the RCT research design—which is as inappropriate as it is impossible. The best research design to test a hypothesis depends on what is being measured and what the measure is to be used for. Any presumption that the RCT is the best method to test the efficacy of NFB requires an argument strong enough to lead to a consensus among researchers. Not only is there no such consensus, but experts in NFB have repeatedly stated viable reasons the RCT design is inappropriate. The insistence that NFB be held to a standard that cannot possibly be met is a no-win situation for this treatment. This study and its publication in JAACAP play a major role in supporting the false narrative that detractors continue to repeat; that is, "Studies show NFB is not an effective treatment." Although the information in this critique challenges the validity and reliability of the study, until the authors publicly demand the study be retracted, it will be considered as authoritative and assumed by most people to be legitimate research. By citing the inaccurate and deceptive conclusion in the study, detractors can falsely claim to have evidence that NFB fails to meet efficacy standards. The deceptive conclusion in the Arnold et al. (2021) study confuses the public and impedes NFB from fairly competing in the healthcare marketplace. As long as detractors of NFB are successful, other novel nondrug treatments will likely find the path to efficacy blocked, leaving drug therapy as the treatment of choice for most problems—which conveniently allows those in power to retain their exalted status and the pharmaceutical industry to continue receiving record profits.

It is unfortunate to have to remind scientists and healthcare providers that it is incumbent upon them to be honest and ethical. The main feelings expressed by the authors we interviewed as well as many NFB providers regarding this study were confusion and profound sadness. Particularly clinicians were confused because the study's conclusion stands in stark contrast to their experience of providing life-changing positive benefits every day to their patients. Many expressed sadness at having wasted precious resources on a meaningless study that does nothing except further erode public confidence in therapeutic research. This study should dispel any illusion that the experts and doctors we consult will provide us with unbiased recommendations since their recommendations are often based on biased studies. The public has a right to be informed regarding the degree to which biases or conflicts of interest skewed data and compromised the validity and reliability of any study they rely on to make treatment decisions. Concerning Arnold et al. (2021), our tax dollars paid "scientists" who had an agenda—meaning they were no longer engaged in research. They were, in fact, playing an exceedingly dangerous game that ultimately deceived the public and undermined the credibility of scientific investigation. By marginalizing NFB, the profits of the financial elite are protected at the expense of the public's health and safety, not to mention robbing ADHD children and adolescents of the opportunity to receive the lifelong benefits of NFB. The only way to help ensure that the information upon which we base healthcare decisions is true and correct is to accept some measure of personal responsibility to expose unethical research and demand the authors and Journal publicly admit and correct their errors. The deceptive methods and misguided motivations that masqueraded as legitimate research in Arnold et al.

(2021) sadly mischaracterized the efficacy of NFB—this must be corrected.

Author Disclosure

The authors of this critique have no current or future relevant or material financial interest in the research described in this paper. The authors further affirm that the information expressed herein is true and correct to the best of our knowledge. The opinions expressed are those of the authors and do not necessarily reflect those of the ISNR or the journal *NeuroRegulation*. Some information cited in this paper came from confidential sources and will not be disclosed. The First Amendment encompasses the right of journalists to maintain the confidentiality of their source. In addition, the Inter-American Declaration of Principles on Freedom of Expression, Principle 8, states "every social communicator has the right to keep his/her source of information, notes, personal and professional archives confidential."

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